UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO**

Commission File Number 001-39513

Outset Medical, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**20-0514392**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
3052 Orchard Dr.	
San Jose, California	**95134**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (669) 231-8200

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, par value $0.001 per share	OM	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☒ NO ☐

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☐
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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

Aggregate market value of registrant's common stock held by non-affiliates of the registrant, based upon the closing price of a share of the registrant's common stock on June 30, 2025 (the last business day of the registrant's most recently completed second quarter) as reported by Nasdaq Global Market on that date was approximately $334.7 million.

The number of shares of the registrant's common stock, par value $0.001 per share, outstanding as of February 10, 2026 was 18,311,626.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2026 Annual Meeting of Stockholders, which is to be filed with the Securities and Exchange Commission within 120 days of the registrant' fiscal year ended December 31, 2025, are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this Annual Report) contains forward-looking statements within the meaning of the federal securities laws. All statements other than statements of historical fact contained in this Annual Report are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions. These forward-looking statements include, but are not limited to, statements about:

- our future results of operations and financial position, including our expectations and projections regarding our revenues, recurring revenues and revenue growth rate, cost of revenues, gross margin, operating expenses, capital expenditures, cash use, cash burn and cash position;
- our business strategy, plans and objectives of management;
- key factors we believe affect our performance, including our beliefs about the opportunities presented by these factors, our ability to successfully address each of these factors and the anticipated impacts of these factors on our business, financial condition and result of operations;
- continued execution of our various initiatives designed to expand gross margins, including by continuing to sell Tablo cartridges, services and accessories for Tablo console, reducing the cost of service and reducing the cost of Tablo consoles;
- our ability to achieve and sustain future profitability, including our ability to expand gross margins, optimize operating expenses (including the anticipated benefits from cost reduction initiatives such as organizational restructurings) and optimize working capital;
- our ability to retain our commercial team, and continued execution of our initiatives to optimize the commercial organization and improve forecasting and order visibility;
- our expectations regarding the market sizes and growth potential for Tablo, and the total addressable market opportunities for Tablo in the acute care and home settings;
- our plans to continue broadening our installed base in the acute and post-acute care markets and expansion within the home dialysis market, as well as our assumptions about these home markets, including expected drivers of home dialysis adoption;
- any ongoing impact of macroeconomic factors (including changes in tariff or trade laws and policies) on our business and results of operations, and on our customers and suppliers;
- our expectations regarding new products, product enhancements, technologies, offerings or services, and our plans to continue to invest in our research and development efforts to enhance existing products and develop new products;
- our ability to respond to any reports, observations or other actions by the FDA or other regulators in a timely and effective manner; and
- our expectations regarding the uses and sufficiency of our capital resources.

The forward-looking statements in this Annual Report are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements are subject to a number of known and unknown risks, uncertainties and assumptions that may cause our actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. Such risks and uncertainties include those described throughout this Annual Report, including in the sections titled "Risk Factors" under Part I, Item 1A below and "Management's Discussion and Analysis of Financial Condition and Results of Operations" under Part II, Item 7 below.

The forward-looking statements in this Annual Report are based upon information available to us as of the date of this Annual Report and, while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These forward-looking statements, like all statements in this Annual Report, speak only as of their date, and except as required by applicable law, we undertake no obligation to update or revise these statements, whether as a result of any new information, future developments or otherwise. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

Unless the context requires otherwise, all references in this Annual Report to "we," "us," "our," "Outset" and "the Company" refer to Outset Medical, Inc.

We have proprietary rights to trademarks, trade names and service marks appearing in this Annual Report that are important to our business. Solely for convenience, the trademarks, service marks, logos and trade names referred to in this Annual Report are without the ® and ™ symbols, but such references are not intended to indicate that we will not assert our rights or the rights of the applicable licensors in these trademarks, service marks and trade names. All trademarks, trade names and service marks appearing in this Annual Report are the property of their respective owners.

PART I

Item 1. Business.

Our Company

Outset is a medical technology company pioneering a first-of-its-kind technology to improve clinical outcomes in dialysis with less cost and complexity. We believe the Tablo® Hemodialysis System (Tablo) represents a significant technological advancement that transforms the dialysis experience for patients and operationally simplifies it for providers. We designed Tablo from the ground up to be a single enterprise solution that can be utilized across the continuum of care, allowing dialysis to be delivered anytime, anywhere and by virtually anyone. Tablo is currently cleared by the U.S. Food and Drug Administration (FDA) for use in the hospital, clinic or home setting. Our technology is designed to elevate the dialysis experience for patients, and help providers overcome traditional care delivery challenges. Our focus on flexibility, ease of use, data analytics and user experience translates to meaningfully reduced training times and fixed infrastructure requirements. Requiring only an electrical outlet and tap water to operate, Tablo frees patients and providers from the burdensome infrastructure required to operate traditional dialysis machines. The integration of water purification and on-demand dialysate production in a single 35-inch compact console enables Tablo to provide clinical and operational flexibility to customers. Tablo leverages cloud technology, making it possible for providers to monitor devices and treatments remotely, perform patient and population analytics and automate clinical recordkeeping. With a simple-to-use touchscreen interface, two-way wireless data transmission and a proprietary data analytics platform, Tablo is a new holistic approach to dialysis care. Unlike traditional hemodialysis machines, which have limited clinical versatility across care settings, Tablo can be used seamlessly across multiple care settings and a wide range of clinical applications.

We have generated meaningful evidence to demonstrate that providers can realize significant operational efficiencies, including reducing the cost of their dialysis programs. In addition, Tablo has been shown to deliver robust clinical care. In studies and surveys we have conducted, patients have reported quality of life benefits on Tablo compared to other dialysis machines. We believe Tablo empowers patients, who have traditionally been passive recipients of care, to regain agency and ownership of their treatment.

Kidney failure can be temporary and occur spontaneously due to an underlying medical condition, as is the case in acute kidney injury (AKI), or can worsen gradually over time, as is the case in chronic kidney disease (CKD), which may result in end-stage renal disease (ESRD). Kidney failure is commonly managed with hemodialysis, a procedure by which waste products and excess fluid are directly removed from a patient's blood using an external dialysis machine. ESRD patients require complex management and the cost burden of administering dialysis is significant. Hemodialysis can be performed in multiple care settings, including the hospital, clinic or the patient's home. Typically, different types of dialysis machines are used in different care settings and for different clinical needs. Tablo is an enterprise dialysis solution that allows providers to standardize to a single technology platform.

Driving adoption of Tablo in the acute setting has been our primary focus since Tablo's clearance by the FDA for use in an acute or chronic care facility. We have experience helping nearly 1,000 acute-care facilities, with the goal of making dialysis financially, operationally and clinically better.

We support hospitals with our expertise, technology, data and analytics, electronic-health-record integration, dedicated service infrastructure, clinical insights and dialysis know-how to help stand up, take to scale and maintain an insourced dialysis service line. By standing up an insourced dialysis service line, certain of our customers have reported saving millions of dollars, reducing central-line blood stream infection rates, reducing length of stay in the intensive care unit (ICU), improving accreditation compliance, and improving nurse satisfaction and retention.

We have invested in growing our economic and clinical evidence, built field service, sales and clinical support teams with significant expertise, and implemented a comprehensive training and customer experience program. Our experience in the acute market has demonstrated Tablo's clinical flexibility and operational versatility, while also delivering meaningful cost savings to the providers. In addition, we are working with skilled nursing facilities (SNFs), long-term acute care hospitals (LTACHs), and other post-acute providers to raise awareness of Tablo's economic and clinical benefits to them and to patients. We plan to continue leveraging our commercial infrastructure, including our sales, field service and marketing teams, to broaden our installed base in the acute and post-acute care markets, as well as driving utilization and fleet expansion with our existing customers.

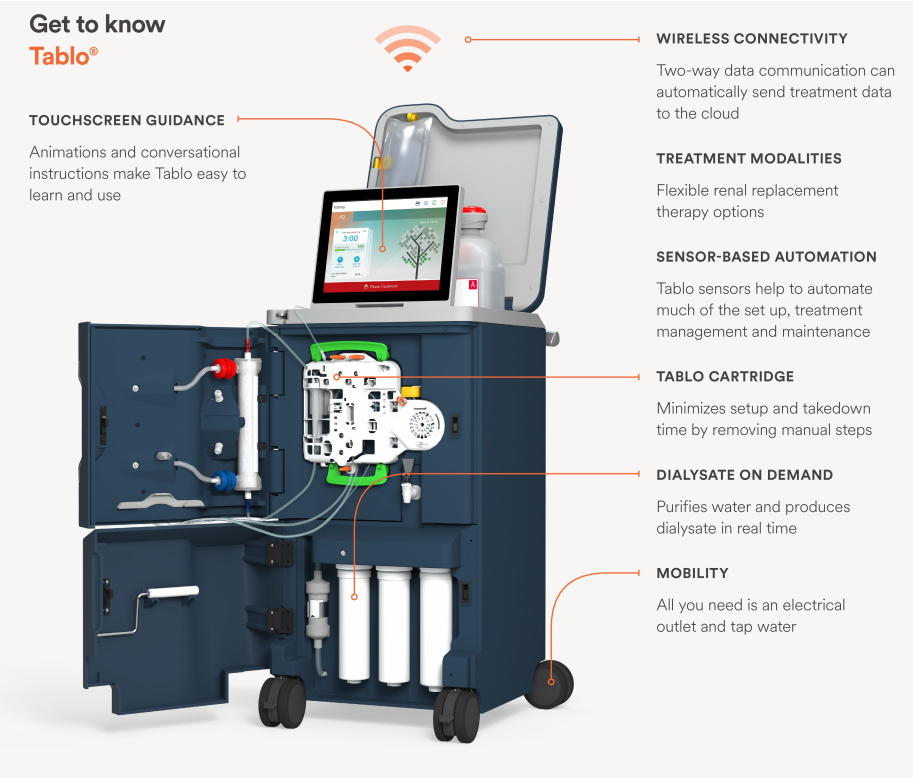
Tablo is also utilized for home-based dialysis. In 2020, Tablo was cleared by the FDA for patient use in the home. We believe our ability to reduce training time, patient dropout, and supplies and infrastructure required to deliver dialysis in the home can drive efficiency and economic improvements to the home care model. In our home investigational device exemption (IDE) trial, patients reported specific quality of life improvements compared to their experience on the incumbent home dialysis machine. To demonstrate the cost advantages of Tablo in the home setting, we are continuing to collect additional patient clinical experience and outcomes data.

Tablo Hemodialysis System

Tablo is an FDA-cleared single enterprise solution for hemodialysis, comprised of a compact console with integrated water purification, on-demand dialysate production and advanced software and connectivity capabilities. We designed Tablo from the ground up to be a single enterprise solution that can be utilized across the continuum of care, allowing dialysis to be delivered anytime, anywhere, and by virtually anyone. Unlike traditional hemodialysis machines, Tablo can be used seamlessly across multiple care settings and a wide range of clinical applications, all with the benefit of remote system management, monitoring and maintenance through two-way wireless data transmission capabilities.

Tablo is comprised of the following components:

- Tablo Console. A proprietary, compact, mobile and versatile machine consisting of an integrated water purification, on-demand dialysate production system and simple-to-use touchscreen interface with 3D animations that guide the user through treatment from start to finish. Using advanced sensors, the console automates much of treatment setup and management and can automatically self-diagnose for potential machine issues. Tablo console can accommodate a wide range of treatment modalities, durations and flow rates, allowing for broad clinical applications. Tablo console requires only a standard electrical outlet and tap water to operate. This eliminates the need for industrial water treatment rooms, separate water purification machines and pre-filled bags of dialysate associated with traditional dialysis machines. We also offer TabloCart with Prefiltration drawer or storage drawer, an accessory for Tablo, that is configured based on the customer's needs.
- Tablo Cartridge. A proprietary, disposable single use pre-strung cartridge that easily clicks into place, minimizing steps, touch points and connections, allowing for set up of treatment supplies in less than 12 minutes. Tablo cartridge was designed to simplify and streamline treatment setup to minimize the potential for user error. Tablo cartridge is intended to facilitate extracorporeal blood purification for patients. One cartridge is used per treatment, except in the case of extended therapy, where multiple cartridges can be used if needed. Tablo cartridge consists of a user-friendly pre-configured blood, saline, and infusion tubing. Tablo cartridge requires only two connections to operate as compared to other machines that require stringing, hanging, snapping and tapping multiple lines. In our home IDE trial, patients were able to set up Tablo cartridge and dialysate concentrates in less than 12 minutes, on average. With an average prime period of approximately eight minutes, an uninterrupted patient can initiate therapy in as little as around 20 minutes, representing a significant improvement over traditional machines, which can take approximately 45 minutes to set up.
- Tablo Data Ecosystem. As further described below in the section entitled "Tablo Data Ecosystem", with Tablo, we are bringing data to dialysis. Tablo is built to live in a connected setting with cloud-based system monitoring, patient analytics and clinical recordkeeping.



Tablo Data Ecosystem

Tablo's two-way wireless data transmission and connectedness help reduce maintenance costs and enable ongoing system improvements. This is all made possible by our team of experienced software, data science, and machine learning engineers.

Tablo leverages cloud technology to make it possible for providers to monitor devices remotely, view treatment data, perform patient and population analytics, and automate clinical recordkeeping. Tablo's wireless connectivity enables us to release training, new features, and enhancements over-the-air (OTA) without interventions by field service engineers (FSEs). This means that customers can train and upgrade their device on their own schedule. We use these OTA updates to add new features designed to extend Tablo's clinical applicability and enhance device uptime. We believe these OTA updates help Tablo get smarter over time.

Tablo's connectedness allows continuous streaming of over 500,000 device performance data points to the cloud for every treatment. We use this data in conjunction with our diagnostic and predictive algorithms to monitor device performance, identify and diagnose failures and, in some instances, predict and prevent potential future device failures or malfunctions. Equipped with this information, our FSEs can visit sites knowing they have the correct parts and consumables to address the issues reported, and sometimes even those that are yet to come. In effect, this contributes to a reduction in service hours and an increase in device uptime.

The above functionality is enabled through the following key platforms: TabloHub®, a customer-facing portal; MyTablo, a patient-facing portal; and TabloDash, an internal data analytics platform.

TabloHub

TabloHub is designed to be a one-stop shop for providers that allows customers to monitor treatments in real-time across their fleet, visualize historical treatment records and statistics, see system disinfection and service records, search documentation, read news about Tablo, and perform various training. It is accessible from any device equipped with a web browser, be it a smart phone, a tablet, or a computer.

Through the Tablo application programming interface (API), providers can integrate Tablo with their Electronic Medical Records (EMR) to receive Tablo treatment data and flowsheets automatically. This helps reduce manual record keeping, record-entry errors, and auditing risks. This additional point of connectedness is designed to deliver data in compliance with the federal Health Insurance Portability and Accountability Act (HIPAA) Security Rule, and does not require any special equipment from the providers: it connects to the cloud using any standard Ethernet or Wi-Fi internet connections. TabloHub strengthens care, simplifies meeting documentation requirements, and makes system management easy.

MyTablo

MyTablo is a version of TabloHub designed for patients who are dialyzing at home or performing self-care at a clinic. Using MyTablo, patients can access training and download their treatment reports.

TabloDash

TabloDash is a powerful data analytics platform used by Outset team members to analyze diagnostic data produced by connected devices across all fleets, data from our customer relationship management system, and various other sources. Tablo captures approximately 3 million machine performance data points for every treatment on average, which are then used to fuel data analytics and machine learning algorithms that drive our research and development pipeline.

Through TabloDash, data can be visualized, graphed, aggregated, and queried to answer complex business intelligence questions, and build performance monitoring dashboards. For example, our service team uses TabloDash to analyze field response times, categorize failures by types, diagnose specific device issues, and monitor customer fleet performance.

TabloDash and its associated analytics network enable our FSEs to remotely monitor device performance, assess issues in real time and proactively determine appropriate corrective actions. These capabilities help reduce unnecessary onsite visits, shorten time to resolution and improve service part utilization. When a visit is required, TabloDash supports more effective dispatch by helping to ensure FSEs arrive prepared to address identified issues, including preventative maintenance needs, during a single visit. TabloDash is an important component of our service infrastructure, supporting efforts to optimize cost to serve while enhancing service quality and reducing device downtime.

With the above features and benefits in mind, we believe Tablo is well-positioned as a differentiated, all-in-one solution enabling transformational dialysis across the continuum of care, from hospital to home, in one of the largest, most expensive, least changed areas of healthcare.

Competition

There are a number of dialysis machine manufacturers and dialysis service providers in the United States, Europe and Asia. Notable competitors in the United States include Fresenius Medical Care AG & Co. KGaA (Fresenius); DaVita, Inc. (DaVita), a dialysis service provider; Mozarc Medical, a dialysis products joint venture formed by DaVita and Medtronic plc (Medtronic); and B. Braun Medical Inc. (B. Braun). Vantive, formerly the Baxter kidney care segment, also offers specialized dialysis products that may be used by hospitals for inpatient dialysis. In addition, Quanta Dialysis Technologies Ltd.'s (Quanta) dialysis system has received FDA 510(k) clearance for use in acute and/or chronic and home settings. Of these competitors, Fresenius is the largest, and is vertically integrated, both manufacturing dialysis products and operating dialysis clinics along with providing inpatient dialysis services to hospitals and health systems. Some of these competitors are significantly larger than us with greater financial, marketing, sales and personnel resources, greater brand recognition and longer operating histories. We believe our ability to compete effectively will be dependent on our ability to effectively demonstrate the value of Tablo and insourcing with Tablo, maintain and improve product quality and feature functionality, build and maintain the infrastructure to support the operating needs of the business and continue to achieve operational efficiencies.

Acute Care

While historically customers in this market have focused on machine functionality and price, we believe they are increasingly focused on the total cost of patient care, which favors technology and services that can provide clinical versatility and improve operational efficiency. In the acute care setting, we compete primarily on the basis that our technology, expert know-how and services support the achievement of financial, clinical and operational improvements over traditional dialysis machines or outsourced dialysis offerings. We believe our ability to compete effectively will depend largely on our ability to demonstrate Tablo's economic, clinical and operational benefits relative to outsourcing dialysis services.

Home Care

We believe competition in the home setting is based on a system's clinical performance, its cost efficiency, its ease of use and patient preference. In the home hemodialysis setting, competitors include Fresenius (through its acquisition of NxStage) and Quanta which received FDA 510(k) clearance for home use in 2024. We believe through Tablo's unique advantages it is easier and faster for patients to learn, and simpler for patients to operate at home, which may position us well against existing or future competitors. We believe these factors will reduce patient or caregiver burn-out, thereby extending patient retention, increasing home hemodialysis growth and improving associated margin for providers. We do not consider peritoneal dialysis (PD) to be competitive to our products given the differences in treatment modality, that PD is clinically limited to patients with certain pre-existing conditions such as congestive heart failure and obesity and that PD is regarded as a "temporary" modality since approximately 80% of patients are on the therapy for less than three years.

Intellectual Property

Our success depends in part on our ability to protect our proprietary technology and intellectual property rights. We rely on a combination of federal, state, common law and international rights, as well as contractual restrictions, to protect our intellectual property.

We seek patent protection for certain of our key innovations, processes and other inventions. We pursue the registration of our trademarks, service marks and domain names in the United States and in certain other locations. We control access to our proprietary technology by entering into confidentiality and invention assignment agreements with our employees and contractors, and confidentiality agreements with third parties. Our intellectual property includes specific algorithms for Tablo console, including those related to pressure sensors, blood leakage and pump control loops.

Patents

As of December 31, 2025, we had 33 issued U.S. patents, as well as 8 pending U.S. patent applications. We had an aggregate of 76 issued patents in Australia, Canada, China, France, Germany, Hong Kong, Japan, Spain, Sweden and the United Kingdom, as well as 32 pending patent applications in Australia, Brazil, Canada, China, the European Patent Office, Hong Kong, Japan, Saudi Arabia and United Arab Emirates. Some of our patents and other intellectual property cover aspects of Tablo that enable it to be used by anyone, including the patient, through the automation of functions formerly performed by dialysis center technicians using traditional dialysis systems. Our proprietary data ecosystem provides what we believe is a unique way of connecting providers and patients for real-time treatment monitoring, automated treatment documentation, and simplified compliance and record-keeping.

Our patents expire between June 2027 and April 2042. The term of individual patents depends upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office (USPTO) in examining and granting a patent, or it may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date. We cannot be sure that our pending patent applications or future patent applications will result in issued patents or that any patents that have issued or might issue in the future will protect our current or future products, provide us with any competitive advantage or will not be challenged, invalidated, or circumvented.

Various aspects of Tablo, including, without limitation, sensor technology, connectivity, automation, analytics and interface are covered by software, algorithms, processes, trade secret or other proprietary rights. We protect our trade secrets through a variety of measures, including confidentiality agreements and proprietary information agreements with suppliers, employees, consultants and others who may have access to our proprietary information. Trade secrets and proprietary information can be difficult to protect, however. While we have confidence in the measures we take to protect and preserve our trade secrets and proprietary information, such measures can be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets and proprietary information may otherwise become known or be independently discovered by competitors.

There is no active patent litigation involving any of our patents, and we have not received any notices claiming that our activities infringe a third party's patent.

Manufacturing, Supply Chain and Logistics

We direct the manufacturing and supporting supply chain, distribution and logistics for Tablo console, Tablo cartridge and other consumables (electrolyte concentrates and plastic tubing that transports the concentrates into Tablo to enable on-demand dialysate production). We operate under a Quality Management System that has been certified to ISO 13485 Medical Device Quality Management System standard.

We manufacture our Tablo consoles and a substantial majority of Tablo cartridges at our manufacturing facility in Tijuana, Mexico. We are operating in Mexico in collaboration with TACNA Services (TACNA), a well-known outsourced business administration service provider that provides all the back-office and facility infrastructure support, allowing us to focus on our core competencies – design and high-volume manufacturing for reliability and cost reduction. Tablo consoles manufactured in our Mexico facility are tested at the facility using an integrated system testing protocols designed by us, and then direct-shipped to our distribution centers, using a network of short-haul and long-haul freight forwarders optimized for time and cost efficiency.

Pursuant to the terms of our manufacturing services agreement with TACNA (the TACNA Agreement), TACNA provides support services in connection with our manufacturing activities in Mexico. Under the TACNA Agreement, TACNA hires employees as requested by us and is responsible for human resource functions including maintenance of employee files and reports. TACNA is also responsible for performing internal statutory accounting and payroll services, as well as payables processing. Additional services that TACNA is obligated to provide under the TACNA Agreement include interfacing with both Mexican and U.S. governmental agencies, preparing import-export documentation, coordinating shipment of equipment, raw materials and finished products, and

obtaining necessary permits and licenses required in Mexico. Under the TACNA Agreement, TACNA's services are generally performed under a pass-through cost model under which costs incurred are approved by us. We are also obligated to pay TACNA fees based on the number of employees under the TACNA Agreement. The TACNA Agreement has an initial three-year term and will continue thereafter until terminated by us or TACNA in accordance with the terms of the TACNA Agreement.

We also manufacture a small portion of Tablo cartridges through Infus Medical Co. Ltd. (Infus), a contract manufacturer with two facilities in Thailand, to supplement our in-house manufacturing production and provide additional flexibility.

The number of suppliers required for Tablo console production is approximately 100 worldwide. We consider a discrete number of these suppliers, located in the United States, Mexico, Europe and Asia, as critical providers of components such as pumps, motors, valves and PCBA boards. The various components for Tablo cartridge are manufactured by 13 different single and dual-source suppliers located in various countries including the United States, Mexico, Europe and Asia.

Government Regulation

United States Food and Drug Administration

In the United States, our products are subject to regulation by the FDA as medical devices pursuant to the Federal Food, Drug, and Cosmetic Act (FDCA). The FDA regulates the development, design, non-clinical and clinical research, manufacturing, safety, efficacy, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, adverse event reporting, advertising, promotion, marketing and distribution, and import and export of medical devices to ensure that medical devices distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FDCA.

FDA Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a 510(k) premarket notification, approval of a de novo application, or approval of a premarket approval (PMA). Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the Quality System Regulation (QSR), facility registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, post-market surveillance, patient registries and FDA guidance documents.

While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Devices deemed by the FDA to pose the greatest risks, such as life sustaining, life supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA. Some pre-amendment devices are unclassified, but are subject to FDA's premarket notification and clearance process in order to be commercially distributed. Tablo is a Class II device subject to 510(k) clearance.

510(k) Clearance Marketing Pathway

To obtain 510(k) clearance, we must submit to the FDA a premarket notification submission demonstrating that the proposed device is "substantially equivalent" to a predicate device already on the market. A predicate device is a legally marketed device that is not subject to PMA, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. The FDA's 510(k) clearance process usually takes from three to twelve months, but often takes longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. In addition, the FDA collects user fees for certain medical device submissions and annual fees for medical device establishments.

If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the "de novo" process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device. If a de novo request is granted, the device may be legally marketed and a new classification is established. If the device is classified as

Class II, the device may serve as a predicate for future 510(k) submissions. If the device is not approved through de novo review, then it must go through the standard PMA process for Class III devices.

After a device receives 510(k) marketing clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, PMA approval. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) marketing clearance or PMA approval is obtained. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

PMA Approval Pathway

Class III devices require approval of a PMA before they can be marketed, although some pre-amendment Class III devices for which the FDA has not yet required a PMA are cleared through the 510(k) process. The PMA process is more demanding than the 510(k) premarket notification process. In a PMA application, the manufacturer must demonstrate that the device is safe and effective, and the PMA application must be supported by extensive data, including data from preclinical studies and human clinical trials. The PMA application must also contain a full description of the device and its components, a full description of the methods, facilities, and controls used for manufacturing, and proposed labeling. Following receipt of a PMA application, the FDA determines whether the application is sufficiently complete to permit a substantive review. If the FDA accepts the application for review, it has 180 days under the FDCA to complete its review of a PMA application, although in practice, the FDA's review often takes significantly longer, and can take up to several years. An advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a pre-approval inspection of the applicant or its third-party manufacturers' or suppliers' manufacturing facility or facilities to ensure compliance with the QSR. PMA devices are also subject to the payment of user fees.

The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA application constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). A PMA may include post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-term follow-up data from patients in the clinical study that supported the PMA or requirements to conduct additional clinical studies post-approval. The FDA may condition PMA approval on some form of post-market surveillance when deemed necessary to protect the public health or to provide additional safety and efficacy data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to the FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which affect the safety or effectiveness of the device, require submission of a PMA supplement. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. Certain other changes to an approved device require the submission of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness. None of our products are currently marketed pursuant to a PMA.

De novo Classification

Medical device types that the FDA has not previously classified as Class I, II or III are automatically classified into Class III regardless of the level of risk they pose. To market low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, a manufacturer may request a de novo down-classification. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. A medical device may be eligible for de novo classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent, or a manufacturer may request de novo classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. The FDA is required to classify the device within 120 calendar days following receipt of the de novo application, although in practice, the FDA's review may take significantly longer. During the pendency of the FDA's review, the

FDA may issue an additional information letter, which places the de novo request on hold and stops the review clock pending receipt of the additional information requested. In the event the de novo requestor does not provide the requested information within 180 calendar days, the FDA will consider the de novo request to be withdrawn. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the de novo request for classification if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed. In the event the FDA determines the data and information submitted demonstrate that general controls or general and special controls are adequate to provide reasonable assurance of safety and effectiveness, the FDA will grant the de novo request for classification. When the FDA grants a de novo request for classification, the device is granted marketing authorization and further can serve as a predicate for future devices of that type, through a 510(k) premarket notification.

Breakthrough Device Program

The FDA has implemented a Breakthrough Device Program that is intended to help patients receive more timely access to breakthrough medical technologies that have the potential to provide more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases or conditions. A device also must meet one of the following criteria: (i) it represents breakthrough technology; (ii) there is no approved or cleared alternative; (iii) it offers significant advantages over existing cleared or approved devices; or (iv) availability of the device is in the best interest of patients. Under the program, a manufacturer is eligible to receive priority review and interactive communications from the FDA regarding device development and clinical trial protocols, all the way through to commercialization decisions.

Clinical Trials

Clinical trials are almost always required to support a PMA and are sometimes required to support a 510(k) submission. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's IDE regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk," to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board (IRB) for each clinical site. The IRB is responsible for the initial and continuing review of the IDE study, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Post-market Regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of investigational products, or the promotion of "off-label" uses of cleared or approved products;
- requirements related to promotional activities;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices, or approval of certain modifications to PMA-approved devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Quality Systems Regulation Requirements

Our manufacturing processes are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR requires that each manufacturer establish a quality systems program by which the manufacturer monitors the manufacturing process and maintains records that show compliance with FDA regulations and the manufacturer's written specifications and procedures relating to the devices. The QSR also requires, among other things, maintenance of records and certain documentation, a device master file, device history file, and complaint files. QSR compliance is necessary to receive and maintain FDA clearance or approval to market new and existing products. As a manufacturer, we are subject to periodic scheduled or unscheduled audits or inspections by the FDA. Our failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, our manufacturing operations and the recall or seizure of our products, which would have a material adverse effect on our business. The discovery of previously unknown problems with any of our products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- FDA untitled letters, FDA Form 483s, FDA warning letters, it has come to our attention letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- recall, detention or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing or delaying our requests for regulatory approvals or clearances of new products or modified products;

- withdrawing of 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

The FDA can also publish Safety Communications or Letters to Health Care Providers when the agency becomes aware of new issues involving a specific product or, more broadly, a product family. These communications are posted on the FDA's website and describe the FDA's analysis of a current issue and provide specific regulatory approaches and clinical recommendations for patient management.

Current FDA Regulatory Status

We currently have regulatory clearances required to market Tablo in the U.S. for use in patients with acute and/or chronic renal failure, with or without ultrafiltration, in an acute or chronic care facility. Tablo is also indicated for use in the home and observed by a trained individual. Treatments must be administered under a physician's prescription and observed by a trained individual who is considered competent in the use of the device. The FDA's authorizations for the Tablo System, Tablo Cartridge and TabloCart with Prefiltration have thus far been granted as 510(k) clearances.

Since Tablo's original clearance by the FDA for home use in March 2020, we have made certain changes to the device over time and, where appropriate, have submitted 510(k) applications for certain modifications to Tablo. In May 2021, we submitted a 510(k) application to the FDA covering the design changes for patient use in the home. In May 2022, after further discussions with the FDA and receiving indications that the clearance of this 510(k) submission would be delayed beyond our original expectations, we implemented a shipment hold on the distribution and marketing of Tablo for use in the home environment pending the FDA's review and clearance of this 510(k) submission. In late July 2022, the FDA cleared this 510(k) submission of Tablo for patient use in the home and we resumed marketing and shipping Tablo for home use.

We continue to seek opportunities for product improvements and feature enhancements, which will, from time to time, require FDA clearance or approval before commercial launch. For example, in January 2026, the FDA granted 510(k) clearance of our next-generation Tablo platform.

The FDA conducted their first quality system inspection of our San Jose, California facility which concluded in February 2023. At completion, the FDA issued a Form FDA-483 identifying four inspectional observations. We provided our response plan to the FDA in March 2023, completed the associated remediation workstreams, and submitted our final update to the FDA regarding actions taken to address these observations. The FDA conducted a follow-up inspection of our San Jose, California facility, which concluded in September 2024. At completion, the FDA did not issue a Form-483. The FDA Establishment Inspection Reports for the 2023 and 2024 inspections were received in February 2025. The FDA concluded that no further regulatory action is necessary and the two inspections are "closed" under 21 CFR 20.64(d)(3). Although we believe we are in material compliance with the QSR, there is no guarantee that subsequent inspections of our facility by the FDA or other regulatory authorities will not result in similar observations with respect to our quality system, which could adversely affect our business.

In July 2023, we received a warning letter (the Warning Letter) from the FDA that raised two observations. The first observation asserted that certain content reviewed by the FDA and found on our website promotes Continuous Renal Replacement Therapy (CRRT), a modality outside of the current indications for Tablo. The second observation asserted that TabloCart with Prefiltration required prior 510(k) clearance for marketing authorization. TabloCart with Prefiltration is an accessory to Tablo launched in the third quarter of 2022. We took action to address the first observation regarding CRRT promotion through revision of processes and procedures and updates to existing labeling and promotional materials. We also took action to address the second observation regarding TabloCart with Prefiltration. Although we evaluated TabloCart with Prefiltration prior to marketing and distributing the product and concluded that no marketing authorization was necessary, we paused distribution of TabloCart with Prefiltration pending the FDA's review and clearance of a 510(k) application for TabloCart with Prefiltration, which we submitted in September 2023. In early May 2024, we received 510(k) clearance from the FDA for TabloCart with Prefiltration, and we subsequently resumed distribution of TabloCart with Prefiltration. In February 2025, we were notified by the FDA that the issues cited in the Warning Letter had been addressed.

Healthcare Fraud and Abuse Laws

Certain U.S. federal healthcare fraud and abuse laws apply to our business because our customers submit claims for payment for our products and services to federal healthcare programs (as that term is defined at 42 U.S.C. § 1320a–7b(f)), such as Medicare and Medicaid. The principal federal fraud and abuse laws that apply in these circumstances are discussed below.

The U.S. federal Anti-Kickback Statute is a broad criminal statute that prohibits, among other things, the knowing and willful offer, solicitation, receipt, or payment of any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, for the purpose of inducing or rewarding the order, purchase, use or recommendation of items or services that may be paid for, in whole or in part, by a federal healthcare program, such as Medicare or Medicaid. This includes products, like Tablo, that are purchased and used

in a service that is paid for by such programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Further, the term "remuneration" has been broadly interpreted to include anything of value. The Patient Protection and Affordable Care Act and the Health Care Reconciliation Act of 2010, as amended (collectively, the ACA), specified that any claims submitted as a result of a violation of the federal Anti-Kickback Statute constitute false claims and are subject to enforcement under the federal False Claims Act, which is discussed in more detail below. Government officials continue to focus their enforcement efforts on the sales and marketing activities of medical device manufacturers and other healthcare companies and routinely bring cases under the federal Anti-Kickback Statute and federal False Claims Act against individuals or entities who allegedly offer unlawful inducements to potential or existing customers in an attempt to procure their business. Judgments and settlements of these cases by healthcare companies have involved significant fines and, in some instances, criminal pleas and convictions, as well as exclusion from participation in federal healthcare programs. A violation of the federal Anti-Kickback Statue includes per violation civil monetary penalties and significant criminal fines, additional civil penalties and treble damages under the federal False Claims Act, as discussed in more detail below, possible imprisonment, and mandatory exclusion from participation in the federal healthcare programs, meaning that federal healthcare programs would no longer cover or reimburse (directly or indirectly) for products or services furnished by the excluded entity or individuals.

Given the breadth of the federal Anti-Kickback Statute, and in order to protect certain common business arrangements and activities that may otherwise implicate the law, there are statutory exceptions and regulatory safe harbors that protect certain arrangements from liability under the law when all elements of an applicable exception or safe harbor are met. However, these exceptions and safe harbors are narrowly drawn, and there are no exceptions or safe harbors for many other common business activities, like the provision of meals, educational grants or reimbursement support programs, among others. Given that the federal Anti-Kickback Statute is an intent-based law, the failure of a transaction or arrangement to fit precisely within an exception or safe harbor does not necessarily mean that it is illegal or that prosecution will be pursued. Rather, the determination of a violation then turns on the specific facts and circumstances, and arrangements that fall outside an available exception or safe harbor are typically subject to greater scrutiny.

The federal civil False Claims Act (FCA) imposes civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment of government funds that are false or fraudulent, or knowingly making, using, or causing to be made or used a false record or statement material to an obligation to pay money to the government, or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. This statute also permits a private individual acting as a "qui tam whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties for each false claim submitted or statement made. Government enforcement agencies and private whistleblowers have investigated medical device manufacturers for, or asserted liability under, the FCA for a variety of alleged inappropriate promotional and marketing activities, including those involving the provision of free product or other items of value to customers, certain financial arrangements with healthcare providers, the provision of billing, coding, and reimbursement advice, and purported "off-label" promotion of products, among other things.

Another key federal healthcare law is the federal all-payor healthcare fraud statute, which was added by HIPAA. The federal all-payor healthcare fraud statute imposes liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for healthcare benefits, items or services by a healthcare benefit program, which includes both government and privately funded benefits programs. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate them in order to have committed a violation.

The Physician Payments Sunshine Act (Sunshine Act) requires us to track and report annually certain data on payments and other transfers of value we make to U.S. teaching hospitals and U.S.-licensed physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants, and certified nurse-midwives. Manufacturers are also required to report ownership and investment interests held by U.S. physicians and their immediate family members in the manufacturer. The data are sent to the Center for Medicare and Medicaid Services (CMS) for public disclosure on the Open Payments website. Failure to timely and accurately report information in accordance with the Sunshine Act may result in significant financial penalties.

In addition to these federal laws, there are state laws and regulations, including state anti-kickback and false claims laws, that may apply to our business practices, including but not limited to: research activities; sales and marketing arrangements; claims involving healthcare items or services reimbursed by any third- party payor, including private insurers; state laws that require medical device companies to comply with the medical device industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug and device manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare

professionals and entities. In some states, applicable state anti-kickback laws apply with respect to all payors, including commercial health insurance companies.

Through our compliance efforts, we strive to design our business operations and relationships with our customers to comply with all applicable law. However, many of the laws and regulations applicable to us are broad in scope and may be interpreted or applied by prosecutorial, regulatory or judicial authorities or whistleblowers in ways that we cannot predict. Thus, it is possible that governmental entities or other parties could interpret these laws differently or assert non-compliance with respect to one or more of our business operations and relationships. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, imprisonment, and/or exclusion from government-funded healthcare programs, such as Medicare and Medicaid. In addition, we may become subject to additional oversight and reporting requirements under a corporate integrity agreement as part of a settlement to resolve allegations of non-compliance with these laws (even if we do not admit violations). We may also need to curtail or restructure our operations as a result of being found to violate these laws, having such violations asserted against us, or based on enforcement actions instituted with respect to comparable practices by others. Any of these outcomes could have an adverse effect on our financial condition and ability to conduct our operations.

Privacy and Security

In the course of performing our business we obtain personally identifiable information (PII), including health-related information. Numerous federal and state laws and regulations, including the Healthcare Insurance Portability and Accountability Act (HIPAA), govern the collection, dissemination, security, use and confidentiality of patient-identifiable health information or personal information. Such laws and regulations relating to privacy, data protection, and consumer protection are evolving and subject to potentially differing interpretations. These requirements may be interpreted and applied in a manner that varies from one jurisdiction to another and/or may conflict with other laws or regulations.

HIPAA establishes a set of national privacy and security standards for the protection of individually identifiable health information, including protected health information (PHI) for certain covered entities, including healthcare providers that submit certain covered transactions electronically, as well as their "business associates," which are persons or entities that perform a function or provide certain services for, or on behalf of, a covered entity that involve creating, receiving, maintaining or transmitting PHI. HIPAA also imposes breach reporting obligations on such covered entities and their respective business associates. Penalties for failure to comply with a requirement of HIPAA vary significantly depending on the failure and could include civil monetary or criminal penalties. HIPAA also authorizes state attorneys general to file suit under HIPAA on behalf of state residents. Courts can award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for HIPAA violations, its standards have been used as the basis for a duty of care claim in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI. The Department of Health and Human Services Office for Civil Rights (OCR) has adopted privacy regulations to govern the use and disclosure of PHI (the Privacy Rule). HHS has also adopted data security regulations that require covered entities and business associates to implement administrative, physical and technical safeguards to protect the confidentiality, integrity and availability of PHI that is electronically created, received, maintained or transmitted (such as between us and our affiliated practices) (the Security Rule). OCR has recently increased its enforcement of compliance with HIPAA, including the Security Rule, bringing actions against entities which have failed to implement security measures sufficient to reduce risks to electronic PHI or to conduct an accurate and thorough risk analysis, among other violations. HIPAA enforcement actions may lead to monetary penalties and costly and burdensome corrective action plans. We are also required to report known breaches of PHI consistent with applicable breach reporting requirements set forth in applicable laws and regulations. Further, on December 10, 2020, OCR issued proposed revisions to the Privacy Rule aimed at reducing regulatory burdens that may exist in discouraging coordination of care, including creating an exception to the minimum necessary standard for healthcare coordination, and other proposals to increase patient access to their health information, among other changes. On April 22, 2024, OCR issued a Final Rule, HIPAA Privacy Rule to Support Reproductive Health Care Privacy, which is intended to strengthen the Privacy Rule by prohibiting the disclosure of PHI related to lawful reproductive health care in certain circumstances. However, this Final Rule has now been repealed.

Additionally, on December 1, 2022, OCR issued a bulletin on the requirements under HIPAA for online tracking technologies (e.g., cookies, pixels) to protect the privacy and security of health information. This bulletin outlined OCR's position on the use of online tracking technology vendors, when certain information received by such vendors constitutes PHI under HIPAA. While subsequent judicial developments vacated the guidance, we may incur additional expense to comply with this bulletin and future guidance from the OCR, and agency's heightened focus on website tracking technologies could pose enforcement risk in the future.

In addition, various federal and state legislative and regulatory bodies, or self-regulatory organizations, may expand current laws or regulations, enact new laws or regulations or issue revised rules or guidance regarding privacy, data protection and consumer protection. For instance, the California Consumer Privacy Act, as amended by the California Privacy Rights Act (CCPA) gives California residents rights to access, correct and delete their personal information, to opt out of the sale or sharing of certain personal information, to limit uses of certain sensitive data under certain circumstances, and to receive detailed information about how their

personal information is used by requiring covered companies to provide disclosures to California consumers (as that term is broadly defined). The 2020 amendments also created a California data protection agency authorized to issue substantive regulations and has resulted in increased privacy and information security enforcement. The CCPA regulations also impose proscriptive requirements on businesses regarding how to properly demonstrate compliance with the law's requirements. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Rulemaking by the California Privacy Protection Agency (CPPA) is ongoing – the CPPA has administrative enforcement authority over CCPA and oversees CCPA rulemaking. Although there are limited exemptions for PHI and the CCPA's implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, the CCPA may increase our compliance costs and potential liability. Additional compliance investment and potential business process changes may be required. Laws similar to the California laws have passed or have been proposed in several other states and also have been proposed at the federal level. To the extent these laws apply to our operations, they may ultimately have conflicting requirements that would further complicate compliance. Further, new health information standards, whether implemented pursuant to HIPAA, congressional action or otherwise, could have a significant effect on the manner in which we handle health-related information, and the cost of complying with these standards could be significant. If we do not comply with existing or new laws and regulations related to patient health information, we could be subject to criminal or civil sanctions.

Additionally, the Federal Trade Commission (FTC) and many state attorneys general are interpreting existing federal and state consumer protection laws to impose evolving standards for the online collection, use, dissemination and security of health-related and other personal information. Courts may also adopt the standards for fair information practices promulgated by the FTC, which concern consumer notice, choice, security and access. Consumer protection laws require us to publish statements that describe how we handle personal information and choices individuals may have about the way we handle their personal information. At the state level, for example, the Washington State My Health My Data Act, which went into effect in 2024, contains requirements such as the provision of specific health-data consumer disclosures and consumer rights (including the right to consent to the processing of their health data) in addition to other compliance and security requirements. The My Health My Data Act considers violations of this law to be an unfair or deceptive act in trade or commerce and an unfair method of competition subject to the Washington Consumer Protection Act. To the extent this or other similar laws apply to us, and the information that we publish is considered untrue or our practices are deemed not to comply with these requirements, we may be subject to government claims of unfair or deceptive trade practices, which could lead to significant liabilities and consequences. Furthermore, according to the FTC, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair or deceptive acts or practices in violation of Section 5 of the FTC Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC has also been active with respect to enforcement of its Health Breach Notification Rule and in scrutinizing the use and disclosure of sensitive personal information. The FTC also finalized changes to the Health Breach Notification Rule in April 2024. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule. Enforcement by the FTC under the FTC Act can result in civil penalties or enforcement actions.

We may also be subject to laws and regulations in foreign countries covering data privacy and other protection of health and employee information that may be more onerous than corresponding U.S. laws. These regulations may require that we obtain individual consent before we collect or process personal data, restrict our use or transfer of personal data, impose technical and organizational measures to ensure the security of personal data, add obligations to our data analytics services, and require that we notify regulatory agencies, individuals or the public about any data security breaches. If we expand our international operations, we may be required to expend significant time and resources to put in place additional mechanisms to ensure compliance with multiple robust and evolving data privacy laws as they become applicable to our business.

Failure to comply with applicable data protection laws and regulations could result in government enforcement actions (which could include civil and/or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Compliance with these laws is difficult, constantly evolving, time consuming, and requires a flexible privacy framework and substantial resources. Compliance efforts will likely be an increasing and substantial cost in the future.

For information related to our cybersecurity risk management, strategy and governance, see the section entitled "Cybersecurity" under Part I, Item 1C below.

Reimbursement in the Clinic and Home Settings

We sell our Tablo to dialysis clinic operators (or providers). These clinics, in turn, provide equipment and services to the patient and are reimbursed by Medicare, Medicaid, and other third-party payors, such as private insurance.

Medicare

In the clinic and home setting, the largest payor of dialysis services is Medicare, and Medicare requires all dialysis patients to be under the care of a dialysis clinic provider, whether they are in the clinic or in the home.

Most patients who require regular dialysis, that is, those with ESRD, have coverage through Medicare Part B, which, effective January 1, 2011, pays dialysis clinics through a prospective, bundled payment system. Reimbursement is generally provided on a per treatment basis, and it is the same whether the patient is treated in the clinic or in the home setting. We believe that the current per treatment reimbursement amount received by our customers under Medicare Part B adequately covers the amortization of the cost of capital equipment, and specifically our Tablo console, as well as the per treatment supplies and disposables cost for Tablo, whether it is in the home or the in-clinic setting. Dialysis clinics' continuing use of Tablo, however, will depend on whether the cost of treatments involving Tablo (including the amortized cost of Tablo console and other capital equipment) will continue to be adequately covered by the reimbursement that the dialysis clinics receive from Medicare and any other third-party payors.

Under the ESRD Prospective Payment System (PPS), CMS generally makes a single bundled payment to the dialysis facility for each dialysis treatment that covers all renal dialysis services, which is broadly defined and includes home dialysis and most related drugs. On November 24, 2025, CMS published the final rule for Calendar Year (CY) 2026, which increased the base reimbursement rate per dialysis treatment to $281.71, an increase of $7.89 over the CY 2025 base rate of $273.82. CMS may adjust the base rate to account for factors that increase the cost of providing dialysis to a certain patient, for example, based on patient factors such as age, body surface area, low body mass index, and certain comorbidities, and based on facility factors like volume and geographic location. With a vast majority of U.S. ESRD patients covered by Medicare, the Medicare reimbursement rate is an important factor in a healthcare provider's decision to use Tablo and limits the fees for which we can sell or rent Tablo. As part of the CY 2026 final rule, CMS continued to extend Medicare coverage to allow payment for renal dialysis services furnished to acute kidney failure (AKI) patients in their homes at a payment rate of $281.71, in line with the updated ESRD PPS base rate. The CY 2026 final rule also terminated the End-Stage Renal Disease Treatment Choices Model (ETC Model), a mandatory payment model that adjusted certain Medicare payments to select ESRD facilities, nephrologists, and other clinicians managing beneficiaries with ESRD, effective December 31, 2025. Additionally, the final rule continues to allow ESRD facilities to bill Medicare for the home and self-dialysis training add-on payment adjustment for beneficiaries with AKI in CY 2026 and updates requirements for the ESRD Quality Incentive Program (QIP) to remove the Facility Commitment to Health Equity measure beginning with the CY 2027 ESRD QIP.

Current CMS rules limit the number of hemodialysis treatments paid for by Medicare Part B to three times a week, unless there is medical justification provided by the dialysis facility based on information from the patient's physician for additional treatments. Using currently available technology, most patients who receive home dialysis have been prescribed to receive more than three treatments per week. Tablo can allow providers to prescribe as few as three home dialysis treatments per week. However, to the extent that providers continue to prescribe more than three home dialysis treatments per week and Medicare contractors determine they will not pay for such additional treatments, use of Tablo could be adversely impacted. As there is not a uniform national standard for what constitutes medical justification, a clinic's decision as to how much it is willing to spend on home dialysis equipment and services will be at least partly dependent on the number of weekly treatments prescribed for home dialysis with Tablo and, if greater than three, the level of confidence the center has in the predictability of receiving reimbursement from Medicare for additional treatments per week based on submitted claims for medical justification.

Since January 1, 2021, there has been a significant increase in dialysis patients enrolled in a Medicare Advantage plan as a result of the 21st Century Cures Act, which amended the Social Security Act to allow ESRD patients covered under Medicare to enroll in Medicare Advantage plans for the first time. While Medicare Advantage plans must provide at least the same level of coverage for Medicare beneficiaries as traditional Medicare, reimbursement to dialysis facilities is most often higher than traditional Medicare with a wide range of variability in payment rates to providers. Reimbursement rates depend on each Medicare Advantage plan's contracts and network agreements with each dialysis facility. The CY 2021 Medicare ESRD PPS final rule, among other things, encouraged the development of new and innovative home dialysis machines to give Medicare beneficiaries more dialysis treatment options in the home and improve their quality of life. Specifically, the CY 2021 final rule included capital equipment in transitional add-on payment adjustments for new and innovative equipment and supplies (TPNIES). For home dialysis equipment CMS provided a pathway for capital related assets (CRA) to secure TPNIES. We applied for and received CRA TPNIES in connection with the use of Tablo by one patient per one machine in the home, pursuant to which Medicare paid 65% of the Medicare Administrative Contractor-determined pre-adjusted per treatment amount for two calendar years beginning in CY 2022. However, this two-year eligibility period ended on December 31, 2023, meaning Tablo has not been eligible for, and providers have not received, TPNIES since January 1, 2024.

Medicaid

Many ESRD patients also have Medicaid coverage that is supplemental to Medicare coverage, as it helps cover Medicare Part B coinsurance and items and services not covered by Medicare Part B. Some ESRD patients, however, may have Medicaid as their primary coverage. Because Medicaid is a state-administered program, Medicaid reimbursement for dialysis services varies by state.

Private Insurance

Finally, some patients may have coverage through private insurance, for example through a marketplace plan set up under the ACA or through an employer or union group health plan. Private insurance reimbursement is generally higher than government reimbursement, but private insurance coverage and reimbursement varies by sponsor and plan.

Reimbursement in the Critical Care Setting

For Medicare patients, both AKI and fluid overload therapies provided in an in-patient hospital setting are reimbursed under Medicare Part A through the Hospital Inpatient Prospective Payment System using the Medicare Severity Diagnosis Related Group System (MS-DRG). Under this system, reimbursement is determined based on a patient's diagnoses, demographics, and procedures furnished during the stay, and is intended to cover all of the hospital's costs of treating the patient. Longer hospitalization stays and higher labor needs, which are typical for patients with acute kidney failure and fluid overload, must be managed in order for care of these patients to be cost-effective. Similar to dialysis clinics that are reimbursed by Medicare Part B under the ESRD bundled payment methodology, we believe that there is a significant incentive for hospitals to find the most cost-efficient way to treat these patients in order to improve hospital economics for these therapies.

In the in-patient setting under Medicare, dialysis and ultrafiltration (UF) are not directly reimbursed, but rather are paid for out of the amount paid to inpatient hospitals in connection with the patient's applicable MS-DRG for his/her admission. In most cases, AKI or fluid overload requiring dialysis or ultrafiltration will increase the severity of the underlying diagnosis and therefore could result in higher reimbursement than those cases without dialysis. Given that dialysis is a "fixed cost" for providers within the MS-DRG, we believe that there is significant motivation for providers to attempt to reduce costs associated with dialysis in order to improve overall service line profitability.

United States Health Reform

Changes in healthcare policy could increase our costs and subject us to additional legislative and regulatory requirements that may interrupt commercialization of our current and future products, decrease our revenue and adversely impact sales of, and pricing of and reimbursement for, our current and future products. The United States and some foreign jurisdictions are considering or have enacted a number of other legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our products. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiatives implemented in the future could impact our revenue from the sale of our products.

The implementation of the ACA in the United States, for example, has changed healthcare financing and delivery by both governmental and private insurers substantially, and affected medical device manufacturers significantly. The ACA, among other things, implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. Additionally, the ACA encouraged states to expand eligibility criteria for Medicaid programs and created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

There have been judicial and Congressional challenges to various elements of the ACA, as well as efforts to modify certain aspects of the ACA. For example, Congress eliminated, starting January 1, 2019, the tax penalty for not complying with the ACA's individual mandate to carry health insurance. The Further Consolidated Appropriations Act of 2020, Pub. L. No. 116-94, signed into law December 20, 2019, fully repealed the ACA's "Cadillac Tax" on certain high-cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share (repeal effective in 2021), and the medical device excise tax on non-exempt medical devices. The American Rescue Plan of 2021, Pub. L. No. 117-2, enacted on March 11, 2021, temporarily increased premium tax credit assistance for those eligible for subsidies for 2021 and 2022 and removed the 400% federal poverty level limit that otherwise applies for purposes of eligibility to receive premium tax credits. Recently, the Inflation Reduction Act of 2022 extended this increased tax credit assistance and removal of the 400% federal poverty limit through 2025. This tax credit assistance expired on December 31, 2025. As a result, it is possible that fewer people may be insured in future years, and a significant reduction in the population covered under private health insurance may result in patient decisions to postpone or decide against receiving services and further difficulties in collecting patient payment and deductible receivables. It is unclear if efforts to challenge, or modify, or alter the implementation or interpretation of the ACA will affect our business, financial condition and results of operations.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, among other things, resulted in reductions in payments to Medicare providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect into 2032 unless additional Congressional action is taken, with the exception of a temporary suspension of the 2% cut in Medicare payments from May

1, 2020 through March 31, 2022 due to the COVID-19 pandemic. The law provided for 1% Medicare sequestration in the second quarter of 2022, with the full 2% sequestration going into effect thereafter through the first eleven months of the FY 2032 sequestration order, unless additional Congressional action is taken. As long as these cuts remain in effect, they could adversely impact payment for any products we may commercialize in the future. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced CMS payments to several types of providers, including hospitals, and extended the statute of limitations period for the government to recover Medicare overpayments to providers from three to five years.

Moreover, other legislative and executive actions have encouraged the development of new payment and care models for ESRD patients. For example, CMS published a final rule on September 29, 2020 that among other things, implemented the End-Stage Renal Disease Treatment Choices (ETC) Model, a mandatory payment model that adjusted certain Medicare payments to select ESRD facilities, nephrologists, and other clinicians managing beneficiaries with ESRD starting January 1, 2021. Specifically, the ETC Model adjusted certain ESRD facilities' treatment base rates under the ESRD Prospective Payment System and managed clinicians' monthly Medicare capitation payments to incentivize greater use of home dialysis and kidney transplants. CMS released its Third Annual Evaluation Report that included results from Measurement Years 4 through 6 on August 24, 2025. However, although the ETC Model was originally set to continue until June 30, 2027, CMS published a final rule on November 24, 2025 that terminated the ETC Model effective December 31, 2025. CMS explained that it has the authority to terminate a model that does not improve quality of care without increasing Medicare spending before concluding that the ETC Model has not enhanced the quality of care for ESRD patients as reflected through the key model measures of home dialysis modalities, transplant waitlisting, and living donor transplantation. As a result, the ETC Model payment adjustments will only apply to claim service dates ending on or before December 31, 2025, and CMS stopped sharing any data sharing and reports as of November 30, 2025, including any information about model performance in Measurement Years 7 through 10.

Additionally, on January 1, 2022, CMS implemented the Kidney Care Choices Model, a voluntary Medicare payment model with four distinct payment options designed to help providers reduce costs and improve quality of care for patients with late-stage chronic kidney disease and ESRD, to delay the need for dialysis, and to encourage kidney transplantation. The Kidney Care Choices Model is set to run through 2027. More recently, on November 26, 2024, CMS issued a final rule announcing a six-year mandatory alternative payment model, the Increasing Organ Transplant Access Model (IOTA Model). The IOTA Model, which will begin on July 1, 2025 and end on June 30, 2031, will test whether performance-based incentives (including both upside and downside risk payments) for participating kidney transplant hospitals will incentivize increased numbers of kidney transplants for patients with ESRD. Specifically, in performance year 1, participating transplant hospitals will only have the potential for a positive payment adjustment, but in performance year 2, the participating hospitals will have the potential for both positive and negative payment adjustments. The final rule also established standard provisions, applicable to the ETC and IOTA Models, that address beneficiary protections, cooperation in model evaluation and monitoring, audits and record retention, rights in data and intellectual property, monitoring and compliance, remedial action, model termination by CMS, limitations on review, provisions on bankruptcy and other notifications, and the reconsideration review process. Changes to the models of patient care, including an increased focus on treatments earlier in disease progression, may adversely affect our customers' businesses and potentially decrease the demand for our product or result in additional pricing pressures. Further, with home dialysis as a growing trend in the industry, a failure to implement our expansion into home dialysis could have a material adverse impact on our business.

We believe that there will continue to be proposals and other actions by legislators and other policymakers at both the federal and state levels, and by regulators and third-party payors to reduce costs and/or expand individual healthcare coverage. Changes to federal and state legislatures and executive offices have resulted in and will likely continue to result in further healthcare policy changes. For example, on July 9, 2021, former President Biden issued an executive order to promote competition in the American economy, including in the healthcare sector. Among the provisions in the executive order was a directive to HHS to standardize plan options in the national health insurance marketplaces (i.e., the Exchanges) to facilitate improved comparison shopping for insurance plans. Additionally, on June 21, 2022, in the case of *Marietta v. DaVita*, the Supreme Court of the United States addressed the question of whether a group health plan that provides limited benefits for outpatient dialysis – but does so uniformly for all plan participants – violates the Medicare Secondary Payer Act (MSPA), a law which makes Medicare a "secondary" payer to an individual's existing insurance plan for certain medical services, including dialysis, when that plan already covers the same services. Specifically, the Supreme Court held that because the Plan's terms apply uniformly to all covered individuals, the Plan does not "differentiate in the benefits it provides" to individuals with ESRD or "take into account" whether an individual is entitled to or eligible for Medicare, and thus does not violate the MSPA.

The current presidential administration has also signaled its intent to continue to pursue healthcare reform measures. For example, President Trump has issued a number of Executive Orders that signal his administration's intent to reduce federal spending on government-funded healthcare programs, such as Medicaid. In addition, on June 28, 2024, the U.S. Supreme Court issued an opinion holding that courts reviewing agency action pursuant to the Administrative Procedure Act (APA) "must exercise their independent judgment" and "may not defer to an agency interpretation of the law simply because a statute is ambiguous." The decision affects how lower courts evaluate challenges to agency interpretations of law, including those by CMS and other agencies with significant oversight of the healthcare industry. The new framework is likely to increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant

regulatory policies may be subject to increased litigation and judicial scrutiny. Any resulting changes in regulation may result in unexpected delays, increased costs, or other negative impacts that are difficult to predict but could have a material adverse effect on our business and financial condition. For example, certain of these changes could impose additional limitations on the rates we will be able to charge for our current and future products or the amounts of reimbursement available for our current and future products from governmental agencies or third-party payors.

Human Capital Resources

As of December 31, 2025, we had 310 full-time employees, with 58% in our field sales and service teams and 42% in the rest of the company. Our workforce hails from across industries, including technology, medical devices, life sciences, hospitals and other healthcare organizations.

As of December 31, 2025, our manufacturing facility in Tijuana, Mexico had 254 full-time team members on-site across quality, engineering, manufacturing, supply chain, and other support functions. TACNA facilitates the hiring of new team members and is responsible for human resource functions and payroll processing.

Starting in 2023 through the beginning of 2025, we implemented four workforce reductions. These actions were taken to align our level of investment with our key strategic priorities, with the goal of continuing to drive efficiency and effectiveness in serving both our patients and our shareholders.

There are no unions represented within our employee base and none of our employees are covered under collective bargaining agreements.

Talent and Pay Philosophies

We are committed to attracting the best talent we can find, while providing our employees with challenging work in a fast-paced environment. We recruit broadly and purposefully, and welcome diverse candidates.

Our work environment is goal-driven, and we believe in paying for outstanding performance and future potential. We offer competitive, market-based salaries, an annual cash bonus program tied to individual and company performance, an equity incentive compensation program including an employee stock purchase plan, a 401(k) retirement savings plan with company match, a comprehensive benefits package, team incentives and peer incentives.

Performance Management, Career Development, Engagement and Inclusive Workplace

We have a structured approach for employee performance management, development and growth. During 2025, managers generally held two key performance conversations per year with their team members; a year-end performance conversation is focused on evaluating the success and learning of the past year, and a mid-year performance conversation is focused on skill development and future growth opportunities.

We offer numerous avenues for employees to gain experience, exposure and build new skills. For example, we have invested in various training and development opportunities for our employees.

We strongly believe in growing from within and provide opportunities for in-role stretch assignments, cross-group short assignments, internal mobility, and promotions. We conduct an enterprise-wide employee survey at least semi-annually to monitor employee engagement and identify areas of focus for our human capital management program.

We are committed to creating and nurturing an inclusive workplace, where everyone feels respected, valued, and included – not only because it's the right thing to do, but also because we strongly believe that it's vital to our success and crucial to fully support the diverse communities we serve.

Employee Health and Safety

At Outset, safety is a priority and is part of everyone's job. We are committed to providing a safe workplace and we comply with applicable health and safety laws and regulations. We strictly prohibit any violent or threatening behavior on our premises or during any work-related activities. Our employees participate in applicable emergency response training and periodic drills to help maintain awareness of security, safety and emergency response protocols.

As an organization, one of our top priorities is to maintain the wellbeing of our employees and their families. Our comprehensive and competitive benefits program is designed to help employees balance their work lives and personal lives by giving them a sense of peace of mind related to their healthcare. We maintain a whole person wellbeing approach, providing resources to support physical, mental, financial, professional and social wellbeing.

Available Information

We make our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports, available free of charge at our website as soon as reasonably practicable after they have been filed with the Securities and Exchange Commission (SEC). Our website address is www.outsetmedical.com. Information on our website is not part of this report. The SEC maintains a website that contains the materials we file with the SEC at www.sec.gov.

Information About Our Executive Officers

The following table sets forth information concerning our executive officers and director as of the date of this Annual Report:

Name	Age	Position(s)
Executive Officers		
Leslie Trigg	55	President, Chief Executive Officer and Chair of the Board
Renee Gaeta	44	Chief Financial Officer
John L. Brottem	52	General Counsel and Secretary
Marc Nash	37	Executive Vice President, R&D, Operations and Service

Leslie Trigg

Leslie Trigg has served as our President and CEO and a member of our Board since November 2014 and as Chair of our Board since February 2022. Ms. Trigg joined the Company from Warburg Pincus, a private equity firm, where she was an Executive in Residence from March 2012 to March 2014. Prior to that, Ms. Trigg served in several roles at Lutonix (acquired by CR Bard), a medical device company, from January 2010 to February 2012, most recently as Executive Vice President, and as Chief Business Officer of AccessClosure (acquired by Cardinal Health), a medical device company, from September 2006 to June 2009. She also previously held positions with FoxHollow Technologies (acquired by ev3/Covidien), a manufacturer of devices to treat peripheral artery disease, Cytyc, a diagnostic and medical device company, Pro-Duct Health (acquired by Cytyc), a medical device company, and Guidant, a cardiovascular medical device company. Ms. Trigg has served on the board of directors of Exact Sciences Corporation, a molecular diagnostics company, since April 2025, and also serves on the board of directors of the Medical Device Manufacturers Association (MDMA). Previously, Ms. Trigg served on the boards of directors of Adaptive Biotechnologies Corporation, a biotechnology company, from March 2021 to June 2023, ARYA Sciences Acquisition Corp IV, a special purpose acquisition company, from March 2021 to July 2024, and Cardiovascular Systems, Inc., a medical device company, from 2010 to 2017. Ms. Trigg holds a B.S. degree from Northwestern University and an M.B.A. from The Haas School of Business, University of California, Berkeley.

Renee Gaeta

Renee Gaeta has served as our Chief Financial Officer since June 2025. Prior to joining the Company, Ms. Gaeta served as the Chief Financial Officer of Shockwave Medical, Inc., a medical device company, from February 2024 until it was acquired by Johnson & Johnson in May 2024. Prior to that, she served as Chief Financial Officer of Eko Health, a cardiopulmonary digital health company, from July 2021 to February 2024. From July 2017 to July 2021, Ms. Gaeta was Chief Financial Officer at Establishment Labs Holdings, Inc., a global medical technology company, and from August 2014 to June 2017, she served as Vice President, Corporate Controller at Sientra, Inc., a medical aesthetics company. Earlier in her career, Ms. Gaeta spent ten years at KPMG LLP where she held various positions of increasing responsibility. Ms. Gaeta has served on the board of directors of Candel Therapeutics, Inc., a biopharmaceutical company, since August 2022. Previously, she also served on the board of directors of SeaSpine Holdings Corporation, a global medical technology company, from February 2019 to January 2023 when it merged with Orthofix Medical. Ms. Gaeta holds a B.S. from Loyola Marymount University and is a Certified Public Accountant in the State of California.

John L. Brottem

John L. Brottem has served as our General Counsel and Secretary since May 2020. Prior to joining the Company, Mr. Brottem served in a number of roles at Omnicell, Inc., a leading provider of medication management automation solutions and adherence tools for healthcare systems and pharmacies: as Vice President, Legal and Deputy General Counsel from September 2019 to May 2020; as Vice President, Legal and Associate General Counsel from April 2016 to September 2019; and Senior Director, Legal and Associate General Counsel from November 2011 to April 2016. Prior to Omnicell, Mr. Brottem was Corporate Counsel at Brocade Communications Systems, Inc., a networking solutions company, from January 2009 to November 2011; Corporate Counsel at Foundry Networks, Inc., a networking solutions company, from February 2008 to January 2009; and Associate at Cooley Godward Kronish LLP, an international law firm, from November 2001 to February 2008. Mr. Brottem holds a B.A. from Occidental College and a J.D. from the University of California, Davis, School of Law.

Marc Nash

Marc Nash has served as our Executive Vice President, R&D, Operations and Service since August 2025. Mr. Nash joined the Company in December 2019 as Senior Director of Operations, was named Vice President, Manufacturing in March 2021 and was named Senior Vice President, Operations, Software and R&D in July 2023. Prior to joining the Company, from June 2016 through June 2019, Mr. Nash served as Director of Operations at Epocal Inc., a medical technology company (and a subsidiary of Alere, Inc. acquired by Siemens Healthineers), during which time he was responsible for the end-to-end manufacturing operations of point of care diagnostics products and platforms. From 2012 through 2016, Mr. Nash held various positions of increasing responsibility at Alere Inc., a medical technology company, where he was responsible for the transfer, consolidation and enhancement of class II and class III point of care and rapid diagnostic products globally. Mr. Nash holds a B.S. from Union College and an M.B.A. from the University of Haifa, Israel.

Item 1A. Risk Factors.

Risk Factors Summary

The following summarizes the principal factors that make an investment in our company speculative or risky, all of which are more fully described in the risk factors section below. This summary should be read in conjunction with the risk factors section and should not be relied upon as an exhaustive summary of the material risks facing our business. The following factors could result in harm to our business, reputation, revenue, financial results, and prospects, among other impacts:

Risks Related to Our Business and Industry

- Our history of net losses and expectation that we will continue to incur losses;
- Our ability to achieve sustainable gross margins, including by reducing manufacturing and service costs;
- Our ability to attain market acceptance for Tablo among providers and patients;
- Concentration of our revenues in a single product and concentration of a large percentage of our revenues from a limited number of customers;
- Financial pressures faced by our customers including capital budget constraints, staffing shortages and increased costs;
- Our ability to expand into the home-based and post-acute hemodialysis markets and the expansion of the home hemodialysis market itself;
- Risks associated with our international manufacturing operations, including the potential for tariffs and other trade disputes;
- Our reliance on third-party suppliers, including single source suppliers and a contract manufacturer, and our ability to overcome any manufacturing or supply chain disruptions;
- Our ability to optimize our sales processes and expand the adoption of Tablo as we focus more heavily on enterprise selling;
- Our ability to continue innovating and improving Tablo, ensure strong product performance and reliability, offer high quality support, ensure proper training and use of Tablo, and increase our sales and marketing capabilities;
- Our ability to compete effectively with existing manufacturers and new entrants;
- Our ability to effectively manage privacy, information and data security risks, including our ability to adequately defend against, respond to and manage increasingly sophisticated cyberattacks in an increasingly complex cyber ecosystem;
- Our estimates of the sizes of the markets for Tablo;
- Our ability to accurately forecast customer demand and manage our inventory;
- The impact of pandemics, natural or man-made disasters and similar events on our business;
- Potential disruptions of service provided by third parties that host our cloud-based ecosystem and information technology systems; and
- Our ability to obtain additional financing, as well as risks related to our credit agreement, including interest rate risk and our ability to access additional capital and/or meet certain covenants.

Risks Related to Government Regulation

- Our compliance with FDA and other medical device regulations applicable to our products and operations, including our ability to: recover from disruptions to our business and operations as a result of the warning letter we received from the FDA in 2023 and our prior distribution pause on TabloCart with Prefiltration; obtain and maintain necessary FDA regulatory clearance or approvals for Tablo, related products, or any future product modifications or new products; comply with ongoing FDA requirements, including related to the manufacturing, marketing and promotion of our products, and the ability of our suppliers to so comply; and manage the risks and expenses associated any clinical trials necessary to support future product submissions to the FDA;
- Impact of potential changes to scope of coverage and reimbursement rates for dialysis treatments or healthcare reform measures;

- Impact of potential adverse medical events associated with Tablo, product failures or malfunctions, or our failure to report such events to the FDA; and
- Our ability to comply with various laws and regulations regarding healthcare, data privacy and security, and environmental and occupational safety.

Risks Related to Our Intellectual Property

- Our ability to obtain, maintain, protect and enforce our intellectual property rights, including our patents, copyrights, trademarks and trade secrets.

Risks Related to Ownership of Our Common Stock

- Fluctuations in the market price of our common stock in response to numerous factors regardless of our operating performance;
- Our ability to maintain the listing of our common stock on Nasdaq;
- Influence of principal stockholders and management over matters subject to stockholder approval; and
- Our organizational documents include certain provisions that may make a change of control more difficult, as well as exclusive forum requirements.

General Risks

- General economic and financial market conditions;
- Substantial resources associated with complying with the laws and regulations affecting public companies;
- Our ability to attract and retain key personnel and maintain our corporate culture;
- Risks associated with potential future acquisitions or investments;
- Our ability to comply with anti-corruption, anti-bribery, anti-money laundering and similar laws;
- Our estimates or judgments relating to our accounting policies; and
- Expectations relating to ESG factors.

The summary risk factors described above should be read together with the text of the full risk factors below and the other information set forth in this Annual Report, including our financial statements and the related notes and the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations", as well as in other documents that we file with the SEC. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us, or that we currently deem to be immaterial, may also arise and materially impact our business. If any of these risks occur, our business, results of operations and financial condition could be materially and adversely affected and the trading price of our common stock could decline.

Risks Related to our Business and Industry

We have a history of net losses, and we expect to continue to incur losses for the foreseeable future. If we ever achieve profitability, we may not be able to sustain it.

We have incurred losses since our inception and expect to continue to incur significant net losses for the foreseeable future. We have incurred net losses of $81.7 million, $128.0 million and $172.8 million for the years ended December 31, 2025, 2024, and 2023, respectively. As of December 31, 2025, we had $172.8 million in cash, cash equivalents, restricted cash and short-term investments, and an accumulated deficit of $1.2 billion. Based on our current planned operations, we believe that our existing cash, cash equivalents and short-term investments, and cash generated from sales will be sufficient to meet our anticipated needs for at least the next 12 months from the date of this Annual Report. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

Our revenue is derived, and we expect it to continue to be derived, primarily from sales of Tablo, its associated consumables and related services. Because of its relatively recent commercial introduction, Tablo may continue to have limited product and brand recognition. In addition, demand for Tablo may decline or may not increase as quickly as we expect. Our ability to generate revenue from sales of Tablo, associated consumables and related services, or from any products we may develop in the future, may not be sufficient to enable us to transition to profitability and generate positive cash flows within the timeframe we anticipate or at all.

While we have undertaken various initiatives designed to reduce operating expenses and working capital to align with anticipated revenue growth, including implementing restructuring plans to streamline our overall organizational structure and renegotiating commitments with suppliers to reduce inventory, we expect to continue to incur significant expenses for the foreseeable future and to incur operating losses in the near term while we make investments to support our anticipated growth. Our ability to achieve and sustain profitability will depend on our ability to grow our revenue while expanding gross margins, as well as the success of our efforts to optimize spending and working capital, including inventory. We may never achieve profitability, and even if we do achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time. If we do not achieve or sustain profitability, it will be more difficult for us to finance our business and accomplish our strategic objectives, either of which would have a material adverse effect on our business, financial condition and results of operations.

Our ability to achieve sustainable gross margins depends on the success of our various initiatives designed to expand gross margin.

We have undertaken a number of initiatives designed to expand gross margins. Our ability to expand gross margins will depend in part on our ability to control the average selling prices of our products and services, including by selling higher-margin accessories, consumables and services. Our ability to maintain our product pricing is dependent on our customers' recognition that the benefits outweigh the higher upfront purchase price. If we are unable to maintain our product pricing or continue to sell higher-margin accessories, consumables and services at the levels we anticipate, our ability to expand gross margins will be adversely affected, which would harm our business, financial condition and results of operations.

In addition, our ability to expand gross margins is also dependent on the success of our initiatives to better leverage our field service team and drive down service costs per console, including through our cloud-based data system, remote monitoring, remote diagnostics and repairs, and other enhancements designed to improve the performance and reliability of Tablo. If we are unable to continuously improve the performance and reliability of Tablo, broaden our installed base or if these initiatives are otherwise unsuccessful, we may fail to better leverage our field service team and drive down service costs per console within the timeframe we anticipate or at all, which could delay or prevent us from achieving sustainable gross margins, and adversely impact our financial condition, results of operation and future growth.

Over the past several years, we have moved the production of Tablo consoles and a substantial majority of Tablo cartridges in-house to our manufacturing facility in Tijuana, Mexico which we operate in collaboration with our outsourced business administration service provider, TACNA. This has helped further our long-term gross margin expansion and supply continuity strategies while reducing the costs of Tablo console production and improving the flexibility of our operations. We plan to continue to use our design, engineering, supply chain, and manufacturing capabilities to help further advance and improve the efficiency of our manufacturing processes, lower the cost of parts and components, and lower our costs of production. However, there is no guarantee that we will be able to sustain cost reductions, achieve planned cost reductions, or otherwise achieve the anticipated benefits from our various initiatives. For example, we may be unable to sustain the savings associated with producing Tablo consoles at our manufacturing facility with TACNA, or the benefits we anticipate will result from insourcing Tablo cartridge production at this same facility may not materialize or be as significant as projected or realized within the timeframe we currently estimate. Moreover, increased tariffs imposed by the current administration, including on goods imported into the United States from Mexico and China, could adversely impact our supply chain and distribution costs, as well as our ability to achieve sustainable gross margins. We currently do not believe we have exposure to these tariffs as Tablo, TabloCart and Tablo cartridges are covered under a special exemption. However, in September 2025, the U.S. Department of Commerce initiated an investigation under Section 232 of the Trade Expansion Act of 1962 to assess the national security implications of imports of personal protective equipment, medical consumables, and medical equipment, including medical devices. The outcome of this investigation could result in additional tariffs or other trade restrictions. While we continue to believe our products will remain exempt, the scope and outcome of the investigation are uncertain and could affect existing exemptions or expand coverage to additional product categories. We cannot predict what actions may ultimately be taken with respect to tariffs or trade relations between the United States and other countries (including Mexico and China), what products may be subject to such actions, or what actions may be taken by the other countries in retaliation. There may also be unforeseen occurrences that increase our costs, such as increased prices of raw materials, changes to labor costs, less favorable terms with third party suppliers, freight providers, or contract manufacturing partners, or disruptions to the operations of our contract manufacturers or third-party suppliers including as a result of public health crises such as the COVID-19 pandemic. If we are unable to reduce our costs or if cost reductions or other anticipated benefits are less significant or less timely than projected, we will not be able to achieve sustainable gross margins, which would adversely affect our ability to invest in and grow our business and adversely impact our business, financial condition and results of operations.

The commercial success of Tablo will depend upon attaining significant market acceptance among providers and patients.

Our success will depend, in part, on growing acceptance of Tablo as safe, easy to learn, easy to use, clinically flexible, operationally versatile and, with respect to providers, cost effective. We began commercializing Tablo in the United States in 2018 and expanded commercialization to support home-based dialysis in 2020. While we have gained commercial experience and expanded our installed base since that time, we must continue to demonstrate the financial, clinical and operational benefits of our technology and services to achieve broader and sustained market acceptance. It remains difficult to evaluate our long-term business performance

and predict our future prospects, including how quickly, or whether, our technology and services will achieve broader market acceptance, adoption and utilization among providers and patients. These constituents must believe that Tablo, and insourcing with Tablo, offer benefits over traditional machines or outsourced dialysis offerings. The degree of market acceptance of Tablo and our service offerings will depend on a number of factors, including:

- whether providers and others in the medical community consider Tablo to be a safe and cost-effective treatment method;
- the potential and perceived advantages of Tablo, and insourcing with Tablo, compared to traditional machines or outsourcing dialysis services to third-party providers, including cost of treatment, convenience, ease of use and maintenance;
- the potential and perceived advantages of Tablo, and insourcing with Tablo, relative to our customers' other capital and operating purchase requirements;
- the effectiveness of our sales and marketing efforts for Tablo;
- our ability to expand into the acute market as well as the post-acute market, including SNFs, LTACHs, and other post-acute providers;
- the success of our initiatives to optimize our commercial organization, infrastructure and sales processes to support the growth of our business in the acute care market as we focus more heavily on enterprise selling;
- our ability to provide incremental data that show the clinical benefits and cost effectiveness of, and operational benefits from, Tablo;
- any changes to the availability of coverage and adequate reimbursement for dialysis from payors, including government authorities;
- pricing pressure, including from Group Purchasing Organizations (GPOs), seeking to obtain discounts on Tablo based on the collective buying power of their GPO members;
- product labeling or product insert requirements by the FDA or other regulatory authorities; and
- limitations or warnings contained in the labeling cleared or approved by the FDA or other authorities.

Additionally, even if Tablo achieves widespread market acceptance, it may not maintain that market acceptance over time if competing products or technologies, that are more cost effective or received more favorably, are introduced. Failure to achieve or maintain broader market acceptance and/or market share would limit our ability to generate revenue and would have a material adverse effect on our business, financial condition and results of operations.

We currently derive substantially all of our revenue from the sale of Tablo and associated consumables and are therefore highly dependent on Tablo for our success.

We derive substantially all of our revenues from sales of Tablo and its associated accessories and consumables, with the remainder of our revenues largely coming from services provided for the support and maintenance of Tablo. Accordingly, our business is exposed to risks that our revenues are concentrated in a single product. As a result, any event that adversely affects Tablo or the market for Tablo and associated accessories and consumables could adversely affect our business, financial condition and results of operation.

Our customers may face financial pressures including, but not limited to, capital budget constraints, staffing shortages and increased costs arising from macroeconomic conditions, evolving policy changes or other factors, that have had, and may continue to have, a negative impact on our financial condition or results of operations.

Beginning in 2022, our existing and prospective customers faced shortages of skilled nurses and other clinical personnel as well as increased labor costs, combined with economic pressures resulting from general economic and financial market conditions, primarily escalating inflation, tightening hospital operating budgets and increased scrutiny of capital purchase decisions, all of which generally have the effect of lengthening the average sales cycle and elongating the timing of installations. These factors negatively impacted our customer base on pipeline development and installation schedules, which, in turn, negatively impacted our bookings, delayed our shipments and adversely impacted our revenues for 2022 and, to a lesser extent, 2023.

Beginning in the third quarter of 2023, we began to observe an increasing number of our existing and prospective customers deferring their decisions to purchase Tablo in an environment of rising interest rates and more cautious capital spending. These deferrals served to further elongate our sales cycle and the timing of delivery and installations which in turn, contributed to an adverse impact on our bookings and revenues starting in the second half of 2023, and through 2025. We have no assurance that these impacts will abate in future periods.

In addition, ongoing uncertainty relating to various policy changes under the current administration, including developments in trade policy (such as increased tariffs), changes in interest rate policy, potential reductions in government reimbursement and shifts in broader healthcare policy, could increase financial pressures faced by our existing and prospective hospital customers. These actual or anticipated policy changes may lead to higher operating costs for our customers, as well as tighter operating budgets and more cautious capital spending decisions. Additionally, broader economic uncertainty and market volatility, driven in part by these evolving policies, could exacerbate financial strain on our customers, potentially resulting in delayed or reduced purchases of our products and services. These factors could adversely impact our revenues, results of operations and financial condition in future periods.

We also believe that there will continue to be proposals and other actions by legislators and other policymakers at both the federal and state levels, and by regulators and third-party payors to reduce costs. For example, the One Big Beautiful Bill Act aims to reform Medicaid by eliminating certain financial incentives, imposing work requirements on certain adult beneficiaries, and requiring states to increase patient cost-sharing amounts for certain services. We cannot predict with any assurance the ultimate effect of these reforms on our business.

If our customers continue to face prolonged periods of rising interest rates, capital budget constraints, volatility, uncertainty, staffing shortages, cash flow challenges, rising costs and other financial pressures, whether due to general macroeconomic conditions, evolving policy changes under the current administration (including trade policy developments, reductions in government reimbursement or shifts in healthcare policy), cybersecurity events or other factors, it could ultimately adversely impact our ability to expand existing customer relationships or attract new customers of Tablo, timely collect amounts due, effectively manage our inventory levels, and have a material adverse effect on our bookings, revenues, results of operations, financial condition, and, ultimately, our future growth and profitability.

Our financial condition or results of operations, including our ability to generate revenue from home-based and post-acute dialysis, is subject to certain risks and uncertainties, including around the use of Tablo in the home and post-acute settings.

In March 2020, Tablo was cleared by the FDA for patient use in the home of patients with acute and/or chronic renal failure, with or without ultrafiltration, and we intend to expand within the home market. However, this goal is subject to certain risks, including our ability to attract, retain and manage patients, as well as our ability to further evolve our commercial infrastructure and sales processes as we scale our business in the home market. Our business strategy, including our pricing of Tablo, while informed by our relatively limited history of selling Tablo in the home care setting, continues to be based in part on certain assumptions about the adoption of Tablo by home dialysis patients, as well as patient retention. If these assumptions about the home market are inaccurate and we are unable to increase our share of the home dialysis market by attracting new patients, or retain such market share once achieved, we would need to significantly change certain aspects of our business strategy, including the pricing of the Tablo console, associated consumables and support and maintenance, which could adversely affect our business, financial condition and results of operations.

Our relatively limited experience in the distribution, logistics and service support that relate to the use of Tablo in the home care setting may also negatively impact our ability to generate revenue from home-based dialysis. Currently, the provision of in-clinic and home dialysis is largely dominated by DaVita and Fresenius, and our expansion within the home dialysis market is dependent on our ability to grow new home programs with health systems and innovative dialysis clinic partners.

In addition, patients and their care partners using Tablo for home dialysis may not successfully operate Tablo, or may require increased service and support from us. Further, providers of dialysis in the home or post-acute setting may not successfully obtain or maintain necessary certifications or approvals to operate a dialysis program, which may negatively impact our financial condition or results of operations. Moreover, given that the home dialysis and post-acute markets remain relatively novel for us, we also face the risk that we may encounter difficulties whose precise nature or magnitude we cannot accurately predict at this time, but which may have a material adverse effect on our business, financial condition or results of operations.

With a significant portion of our manufacturing operations, as well as key software development and certain IT personnel, located outside of the United States, we may experience operational disruptions, and be subject to additional risks associated with international manufacturing operations, including uncertain or changing regulatory and/or labor requirements.

We have insourced the production of Tablo consoles, and a substantial majority of Tablo cartridges, at our manufacturing facility in Tijuana, Mexico which we operate in collaboration with our outsourced business administration service provider, TACNA. Under our arrangement with TACNA, we control the operations, engineering, quality and materials supply functions at the facility, while TACNA provides manufacturing space, the workforce, utilities, cross-border logistics, local permits and licenses. We are subject to a number of additional risks associated with operating our Mexico-based manufacturing facility, and many of these risks may heighten to the extent we continue to ramp our cartridge manufacturing capabilities and increase our dependence on our Mexico-based manufacturing operations. We may experience strikes, work stoppages, work slowdowns, high personnel turnover, grievances, complaints, claims of unfair labor practices, other collective bargaining disputes or other labor disputes at our new facility. Our manufacturing operations at the facility may also suffer disruptions from global or regional public health crises such as the COVID-19

pandemic, natural disasters, cyber security attacks, vandalism, terrorism or other political hostilities. Any such occurrences could negatively impact our ability to produce Tablo consoles and cartridges.

In addition, we rely on certain key software development personnel located in Mexico to support the development, maintenance and enhancement of our products. Disruptions affecting the availability or retention of these software development personnel, including due to labor market conditions, regulatory changes, public health events, political instability or other factors beyond our control, could delay or impair our product development efforts. Replacing or scaling software development capabilities could be difficult, time-consuming and costly, and any such disruption could adversely affect our business, financial condition and results of operations. We also utilize certain IT personnel located in Mexico to support certain internal systems and infrastructure. In the event these resources become unavailable or are disrupted, we believe alternative IT resources could be obtained; however, any such transition could result in temporary disruptions to our business operations and could increase our costs.

We are also subject to a variety of foreign laws and regulations, including trade and labor restrictions and laws relating to importation, exportation and taxation of goods, and U.S. laws and regulations relating to foreign operations, including anti-corruption, anti-bribery and anti-money laundering laws. For example, the current administration has advocated greater restrictions on trade generally and, in particular, tariff increases on certain goods imported into the United States, including from Mexico and China. In February 2025, the current administration issued executive orders imposing additional 25% tariffs on products imported from Mexico and additional 10% tariffs on products imported from China. While the tariffs on products from China went into effect in February 2025 (and increased from 10% to 20% in March 2025), the tariffs on products from Mexico were suspended for an additional month. These tariffs could potentially impact certain areas of our supply chain, including raw materials entering Mexico, raw materials entering the United States from China for use by our United States-based suppliers, and finished goods imported from Mexico into the United States. We currently do not believe we have exposure to these tariffs as Tablo, TabloCart and Tablo cartridge are covered under a special exemption. However, in September 2025, the U.S. Department of Commerce initiated an investigation under Section 232 of the Trade Expansion Act of 1962 to assess the national security implications of imports of personal protective equipment, medical consumables, and medical equipment, including medical devices. The outcome of this investigation could result in additional tariffs or other trade restrictions. While we continue to believe our products will remain exempt, the scope and outcome of the investigation are uncertain and could affect existing exemptions or expand coverage to additional product categories. We cannot predict what actions may ultimately be taken with respect to tariffs or trade relations between the United States and other countries (including Mexico and China), which products may become subject to such actions, or how other countries may respond in retaliation. The adoption and expansion of trade restrictions, the occurrence of a trade war, other governmental action related to tariffs or trade agreements or policies, or the related uncertainties, has the potential to adversely impact our supply chain and distribution costs, which could in turn adversely affect our business, financial condition, and results of operations, including our ability to expand gross margins.

Furthermore, although prior proposals to amend Mexico's federal labor law, including a reduction in maximum workweek hours from 48 to 40 hours, were rejected by the Mexican Congress in 2024, in December 2025, the Mexican government formally reintroduced proposed legislation for congressional consideration. The proposed legislation contemplates a phased reduction in the maximum workweek hours, with the first reduction expected to take effect as early as 2027 and the ultimate goal of achieving a 40-hour workweek by 2030. While the specific details, timing and scope of implementation remain uncertain and are subject to the legislative process, if enacted, these potential legislative changes are expected to increase our labor costs and, ultimately, could potentially negatively impact the productivity of our manufacturing operations to the extent our efforts to mitigate the impact of the changes are not successful. In addition, because certain of our Mexico-based manufacturing operations incur costs that are denominated in Mexican Pesos (MXN), we are exposed to additional risk of currency fluctuations between the U.S. dollars (USD) and MXN, which could increase our product and labor costs, thus reducing our gross profit. Moreover, while certain members of our management team have some manufacturing experience, as an organization, we do not have any prior experience in this type of manufacturing arrangement, and we could accordingly experience other risks, the nature and magnitude of which we are unable to assess precisely at this time. Furthermore, we are subject to increased risks related to changes in export or import regulation, other trade barriers, security measures and uncertainties impacting the cost and the ability to move inventory and manufacturing equipment across the United States-Mexico border. These risks may disrupt our Mexico-based manufacturing operations, subject us to increased costs, restrict or delay our ability to deliver products to our customers and meet our customers' demand on a timely basis, and result in customer dissatisfaction, all of which would adversely impact our results of operations.

In addition, we continue to utilize a contract manufacturing partner in Southeast Asia, for the production of a small portion of our Tablo cartridges to supplement our in-house manufacturing production and provide additional flexibility. If this contract manufacturing partners' facilities were disrupted, by labor disputes, work stoppages, public health crises such as the COVID-19 pandemic, riots, terrorism, vandalism, cyber security attacks, natural disaster, regulatory action or otherwise, or if we are unable to agree on acceptable terms and conditions in connection with the renewal or renegotiation of our arrangement with this partner, we may need to reallocate production to our in-house manufacturing facility. Such a shift could result in temporary operational inefficiencies or increased costs. While we believe we have the ability to mitigate the impact of disruptions affecting our contract

manufacturing partner, including through internal manufacturing capacity, there can be no assurance that such mitigation efforts would fully eliminate all operational impacts, particularly in the short term.

We depend upon third-party suppliers, including a contract manufacturer and single source suppliers, making us vulnerable to supply problems and price fluctuations.

We rely on third-party suppliers, including in some instances single source suppliers, to provide us with certain components of Tablo. The number of suppliers required for Tablo console production is approximately 100 worldwide. We consider a discrete number of these suppliers, located in the United States, Mexico, Europe and Asia, as critical providers of components such as pumps, motors, valves and Printed Circuit Board Assembly (PCBA) boards. While we are undertaking a second source qualification process for the majority of these critical components, we may not ultimately be successful in securing second sourcing for all of them.

In addition, we purchase supplies through purchase orders and do not have long-term supply agreements with, or guaranteed commitments from all, our suppliers, including single source suppliers. Moreover, while we manufacture a substantial majority of Tablo cartridges in-house, we continue to utilize a contract manufacturer for the production of a small portion of Tablo cartridges. Many of our suppliers and our contract manufacturer are not obligated to perform services or supply products for any specific period, in any specific quantity or at any specific price, except as may be provided in a particular purchase order. We depend on our suppliers and contract manufacturer to provide us and our customers with materials in a timely manner that meet our and their quality, quantity and cost requirements. These suppliers and contract manufacturer may encounter problems during manufacturing for a variety of reasons, including as a result of public health crises such as the COVID-19 pandemic, labor disputes, work stoppages, damage or interruption from fires, severe weather or other natural disasters, vandalism, terrorism or other political hostilities, any of which could delay or impede their ability to meet our demand. These suppliers and contract manufacturer may cease producing the components we purchase from them or otherwise decide to cease doing business with us. As part of our supply continuity planning, we maintain limited quantities of raw material, work in progress and finished good product at both suppliers and contract manufacturers. However, if we inaccurately forecast demand for finished goods, we may be unable to meet customer demand which could harm our competitive position and reputation. Further, if we fail to effectively manage our relationships with our suppliers and contract manufacturer, we may be required to change suppliers or contract manufacturers. While we believe replacement suppliers exist for all most all materials, components and services necessary to continue manufacturing Tablo, establishing additional or replacement suppliers for any of these materials, components or services could be time-consuming and expensive, may result in interruptions in our operations and product delivery, may affect the performance specifications of Tablo or could require that we modify Tablo's design. Even if we are able to find replacement suppliers, we will be required to verify that the new supplier maintains facilities, procedures and operations that comply with our quality expectations and applicable regulatory requirements. Any of these events could require that we obtain a new regulatory authority approval before we implement the change, which could result in further delay and which may not be obtained at all. If our third-party suppliers fail to deliver the required commercial quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement suppliers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality on a timely basis, the continued commercialization of Tablo, the supply of our products to customers and the development of any future products will be delayed, limited or prevented, which could have a material adverse effect on our business, financial condition and results of operations.

For example, we have worked closely with our manufacturing partners and suppliers to enable us to source key components and maintain appropriate inventory levels to meet customer demand, and have not experienced material disruptions in our supply chain to date. However, macroeconomic factors such as rising inflation, increasing labor costs, and surges and shifts in consumer demand, have disrupted the operations of certain of our third-party suppliers, resulting, in some cases, in increased lead times and higher component costs. Moreover, we believe that localizing production of a substantial majority of Tablo cartridges in Mexico (in-house at our manufacturing facility) has helped achieve cost reductions through lower freight costs, further our long-term gross margin expansion and supply continuity strategies and improve the flexibility of our operations. However, we may face increased supply chain constraints or the impact of tariffs in the future, which could negatively impact our ability to meet customer demand on a timely basis, result in customer dissatisfaction and adversely impact our operating margins and results of operations.

If we fail to expand the adoption of Tablo as we focus more heavily on enterprise selling, we may not be able to generate revenue growth.

We may periodically adjust our sales organization or sales strategies in response to market shifts or opportunities, changes in our current or prospective customers, competitive threats, management changes, sales headcount changes, product and service introductions or enhancements, sales performance, cost reduction initiatives, and other internal and external considerations. Any such changes may result in disruptions in our sales cycle or a reduction of productivity, which could negatively impact our revenue growth. For example, during the second quarter of 2024, we observed a further elongation of our sales cycle, which contributed to an adverse impact on our revenues for the quarter, and which we believe was due in part to our transition beyond earlier stage adoption of Tablo. We identified a need to evolve our sales strategy to focus more heavily on enterprise selling, which often requires approvals and commitment across a larger base of stakeholders within a health system including clinical, financial and operational executives, and can elongate the sales cycle. We determined that this shift requires additional training, skill-building and optimization of our sales

team and sales processes. In connection with our initiatives to help optimize our commercial organization, and to help improve operational efficiencies and reduce operating expenses to align with anticipated revenue growth, in the third quarter of 2024, we completed a restructuring primarily impacting our commercial organization. These actions could result in short-term or long-term disruption of our sales cycle and may not produce the cost savings, efficiencies and other benefits we anticipate or desire. Our ability to achieve the anticipated cost savings, efficiencies and other benefits from these actions on the timeframe we expect, or at all, is subject to estimates and assumptions, which are subject to uncertainties. If our estimates and assumptions are incorrect, if we are unsuccessful at implementing these changes or if we otherwise encounter deficiencies or inefficiencies in our infrastructure or processes which we did not anticipate, it could harm our business, financial condition, results of operations and, ultimately, our future growth and profitability. For example, as we continued to focus more heavily on enterprise selling in 2025, sales cycles for these enterprise customers were longer than expected, which contributed to an adverse impact on our revenues during the period.

If we fail to provide strong product performance, customer dissatisfaction could adversely affect our reputation and results of operations.

We need to maintain and continuously improve the performance and reliability of Tablo to achieve our profitability objectives. Poor product performance and reliability could lead to customer dissatisfaction, adversely affect our reputation, lower the rates at which customers purchase consumables, reduce our service revenue, or increase our service and distribution costs and working capital requirements. Software and hardware incorporated into Tablo may contain errors or defects, especially when first introduced and while we have made efforts to test this software and hardware extensively, we cannot assure that the software and hardware, or software and hardware developed in the future, will not experience errors or performance problems.

If we are unable to continue to innovate and improve Tablo, we could lose customers or market share.

Our success will depend on our ability to keep ahead of developments in the dialysis industry. It is critical to our competitiveness that we continue to innovate and make improvements to Tablo's functionality and efficiency. If we fail to make improvements to Tablo's functionality over time, our competitors may develop products that offer features and functionality similar or superior to those of Tablo. If we fail to make improvements to Tablo's efficiency, our competitors may develop products that are more cost effective than Tablo. Our failure to make continuous improvements to Tablo to keep ahead of the products of our competitors could result in the loss of customers or market share that would adversely affect our business, results of operations, and financial condition.

We face competition from many sources, including larger companies and new entrants, and we may be unable to compete successfully.

There are a number of dialysis machine manufacturers and dialysis service providers in the United States, Europe and Asia. Notable competitors in the United States include Fresenius; DaVita, a dialysis service provider; Mozarc Medical, a dialysis products joint venture formed by DaVita and Medtronic; and B. Braun. Vantive, formerly the Baxter kidney care segment, also offers specialized dialysis products that may be used by hospitals for inpatient dialysis. In addition, Quanta's dialysis system has received FDA 510(k) clearance for use in acute and/or chronic and home settings. Of these competitors, Fresenius is the largest and it supplies dialysis products, operates a significant number of dialysis clinics and provides outsourced dialysis services in many hospitals. In the home hemodialysis setting, competitors primarily include Fresenius (through its acquisition of NxStage) and Quanta. Some of our competitors are significantly larger than us or otherwise possess competitive advantages, including:

- longer operating histories;
- substantially greater market share and brand recognition;
- broader, deeper or longer-standing relationships with healthcare professionals, customers and third-party payors;
- more established distribution networks;
- broader product portfolios and the ability to offer bundled products, rebates or other pricing incentives;
- greater experience in conducting research and development, manufacturing, clinical trials, marketing and obtaining regulatory clearance or approval for products; and
- greater financial and personnel resources to devote to marketing, sales, product development and other product initiatives.

Our continued success depends on our ability to:

- demonstrate the financial, clinical and operational benefits of Tablo and insourcing with Tablo relative to traditional dialysis machines or outsourcing dialysis services;

- further penetrate the acute care market and drive utilization and fleet expansion among our existing customers in the acute care setting;
- successfully expand within the home dialysis market;
- maintain and widen our technology lead over competitors by continuing to innovate and deliver new product enhancements on a continuous basis;
- cost-effectively manufacture Tablo and its component parts as well as drive down the cost of service;
- overcome potential customer sentiment around our perceived financial health as a result of our low stock price; and
- overcome the adverse impact in the field from the Warning Letter and our prior distribution pause on TabloCart with Prefiltration which created a certain amount of marketplace confusion (exacerbated, we believe, in some cases by our competitors) particularly regarding Tablo's use in the intensive care unit (ICU).

In addition, competitors, including those with greater financial resources than ours, could acquire, combine with or partner with other companies to gain enhanced name recognition and market share, as well as new technologies, products or services that could effectively compete with our existing solutions, which may cause our revenue to decline and would harm our business. For example, in 2023, Medtronic and DaVita launched an independent company focused on kidney care named Mozarc Medical, and in 2022, Fresenius Health Partners (the value-based care division of Fresenius), InterWell Health and Cricket Health, Inc. merged the three businesses into a new independent company focused on kidney care. In the future, we may also face competition from new entrants or companies spun off from our larger competitors. For example, in 2025, Baxter International, Inc. completed its spin off of its kidney care segment into a new independent company named Vantive.

Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, as well as in acquiring technologies complementary to, or necessary for, Tablo. Because of the complex and technical nature of Tablo and the dynamic market in which we compete, any failure to attract and retain a sufficient number of qualified employees could materially harm our ability to develop and commercialize Tablo, which would have a material adverse effect on our business, financial condition and results of operations.

As we attain greater commercial success, our competitors are likely to develop products that offer features and functionality similar to Tablo. Improvements in existing competitive products or the introduction of new competitive products may make it more difficult for us to compete for sales, particularly if those competitive products demonstrate better reliability, convenience or effectiveness or are offered at lower prices.

More generally, the development of viable medical, pharmacological and technological advances in treating or preventing kidney failure may also limit the opportunity for Tablo and our services. While kidney transplantation is the treatment of choice for most patients with ESRD, it is not currently a viable treatment for most patients. This may change, however, with the development of new medications designed to reduce the incidence of kidney transplant rejection, progress in using kidneys harvested from genetically engineered animals as a source of transplants as demonstrated by the first pig-to-human kidney transplant in 2021, and other advances in kidney transplantation. Moreover, developments in the healthcare marketplace related to new or innovative technologies, drugs and other treatments have the potential to impact the rate of growth of the ESRD patient population or otherwise reduce demand for dialysis treatments. For example, in October 2023, a pharmaceutical manufacturer announced the early termination of its study, which sought to demonstrate the effectiveness of its glucagon-like peptide (GLP-1) receptor agonist indicated for type 2 diabetes in delaying the progression of CKD and lowering the risk of cardiovascular mortality, as a result of the study having met certain endpoints. This development generated uncertainty in the marketplace with respect to the potential impact of these or other similar classes of drugs or new classes of drugs or treatments on the rate of growth of the ESRD patient population. We believe increased adoption of GLP-1 receptor agonists has the potential to reduce cardiovascular disease and events, which is the leading cause of mortality amongst patients with chronic kidney disease and on dialysis, resulting in lower mortality rates and likely an increase in the ESRD patient population over time. However, any sustained or significant decline in the rate of growth of the ESRD patient population or demand for Tablo, whether as a result of developments related to new or innovative technologies, drugs, treatments or otherwise, may adversely impact our business, results of operation, financial condition, cash flows and stock price.

We may face additional costs, loss of revenue, significant liabilities, harm to our brand, decreased use of our platform and business disruption if there are any security or data privacy breaches or other unauthorized or improper access.

In connection with various facets of our business, we collect and use a variety of personal information as part of the Tablo data ecosystem, such as name, street address, email addresses, mobile telephone number, and prescription information. Security breaches, computer malware and computer hacking attacks have become more prevalent across industries and may occur on our systems or those of our third-party service providers, suppliers or other partners. Despite the implementation of security measures, our internal computer systems and those of our third-party service providers, suppliers and other partners are vulnerable to damage from computer viruses, hacking and other means of unauthorized access, denial of service and other attacks, natural disasters, terrorism, war

and telecommunication and electrical failures. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Further, we may face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who may work remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. In addition to unauthorized access to or acquisition of personal information, confidential information, intellectual property or other sensitive information, such attacks could include the deployment of harmful malware and ransomware, and may use a variety of methods, including denial-of-service attacks, social engineering and other means, to attain such unauthorized access or otherwise affect service reliability and threaten the confidentiality, integrity and availability of information. Any failure to prevent or mitigate security breaches or improper access to, or use or disclosure of, our data or consumers' personal information, including information hosted by third party service providers such as Amazon Web Services (AWS), could result in significant liability under applicable data protection laws, such as state breach notification laws and the HIPAA and its implementing regulations. Such an incident may also cause a material loss of revenue from the potential adverse impact to our reputation and brand, affect our ability to retain or attract new users of Tablo and potentially disrupt our business, as well as require significant expenditure of resources to contain, mitigate and remediate the incident. Because the techniques used to obtain unauthorized access, disable or degrade service or sabotage systems change frequently or may be designed to remain dormant until a predetermined or other future event and often are not recognized until launched against a target, we and our partners may be unable to anticipate these techniques or to implement adequate preventative measures.

Further, we do not have any direct control over the operations of the facilities or technology of AWS or our other cloud and service providers. Our systems, servers and platforms, those of our cloud service providers, and Tablo's two-way wireless communication system, may be vulnerable to computer viruses or physical or electronic break-ins that our or their security measures may not detect or effectively block, and may be breached due to the actions of outside parties, employee error or misconduct, malfeasance, or a combination of these and, as a result, an unauthorized party may obtain access to our data or the personal information maintained by us or on our behalf.

Moreover, any unauthorized access to, or compromise of, Tablo devices could result in device malfunction, interruption or alteration of treatment or inaccurate data transmission, any of which could adversely affect patient health or safety. Any such incident could subject us to product liability claims, FDA or other regulatory enforcement actions, increased regulatory scrutiny, and reputational harm. In addition, certain privacy and data protection laws provide for private rights of action, and we could also be subject to contractual claims by customers or other counterparties in connection with a cybersecurity or privacy incident. Even the perception that Tablo is vulnerable to cybersecurity threats could reduce patient and provider confidence and materially harm adoption and use of Tablo and our business.

Additionally, outside parties may attempt to fraudulently induce employees to disclose sensitive information in order to gain access to the data and personal information we maintain, including through phishing or other social engineering attacks. Threat actors, including individuals, criminal groups, state sponsored actors or others may be able to circumvent such security measures and misappropriate our confidential or proprietary information, disrupt our operations, corrupt our data, damage our computers or otherwise impair our reputation and business. Although we currently invest in our resources and infrastructure, we may need to expend significant resources and make significant capital investment in the future to protect against security breaches or to mitigate the impact of any such breaches. In addition, to the extent that our cloud and other service providers experience security breaches that result in the unauthorized or improper use of confidential information, employee information or personal information, we may not be indemnified for any losses resulting from such breaches. Moreover, we have engaged a leading third-party information security consulting firm for CISO advisory services to support our information security program, which will continue to be overseen by our Vice President of Information Technology. While this consulting firm has significant experience in supporting and managing information security programs, has previously been involved in various aspects of our cybersecurity risk management program and ongoing cybersecurity operations, and the engagement is designed to enhance our program, there can be no assurance that the integration of external resources for CISO advisory services will be seamless or free of operational or security risks, which could result in unforeseen vulnerabilities or costs. If we are unable to prevent or mitigate the impact of security breaches or other cyber events that impact our operations, our ability to attract and retain new customers, patients, and other partners could be harmed, as they may be reluctant to entrust us with their data, and we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business or other adverse consequences.

We may encounter difficulties in managing our growth, which could disrupt our operations.

As of December 31, 2025, we had 310 full-time employees. We may not be able to recruit and train additional qualified personnel and expand our operations in the timeframe that we desire for various reasons which include our limited financial resources, the impact of macroeconomic conditions on us or our customers, or any inability to overcome the adverse impacts of regulatory, competitive or other challenges. Our growth may, instead, require us to leverage and optimize our existing personnel while increasing the scale of our operations in an effort to grow our revenue and expand gross margins. If we are unable to effectively manage our growth in the face of these challenges, the execution of our business plans could be delayed, which would have a material adverse effect on our business, financial condition and results of operations.

The home hemodialysis market may not expand sufficiently to support our growth prospects.

We believe a significant growth opportunity exists within the home hemodialysis market. However, home hemodialysis therapies to date have not been extensively adopted. We believe that the home hemodialysis market is sufficient to fuel our growth in the near term if we are able to capture sufficient market share; however, there can be no assurance that we will be successful in increasing our market share.

Our long-term growth will require us to shift patients' and the medical community's understanding and view of home hemodialysis and will require greater acceptance of home hemodialysis from patients as compared to current levels, physicians who are willing to prescribe home hemodialysis, and dialysis centers that are willing to support home hemodialysis growth. Most dialysis centers presently do not have the infrastructure to support a significant home hemodialysis patient population, including the availability of home hemodialysis training nurses, and may not be motivated to invest in home hemodialysis programs. The nationwide shortage of nurses and other clinical personnel poses increased challenges for dialysis centers looking to retain or attract the staff necessary to support a home hemodialysis program. We will need to continue to devote significant resources to support the expansion of the home hemodialysis market, but these efforts ultimately may not be successful.

We traditionally have had significant customer concentration.

For the year ended December 31, 2025, our largest customer accounted for 15% of revenues. There are risks whenever a large percentage of total revenues are concentrated with a limited number of customers. It is not possible for us to predict the level of demand for Tablo that will be generated by any of these customers in the future. In addition, revenues from these larger customers may fluctuate from time to time based on these customers' business needs and customer experience, the timing of which may be affected by market conditions or other factors outside of our control. Furthermore, because our business model consists of an upfront capital purchase by our customers, and relatively lower annual recurring revenue from future sales of consumables and services, revenues from these larger customers may not represent a substantial portion of our revenues in future periods. These customers could also potentially pressure us to reduce the prices we charge for Tablo, which could have an adverse effect on our margins and financial position and could negatively affect our revenues and results of operations. If any of our large customers terminate their relationship with us, such termination could negatively affect our revenues and results of operations.

Any failure to offer high-quality product support for Tablo may adversely affect our relationships with providers and negatively impact our reputation among patients and providers, which may adversely affect our business, financial condition, and results of operations.

We operate a multichannel model, including remote and on-site product support to respond to and resolve issues reported to us by providers and nurses on behalf of their patients. In implementing and using Tablo, providers depend on our support to resolve product quality- and performance-related issues in a timely manner. We may be unable to respond quickly enough to accommodate short-term increases in demand for customer support. Increased customer demand for product support could increase costs and adversely affect our business, financial condition and results of operations. Our sales are highly dependent on our reputation and on positive recommendations from our existing patients, care partners and providers. Any failure to maintain high-quality customer support for our products, or a market perception that we do not maintain high-quality customer support for our products, could adversely affect our reputation, our ability to sell Tablo or associated consumables, our ability to renew service contracts, and in turn our business, results of operations, and financial condition.

Our results of operations will be materially harmed if we are unable to accurately forecast customer demand for, and utilization of, Tablo and manage our inventory.

To ensure adequate inventory supply, we must forecast inventory needs and manufacture Tablo consoles and Tablo cartridges based on our estimates of future demand for Tablo. Our ability to accurately forecast demand for Tablo could be negatively affected by many factors, including our failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for Tablo or for products of our competitors, our failure to accurately forecast customer acceptance of new products, failure of our initiatives to optimize the commercial organization and improve forecasting and order visibility, potential disruption in our supply chain from regional or global public health crises such as the COVID-19 pandemic, unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions. Inventory levels in excess of customer demand may result in inventory write-downs or write-offs, which would cause our gross margin to be adversely affected and could impair the strength of our brand. Conversely, if we underestimate customer demand for Tablo, our supply chain, manufacturing partners and/or internal manufacturing team may not be able to deliver components and products to meet our requirements, and this could result in damage to our reputation and customer relationships. In addition, if we experience a significant increase in demand, additional supplies of raw materials or additional manufacturing capacity may not be available when required on terms that are acceptable to us, or at all, or suppliers may not be able to allocate sufficient capacity in order to meet our increased requirements, which will adversely affect our business, financial condition and results of operations.

A pandemic, epidemic or outbreak of an infectious disease in the United States or worldwide such as the COVID-19 pandemic could adversely affect our business.

If a pandemic, epidemic or outbreak of an infectious disease occurs in the United States or worldwide, our business may be adversely affected. For example, precautionary measures designed to contain the spread and mitigate the impact of COVID-19, such as travel restrictions, "shelter-in-place" orders, quarantines and business shutdowns impacted many of the regions in which we, our customers and our suppliers operate. Disruptions or potential disruptions to our business from a future pandemic include the inability of our suppliers to manufacture components and parts and to deliver these to us on a timely basis, or at all; disruptions in our production schedule and ability to manufacture and assemble products; inventory shortages or obsolescence; diversion of or limitations on employee resources that would otherwise be focused on the operations of our business; delays in growing or reductions in our sales organization, including through delays in hiring, lay-offs, furloughs or other losses of sales representatives; business adjustments or disruptions of or to certain third parties, including suppliers and customers; delays to any clinical trials we are conducting or plan to conduct; delays in our ability to timely submit 510(k) notifications or PMAs or PMA supplements, as applicable, and to obtain clearance or approval from the FDA to market our products; and additional government requirements or other incremental mitigation efforts that may further impact our or our suppliers' capacity to manufacture Tablo.

In addition, a pandemic, epidemic or other outbreak could disrupt our business operations and adversely impact the health and availability of our workforce. For example, in response to the COVID-19 pandemic, we made modifications to our normal operations, employing precautionary measures designed to help protect our employees while providing ongoing support for our customers and their patients. Among other measures, we restricted non-essential travel of our employees and asked the majority of our employees to work from home. If significant or critical portions of our workforce become unable to work effectively, or at all, as a result of a future pandemic, including because of illness, quarantines, facility closures, ineffective remote work arrangements or technology failures or limitations, our operations would be materially adversely impacted.

Moreover, the COVID-19 pandemic resulted in, and future pandemics, epidemics or other outbreaks may result in, significant disruption of global financial markets, which could result in a reduction in our ability to access capital and delays in payments of outstanding receivables that could adversely affect our liquidity. While the potential economic impact brought by, and the duration of any pandemic, epidemic or outbreak may be difficult to assess or predict, a recession or market correction resulting from the spread of an infectious disease, including COVID-19, could materially affect our business. Such economic recession could very likely have a material adverse effect on our long-term business.

Natural or man-made disasters and other similar events may significantly disrupt our business, and negatively impact our business, financial condition and results of operations.

A significant portion of our employee base, operating facilities and infrastructure are centralized in Northern California. Any of our facilities may be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, wildfires, floods, nuclear disasters, riots, acts of terrorism or other criminal activities, infectious disease outbreaks or pandemic events, such as the COVID-19 pandemic, power outages and other infrastructure failures, which may render it difficult or impossible for us to operate our business for some period of time. Our facilities would likely be costly to repair or replace, and any such efforts would likely require substantial time. Any disruptions in our operations could adversely affect our business and results of operations and harm our reputation. Moreover, although we have disaster recovery plans, they may prove inadequate. We may not carry sufficient business insurance to compensate for losses that may occur. Any such losses or damages could have a material adverse effect on our business and results of operations. In addition, our facility in Mexico and the facilities of our suppliers and manufacturers may be harmed or rendered inoperable by such natural or man-made disasters, which may cause disruptions, difficulties or otherwise materially and adversely affect our business.

Inadequate training of, and improper use of Tablo by, nurses, dialysis technicians, care partners and patients may lead to negative patient outcomes, affect use of Tablo and adversely affect our business.

The success of Tablo depends in part on the proper training and use of Tablo by nurses and dialysis technicians in the acute setting and patients and care partners in the home setting. We train nurses and dialysis technicians on the appropriate use of Tablo, as well as how to train other users, including patients and care partners who use Tablo in the home setting, on the appropriate use of Tablo. If nurses and dialysis technicians, including those we train directly and those trained by others, or patients and care partners, who are not trained by us directly, use Tablo inappropriately or incorrectly, or with supplies that are not compatible with Tablo or without adhering to or completing training sessions, patient outcomes may not be consistent with expected results. This may result in adverse events, including reduced treatment efficacy, and may negatively impact the perception of patient benefit and safety and limit adoption of Tablo, which would have a material adverse effect on our business, financial condition and results of operations. In addition, we may face liability for inadequate training and training materials for nurses and other providers who use our products.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

Our quarterly and annual results of operation, including our revenue, gross margin, profitability and cash flows, may fluctuate significantly, which makes it difficult for us to predict our future operating results. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our quarterly and annual operating results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. These fluctuations may occur due to a variety of factors, including, but not limited to:

- the level of demand for Tablo, which may vary significantly, our ability to accurately forecast and meet customer demand and the timing of customer orders and installation schedules;
- the cost of manufacturing Tablo, which may vary depending on the quantity of production, the terms of our agreements with third-party suppliers and manufacturers, costs of raw materials and components, and any related foreign currency impact;
- expenditures that we may incur to acquire, develop or commercialize additional products and technologies;
- unanticipated pricing pressures;
- the degree of competition in our industry and any change in the competitive landscape of our industry, including product enhancements or the introduction of new products or technologies by our competitors, or consolidation among our competitors or future partners;
- coverage and reimbursement policies with respect to dialysis equipment, and potential future products that compete with Tablo;
- the timing and success or failure of clinical trials for Tablo or any enhancements to Tablo we develop, or changes made to competing products;
- positive or negative coverage, or public perception, of our company, Tablo or products of our competitors or broader industry trends;
- our customers' ability to maintain their financial condition and to pay us amounts due;
- the impact, if any, that public health crises such as the COVID-19 pandemic may have on our operations, financial results and the number of patients treated;
- the timing and cost of, and level of investment in, research, development, licenses, regulatory approval, commercialization activities, acquisitions and other strategic transactions, or other significant events relating to Tablo, which may change from time to time;
- our ability to effectively retain, leverage and optimize our commercial team, the speed at which any newly hired salespeople become effective, and the cost and level of investment therein, as well as the success of our initiatives to optimize our commercial organization, infrastructure and sales processes to support the growth of our business in the acute care market as we focus more heavily on enterprise selling;
- the timing and cost of obtaining and maintaining regulatory approvals or clearances for our products or product enhancements, or other regulatory actions with respect to our products (such as the Warning Letter we received in July 2023 and our prior distribution pause on TabloCart with Prefiltration);
- pricing and discounts for Tablo or competing products;
- legal, accounting and other expenses we may incur as a result of operating as a public company, including costs related to compliance with new compliance initiatives and requirements;
- future accounting pronouncements or changes in our accounting policies; and
- general economic and financial market conditions or political instability, including changes in tariff or trade laws and policies (such as the tariffs imposed by the current administration on products imported into the United States from Mexico and China), as well as inflationary pressures (whether caused by economic policy or by other disruptions).

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual financial results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Further, our historical results are not necessarily indicative of results expected for any future period, and quarterly results are not necessarily indicative of the results to be expected for the full year or any other period, and accordingly should not be relied upon as indicative of future performance.

This variability and unpredictability could also result in our failure to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, it will negatively affect our business, financial condition and results of operations.

The sizes of the markets for Tablo in the acute and home settings have not been established with precision and may be smaller than we estimate and may decline.

Our estimates of the annual total addressable market for Tablo are based on a number of internal and third-party estimates, including, without limitation, the assumed prices at which we can sell Tablo in the acute and home markets. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors.

As a result, our estimates of the annual total addressable market for Tablo in different settings may prove to be incorrect. If the actual number of patients who would benefit from Tablo, the price at which we can sell Tablo, or the total addressable market for Tablo is smaller than we have estimated, it may impair our sales growth and negatively affect our business, financial condition and results of operations.

We use Amazon Web Services to support Tablo's cloud connectivity and any disruption of service could interrupt or delay our ability to receive and deliver certain treatment and reporting information from and to providers and patients.

We currently use AWS to host our cloud-based ecosystem. We also use other cloud service providers in our operations. We do not have direct control over the operations of the facilities of AWS or of our other cloud service providers and these facilities are vulnerable to damage or interruption from earthquakes, hurricanes, floods, fires, cyber security attacks, terrorist attacks, power losses, telecommunications failures and similar events. The occurrence of a natural disaster or an act of terrorism, a decision by AWS or another cloud service provider to close the facilities without adequate notice, or other unanticipated problems could result in lengthy interruptions in, or curtailment of, Tablo's functionality and our ability to provide software updates or analyze patient and machine data. The facilities also could be subject to break-ins, computer viruses, sabotage, intentional acts of vandalism and other misconduct. The continuing and uninterrupted performance of Tablo is critical to our success. Because our customer-facing software platform is used by providers to gain insight into treatment performance, it is critical that our customer facing software platform be accessible without interruption or degradation of performance or data. Providers and patients may become dissatisfied by any system failure that interrupts our ability to provide the full suite of Tablo capabilities to them. Outages could lead to the triggering of our service level agreements and the issuance of credits to our clients, in which case, we may not be fully indemnified for such losses pursuant to our agreement with AWS or our agreements with our other cloud service providers. We may not be able to easily switch our AWS operations to another cloud provider if there are sustained disruptions or interference with our use of AWS. Repeated or prolonged system failures may reduce the attractiveness of Tablo to providers and patients and result in a decreased demand for Tablo, thereby adversely affecting our business, financial condition and results of operations. Moreover, negative publicity arising from these types of disruptions could damage our reputation and may adversely impact use of Tablo.

AWS and our other cloud service providers are not obligated to renew agreements with us on commercially reasonable terms, or at all. If we are unable to renew our agreements with AWS or our other cloud service providers on commercially reasonable terms, if our agreements with AWS or our other cloud service providers are prematurely terminated, or if in the future we add additional data providers, we may experience costs or downtime in connection with the transfer to, or the addition of, new providers. If these providers were to increase the cost of their services, we may have to increase the price of Tablo or take other measures to offset such cost increases, which could have a material adverse effect on our business, financial condition and results of operations.

If we experience significant disruptions in our information technology systems, our business may be adversely affected.

We depend on our information technology systems for the efficient functioning of our business, including the manufacture, distribution and maintenance of Tablo, as well as for accounting, data storage, compliance, purchasing and inventory management. We do not have redundant information technology in all aspects of our systems at this time. Our information technology systems may be subject to computer viruses, ransomware or other malware, attacks by computer hackers or malicious insiders, failures during the process of upgrading or replacing software, databases or components thereof, power outages, damage or interruption from fires or other natural disasters, hardware failures, telecommunication failures and user errors, among other malfunctions. We could be subject to an unintentional event that involves a third party gaining unauthorized access to our systems, which could disrupt our operations, corrupt our data or result in release of our confidential information. Technological interruptions or malfunction would disrupt our operations, including our ability to timely ship and track Tablo orders, project inventory requirements, ensure the integrity of our data analytics services, manage our supply chain and otherwise adequately service our customers or disrupt our customers' ability to use Tablo. In the event we experience significant disruptions, we may be unable to repair our data or systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our business, financial condition and results of operations. Currently, we carry business interruption coverage to mitigate certain

potential losses but this insurance is limited in amount, and we cannot be certain that such potential losses will not exceed our policy limits. We are increasingly dependent on complex information technology to manage our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance our existing systems. Failure to maintain or protect our information systems and data integrity effectively could have a material adverse effect on our business, financial condition and results of operations.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit or halt the marketing and sale of Tablo. The expense and potential unavailability of insurance coverage for liabilities resulting from Tablo could harm us and our ability to sell Tablo.

We face an inherent risk of product liability as a result of the marketing and sale of Tablo. For example, we may be sued if Tablo or any of its component parts causes, or is perceived to cause, injury or is found to be otherwise unsuitable during manufacturing, marketing or sale. Any such product liability claim may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. In addition, we may be subject to claims against us even if the apparent injury is due to the actions of others or the pre-existing health conditions of the patient. For example, nurses, dialysis technicians, care partners and patients operate Tablo. If these nurses, dialysis technicians, care partners or patients are not properly trained, are negligent or use Tablo incorrectly, the capabilities of Tablo may be diminished or the patient may suffer critical injury. We may also be subject to claims that are caused by the activities of our suppliers, such as those who provide us with components and sub-assemblies, or manufacturers who produce Tablo consoles and cartridges.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or halt the marketing and sale of Tablo. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for Tablo;
- harm to our reputation;
- initiation of investigations by regulators, which could result in enforcement action against us or our contract manufacturers;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and
- exhaustion of any available insurance and our capital resources.

We believe we have adequate product liability insurance, but it may not prove to be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain or obtain insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our insurance policy contains various exclusions, and we may be subject to a product liability claim for which we have no coverage. The potential inability to obtain sufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or inhibit the marketing and sale of Tablo. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts, which would have a material adverse effect on our business, financial condition and results of operations. In addition, any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our reputation in the industry, significantly increase our expenses and reduce product sales.

Any failure to obtain additional financing when needed on acceptable terms, or at all, could force us to delay, limit, reduce or eliminate our commercialization, sales and marketing efforts, product development programs or other operations.

While we have raised equity and taken actions to reduce operating expenses and working capital to align with anticipated revenue growth including implementing restructuring plans to streamline our overall organizational structure and renegotiating commitments with suppliers to reduce inventory, we expect to continue to incur operating losses in the near term while we make investments to support our anticipated growth. We also entered into a senior secured credit facility on January 3, 2025, which replaces our prior credit facilities with SLR Investment Corp (SLR) and provides for up to $125.0 million term loans (the Term Loan Facility) pursuant to a credit agreement and guaranty, dated as of January 3, 2025 (the Credit Agreement) with Perceptive Credit Holdings IV, LP as administrative agent (the Agent) and the lenders from time to time party thereto, under which we have already borrowed a term loan of $100.0 million. The additional $25.0 million term loan under the Term Loan facility is subject to us achieving certain revenue

milestone and other customary conditions. We may seek to raise any necessary additional capital through a combination of public or private equity offerings or debt financings. There can be no assurance, however, that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable to us. If adequate funds are not available on acceptable terms when needed, we may be required to significantly reduce operating expenses, which may negatively affect our business, financial condition and results of operations. If we do raise additional capital through public or private equity or convertible debt offerings, such offerings could result in dilution, including potentially significant dilution, of the ownership interest of our existing stockholders, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing (including through refinancing our existing debt), we may be subject to, among other things, an increase in our interest expense which may negatively affect our cash flow and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Additional capital may not be available on reasonable terms, or at all.

The terms of our credit agreement require us to meet certain operating and financial covenants, place restrictions on our operating and financial flexibility and subject us to interest rate risk, and our ability to access additional borrowings is subject to us achieving certain revenue milestone and obtaining lenders' credit approval.

We entered into the Credit Agreement on January 3, 2025, which provides term loans in an aggregate principal amount of up to $125.0 million, comprised of (i) a term loan of $100.0 million (the Initial Term Loan), which was funded to us on January 8, 2025, and (ii) a delayed draw term loan of up to $25.0 million (the Delayed Draw Loan, and together with the Initial Term Loan, the Loans). The Delayed Draw Loan is available for funding until July 14, 2027, subject to the achievement of certain revenue milestone and other customary conditions. As a result, we cannot rely on further borrowings under the Term Loan Facility to fund our operations. In addition, outstanding Loans accrue interest at variable interest rates tied to Secured Overnight Financing Rate (SOFR). As a result, our borrowings under the Term Loan Facility are subject to interest rate risk. An adverse change in interest rates for our borrowings would increase our borrowing costs which may restrict our access to capital in the future and, ultimately, could adversely affect our financial condition and results of operations. See the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Debt Obligations – Perceptive Credit Agreement."

On January 8, 2025, we repaid in full all amounts due under our two prior senior secured credit facilities with (i) SLR and (ii) Gemino Healthcare Finance, LLC d/b/a SLR Healthcare ABL, respectively, each dated as of November 3, 2022 using the proceeds of the Initial Term Loan, together with cash on hand.

The Credit Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among others, requirements as to financial reporting and insurance and restrictions on our ability to dispose of its business or property, to change our line of business, to liquidate or dissolve, to enter into any change in control transaction, to merge or consolidate with any other entity or to acquire all or substantially all the capital stock or property of another entity, to incur additional indebtedness, to incur liens on our property or to pay any dividends or other distributions on capital stock, in each case with certain exceptions. Accordingly, the terms may restrict our current and future operations, particularly our ability to respond to certain changes in our business or industry or take future actions. We have also agreed to certain financial covenants that require us to (i) maintain a minimum cash balance of at least $10.0 million in accounts subject to control agreements in favor of the Agent, and (ii) achieve certain trailing twelve-month net revenue targets as set forth in the Credit Agreement.

In addition, the Credit Agreement contains customary events of default that entitle the Agent to cause our indebtedness under the Credit Agreement to become immediately due and payable, and to exercise remedies against us and the collateral securing the obligations owed under the Credit Agreement. Under the Credit Agreement, an event of default will occur if, among other things, we fail to make payments under the Credit Agreement, we breach certain covenants under the Credit Agreement, subject to specified cure periods with respect to certain breaches, a material adverse change or a material regulatory event has occurred under the Credit Agreement, or we or our assets become subject to certain legal proceedings, such as bankruptcy proceedings. If the debt under the Credit Agreement was accelerated, we may not have sufficient cash or be able to sell sufficient assets to repay this debt, which would harm our business and financial condition.

Performance issues, service interruptions or price increases by our shipping carriers and warehousing providers could adversely affect our business and harm our reputation and ability to provide our services on a timely basis.

Expedited, reliable shipping and secure warehousing are essential to our operations. We rely heavily on providers of transport services for reliable and secure point-to-point transport of Tablo to our customers and for tracking of these shipments, and from time to time require warehousing for our products. Should a carrier encounter delivery performance issues such as loss, damage or destruction of any systems, it would be costly to replace such systems in a timely manner and such occurrences may damage our reputation and lead to decreased demand for Tablo and increased cost and expense to our business. In addition, any significant increase in shipping or warehousing rates could adversely affect our operating margins and results of operations. If freight costs escalate and/or remain high for a sustained period of time, our operating margins and results of operations would be adversely

impacted. Similarly, strikes, severe weather, natural disasters or other service interruptions affecting delivery or warehousing services we use would adversely affect our ability to process orders for Tablo on a timely basis.

We bear the risk of warranty claims on Tablo.

We bear the risk of warranty claims on Tablo. We may not be successful in claiming recovery under any warranty or indemnity provided to us by our suppliers or vendors in the event of a successful warranty claim against us by a customer or any recovery from such vendor or supplier may not be adequate. In addition, warranty claims brought by our customers related to third-party components may arise after our ability to bring corresponding warranty claims against such suppliers expires, which could result in costs to us.

Cost-containment efforts of our customers, purchasing groups and governmental organizations could have a material adverse effect on our sales and profitability.

In an effort to reduce costs, many hospitals in the United States are members of GPOs and Integrated Delivery Networks (IDNs). GPOs and IDNs negotiate pricing arrangements with medical device companies and distributors and then offer these negotiated prices to affiliated hospitals and other members. GPOs and IDNs typically award contracts on a category-by-category basis through a competitive bidding process. Bids are generally solicited from multiple providers with the intention of driving down pricing or reducing the number of vendors. Due to the highly competitive nature of the GPO and IDN contracting processes, we may not be able to obtain new, or maintain existing, contract positions with major GPOs and IDNs. Furthermore, the increasing leverage of organized buying groups may reduce market prices for Tablo, thereby reducing our revenue and margins.

While having a contract with a GPO or IDN for a given product category can facilitate sales to members of that GPO or IDN, such contract positions can offer no assurance that any level of sales will be achieved, as sales are typically made pursuant to individual purchase orders. Even when a provider is the sole contracted supplier of a GPO or IDN for a certain product category, members of the GPO or IDN are generally free to purchase from other suppliers. Furthermore, GPO and IDN contracts typically are terminable without cause by the GPO or IDN upon 60 to 90 days' notice. Accordingly, the members of such groups may choose to purchase alternative products due to the price or quality offered by other companies, which could result in a decline in our revenue.

Litigation and other legal proceedings may adversely affect our business.

From time to time we may become involved in legal proceedings relating to patent and other intellectual property matters, product liability claims, employee claims, tort or contract claims, federal regulatory investigations, securities and stockholder actions and other legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. For example, on August 29, 2024 and October 18, 2024, two purported securities class action lawsuits were filed against the Company, our Chief Executive Officer, then-Chief Financial Officer and prior Chief Financial Officer, in the U.S. District Court for the Northern District of California alleging that the defendants violated federal securities laws by making false or misleading statements about our business, operations and prospects related to the sale and marketing of the Tablo Hemodialysis System and TabloCart with Prefiltration, including concerning the impact of certain FDA processes for these products on our revenue growth. These cases have been consolidated into a single action. Further, on November 29, 2024, April 28, 2025, May 8, 2025 and June 16, 2025 Outset stockholders purporting to act on behalf of the Company filed lawsuits in the U.S. District Court for the Northern District of California against current and former members of our Board of Directors and certain of our officers, alleging that the defendants breached their fiduciary duties to the Company in connection with the same alleged events and alleged materially false and misleading statements asserted in the stockholder securities class action lawsuits. For more information, see the section entitled "Litigation" in Note 6, Commitments and Contingencies, to our audited financial statements included in this Annual Report. Litigation is inherently unpredictable and can result in excessive or unanticipated verdicts and/or injunctive relief that affect how we operate our business. We could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. There may be an increase in the scope of these matters or there may be additional lawsuits, claims, proceedings or investigations in the future, which could have a material adverse effect on our business, financial condition and results of operations. Adverse publicity about regulatory or legal action against us could damage our reputation and brand image, undermine our customers' confidence and reduce long-term demand for Tablo, even if the regulatory or legal action is unfounded or not material to our operations.

We may seek strategic alliances, joint ventures or collaborations, or enter into licensing or partnership arrangements in the future and may not be successful in doing so, and even if we are, we may not realize the benefits or costs of such relationships.

We may form or seek strategic alliances, make minority investments, create joint ventures or collaborations or enter into licensing or partnership arrangements with third parties that we believe will compliment or augment our sales and marketing and/or product development efforts with respect to Tablo. We may not be successful in our efforts to establish such collaborations for Tablo. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant

competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic alliance or other alternative arrangements for Tablo. We cannot be certain that, following a strategic alliance or similar arrangement, we will achieve the revenue, cash flows or specific net income that justifies such transaction. In addition, any potential future collaborations may be terminable by our collaborators, and we may not be able to adequately protect our rights under these agreements. Any termination of collaborations we enter into in the future, or delays in entering into new strategic partnership agreements could delay our sales and marketing efforts, which would harm our business prospects, financial condition and results of operations.

To the extent we enter into foreign markets, we would be subject to additional regulatory burdens and other risks and uncertainties.

To the extent we enter into foreign markets in the future, we would face additional risks and uncertainties. We are not permitted to market or promote Tablo before we receive regulatory approval from the applicable regulatory authority in that foreign market, and we may never receive such regulatory approval for Tablo. To obtain separate regulatory approvals in other countries we may be required to comply with numerous and varying regulatory requirements of such countries regarding the safety and efficacy of Tablo and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product, and we cannot predict success in these jurisdictions. Such activities may result in incremental expenses and diversion of management's time and attention, and we may not ultimately obtain the requisite approvals in a timely manner or at all. If we obtain approval of Tablo and sell Tablo in foreign markets, we would be subject to additional risks and uncertainties in those markets, including:

- foreign currency exchange rate fluctuations and currency controls;
- increased costs associated with maintaining compliance, sales and marketing, and service for customers outside the United States, especially as we establish ourselves in these markets;
- economic weakness, including inflation, or political instability in particular economies and markets;
- potentially adverse and/or unexpected tax consequences, including penalties due to the failure of tax planning or due to the challenge by tax authorities on the basis of transfer pricing and liabilities imposed from inconsistent enforcement;
- the burden of complying with complex and changing regulatory, tax, accounting and legal requirements, many of which vary between countries;
- different medical practices and customs in multiple countries affecting acceptance of medical products in the marketplace;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- tariffs, trade barriers, import or export licensing requirements or other restrictive actions;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- reduced or loss of protection of intellectual property rights in some foreign countries; and
- becoming subject to the different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations.

Our ability to utilize our net operating loss carryforwards and research and development credit may be limited.

As of December 31, 2025, we had U.S. federal and state net operating loss (NOL) carryforwards of $815.1 million and $453.9 million, respectively. If not utilized, our U.S. federal NOLs carryforwards generated in taxable years beginning before 2018 will begin to expire in 2026 and our state NOLs began to expire in 2026. Deductibility of U.S. federal NOLs generated in taxable years beginning after 2017 generally may be carried forward indefinitely. However, for taxable years beginning after 2020, the deductibility of NOL carryforwards is limited to 80% of our taxable income before the deduction of such NOLs. As of December 31, 2025, we also had U.S. federal and state research and development credits of $13.4 million and $9.2 million, respectively. Our U.S. federal research and development credits will begin to expire in 2030. State research and development credits do not expire. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code) a corporation that undergoes an ownership change, generally defined as a greater than 50% change by value in its equity ownership by one or more "5-percent shareholders" over a rolling three-year testing period, is subject to limitations on its ability to utilize its pre-change NOL and its research and development credit carryforwards to offset future taxable income. Our existing NOLs and research and development credit carryforwards may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change, our ability to utilize NOLs and research and development credit carryforwards could be further limited by Sections 382 and 383 of the Code. Similar rules may apply under state tax laws. In addition, our ability to deduct net interest expense may be limited if we have insufficient taxable income for the year during which the interest is incurred, and any future carryovers of such disallowed interest would be subject to the limitation rules similar to those applicable to NOL carryforwards and other attributes. Future changes in our stock ownership, some of which might be beyond our control, could result in an ownership change under Section 382 of the Code. For these reasons, in the

event we experience a change of control, we may not be able to utilize a material portion of the existing NOLs, research and development credit carryforwards or future disallowed interest expense carryovers, even if we attain profitability. Any limitation on using NOL carryforwards could adversely impact operating results and result in our retaining less cash after payment of U.S. federal and state income taxes.

Risks Related to Governmental Regulation

As we continue to modify Tablo from time to time, such modifications may require new clearances or approvals from the FDA, which we may not be able to obtain on a timely basis or at all.

Although we currently market our products exclusively under 510(k) clearances, modifications to Tablo and associated consumables may require new regulatory approvals or clearances, including additional 510(k) clearances, de novo classification, or approval of PMAs or PMA supplements. As we continue to modify Tablo from time to time, we may determine that such modifications could significantly affect safety and effectiveness of the device or represent a major change in its intended use and thereby require new 510(k) clearances. Further, even in instances where we determine modifications to Tablo do not require a new 510(k) clearance or a PMA, the FDA may review our decision and disagree, or otherwise determine on its own initiative that a new clearance or approval is required. In this case, we may ultimately be required to make additional changes to Tablo, we may need to submit a new 510(k) application or a PMA and obtain clearance or approval, we may be required to temporarily suspend shipment of, withdraw or recall Tablo until such clearance or approval is obtained (which may not happen in a timely manner or at all), and/or we may be subject to other enforcement actions or proceedings and litigation, all of which would materially and adversely disrupt and harm our business and future growth. Where we determine that modifications to Tablo do require a new 510(k) clearance from the FDA or PMA approval, we may not be able to obtain such clearance or approval in a timely manner, or at all. Obtaining clearances or approvals can be a time-consuming and costly process, which may in some cases require us to conduct clinical trials, and delays in obtaining required future clearances or approval could adversely affect our ability to make updates and enhancements to Tablo in a timely manner, which in turn would harm our future growth.

For example, since Tablo's original clearance by the FDA for home use in March 2020, we have made certain changes to the device over time and, where appropriate, have submitted 510(k) notifications for certain modifications to Tablo. In May 2021, we submitted a 510(k) application to the FDA covering the design changes for patient use in the home. In May 2022, after further discussions with the FDA and receiving indications that the clearance of this 510(k) submission would be delayed beyond our original expectations, we implemented a shipment hold on the distribution and marketing of Tablo for use in the home environment pending the FDA's review and clearance of this 510(k) submission. In late July 2022, the FDA cleared this 510(k) submission of Tablo for patient use in the home and we resumed marketing and shipping Tablo for home use.

Changes to the reimbursement rates for dialysis treatments and measures to reduce healthcare costs may adversely impact our business.

Our customers depend upon reimbursement by government and other third-party insurance payors for dialysis services using our products. With a vast majority of U.S. patients with ESRD and AKI covered by Medicare, the Medicare reimbursement rate is an important factor in a customer's decision to use Tablo and limits the prices we may charge for our products. For patients with Medicare fee-for-service coverage, virtually all payments for renal dialysis services are currently made under a single bundled payment rate which provides a fixed payment rate to encompass virtually all goods and services provided during the dialysis treatment. The bundled payment rate is also adjusted for certain patient characteristics, a geographic wage index, and other factors. The ESRD PPS is subject to rebasing, which can have a positive financial effect, or a negative one if the government fails to rebase in a manner that adequately addresses the costs borne by dialysis facilities. Additionally, reimbursement rates and coverage policies under Medicare Advantage plans may also be subject to change. We cannot anticipate whether the government and/or Medicare Advantage plans will decrease payment rates in the coming years or if any future rate increases will adequately cover facilities' costs, which could adversely harm our business.

CMS rules limit the number of hemodialysis treatments paid for by Medicare Part B to three times a week, unless there is medical justification provided by the dialysis facility based on information from the patient's physician for additional treatments. To the extent that over three treatments per week are prescribed for Tablo patients and Medicare contractors determine they will not pay for additional treatments, adoption of Tablo could be impaired. As there is not a uniform national standard for what constitutes medical justification, a clinic's decision as to how much it is willing to spend on home dialysis equipment and services will be at least partly dependent on the number of weekly treatments prescribed for home dialysis, and if greater than three, the level of confidence the center has in the predictability of receiving reimbursement from Medicare for additional treatments per week based on submitted claims for medical justification.

Many ESRD patients have Medicaid coverage that is supplemental to Medicare coverage, and some ESRD patients may have Medicaid as their primary coverage. Because Medicaid is a state-administered program, Medicaid reimbursement for dialysis services

varies by state. Changes in state Medicaid or other non-Medicare government-based programs or payment rates could have an adverse effect on our customers' business.

Additionally, some patients may have coverage through private insurance, for example through a marketplace plan set up under the ACA or through an employer or union group health plan. Private insurance reimbursement is generally higher than government reimbursement, but it varies by sponsor and plan. Commercial payment rates are negotiated between our customers and insurers or other third-party administrators, and commercial payors may also exert downward pressure on payment rates for dialysis services.

Recent litigation regarding payor coverage of ESRD services may also affect our business. For example, on June 21, 2022, in the case of *Marietta v. DaVita*, the Supreme Court of the United States addressed the question of whether a group health plan that provides limited benefits for outpatient dialysis – but does so uniformly for all plan participants – violates the MSPA, a law which makes Medicare a "secondary" payer to an individual's existing insurance plan for certain medical services, including dialysis, when that plan already covers the same services. Specifically, the Supreme Court held that because the Plan's terms apply uniformly to all covered individuals, the Plan does not "differentiate in the benefits it provides" to individuals with ESRD or "take into account" whether an individual is entitled to or eligible for Medicare, and thus does not violate the MSPA.

The Court's decision may have continued impacts on our business, including potential increases in adverse ESRD coverage actions may be taken by health plans and we cannot predict whether regulatory guidance or new legislation may be issued that further limit ESRD coverage.

Any reduction in reimbursement rates for dialysis treatments may adversely affect our customers' businesses and cause them to enact cost reduction measures that may result in reducing the scope of their home hemodialysis programs, which could result in reduced demand for our product or additional pricing pressures.

Healthcare reform measures could hinder or prevent the commercial success of Tablo.

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that may harm our future revenues and profitability and the demand for Tablo. As discussed in the section titled "Business – Government Regulation – United States Health Reform" above, federal and state lawmakers regularly propose and, at times, enact legislation and propose and finalize regulations that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services, improve quality and/or expand access. Current and future legislative or regulatory proposals to further reform healthcare or reduce healthcare costs may limit coverage of and/or lower reimbursement for the procedures associated with the use of Tablo. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of Tablo.

By way of example, in the United States, the ACA substantially changed the way healthcare is financed by both governmental and private insurers, and continues to significantly impact our industry. The Affordable Care Act contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which impact existing government healthcare programs and have resulted in the development of new programs.

As discussed in the section titled "Business – Government Regulation – United States Health Reform" above, there have been, and continue to be, judicial and Congressional challenges to several elements of the ACA, as well as efforts by both the executive and legislative branches of the federal government to modify certain aspects of the ACA. It is unclear how these and other efforts to challenge or modify, or alter the implementation or interpretation of the ACA will affect our business, financial condition and results of operations.

In addition, as discussed in the section titled "Business – Government Regulation – United States Health Reform" above, other legislative and executive actions have encouraged the development of new payment and care models for ESRD patients. Changes to the models of patient care, including an increased focus on treatments earlier in disease progression, may adversely affect our customers' businesses and potentially decrease the demand for our product or result in additional pricing pressures. Further, with home dialysis as a growing trend in the industry and the implementation of the IOTA Model, a failure to implement our expansion into home dialysis could have a material adverse impact on our business.

The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may harm our ability to set a price that we believe is fair for Tablo, our ability to generate revenue and achieve or maintain profitability, and the availability of capital.

We believe that there will continue to be proposals and other actions by legislators and other policymakers at both the federal and state levels, and by regulators and third-party payors to reduce costs and/or expand individual healthcare coverage. We cannot predict what other healthcare policies will ultimately be proposed or implemented at the federal or state level or the effect of any future legislation or regulation in the United States on our business, financial condition and results of operations. Future changes in healthcare policy could increase our costs and subject us to additional legislative and regulatory requirements that may interrupt

commercialization of our current and future solutions, decrease our revenue and impact sales of and pricing for our current and future products.

We must comply with anti-kickback, fraud and abuse, false claims, transparency, and other healthcare laws and regulations.

Our current and future operations are subject to various federal and state healthcare laws and regulations. These laws affect our sales, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with dialysis providers, hospitals, physicians or other potential purchasers or users, including patients, of medical devices and services. They also impose additional administrative and compliance burdens on us. In particular, these laws influence, among other things, how we structure our sales and rental offerings, including discount practices, customer support, education and training programs and physician consulting and other service arrangements. These laws include, but are not limited to, the healthcare fraud and abuse laws described in the section titled "Business – Government Regulation – Healthcare Fraud and Abuse Laws" above, and the Federal Food, Drug, and Cosmetic Act, which governs, among other things, the misbranding and adulteration of medical devices.

If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, compliance oversight and reporting requirements and the curtailment or restructuring of our operations. Moreover, any investigation into our practices could cause adverse publicity and require a costly and time-consuming response.

Tablo and our operations are subject to extensive government regulation and oversight in the United States. If we fail to obtain or maintain necessary regulatory approvals for Tablo and related products, or if approvals or clearances for future products are delayed or not issued, it will negatively affect our business, financial condition and results of operations.

Tablo is a medical device subject to extensive regulation in the United States and elsewhere, including by the FDA and its foreign counterparts. Government regulations specific to medical devices are wide ranging and govern, among other things:

- product design, development, manufacture, and release;
- laboratory and clinical testing, labeling, packaging, storage and distribution;
- product safety and efficacy;
- premarketing clearance or approval;
- service operations;
- record keeping;
- product marketing, promotion and advertising, sales and distribution;
- post-marketing surveillance, including reporting of deaths or serious injuries and recalls and correction and removals;
- post-market approval studies; and
- product import and export.

We have obtained 510(k) clearances to market Tablo for use in patients with acute and/or chronic renal failure, with or without ultrafiltration, in the settings of an acute or chronic care facility and the home.

The FDA or other regulators could delay, limit, or deny clearance or approval of a device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that Tablo, or any other future device, and any accessories are substantially equivalent to a legally marketed predicate device or safe or effective for their proposed intended use;
- the disagreement of the FDA with the design or implementation of any clinical trials or the interpretation of data from preclinical studies or clinical trials;
- serious and unexpected adverse device effects experienced by participants in our clinical trials;
- the insufficiency of the data from preclinical studies or clinical trials to support clearance or approval, where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the failure of our manufacturing process or facilities to meet applicable requirements; and

- the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval.

The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. The FDA enforces these regulatory requirements through, among other means, periodic unannounced inspections. We do not know whether we will be found compliant in connection with any future regulatory inspections. Moreover, the FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by any such agency, which may include any of the following sanctions:

- adverse publicity, warning letters, untitled letters, it has come to our attention letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of Tablo;
- operating restrictions, partial suspension or total shutdown of production;
- denial of our requests for regulatory clearance or PMA approval of new products or services, new intended uses or modifications to existing products or services;
- withdrawal of regulatory clearance or PMA approvals that have already been granted; or
- criminal prosecution.

If any of these events were to occur, it would negatively affect our business, financial condition and results of operations. For example, in July 2023, we received a warning letter (the Warning Letter) from the FDA that raised two observations. The first observation asserted that certain content on our website promoted CRRT, a modality outside of Tablo's current indications, which we addressed through revision of processes and procedures and updates to existing labeling and promotional materials. The second observation asserted that TabloCart with Prefiltration, an accessory to Tablo, required prior 510(k) clearance for marketing authorization, which we addressed by pausing distribution of this accessory until receiving 510(k) clearance in May 2024, after which we resumed distribution. Our business and operations experienced certain disruptions as a result of the Warning Letter and the distribution pause. In February 2025, we were notified by the FDA that the issues cited in the Warning Letter had been addressed. However, we cannot guarantee that we will not receive other warning letters or be subject to other FDA enforcement actions in the future.

Our future success depends on our ability to develop, receive regulatory clearance or approval for, and introduce new products that will be accepted by the market in a timely manner. There is no guarantee that the FDA will grant 510(k) clearance or PMA approval of our future products on a timely basis, if at all, and failure to obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business.

It is important to our business that we build a pipeline of product offerings that address limitations of current dialysis products. As such, our success will depend in part on our ability to develop and introduce new products. However, we may not be able to successfully develop and obtain regulatory clearance or approval for product enhancements, or new products for any number of reasons, including due to the cost associated with certain regulatory approval requirements, or these products may not be accepted by physicians or users.

The success of any new product offering or enhancement to an existing product will depend on a number of factors, including our ability to, among others:

- identify and anticipate physician and patient needs properly;
- develop and introduce new products or product enhancements in a timely manner;
- avoid infringing upon the intellectual property rights of third parties;
- demonstrate, if required, the safety and efficacy of new products with data from clinical studies;
- obtain the necessary regulatory clearances or approvals for new products or product enhancements;
- comply fully with the FDA and applicable foreign regulations on marketing of new products or modified products; and
- provide adequate training to potential users of Tablo.

If we do not develop new products or product enhancements in time to meet market demand or if there is insufficient demand for these products or enhancements, or if our competitors introduce enhanced or new products with functionalities that are superior to ours, our results of operations will suffer.

Some of our future products will require FDA clearance of a 510(k). Other products may require the approval of a PMA. In addition, some of our future products may require clinical trials to support regulatory approval and we may not successfully complete these clinical trials. The FDA may not approve or clear these products for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510(k) clearance or PMA approval of new products. Failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

If we or our suppliers fail to comply with ongoing FDA or other foreign regulatory authority requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Even though we have obtained 510(k) clearance for Tablo, it and any other product for which we obtain clearance or approval, and the manufacturing processes, post-market surveillance, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight, requirements, and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our suppliers are required to comply with FDA's QSR and other regulations enforced outside the United States which cover the manufacture of our products and the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of medical devices. The QSR requires that each manufacturer establish a quality systems program by which the manufacturer monitors the manufacturing process and maintains records that show compliance with FDA regulations and the manufacturer's written specifications and procedures relating to the devices. QSR compliance is necessary to receive and maintain FDA clearance or approval to market new and existing products. Regulatory bodies, such as the FDA, enforce the QSR and other regulations through periodic audits and inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions:

- FDA untitled letters, FDA Form 483s, FDA warning letters, it has come to our attention letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement, refunds;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or PMA approval of new products or modified products;
- withdrawal of 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

For example, the FDA has conducted quality system inspections of our San Jose, California facility. Our first inspection in 2023 resulted in a Form FDA-483 that identified several inspectional observations that we remediated, and the follow-up inspection in 2024 resulted in no FDA-483. In February 2025, the FDA subsequently closed both inspections, concluding that no further regulatory action was necessary. Although we believe we are in material compliance with the QSR, there is no guarantee that subsequent inspections of our facility by the FDA or other regulatory authorities will not result in similar observations with respect to our quality system, which could adversely affect our business.

The FDA can also publish Safety Communications or Letters to Health Care Providers when the agency becomes aware of new issues involving a specific product or, or more broadly, a product family. These communications are posted on the FDA's website and describe the FDA's analysis of a current issue and provide specific regulatory approaches and clinical recommendations for patient management. If any of these actions were to occur it would harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

In addition, we are required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products.

Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute,

fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

We are subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. Manufacturers are also expected to maintain certain policies, procedures, and records regarding complaints and medical device reporting. If we fail to comply with our reporting and recordkeeping obligations, the FDA could take action, including warning letters, untitled letters, it has come to our attention letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance or approval, seizure of our products or delay in clearance or approval of future products.

The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found and we have done so from time to time. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new clearances or approvals for the device before we may market or distribute the corrected device. Seeking such clearances or approvals may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

Our products, such as Tablo, may in the future be subject to product recalls that could harm our reputation, business and financial results.

Medical devices can experience performance problems in the field that require review and possible corrective action. The occurrence of component failures, manufacturing errors, software errors, design defects or labeling inadequacies affecting a medical device could lead to a government-mandated or voluntary recall by the device manufacturer, in particular when such deficiencies may endanger health. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, will distract management from operating our business and may harm our reputation and financial results.

We may be subject to regulatory or enforcement actions if we engage in improper marketing or promotion of Tablo.

Our educational and promotional activities and training methods must comply with FDA and other applicable laws, including the prohibition of the promotion of a medical device for a use that has not been cleared or approved by the FDA. Use of a device outside of its cleared or approved indications is known as "off-label" use. Physicians may use Tablo off-label in their professional medical judgment, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA determines that our educational and promotional activities or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of warning letters, untitled letters, fines, penalties, injunctions, or seizures, any of which could have an adverse impact on our reputation and financial results. For example, in the Warning Letter we received in July 2023, the FDA asserted that certain content reviewed on our website promoted CRRT, a modality outside of Tablo's current indications. We addressed this observation through a

revision of processes and procedures and updates to existing labeling and promotional materials and were notified by the FDA in February 2025 that the issue had been addressed. However, there is no guarantee that the FDA will not issue similar warning letters to us or subject us to other regulatory or enforcement actions for marketing or promotion of Tablo that the agency deems improper in the future.

It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our educational and promotional activities or training methods to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged, and adoption of the products could be impaired. Although our policy is to refrain from statements that could be considered off-label promotion of Tablo, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. It is also possible that other federal, state or foreign enforcement authorities might take action, including, but not limited to, through a whistleblower action under the FCA, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil or administrative penalties, treble damages, fines, disgorgement, exclusion from participation in government healthcare programs, reporting requirements and compliance oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations. In addition, the off-label use of Tablo may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us, and harm our reputation.

Legislative or regulatory reforms may make it more difficult and costly for us to obtain regulatory clearance or approval of any future products or product enhancements and to manufacture, market and distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval or clearance of our future products under development or impact our ability to modify our currently cleared products on a timely basis. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of planned or future products or product enhancements. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain clearance or approval for, manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to obtaining clearance or approval; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay regulatory clearance or approval of our product candidates or enhancements. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad.

Any change in the laws or regulations that govern the clearance and approval processes relating to our current, planned and future products or product enhancements could make it more difficult and costly to obtain clearance or approval for new products or to produce, market and distribute existing products. Significant delays in receiving clearance or approval or the failure to receive clearance or approval for any new products or enhancements would have an adverse effect on our ability to expand our business. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing clearance that we may have obtained and we may not achieve or sustain profitability.

For example, medical device cybersecurity continues to be an area of focus for and evolving guidance from the FDA. The FDA has published guidance documents regarding cybersecurity and publication of future guidance documents or other materials may necessitate additional time and cost for product development, submission and approval or clearance. For example, in January 2026, the FDA granted 510(k) clearance of our next-generation Tablo platform which incorporates the FDA's recent guidance on medical device cybersecurity published in June 2025.

Clinical trials may be necessary to support future product submissions to the FDA. The clinical trial process is lengthy and expensive with uncertain outcomes, and often requires the enrollment of large numbers of patients, and suitable patients may be

difficult to identify and recruit. Delays or failures in our clinical trials will prevent us from commercializing any modified or new products and will adversely affect our business, operating results and prospects.

Initiating and completing clinical trials necessary to support any future PMAs, and additional safety and efficacy data beyond that typically required for a 510(k) clearance, for our possible future product candidates, will be time-consuming and expensive and the outcome uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product we advance into clinical trials may not have favorable results in later clinical trials. The results of preclinical studies and clinical trials of our products conducted to date and ongoing or future studies and trials of our current, planned or future products may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Our interpretation of data and results from our clinical trials do not ensure that we will achieve similar results in future clinical trials. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in preclinical studies and earlier clinical trials have nonetheless failed to replicate results in later clinical trials. Products in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical trials. Failure can occur at any stage of clinical testing. Our clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non-clinical testing in addition to those we have planned.

The initiation and completion of any of clinical studies may be prevented, delayed, or halted for numerous reasons. We may experience delays in our ongoing clinical trials for a number of reasons, which could adversely affect the costs, timing or successful completion of our clinical trials, including related to the following:

- we may be required to submit an IDE application to the FDA, which must become effective prior to commencing certain human clinical trials of medical devices, and the FDA may reject our IDE application and notify us that we may not begin clinical trials;
- regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;
- regulators and/or an IRB, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective contract research organizations (CROs), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of subjects or patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, including those manufacturing products or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials for various reasons, including the withdrawal of approval of an IDE by the FDA based on, for example, a finding that the subjects are being exposed to unacceptable health risks;
- we may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB and/or regulatory authorities for re-examination;
- regulators, IRBs, or other parties may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements;
- the cost of clinical trials may be greater than we anticipate;
- clinical sites may not adhere to the clinical protocol or may drop out of a clinical trial;
- we may be unable to recruit a sufficient number of clinical trial sites;
- regulators, IRBs, or other reviewing bodies may fail to approve or subsequently find fault with our manufacturing processes or facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical trials may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;

- approval policies or regulations of the FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for approval;
- our current or future products may have undesirable side effects or other unexpected characteristics; and
- impacts of regional or global public health crises such as the recent COVID-19 pandemic could adversely affect any clinical trials we are conducting or plan to conduct, including delays or difficulties in enrolling or onboarding patients, initiating clinical sites, or obtaining the requisite regulatory approvals, interruption of key clinical trial activities, or supply chain disruptions that delay or make it more difficult or costly to obtain the supplies and materials we need for clinical trials.

Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Clinical trials must be conducted in accordance with applicable laws and regulations of the FDA and other regulatory authorities' applicable legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. Conducting successful clinical studies will require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects, the availability of appropriate clinical trial investigators, support staff, and proximity of patients to clinical sites and able to comply with the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of our products or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts.

We depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with good clinical practice (GCP) requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both. In addition, clinical trials that are conducted in countries outside the United States may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening and medical care.

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required and we may not adequately develop such protocols to support clearance and approval. Further, the FDA may require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our clinical trials. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays in the approval and attempted commercialization of our products or result in the failure of the clinical trial. In addition, despite considerable time and expense invested in our clinical trials, the FDA may not consider our data adequate to demonstrate safety and efficacy. Such increased costs and delays or failures could adversely affect our business, operating results and prospects.

If the third parties on which we rely to conduct our clinical trials and to assist us with pre-clinical development do not perform as required or expected, we may not be able to obtain regulatory clearance or approval for or commercialize our products.

We may not have the ability to independently conduct our pre-clinical and clinical trials for our future products and we may need to rely on third parties, such as CROs, medical institutions, clinical investigators and contract laboratories to conduct such trials. We would depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with GCP requirements, and other regulatory requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, including on account of the outbreak of infectious disease, such as the COVID-19 pandemic, or otherwise, we may be affected by increased costs, program delays or both, any resulting data may be unreliable or unusable for regulatory purposes, and we may be subject to enforcement action.

If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected.

The results of our clinical trials may not support our product candidate claims or may result in the discovery of adverse side effects.

We cannot be certain that the results of our future clinical trials will support our future product claims or that the FDA will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the future product's profile.

The medical device industry is subject to extensive regulatory obligations and policies that are subject to change, including due to judicial challenges, election cycles, and resulting regulatory updates and changes in policy priorities.

Federal agency priorities, leadership, policies, rulemaking, communications, spending, and staffing may be significantly impacted by election cycles, including, for example, the current administration's commitment to significantly reduce government spending through cuts to federal healthcare programs and reductions in the workforces of key government agencies, such as HHS, FDA, and CMS. Efforts by the current administration to limit federal agency budgets or personnel may result in reductions to agency budgets, employees and operations, which may lead to slower response times, less guidance from the agency, and longer review periods, potentially affecting our ability to progress development of, or obtain regulatory clearance or approval for, any future product modifications or new products. The administration and agencies have also made abrupt announcements about new or changed regulatory policies, such as policies related to use of AI to review product applications. And, recent and possible future federal government shutdowns may impact the ability of FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, and may significantly impact the ability of the FDA to timely review and process our regulatory submissions. These developments may lead to greater uncertainty regarding FDA policies, slower response times, longer review periods, unexpected delays, increased costs, or other negative impacts on both our business and that of our customers that are difficult to predict. These changes may potentially affect our ability to progress development of, or obtain regulatory clearance or approval for, any future product modifications or new products.

Additionally, on June 28, 2024, the U.S. Supreme Court issued an opinion holding that courts reviewing agency action pursuant to the APA "must exercise their independent judgment" and "may not defer to an agency interpretation of the law simply because a statute is ambiguous." The decision has affected how lower courts evaluate challenges to agency interpretations of law, including those by HHS, FDA, CMS and other agencies with significant oversight of the medical device industry. The new framework is likely to increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies will be subject to increased litigation and judicial scrutiny. Any resulting changes in regulation may result in unexpected delays, increased costs, or other negative impacts on our business that are difficult to predict.

Our use, disclosure, and other processing of personally identifiable information, including health information, is subject to HIPAA and other federal, state, and data privacy and security regulations, and our failure to comply with those regulations or to adequately secure the information we hold could result in significant liability or reputational harm and, in turn, a material adverse effect on our client base, member base and revenue.

Numerous state and federal laws and regulations govern the collection, dissemination, use, privacy, confidentiality, security, availability, integrity, and other processing of PHI and PII. These laws and regulations include HIPAA. HIPAA establishes a set of national privacy and security standards for the protection of PHI (as defined in HIPAA) by health plans, healthcare clearinghouses and certain healthcare providers, referred to as covered entities, and the business associates with whom such covered entities contract to provide specified services or perform a function for or on behalf of such covered entities. We are a business associate under HIPAA, and it is our policy to execute business associate agreements with our clients and our sub-business associates.

HIPAA requires covered entities and business associates, such as us, to develop and maintain policies with respect to the protection, use and disclosure of electronic PHI, including the adoption of administrative, physical and technical safeguards to protect such information, and imposes certain notification and reporting requirements in the event of a data breach.

Violations of HIPAA may result in significant civil and criminal penalties. HIPAA also authorizes state attorneys general to file suits on behalf of their residents. Courts may award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI. OCR has recently increased its enforcement efforts on compliance with HIPAA, including the security regulations (Security Rule), bringing actions against entities which have failed to implement security measures sufficient to reduce risks to electronic protected health information or to conduct an accurate and thorough risk analysis, among other violations. HIPAA

enforcement actions may lead to monetary penalties and costly and burdensome corrective action plans. We are also required to report known breaches of PHI consistent with applicable breach reporting requirements set forth in applicable laws and regulations.

In addition, HIPAA mandates that the Secretary of HHS conduct periodic compliance audits of HIPAA covered entities and business associates. With regard to business associates, those audits assess the business associate's compliance with the HIPAA Privacy and Security Rules. Such audits are conducted randomly and after an entity experiences a breach affecting more than 500 individuals' data. Undergoing an audit can be costly, can result in fines or onerous obligations, and can damage a business associate's reputation.

Finally, on December 10, 2020, OCR issued a proposed rule aimed at reducing regulatory burdens that may exist in discouraging coordination of care, including creating an exception to the minimum necessary standard for healthcare coordination, among other changes. While a final rule has not yet been issued, if adopted, these proposed changes may require us to update our HIPAA policies and procedures to comply with the new requirements.

In addition to HIPAA, numerous other federal and state laws and regulations protect the confidentiality, privacy, availability, integrity and security of PHI and other types of PII. Some of these laws and regulations may be preempted by HIPAA with respect to PHI, or may exclude PHI from their scope but impose obligations with regard to PII that is not PHI, and in some cases, can impose additional obligations with regard to PHI. These laws and regulations are often uncertain, contradictory, and subject to changed or differing interpretations, and we expect new laws, rules and regulations regarding privacy, data protection, and information security to be proposed and enacted in the future. Although these other laws include limited exceptions, including for PHI maintained by a covered entity or business associate, they may regulate or impact our processing of personal information depending on the context and increase our compliance costs and potential liability. Additionally, our machine learning and data analytics offerings may be subject to laws and evolving regulations regarding the use of artificial intelligence, controlling for data bias, and antidiscrimination.

Additionally, the FTC and many state attorneys general are interpreting existing federal and state consumer protection laws to impose evolving standards for the online collection, use, dissemination and security of health-related and other personal information. Courts may also adopt the standards for fair information practices promulgated by the FTC, which concern consumer notice, choice, security and access. Consumer protection laws require us to publish statements that describe how we handle personal information and choices individuals may have about the way we handle their personal information. If such information that we publish is considered untrue, we may be subject to government claims of unfair or deceptive trade practices, which could lead to significant liabilities and consequences. Furthermore, according to the FTC, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair or deceptive acts or practices in violation of Section 5 of the FTC Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule. Enforcement by the FTC under the FTC Act can result in civil penalties or enforcement actions.

Recent guidance from OCR regarding the collection of PHI via websites, and ongoing enforcement by both HHS and the FTC regarding the collection of personal data via third-party tracking technologies such as web beacons and pixels, creates an ongoing compliance effort to ensure our website remains in compliance and that collection of website user data is transparent and appropriate. Failure to comply with regulations and guidance regarding the use of third-party tracking technologies on our website could lead to monetary penalties and the imposition of corrective action plans, as well as reputational damage.

This complex, dynamic legal landscape regarding privacy, data protection, data analytics and information security creates significant compliance issues for us and our clients and potentially exposes us to additional expense, adverse publicity and liability. While we have implemented data privacy and security measures in an effort to comply with applicable laws and regulations relating to privacy and data protection, some PHI and other PII or confidential information is transmitted to us by third parties, who may not implement adequate security and privacy measures, and it is possible that laws, rules and regulations relating to privacy, data protection, or information security may be interpreted and applied in a manner that is inconsistent with our practices or those of third parties who transmit PHI and other PII or confidential information to us. If we or these third parties are found to have violated such laws, rules or regulations, it could result in government-imposed fines, orders requiring that we or these third parties change our or their practices, or criminal charges, which could adversely affect our business. Complying with these various laws and regulations could cause us to incur substantial costs or require us to change our business practices, systems and compliance procedures in a manner adverse to our business.

Our employees, collaborators, independent contractors and consultants may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, collaborators, independent contractors and consultants may engage in fraudulent or other illegal activity with respect to our business. Misconduct by these persons could include intentional, reckless and/or negligent conduct or unauthorized activity that violates:

- FDA requirements, including those laws requiring the reporting of true, complete and accurate information to the FDA authorities;
- manufacturing standards;
- federal and state healthcare fraud and abuse laws and regulations; or
- laws that require the true, complete and accurate reporting of financial information or data.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commissions, customer incentive programs and other business arrangements. Misconduct by these parties could also involve individually identifiable information, including, without limitation, the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Any incidents or any other conduct that leads to an employee, contractor, or other agent, or our company, receiving an FDA debarment or disqualification from clinical trials, or exclusion by the Department of Health and Human Services, Office of Inspector General could result in penalties, a loss of business from third parties, and severe reputational harm.

It is not always possible to identify and deter misconduct by our employees and other agents, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, treble damages, monetary fines, disgorgement, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, reporting requirements and compliance oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations.

We must comply with environmental and occupational safety laws.

Our research and development programs as well as our manufacturing operations involve the controlled use of hazardous materials. Accordingly, we are subject to federal, state and local laws, as well as the laws of foreign countries, governing the use, handling and disposal of these materials. In the event of an accident or failure to comply with environmental or occupational safety laws, we could be held liable for resulting damages, and any such liability could exceed our insurance coverage and may accordingly adversely affect our business, financial condition or results of operations.

Risks Related to our Intellectual Property

We have to protect our intellectual property.

Our commercial success will depend in part in our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our technology. We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws, to protect our proprietary technology and prevent others from duplicating Tablo. However, these means may afford only limited protection and may not prevent our competitors from duplicating Tablo, prevent our competitors from gaining access to our proprietary information and technology, or permit us to gain or maintain a competitive advantage.

Any of our patents, including those we may license, may be challenged, invalidated, rendered unenforceable or circumvented. We may not prevail if our patents are challenged by competitors or other third parties. The U.S. federal courts or equivalent national courts or patent offices elsewhere may invalidate our patents, find them unenforceable, or narrow their scope. Furthermore, competitors may be able to design around our patents, or obtain patent protection for more effective technologies, designs or methods for treating kidney failure. If these developments were to occur, Tablo may become less competitive and sales of Tablo may decline.

We have filed numerous patent applications seeking protection of products and other inventions originating from our research and development. Our patent applications may not result in issued patents, and any patents that are issued may not provide meaningful protection against competitors or competitive technologies. Further, the examination process may require us to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The scope of a patent may also be reinterpreted after issuance. The rights that may be granted under our future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we are unable to obtain and maintain patent protection for our technology, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize products similar or superior to ours, and our competitive position may be adversely affected. It is also possible that we will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them. In addition, the patent prosecution process is expensive, time-consuming and complex,

and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner.

Additionally, while software and other of our proprietary works may be protected under copyright law, we have chosen not to register any copyrights in these works, and instead, primarily rely on protecting our software with patents and as a trade secret. In order to bring a copyright infringement lawsuit in the United States, the copyright must be registered. Accordingly, the remedies and damages available to us for unauthorized use of our software may be limited.

We may be subject to claims challenging the ownership or inventorship of our patents and other intellectual property and, if unsuccessful in any of these proceedings, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms, or at all, or to cease the development, manufacture and commercialization of Tablo.

We may be subject to claims that current or former employees, collaborators or other third parties have an interest in our patents, trade secrets or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing Tablo. Litigation may be necessary to defend against these and other claims challenging inventorship of our patents, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to Tablo. If we were to lose exclusive ownership of such intellectual property, other owners may be able to license their rights to other third parties, including our competitors. We also may be required to obtain and maintain licenses from third parties, including parties involved in any such disputes. Such licenses may not be available on commercially reasonable terms, or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture and commercialization of Tablo. The loss of exclusivity or the narrowing of our patent claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position may be harmed.

In addition to seeking patent protection for Tablo, we also rely upon unpatented trade secrets, know-how and continuing technological innovation to develop and maintain a competitive position. We seek to protect such proprietary information, in part, through confidentiality agreements with our employees, collaborators, contractors, advisors, consultants and other third parties and invention assignment agreements with our employees. We also have agreements with some of our consultants that require them to assign to us any inventions created as a result of their working with us. The confidentiality agreements are designed to protect our proprietary information and, in the case of agreements or clauses containing invention assignment, to grant us ownership of technologies that are developed through a relationship with employees or third parties.

We cannot guarantee that we have entered into such agreements with each party that has or may have had access to our trade secrets or proprietary information. Additionally, despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to, or independently developed by, a competitor or other third party, our competitive position would be materially and adversely harmed. Furthermore, we expect these trade secrets, know-how and proprietary information to over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology and the movement of personnel from academic to industry scientific positions.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known, or be independently discovered by, competitors. To the extent that our employees, consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions, which could have a material adverse effect on our business, financial condition and results of operations.

We may be subject to claims that we or our employees have misappropriated the intellectual property of a third party, including trade secrets or know-how, or are in breach of non-competition or non-solicitation agreements with our competitors and third parties may claim an ownership interest in intellectual property we regard as our own.

Many of our employees and consultants were previously employed at or engaged by other medical device, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and contractors, may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these individuals have, inadvertently or otherwise, misappropriated the intellectual property or disclosed the alleged trade secrets or other proprietary information, of these former employers or competitors.

Additionally, we may be subject to claims from third parties challenging our ownership interest in intellectual property we regard as our own, based on claims that our employees or consultants have breached an obligation to assign inventions to another employer, to a former employer, or to another person or entity. Litigation may be necessary to defend against any other claims, and it may be necessary or we may desire to enter into a license to settle any such claim; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to Tablo, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers.

An inability to incorporate technologies or features that are important or essential to our product could have a material adverse effect on our business, financial condition and results of operations, and may prevent us from selling Tablo. In addition, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our product, which could have an adverse effect on our business, financial condition and results of operations.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future products.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In 2011, the Leahy-Smith America Invents Act (Leahy-Smith Act) was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and also may affect patent litigation. These also include provisions that switched the United States from a first-to-invent system to a first-to-file system, allow third-party submission of prior art to the USPTO during patent prosecution and set forth additional procedures to attack the validity of a patent by the USPTO administered post grant proceedings. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition and results of operations.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications. Furthermore, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

If our trademarks and tradenames are not adequately protected, then we may not be able to build name recognition in our markets and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be violating or infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners and customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement or dilution claims brought by owners of other

trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names or other intellectual property may be ineffective, could result in substantial costs and diversion of resources and could adversely affect our business, financial condition and results of operations.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents, or we may be required to enforce patents issued or licensed to us, to protect our trade secrets or know-how, to defend against claims of infringement of the rights of others or to determine the scope and validity of the proprietary rights of others. In addition, our patents also may become involved in inventorship, priority or validity disputes. To counter or defend against such claims can be expensive and time-consuming and could divert our attention from other functions and responsibilities. In an infringement proceeding, a court may decide that a patent owned by us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover such technology. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, even if our patents are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages and/or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer's competition in the market. Adverse determinations in litigation could subject us to significant liabilities to third parties, require us to seek licenses from third parties and prevent us from manufacturing, selling or using the product, any of which could severely harm our business. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our management and other personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on our common stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

Our use of "open source" software could subject our proprietary software to general release, adversely affect our ability to sell Tablo and subject us to possible litigation.

A portion of the products or technologies licensed, developed and/or distributed by us incorporate so-called "open source" software and we may incorporate open-source software into other products in the future. Such open-source software is generally licensed by its authors or other third parties under open-source licenses. Some open-source licenses contain requirements that we disclose source code for modifications we make to the open-source software and that we license such modifications to third parties at no cost. In some circumstances, distribution of our software in connection with open-source software could require that we disclose and license some or all of our proprietary code in that software, as well as distribute our software that uses particular open-source software at no cost to the user. We monitor our use of open-source software in an effort to avoid uses in a manner that would require us to disclose or grant licenses under our proprietary source code; however, there can be no assurance that such efforts will be successful. Open-source license terms are often ambiguous and such use could inadvertently occur. There is little legal precedent governing the interpretation of many of the terms of these licenses, and the potential impact of these terms on our business may result in unanticipated obligations regarding Tablo and our technologies. Companies that incorporate open-source software into their products have, in the past, faced claims seeking enforcement of open-source license provisions and claims asserting ownership of open-source software incorporated into their product. If an author or other third party that distributes such open-source software were to allege that we had not complied with the conditions of an open-source license, we could incur significant legal costs defending ourselves against such allegations. In the event such claims were successful, we could be subject to significant damages or be enjoined from the distribution of Tablo. In addition, if we combine our proprietary software with open-source software in certain ways, under some open-source licenses, we could be required to release the source code of our proprietary software, which could substantially help our competitors develop products that are similar to or better than ours and otherwise adversely affect our business. These risks could be difficult to eliminate or manage, and, if not addressed, could harm our business, financial condition and results of operations.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to Tablo or utilize similar technology but that are not covered by the claims of our patents or that incorporate certain technology in Tablo that is in the public domain;
- we, or our future licensors or collaborators, might not have been the first to make the inventions covered by the applicable issued patent or pending patent application that we own now or may own or license in the future;
- we, or our future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our current or future pending patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Third parties may attempt to commercialize competitive products or services in foreign countries where we do not have any patents or patent applications and/or where legal recourse may be limited. This may have a significant commercial impact on any foreign business operations.

Filing, prosecuting and defending patents on Tablo in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with Tablo, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition and results of operations may be adversely affected.

Risks Related to Ownership of Our Common Stock

The market price of our common stock has been and may continue to be volatile and may decline steeply or suddenly regardless of our operating performance, which could result in substantial losses for holders of our common stock, and we may not be able to meet investor or analyst expectations.

The market price of our common stock has been and may continue to be highly volatile and may continue to fluctuate or decline significantly in response to numerous factors, many of which are beyond our control, including:

- actual or anticipated changes in our operating results, and variations between our actual operating results and the expectations of securities analysts, investors and the financial community;
- any forward-looking financial or operating information we may provide to the public or securities analysts, any changes in this information or our failure to meet expectations based on this information;
- actions of securities analysts who initiate or maintain coverage of us, changes in financial estimates by any securities analysts who follow our company or our failure to meet these estimates or the expectations of investors;
- additional shares of our common stock being sold into the market by us or our existing stockholders, or the anticipation of such sales;
- hedging activities by market participants;
- regulatory actions with respect to our products or our competitors' products, or announcements by us in relation to such regulatory actions;
- announcements by us or our competitors of significant products or features, technical innovations, acquisitions, strategic partnerships, joint ventures or capital commitments;
- changes in operating performance and stock market valuations of companies in our industry, including our competitors;
- price and volume fluctuations in the overall stock market, including as a result of trends in the economy as a whole;
- lawsuits threatened or filed against us;
- developments in new legislation and pending lawsuits or regulatory actions, including interim or final rulings by judicial or regulatory bodies; and
- other events or factors, including those resulting from political conditions, election cycles, war or incidents of terrorism, or responses to these events.

In addition, extreme price and volume fluctuations in the stock markets have affected and continue to affect many life sciences and technology companies' stock prices. Stock prices often fluctuate in ways unrelated or disproportionate to the companies' operating performance. In the past, stockholders have filed securities class action litigation following periods of market volatility. We and certain of our directors and officers have previously been named as defendants in securities class actions and derivative lawsuits alleging violations of federal securities laws. For more information, see the section entitled "Litigation" in Note 6, Commitments and Contingencies, to our audited financial statements included in this Annual Report. Any such securities litigation could subject us to substantial costs, divert resources and the attention of management from our business and seriously harm our business.

Moreover, because of these fluctuations, comparing our operating results on a period-to-period basis may not be meaningful. You should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failure to meet the expectations of industry or financial analysts or investors for any period. If our revenues or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings forecasts that we may provide.

We may not be able to maintain the listing of our common stock on Nasdaq, which could adversely affect our liquidity and the trading volume and market price of our common stock.

Our common stock is listed on The Nasdaq Global Select Market, which imposes continued listing requirements with respect to listed securities, including a minimum bid price requirement. As previously disclosed, in September 2024, we received notice from The Nasdaq Stock Market LLC (Nasdaq) that, because the closing bid price for our common stock had fallen below $1.00 per share for 30 consecutive trading days, we no longer complied with the minimum bid price requirement for continued listing on the Nasdaq Global Select Market under Nasdaq Listing Rule 5450(a)(1). After regaining compliance in December 2024, we received a second notice of non-compliance in February 2025 after again failing to meet the minimum bid price requirement. In March 2025, we effected

a reverse stock split of our common stock on a 15-for-one basis (the Reverse Stock Split), and subsequently regained compliance with Nasdaq's minimum bid price requirement as of early April 2025.

However, there is no assurance that we will be able to maintain compliance with the minimum bid price requirement or other applicable Nasdaq listing rules. Moreover, if we fall out of compliance with the minimum bid price requirement within one year of effecting the Reverse Stock Split, Nasdaq will provide notice that our common stock will be subject to delisting. If Nasdaq delists our common stock, it is unlikely that we will be able to list our common stock on another national securities exchange and, as a result, we expect our securities would be quoted on an over-the-counter market. If this were to occur, we and our stockholders could face significant adverse consequences, including limited availability of market quotations and analyst coverage for our common stock, and reduced liquidity for trading of our securities, all of which would likely reduce the market price of our common stock. In addition, our common stock could be considered a "penny stock," which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in reduced trading activity in the secondary trading market for our common stock. Delisting could result in additional adverse consequences including reduced ability to issue additional securities or obtain additional financing on terms acceptable to us, or at all, as well as the potential loss of confidence of our customers, suppliers and employees, any of which could harm our business and future prospects. Even the perception that we are at heightened risk of delisting could also result in certain of the above these consequences, which could negatively impact the market price and trading volume of our common stock, and harm our stockholders and our business.

We do not intend to pay dividends for the foreseeable future and, as a result, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We have never declared or paid any cash dividends on our common stock and do not intend to pay any cash dividends on our common stock in the foreseeable future. We anticipate that we will retain all of our future earnings for use in the development of our business and for general corporate purposes. Any determination to pay dividends on our common stock in the future will be at the discretion of our board of directors. In addition, the terms of the Credit Agreement restrict our ability to pay dividends to limited circumstances. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments.

If securities or industry analysts either do not publish research about us or publish inaccurate or unfavorable research about us, our business or our market, or if they change their recommendations regarding our common stock adversely, the trading price or trading volume of our common stock could decline.

The trading market for our common stock is influenced in part by the research and reports that securities or industry analysts may publish about us, our business, our market or our competitors. If one or more analysts initiate research with an unfavorable rating or downgrade our common stock, provide a more favorable recommendation about our competitors or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If any analyst who may cover us were to cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the trading price or trading volume of our common stock to decline.

Our principal stockholders and management own a significant percentage of our stock and are able to exercise significant influence over matters subject to stockholder approval.

Based on available information, we believe that, as of January 26, 2026, our executive officers, directors and 5% stockholders beneficially owned approximately 76.0% of the outstanding shares of our common stock. In addition, as of January 26, 2026, our executive officers and directors held options to purchase an aggregate of 67,604 shares of our common stock at a weighted-average exercise price of $147.61 per share, and 530,851 restricted stock units, which would give our officers and directors ownership of approximately 5.4% of our outstanding common stock as of January 26, 2026 if such awards were fully vested and exercised or settled in full (assuming over-achievement of any performance conditions). Therefore, these stockholders have the ability to influence us through these ownerships position. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could attempt to delay or prevent a change in control of us, even if such change in control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of us or our assets and might affect the prevailing market price of our common stock due to investors' perceptions that conflicts of interest may exist or arise. As a result, this concentration of ownership may not be in the best interests of our other stockholders.

Future securities issuances could result in significant dilution to our stockholders and impair the market price of our common stock.

Future issuances of shares of our common stock, or the perception that these sales may occur, could depress the market price of our common stock and result in dilution to existing holders of our common stock. Also, to the extent outstanding options or warrants to purchase shares of our common stock are exercised or options, restricted stock units or other stock-based awards are

issued or become vested, there will be further dilution. For example, in connection with the Term Loan Facility, we issued a warrant to purchase up to 375,000 shares of our common stock. The amount of dilution could be substantial depending upon the size of the issuances or exercises. Furthermore, we may issue additional equity securities that could have rights senior to those of our common stock. As a result, purchasers of our common stock bear the risk that future issuances of debt or equity securities may reduce the value of our common stock and further dilute their ownership interest.

Delaware law and provisions in our amended and restated certificate of incorporation and bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

Our amended and restated certificate of incorporation and bylaws contain provisions that could depress the trading price of our common stock by acting to discourage, delay or prevent a change of control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions include the following:

- establish a classified board of directors so that not all members of our board of directors are elected at one time;
- permit the board of directors to establish the number of directors and fill any vacancies and newly-created directorships;
- provide that directors may only be removed for cause and only by the affirmative vote of the holders of at least a majority of the voting power of all then-outstanding shares of our capital stock;
- require super-majority voting to amend some provisions in our amended and restated certificate of incorporation and bylaws;
- authorize the issuance of "blank check" preferred stock that our board of directors could use to implement a stockholder rights plan;
- prohibit stockholders from calling special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- provide that the board of directors is expressly authorized to make, alter or repeal our bylaws;
- restrict the forum for certain litigation against us to Delaware; and
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

Any provision of our amended and restated certificate of incorporation or bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated certificate of incorporation designates a state or federal court located within the State of Delaware as the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to choose the judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf under Delaware law, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action arising pursuant to any provision of the Delaware General Corporation Law (DGCL), our amended and restated certificate of incorporation or bylaws, (4) any other action asserting a claim that is governed by the internal affairs doctrine, or (5) any other action asserting an "internal corporate claim," as defined in Section 115 of the DGCL, shall be the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) in all cases subject to the court having jurisdiction over indispensable parties named as defendants. These exclusive-forum provisions do not apply to claims under the Securities Act or the Exchange Act.

To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. However, our amended and restated certificate of incorporation contains a federal forum provision which provides that unless the company consents in writing to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act.

Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to this provision. This exclusive forum provision may limit a stockholder's ability to bring a claim in a judicial forum of its choosing for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find the exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could harm our results of operations.

General Risks

General economic and financial market conditions may exacerbate our business risks.

Global macroeconomic conditions and the world's financial markets remain susceptible to significant stresses, including global geopolitical instability (such as the ongoing conflict between Russia and Ukraine and related economic and other retaliatory measures taken by the United States, European Union and others, the ongoing hostilities in the Middle East as well as the potential escalation or geographic expansion of such conflicts, and the risk of increased tensions between China and Taiwan), pandemics (such as the COVID-19 pandemic), changes in tariff or trade laws and policies (such as the tariffs imposed by the current administration on products imported into the United States from Mexico and China), inflationary pressures (such as current inflation related to global supply chain disruptions), extreme weather conditions and natural disasters, market declines and uncertainty, fluctuating interest and foreign currency rates and credit availability, government austerity measures, fluctuating fuel and other energy costs, fluctuating commodity prices, and general uncertainty regarding the overall future economic environment. The ultimate impact of these conflicts on fuel prices, inflation, volatility of global financial markets, the global supply chain and other macroeconomic conditions is unknown and could materially adversely affect the availability and cost of materials, access to capital, global economic growth, consumer confidence and demand for our products and services.

Our customers may respond to such economic pressures by reducing or deferring their capital spending or reducing staff. Furthermore, unfavorable changes in foreign exchange rates versus USD could increase our product and labor costs, thus reducing our gross profit.

We are highly dependent on our senior management team and key personnel, and our business could be harmed if we are unable to attract and retain personnel necessary for our success in a cost-effective manner.

We are highly dependent on our senior management, including our chief executive officer, Leslie Trigg, and other key personnel. Our success will depend on our ability to retain senior management and to attract and retain qualified personnel in the future, including sales and marketing professionals, scientists, clinical specialists, engineers and other highly skilled personnel and to integrate current and additional personnel in all departments. The loss of members of our senior management, sales and marketing professionals, scientists, clinical and regulatory specialists and engineers could result in delays in product development and harm our business. If we are not successful in attracting and retaining highly qualified personnel, or if we are unable to do so in a cost-effective manner, it would have a material adverse effect on our business, financial condition, and results of operations.

Competition for skilled personnel in our market is intense and has recently intensified further due to industry trends in many areas where our employees are located. Further, the increased availability of hybrid or remote working arrangements has expanded the pool of companies that can compete for our employees and employment candidates. Such competition may limit our ability to hire and retain highly qualified personnel on acceptable terms, or at all. We may experience higher compensation costs to retain senior management and experienced personnel that may not be offset by improved productivity. Moreover, in order to improve operational efficiencies, reduce operating expenses, and streamline our overall organizational structure, we have completed several organizational restructurings beginning in late 2023 through early 2025. These restructurings, as well as any future restructurings, may adversely affect our ability to attract and retain employees. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have issued and may continue to issue equity awards that vest over time. The value to employees of equity awards that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Our employment arrangements with our employees provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We also do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees.

We will continue to incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies in the United States, which may harm our business.

We have incurred and will continue to incur substantial legal, accounting and other expenses as a result of operating as a public company. In addition, changing laws, regulations, and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and The Nasdaq Stock Market, may increase legal and financial compliance costs and

make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations, and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If, notwithstanding our efforts, we fail to comply with new laws, regulations, and standards, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Any failure to comply with applicable rules and regulations may make it more expensive for us to obtain director and officer liability insurance. Given recent developments in the market for such coverage, we expect to incur substantially higher costs to obtain and maintain the same or similar coverage. These factors could also make it more difficult for us to attract and retain qualified executive officers and members of our board of directors.

Our corporate culture has contributed to our success, and if we cannot maintain this culture as we grow, we could lose the innovation, creativity and teamwork fostered by our culture and our business may be harmed.

We believe that our culture has been and will continue to be a critical contributor to our success and our ability to attract highly skilled personnel. If we do not continue to develop our corporate culture or maintain and preserve our core values as we grow and evolve, we may be unable to foster the innovation, curiosity, creativity, focus on execution, teamwork and the facilitation of critical knowledge transfer and knowledge sharing we believe we need to support our growth.

We may acquire other businesses which could require significant management attention, disrupt our business, dilute stockholder value and adversely affect our results of operations.

As part of our business strategy, we may in the future make acquisitions or investments in complementary companies, products or technologies that we believe fit within our business model and can address the needs of our customers and potential customers. In the future, we may not be able to acquire and integrate other companies, products or technologies in a successful manner. We may not be able to find suitable acquisition candidates, and we may not be able to complete such acquisitions on favorable terms, if at all. In addition, the pursuit of potential acquisitions may divert the attention of management and cause us to incur additional expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. If we do complete acquisitions, we may not ultimately strengthen our competitive position or achieve our goals, including increases in revenue, and any acquisitions we complete could be viewed negatively by our customers, investors and industry analysts.

Future acquisitions may reduce our cash available for operations and other uses and could result in amortization expense related to identifiable assets acquired. We may have to pay cash, incur debt or issue equity securities to pay for any such acquisition, each of which could adversely affect our financial condition or the value of our common stock. The sale or issuance of equity or convertible debt to finance any such acquisitions would result in dilution to our stockholders. The incurrence of indebtedness to finance any such acquisition would result in fixed obligations and could also include covenants or other restrictions that could impede our ability to manage our operations. In addition, our future results of operations may be adversely affected by the dilutive effect of an acquisition, performance earn-outs or contingent bonuses associated with an acquisition. Furthermore, acquisitions may require large, onetime charges and can result in increased debt or contingent liabilities, adverse tax consequences, additional stock-based compensation expenses and the recording and subsequent amortization of amounts related to certain purchased intangible assets, any of which items could negatively affect our future results of operations. We may also incur goodwill impairment charges in the future if we do not realize the expected value of any such acquisitions.

Also, the anticipated benefit of any strategic alliance, joint venture or acquisition may not materialize, or such strategic alliance, joint venture or acquisition may be prohibited. In January 2025, we entered into the Term Loan Facility (which replaced our prior credit facilities with SLR) which also restrict our ability to pursue certain acquisitions, mergers, or consolidations that we may believe to be in our best interest. Additionally, future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

If we fail to comply with anti-corruption, anti-bribery, anti-money laundering and similar laws, we could suffer severe penalties.

We are subject to the U.S. Foreign Corrupt Practices Act which generally prohibits U.S. companies from engaging in bribery or other prohibited payments to foreign officials for the purpose of obtaining or retaining business and requires companies to maintain accurate books and records and internal controls, including at foreign controlled subsidiaries. We are also subject to requirements under the U.S. Treasury Department's Office of Foreign Assets Control, U.S. domestic bribery laws and other anti-corruption, anti-bribery and anti-money laundering laws. While we have policies and procedures in place designed to promote compliance with such laws, our employees or other agents may nonetheless engage in prohibited conduct under these laws for which we or our executives

might be held responsible. If our employees or other agents are found to have engaged in such practices, we could suffer severe penalties and other consequences that may have an adverse effect on our business, financial condition and results of operations.

If our estimates or judgments relating to our accounting policies prove to be incorrect, our results of operations could be adversely affected.

The preparation of financial statements in conformity with the United States generally accepted accounting principles (U.S. GAAP) and our key metrics require management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes and amounts reported in our key metrics. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, as provided in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." The results of these estimates form the basis for making judgments about the carrying values of assets, liabilities and equity and the amount of revenue and expenses that are not readily apparent from other sources. Significant assumptions and estimates used in preparing our financial statements include those related to allowance for credit losses, assessment of the useful life and recoverability of long-lived assets, warranty obligations, fair values of stock-based awards, warrants, contingent consideration, and income taxes. Our results of operations may be adversely affected if our assumptions change or if actual circumstances differ from those in our assumptions, which could cause our results of operations to fall below the expectations of securities analysts and investors, resulting in a decline in the trading price of our common stock.

Expectations relating to ESG factors may impose additional costs and expose us to new risks.

Certain investors, customers and other stakeholders may focus on ESG factors, including greenhouse gas emissions and climate-related risks; diversity, equity, and inclusion; responsible sourcing and supply chain; human rights and social responsibility; and corporate governance and oversight. Some investors may use ESG factors to guide their investment strategies and, in some cases, may choose not to invest in us if they believe our policies and actions relating to ESG matters are inadequate or are not aligned with their investment strategies, which could have a material adverse effect on our reputation and cause the trading price of our common stock to decline. In addition, we are subject to diverse, evolving and sometimes conflicting ESG regulatory requirements in the jurisdictions in which we operate. If our ESG practices fail to meet regulatory requirements, or investor, customer, employee or other stakeholders' evolving expectations and standards for responsible corporate citizenship, our reputation, brand and employee retention may be negatively impacted, and our customers and suppliers may be unwilling to continue to do business with us.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity

At Outset, we strive to protect the confidentiality, integrity and availability of the data entrusted to us. We continue to invest in our cybersecurity program in an effort to enhance our ability to prevent, detect, contain, and mitigate cybersecurity threats.

Risk Oversight

Oversight of our information security program, including oversight of risks related to cybersecurity threats and the assessment and management of such risks, is accomplished through a governance structure which includes our Board, Audit Committee, and executive management.

BOARD AND AUDIT COMMITTEE OVERSIGHT

One of the key functions of our Board is informed oversight of our risk management process. Our Board focuses on the overall risks affecting us and delegates responsibility for oversight of certain specific risks to its standing committees. For significant risks related to cybersecurity, the Board has delegated oversight responsibility to the Audit Committee.

Our Audit Committee is responsible for overseeing our major financial, legal, and regulatory risk exposures, which span a variety of areas, including cybersecurity.

Our full Board and Audit Committee are kept informed about significant risks related to cybersecurity, including enterprise-level risks from cybersecurity threats. The Board receives written updates, generally on a quarterly basis, regarding the status of our information security program. In addition, the Audit Committee receives in-person updates on our information security programs on at least an annual basis. These updates generally cover topics such as our cybersecurity strategy, the threat landscape, key cybersecurity risk areas facing the organization, any key findings of audits and testing, the status of key initiatives, as well as a review of any major incidents.

MANAGEMENT

Executive management plays a significant role in assessing and managing material risks from cybersecurity threats. Our VP of Information Technology manages our information security program.

Executive leadership

Our VP of Information Technology periodically presents information about the Company's information security program, including program goals and strategy, and progress against key initiatives and key risks, to our executive leadership team. As described above, significant risks related to cybersecurity are escalated to the Audit Committee and/or the full Board as appropriate.

Cross-functional engagement

We maintain an integrated cybersecurity program that involves collaboration across key functions, including information technology (IT), software engineering, regulatory, legal, privacy, finance, and operations. This cross-functional approach supports alignment with regulatory requirements and proactive risk management, and representatives of these functions meet regularly to review our cybersecurity posture, evolving threats, and related action plans.

Governance of information security risks

We have also established a risk governance committee, which generally meets on a quarterly basis. This committee, which is sponsored by our VP of Information Technology, is comprised of our information security advisor and Company leaders from IT, legal, privacy, finance, operations, and other functions, who have experience in managing cybersecurity risks, who review the cybersecurity threat landscape, and who evaluate key emerging data security risks. The committee reviews certain cybersecurity-related risks facing the company; discusses open policy exceptions and key risk indicators; and manages cybersecurity risks presented by the team and proposed mitigation actions. Members of this committee review the key risks identified as an outcome of our cybersecurity risk management strategy described below.

Risk Management and Strategy

Our cybersecurity risk management program is designed to identify, assess, and manage reasonably foreseeable material risks facing Outset from cybersecurity threats. We identify cybersecurity risks in various ways, including but not limited to the ongoing monitoring of our systems using various technologies and processes, monitoring of emerging threats, third-party penetration testing of our device and systems, vulnerability scanning and assessments, and cross-functional risk discussions. We have also received Systems and Organizations Controls 2 (SOC 2) certification for Tablo Cloud. We have developed processes to help us track, prioritize, and manage identified cybersecurity risks. For example, risks are defined, categorized, and assigned a risk rating based on potential impact and likelihood, which informs acceptance, mitigation or remediation actions which should be undertaken. The Risk Governance Committee reviews key identified risks and discusses related mitigation actions in response to such risks.

We have operationalized key processes to help us identify, assess, manage, and mitigate reasonably foreseeable risks from potential cybersecurity threats. For example:

- **USE OF THIRD PARTIES:** We engage third-party cybersecurity consulting firms to assist us with various aspects of our cybersecurity risk management program. For example, we have engaged a leading third-party information security consulting firm for CISO advisory services to support our information security program, which will continue to be overseen by our VP of Information Technology. We also currently consult with third party firms to assist with our annual penetration testing for the Tablo device, Tablo Cloud and IT infrastructure. In addition, we used a third-party audit firm accredited by the American Institute of Certified Public Accountants (AICPA) to support us in the SOC 2 certification process for Tablo Cloud.
- **VENDOR ASSESSMENT:** We leverage a third-party risk assessment tool to help us identify cybersecurity, privacy, and operational related risks associated with our use of certain third-party service providers.
- **INCIDENT PREPAREDNESS AND RESPONSE:** We maintain a Cybersecurity Incident Response Plan (IRP) which establishes a framework designed to enable us to respond to cybersecurity incidents in a consistent, timely and effective manner. Our IRP outlines procedures for identifying, reporting, investigating, assessing, and responding to cybersecurity incidents, including incident response team formation, roles and responsibilities by department, and communication and escalation protocols. The IRP also includes an addendum that specifically addresses incidents involving protected health information and describes our obligations under HIPAA, including compliance with the HIPAA breach notification rule and our applicable contractual requirements. Depending on the severity of the cybersecurity incident, our IRP contemplates escalation to our executive leadership team and the Audit Committee and/or the full Board, as well as periodic briefings on developments related to the incident response. We periodically review and update our IRP and have

conducted training of key team members regarding the IRP. In addition, we have conducted a tabletop exercise to simulate a response to a cybersecurity incident.

- **SECURITY STANDARDS**: Our IT and Tablo Cloud security architecture are designed to comply with the HIPAA Security Rule. In addition, our Tablo Cloud security architecture leverages recognized frameworks designed to protect customer data. For example, we have received SOC 2 certification for Tablo Cloud. In addition, in January 2026, the FDA granted 510(k) clearance of our next-generation Tablo platform which incorporates the FDA's recent guidance on medical device cybersecurity published in June 2025. We periodically examine our security controls and take steps to review, prioritize and address key compliance gaps where identified, using a risk-based approach.
- **TECHNICAL SAFEGUARDS**: We perform information security maturity assessments and penetration testing for the Tablo device and Tablo Cloud (including in connection with new product features and services), as well as for our enterprise IT infrastructure. We conduct vulnerability scans across key assets, core infrastructure, and endpoints to identify potential vulnerabilities and potential cybersecurity events. We assess and prioritize the remediation of vulnerabilities and other cybersecurity risks identified through these activities, using a risk-based approach.
- **THREAT LANDSCAPE AWARENESS:** We regularly receive and review threat landscape bulletins from Health Information Sharing and Analysis Center (H-ISAC), Cybersecurity and Infrastructure Security Agency (CISA) and other sources, and incorporate enhancements into our ongoing cybersecurity program based on this review.
- **INSURANCE**: We maintain information security risk insurance coverage to mitigate potential losses in the event of a business disruption.
- **TRAINING**: All Outset employees are assigned HIPAA and information security awareness training as part of the new employee onboarding process and refresher training is assigned annually. Our IT team also conducts continuous automated phishing simulation campaigns, which can trigger additional training for employees on how to recognize social engineering attempts (e.g., phishing, smishing, etc.). We track employee performance on phishing exercises to help us monitor the awareness of our employees and inform future training priorities. For employees whose jobs require access to sensitive data, including PHI, additional security training may be required.

Risks from Cybersecurity Threats

Our business relies on secure and continuous processing of information and the availability of our IT networks and IT resources, as well as critical IT vendors that support our technology and data processing operations. Security breaches, computer malware and computer hacking attacks have become more prevalent across industries and may occur on our systems or those of our third-party service providers. Attacks upon IT systems are increasing in their frequency, levels of persistence, sophistication, and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. We may face increased risks from cybersecurity threats due to our reliance on internet technology and the increased frequency of employees working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities.

We regularly monitor for, defend against, and respond to cybersecurity threats to our networks and information systems, as well as other types of security threats and incidents. Despite our information security efforts, our facilities, systems, servers, platforms and data, as well as those of our third-party cloud and other service providers and Tablo's two-way wireless communication system, may be vulnerable to privacy and information security incidents and may be breached due to the actions of outside parties, employee error or misconduct, malfeasance, or a combination of these and, as a result, an unauthorized party may obtain access to our data or the personal information maintained by us or on our behalf. These include data breaches, viruses or other malicious code, exploitation of known or unknown vulnerabilities, coordinated attacks, data loss, phishing attacks, ransomware, denial of service attacks, insider threats or other security or IT incidents caused by threat actors, technological vulnerabilities, or human error. Additionally, outside parties may attempt to fraudulently induce employees to disclose sensitive information to gain access to the data and personal information we maintain. As of the date of this Annual Report, we are not aware of any material adverse impact to our business or operations from cybersecurity threats or incidents. We do, however, recognize that the cybersecurity landscape evolves rapidly and that we are not immune to such incidents. If we, or any of our third-party service providers, fail to comply with laws requiring the protection of sensitive personal information, or fail to safeguard and defend personal information or other critical data assets or IT systems, or if our incident response, containment or mitigation measures are inadequate in the face of a particular data breach or cybersecurity incident, we may face significant business interruptions, incur reputational damage, and be subject to regulatory enforcement and fines as well as private civil actions. We may be required to expend significant resources in the response, containment, and mitigation of cybersecurity incidents as well as in defense against claims that our information security was unreasonable or otherwise violated applicable laws or contractual obligations. In addition, to the extent that our cloud and other service providers experience security breaches that result in the unauthorized or improper use of confidential information, employee information or personal information, we may not be indemnified for any losses resulting from such breaches. Moreover, we have engaged a leading third-party information security consulting firm for CISO advisory services to support our information security program, which will continue to be overseen by our VP of Information Technology. While this consulting firm has significant

experience in supporting and managing information security programs, has previously been involved in various aspects of our cybersecurity risk management program and ongoing cybersecurity operations, and the engagement is designed to enhance our program, there can be no assurance that the integration of external resources for CISO advisory services will be seamless or free of operational or security risks, which could result in unforeseen vulnerabilities or costs. If we are unable to prevent or mitigate the impact of such security breaches or other cyber events that impact our operations, our ability to attract and retain new customers, patients, and other partners could be harmed, as they may be reluctant to entrust us with their data, and we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business or other adverse consequences.

Moreover, any unauthorized access to, or compromise of, Tablo devices could result in device malfunction, interruption or alteration of treatment or inaccurate data transmission, any of which could adversely affect patient health or safety. Any such incident could subject us to product liability claims, FDA or other regulatory enforcement actions, increased regulatory scrutiny, and reputational harm. In addition, certain privacy and data protection laws provide for private rights of action, and we could also be subject to contractual claims by customers or other counterparties in connection with a cybersecurity or privacy incident. Even the perception that Tablo is vulnerable to cybersecurity threats could reduce patient and provider confidence and materially harm adoption and use of Tablo and our business.

In addition, manufacturing operations at our Mexico-based facility may also suffer disruptions from cybersecurity attacks, which could negatively impact our ability to produce Tablo consoles and cartridges, restrict or delay our ability to deliver products to our customers and meet our customers' demand on a timely basis, and result in customer dissatisfaction, all of which would adversely impact our results of operations. Moreover, we use Amazon Web Services to support Tablo's cloud connectivity and any disruption of service as a result of cybersecurity attacks could interrupt or delay our ability to receive and deliver certain treatment and reporting information from and to providers and patients. The continuing and uninterrupted performance of Tablo is critical to our success and any repeated or prolonged system failures may damage our reputation, reduce the attractiveness of Tablo to providers and patients, and result in decreased demand for Tablo, thereby adversely affecting our business, financial condition and results of operations.

For more information on the risks we face from cybersecurity threats and the potential impacts on our company, see the section above entitled "Risk Factors" under Part I, Item 1A, including the risk factor entitled "We may face additional costs, loss of revenue, significant liabilities, harm to our brand, decreased use of our platform and business disruption if there are any security or data privacy breaches or other unauthorized or improper access."

Item 2. Properties.

We currently lease 40,413 square feet of office space for our corporate headquarters located in San Jose, California under a lease agreement that terminates in 2027. This facility supports research and development and general and administrative activities. In Tijuana, Mexico, we also lease 87,187 square feet of space for our manufacturing facility under a lease agreement that will expire in 2026 (or 2031 if and when our renewal option is exercised and mutually agreed) and 7,739 square feet of office space for certain research and development and general and administrative activities under a lease agreement that will expire in 2028.

We believe that these facilities are suitable and sufficient to meet our current and anticipated needs in the near term and that additional space can be obtained on commercially reasonable terms as needed.

Item 3. Legal Proceedings.

The information set forth under "Litigation" in Note 6, Commitments and Contingencies, of the notes accompanying our audited financial statements in this Annual Report is incorporated herein by reference.

From time to time, we may become involved in legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, results of operations, financial condition or cash flows.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock has been listed on the Nasdaq Global Select Market under the symbol "OM" since September 15, 2020. Prior to that date, there was no public trading market for our common stock.

Holders of Common Stock

We effected a 15:1 reverse stock split of our common stock on March 20, 2025 (the Reverse Stock Split). All share and per share information has been retroactively adjusted to give effect to the Reverse Stock Split for all periods presented, unless otherwise indicated.

As of February 10, 2026, there were 104 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

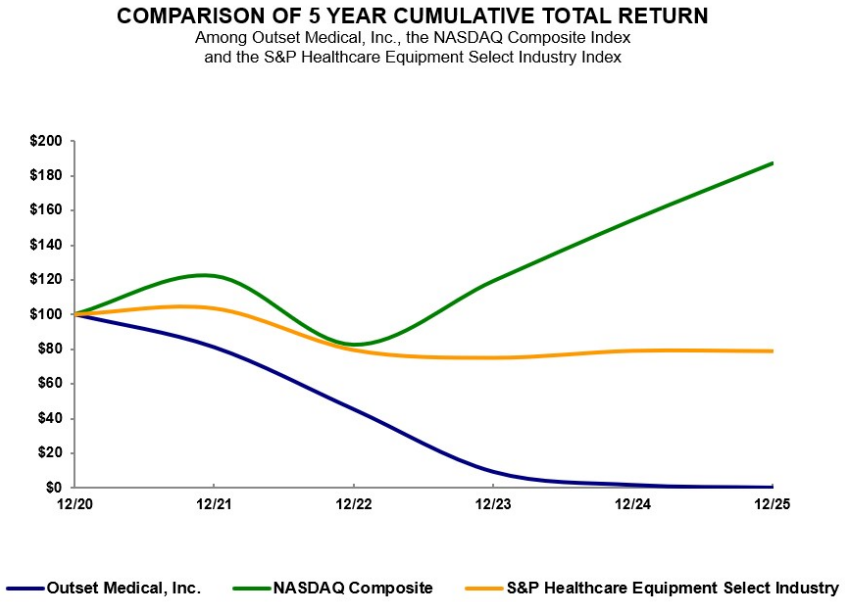
Dividend Policy

We have never declared or paid, and do not anticipate declaring or paying in the foreseeable future, any cash dividends on our capital stock. Any future determination as to the declaration and payment of dividends, if any, will be at the discretion of our board of directors, subject to applicable laws and will depend on then existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects, and other factors our board of directors may deem relevant.

Stock Performance Graph

The following shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or incorporated by reference into any of our other filings under the Exchange Act or the Securities Act of 1933, as amended, except to the extent we specifically incorporate it by reference into such filing.

The following graph compares the cumulative total return on our common stock relative to the cumulative total returns of the NASDAQ Composite Index and the S&P Healthcare Equipment Select Industry Index (SPSIHE) for the period from December 31, 2020 through December 31, 2025. The graph assumes an investment of $100 on December 31, 2020 and its relative performance is tracked through December 31, 2025. Pursuant to applicable SEC rules, all values assume reinvestment of the full amount of all dividends, however no dividends have been declared on our common stock to date. Note that historic stock price performance is not necessarily indicative of future stock price performance. Per share data has been adjusted on a retroactive basis to reflect the Reverse Stock Split effected on March 20, 2025 for activity prior to that date.



Recent Sales of Unregistered Securities

None.

Issuer Purchases or Equity Securities

None.

Item 6. [Reserved].

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion of our financial condition and results of operations is expected to better allow investors to view the Company from management's perspective and should be read together with our audited financial statements and related notes and other financial information included elsewhere in this Annual Report. The following discussion contains forward-looking statements that reflect our current plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements as a result of various factors, including those discussed below and elsewhere in this Annual Report, particularly in the section titled "Risk Factors." Our historical results are not necessarily indicative of the results that may be expected for any period in the future.

We have elected to omit discussion of the earliest of the three years covered by the audited financial statements presented. Refer to Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations", located in our annual report on Form 10-K for the year ended December 31, 2024 for reference to discussion of the year ended December 31, 2024, the earliest of the three fiscal years presented.

Overview

Our technology is designed to elevate the dialysis experience for patients and help providers overcome traditional care delivery challenges. Requiring only an electrical outlet and tap water to operate, our Tablo® Hemodialysis System (Tablo) frees patients and providers from the burdensome infrastructure required to operate traditional dialysis machines. The integration of water purification and on-demand dialysate production in a single 35-inch compact console enables Tablo to provide clinical and operational flexibility to customers. With a simple-to-use touchscreen interface, two-way wireless data transmission and a proprietary data analytics platform, Tablo is a holistic approach to dialysis care. Unlike existing hemodialysis machines, which have limited clinical versatility across care settings, Tablo can be used seamlessly across multiple care settings and a wide range of clinical applications. Tablo is cleared by the FDA for use in the hospital, clinic, or home setting.

Tablo leverages cloud technology, making it possible for providers to monitor devices remotely, view treatment data, perform patient and population analytics, and automate clinical recordkeeping. Tablo's wireless connectivity enables us to release training, new features and enhancements over-the-air without interventions by FSEs. Tablo's connectedness allows continuous streaming of an average of approximately 3 million machine performance data points to the cloud for every treatment. We use this data, in conjunction with our diagnostic and predictive algorithms, to monitor device performance, identify and diagnose failures and, in some instances, predict and prevent potential future device failures or malfunctions. In effect, this contributes to a reduction in service hours and an increase in device uptime.

We have generated meaningful evidence to demonstrate that providers can realize significant operational efficiencies, including reducing the cost of their dialysis programs. In addition, Tablo has been shown to deliver robust clinical care. In studies and surveys we have conducted, patients have reported quality of life benefits on Tablo compared to other dialysis machines. We believe Tablo empowers patients, who have traditionally been passive recipients of care, to regain agency and ownership of their treatment.

Driving adoption of Tablo in the acute care setting has been our primary focus to date. We have invested in growing our economic and clinical evidence, built a veteran sales and clinical support team with significant expertise, and implemented a comprehensive training and customer experience program. Our experience in the acute care market has demonstrated Tablo's clinical flexibility and operational versatility, while also delivering meaningful cost savings to the providers. In addition, we are also working with SNFs, LTACHs, and other post-acute providers to raise awareness of Tablo's economic and clinical benefits to them and to patients. We plan to continue leveraging our commercial infrastructure to broaden our installed base in the acute and post-acute care markets, as well as driving utilization and fleet expansion with our existing customers.

Tablo is also utilized for home-based dialysis. We believe our ability to reduce training time, patient dropout, and the supplies and infrastructure required to deliver dialysis in the home can drive efficiency and economic improvements to the home care model. In our home IDE trial, patients reported specific quality of life improvements compared to their experience on the incumbent home dialysis machine. To penetrate this market successfully, we have made investments in and continue to focus on refining our home distribution, logistics and support systems to help ensure they are ready for scale.

We generate revenue from the placement of Tablo consoles along with accessories, and shipping and handling charged to customers, which revenue is recognized up-front. For the years ended December 31, 2025, 2024, and 2023, sales of our consoles, which includes Tablo consoles and accessories, accounted for 26%, 26% and 47% of our revenue, respectively. We also earn recurring revenue from sales of consumables, including Tablo cartridge, and services, which generates significant total revenue over the life of Tablo console. For the years ended December 31, 2025, 2024, and 2023, sales of our consumables accounted for 45%, 45% and 32% of our revenue, respectively, and sales of service and other accounted for 29%, 29% and 21% of our revenue, respectively.

We primarily sell our solutions through our direct sales organization, which covers most major metropolitan markets in the United States. Our sales organization is comprised of our capital sales team, responsible for generating new customer demand for Tablo, and our clinical sales team, responsible for driving utilization and fleet expansion of Tablo at existing customer sites. In

addition, our field service team provides maintenance services and product support to our customers. Our field sales and service teams represent 58% of our total full-time employees as of December 31, 2025. The same sales organization and field service team drive Tablo penetration in both the acute and home markets. We believe the ability to leverage one team to serve both markets will result in significant productivity and cost optimization as we continue to scale our business.

Key Factors Affecting Our Performance

We believe that our financial performance has been, and in the foreseeable future will continue to be, primarily driven by the following factors. While we believe each of these factors presents significant opportunities for our business, they also pose important challenges that we must successfully address in order to sustain our growth and improve our results of operations. Our ability to successfully address the factors below is subject to various risks and uncertainties, including those described in the section titled "Risk Factors."

Market Acceptance of Tablo in Acute Setting

We plan to further broaden our installed base by continuing to target national and regional integrated delivery networks and health systems, SNFs, LTACHs and other post-acute providers. In addition, we focus on driving utilization and fleet expansion with existing customers by providing an exceptional user experience delivered through our commercial team and a steady release of software enhancements that amplify Tablo's operational reliability and clinical versatility. Our ability to successfully execute on this strategy, and thereby increase our revenue in the acute market, will depend on several factors. These factors include the success of our initiatives to optimize and further evolve our commercial organization, infrastructure and sales processes to support the growth of our business in the acute and post-acute care markets as we focus more heavily on enterprise selling and transition beyond earlier stage adoption of Tablo.

Expansion of Tablo within the Home Setting

We believe that a significant growth opportunity exists within the home hemodialysis market. We are partnering with innovative dialysis clinic providers, health systems and other adjacent healthcare providers who are motivated to grow their home hemodialysis population, and who share our vision of creating a seamless and supported transition to the home. We are also investing in market development over the longer term to expand the home hemodialysis market itself. The expansion of the home hemodialysis market and our ability to penetrate this market will be an important factor in driving the future growth of our business. In addition, the success of our efforts to expand within the home market, help grow new home programs and increase our revenue generated from home-based dialysis on the timeline that we anticipate will depend on several factors. These factors include the success of our initiatives to optimize and further evolve our commercial organization, infrastructure and sales processes as we scale our business in the home market.

Gross Margin

Our ability to expand our gross margins depends on: first, our ability to continue to sell Tablo cartridges, services, and accessories for Tablo consoles; second, our ability to reduce the cost of service and third, our ability to reduce the cost to manufacture Tablo consoles. Our ability to expand gross margins will also depend in part on our ability to control the average selling prices of our products and services, including by selling higher-margin accessories, consumables and services. Further, we will continue to utilize our cloud-based data system, as well as enhanced product and support performance, to improve service margin and drive down service costs per console. In addition, over the past several years, we have moved the production of Tablo consoles and a substantial majority of Tablo cartridges in-house to our manufacturing facility in Tijuana, Mexico which we operate in collaboration with TACNA, as part of our cost reduction activities. This has helped further our long-term gross margin expansion and supply continuity strategies while reducing the costs of Tablo console production and improving the flexibility of our operations. We will continue our cost reduction activities by using our design, engineering, supply chain and manufacturing capabilities to help further advance and improve the efficiency of our manufacturing processes, lowering the cost of parts and components and lowering our costs of production. Our ability to expand gross margins depends on our ability to successfully execute these strategies, as well as the impact of macroeconomic factors described below, including the tariffs imposed by the current administration.

Profitability Initiatives

Our ability to achieve and sustain profitability depends on several key factors: first, our ability to grow our revenue while expanding gross margins, as discussed above; second, our ability to optimize operating expenses; and third, our ability to optimize working capital. We have undertaken various initiatives designed to improve operational efficiencies, reduce operating expenses to align with anticipated levels of revenue growth and streamline our overall cost structure, including several organizational restructurings implemented beginning in the fourth quarter of 2023 through early 2025. We are also taking steps to improve our ability to efficiently manage working capital, including inventory. Our ability to transition to profitability will depend on the success of our efforts to optimize spending and working capital, including inventory.

Impacts of Macroeconomic Factors

Global macroeconomic conditions, including inflationary pressures, rising interest rates, changes in tariff or trade laws and policies (such as the tariffs imposed by the current administration), increased labor costs, staffing shortages and global supply chain disruptions, may impact our business and results of operations, and those of our customers, manufacturing partners and suppliers. As the duration and severity of these macroeconomic conditions remain uncertain and depend on various factors, we cannot predict what effects these macroeconomic conditions will ultimately have on our business and results of operations, our customers, or our suppliers.

Beginning in the third quarter of 2023, we began to observe an increasing number of our existing and prospective customers deferring their decisions to purchase Tablo in an environment of rising interest rates and more cautious capital spending. These deferrals served to elongate our sales cycle and the timing of delivery and installations, which, in turn, contributed to an adverse impact on our bookings and revenues starting in the second half of 2023 and through 2025. We may see disruption from this in future periods. In addition, ongoing uncertainty relating to various policy changes under the current administration – including developments in trade policy (such as increased tariffs), changes in interest rate policy, potential reductions in government reimbursement and shifts in broader healthcare policy – could increase financial pressures faced by our existing and prospective hospital customers. These actual or anticipated policy changes may lead to higher operating costs for our customers, as well as tighter operating budgets and more cautious capital spending decisions. Additionally, broader economic uncertainty and market volatility – driven in part by these evolving policies – could exacerbate financial strain on our customers, potentially resulting in delayed or reduced purchases of our products and services. These factors could adversely impact our revenues, results of operations and financial condition in future periods.

If our customers continue to face prolonged periods of rising interest rates, capital budget constraints, volatility, uncertainty, staffing shortages, cash flow challenges, rising costs and other financial pressures, whether due to general macroeconomic conditions, evolving policy changes under the current administration (including trade policy developments, reductions in government reimbursement or shifts in healthcare policy), cybersecurity events or other factors, it could ultimately adversely impact our ability to expand existing customer relationships or attract new customers of Tablo, timely collect amounts due, effectively manage our inventory levels, and have a material adverse effect on our bookings, revenues, results of operations, financial condition, and, ultimately, our future growth and profitability.

From a supply chain perspective, we have worked closely with our manufacturing partners and suppliers to enable us to source key components and maintain appropriate inventory levels to meet customer demand, and have not experienced material disruptions in our supply chain to date. However, macroeconomic factors such as rising inflation, increasing labor costs, and surges and shifts in consumer demand have disrupted the operations of certain of our third-party suppliers, resulting, in some cases, in increased lead times and higher component costs. We believe that localizing production of a substantial majority of Tablo cartridges in Mexico (in-house at our manufacturing facility) has helped achieve cost reductions through lower freight costs, further our long-term gross margin expansion and supply continuity strategies and improve the flexibility of our operations. However, we may face increased supply chain constraints in the future, which could negatively impact our ability to meet customer demand on a timely basis, result in customer dissatisfaction and adversely impact our operating margins and results of operations. Moreover, increased tariffs imposed by the current administration, including on goods imported into the United States from Mexico and China, could adversely impact our supply chain and distribution costs, as well as our ability to achieve sustainable gross margins. We currently do not believe we have exposure to these tariffs as Tablo, TabloCart and Tablo cartridge are covered under a special exemption. However, in September 2025, the U.S. Department of Commerce initiated an investigation under Section 232 of the Trade Expansion Act of 1962 to assess the national security implications of imports of personal protective equipment, medical consumables, and medical equipment, including medical devices. The outcome of this investigation could result in additional tariffs or other trade restrictions. While we continue to believe our products will remain exempt, the scope and outcome of the investigation are uncertain and could affect existing exemptions or expand coverage to additional product categories. We cannot predict what actions may ultimately be taken with respect to tariffs or trade relations between the United States and other countries (including Mexico and China), what products may be subject to such actions, or what actions may be taken by the other countries in retaliation.

Components of Operating Results

Revenue

We generate our revenue primarily from the sale of products and services. In addition, in limited instances, we may enter into console operating lease arrangements that contain lease and non-lease components. Our product and services revenues are generated primarily through direct sales to customers in the United States.

Product Revenue

We generate product revenue primarily from the sale of our Tablo consoles, including accessories, and the sale of related consumables, including Tablo cartridges. Our Tablo consoles and consumables are generally sold without the right of return. Revenue is recognized when control of our Tablo consoles is transferred, generally upon shipment, and excludes the value of the initial service

agreement, which is recognized as service and other revenue over the term of the initial service agreement. Leases of Tablo consoles are considered operating leases and recognized as revenue over their lease term. Consumables are recognized primarily upon shipment. Revenue is recognized net of any sales incentive, rebates and any taxes collected from customers.

Service and Other Revenue

We generate service revenue primarily from service agreements for our Tablo consoles and other revenue from shipping and handling charged to customers. Under the service agreements, we provide maintenance, repair and training services, connectivity to our cloud infrastructure, including TabloHub, as well as software updates, when and if available, for Tablo consoles. The service agreements are typically entered into for a one-year term. Revenue from the sale of service agreements is recognized ratably over the service period.

Cost of Revenue

Cost of Product Revenue

Cost of product revenue primarily consists of finished goods, inbound freight costs, and manufacturing costs incurred in the production process including personnel and related costs, costs of component materials, manufacturing overhead, and infrastructure costs including facilities and information technology. In addition, cost of product revenue includes warranty costs and provisions for excess and obsolete inventory. We expect cost of product revenue as a percentage of revenue to decrease over the long-term primarily as, and to the extent that, our efforts to reduce manufacturing costs of our products are successful, the percentage of our product revenues attributable to consumables increase, and our product revenue grows. However, our cost of product revenue as a percentage of revenue may fluctuate from period to period.

Cost of Service and Other Revenue

Cost of service and other revenue primarily consists of personnel and related costs, travel, and component costs incurred in connection with our obligations under our service agreements. We plan to further utilize our cloud-based data systems, as well as enhanced product performance, to lower the cost of service as a percentage of revenue. We expect cost of service and other revenue as a percentage of revenue to decrease over the long-term primarily as, and to the extent, our service and other revenue grows. However, our cost of service and other revenue as a percentage of revenue may fluctuate from period to period.

Gross Profit and Gross Margin

We calculate gross margin as gross profit divided by total revenue. Our gross profit has been and will continue to be, affected by a variety of factors, including market conditions that may impact our pricing; product mix and average selling prices; excess and obsolete inventories; our cost structure for manufacturing operations relative to volume; inbound freight costs, and product warranty obligations. We expect our gross margin to increase over the long term to the extent that we are successful in our ability to lower production costs, that we generate recurring revenues from sales of our consumables and services, and that we can lower cost of service and other revenue as a percentage of revenue. We continue to use our design, engineering, and manufacturing capabilities to further advance and improve the efficiency of our manufacturing processes, which, if successful, we believe will lower production costs and enable us to increase our gross margin. While we expect gross margin to increase over the long term, we also anticipate it will likely fluctuate from quarter to quarter.

Operating Expenses

Research and Development

Research and development expenses primarily consist of personnel and related costs, regulatory fees, consulting services, laboratory supplies and materials expenses, and infrastructure costs including facilities, depreciation and information technology.

We plan to continue to invest in our research and development efforts to grow our economic and clinical evidence, and enhance existing products to improve reliability and reduce costs. We expect research and development expenses to vary over time, depending on the level and timing of the enhancement of the existing products as well as cost reduction initiatives. As a percentage of revenue, however, we expect research and development expenses to continue to decrease over the long-term primarily as, and to the extent, our revenue grows.

Sales and Marketing

Sales and marketing expenses primarily consist of personnel and related costs, including sales commissions and travel. Other sales and marketing expenses include marketing and promotional activities, costs of outside consultants, customer services costs, and infrastructure costs including facilities, depreciation, and information technology. Shipping and handling costs, as well as the associated personnel expenses, are included in sales and marketing expenses.

As we continue to drive the expansion of Tablo, we expect shipping and handling costs to also increase. However, the full year impact of mid-year cost saving initiatives in 2024 will result in lower year over year spend. We plan to continue to invest in infrastructure to support our growth and expect sales and marketing expenses as a percentage of revenue to continue to decrease over the long-term primarily as, and to the extent, our revenue grows.

General and Administrative

General and administrative expenses primarily consist of personnel and related costs, accounting and legal expenses, general corporate expenses, and infrastructure costs including facilities, depreciation, and information technology. As a percentage of revenue, we expect general and administrative expenses to decrease over the long-term primarily as, and to the extent, our revenue grows.

We expect our stock-based compensation expense allocated to cost of revenue, research and development expenses, sales and marketing expenses, and general and administrative expenses to fluctuate based on our stock price at particular points in time as we issue additional stock-based awards under our equity incentive plan and employee stock purchase plan to attract and retain employees.

Interest Income and Other Income, Net

Interest income and other income, net, primarily consists of interest earned on our cash and cash equivalents and short-term investments.

Interest Expense

Interest expense consists of interest on our debt and amortization of associated debt discount. See Note 7 to the financial statements for further details.

Loss on Extinguishment of Term Loan

Loss on extinguishment of term loan is related to the repayment of the SLR Term Loan in January 2025, which included final payment and termination fees.

Provision for Income Taxes

Provision for income taxes primarily consists of foreign taxes in Mexico. We have a full valuation allowance for deferred tax assets, including net operating loss carryforwards and tax credits related primarily to research and development.

Results of Operations

In this section, we discuss the results of our operations for the year ended December 31, 2025 compared to the year ended December 31, 2024.

The following table sets forth, for the years indicated, our results of operations (in thousands):

	Years Ended December 31,		
	2025	2024	2023
Revenue:			
Product revenue	$ 84,808	$ 80,977	$ 103,537
Service and other revenue	34,668	32,712	26,839
Total revenue	119,476	113,689	130,376
Cost of revenue:			
Cost of product revenue	43,765	46,449	74,454
Cost of service and other revenue	28,957	28,676	26,922
Total cost of revenue	72,722	75,125	101,376
Gross profit	46,754	38,564	29,000
Operating expenses:			
Research and development	21,235	38,397	57,307
Sales and marketing	54,361	70,044	96,232
General and administrative	37,864	43,498	45,231
Total operating expenses	113,460	151,939	198,770
Loss from operations	(66,706)	(113,375)	(169,770)
Interest income and other income, net	7,408	9,761	10,171
Interest expense	(13,952)	(23,871)	(12,675)
Loss on extinguishment of term loan	(7,685)	—	—
Loss before provision for income taxes	(80,935)	(127,485)	(172,274)
Provision for income taxes	718	491	523
Net loss	$ (81,653)	$ (127,976)	$ (172,797)

Revenue

	Years Ended December 31,		Change	
(dollars in thousands)	2025	2024	$	%
Revenue:				
Product revenue	$ 84,808	$ 80,977	$ 3,831	5%
Service and other revenue	34,668	32,712	1,956	6%
Total revenue	$ 119,476	$ 113,689	5,787	5%

The increase in product revenue was mainly due to a $2.9 million increase in consumables revenue attributable to the growth in our console installed base and a $0.9 million increase in console revenue as a result of a higher average selling price in 2025 as compared to the prior year.

The increase in service and other revenue was primarily due to services associated with the growth in our console installed base.

Gross Profit and Gross Margin

	Years Ended December 31,		Change	
(dollars in thousands)	2025	2024	$	%
Gross profit and gross margin:				
Gross profit	$ 46,754	$ 38,564	$ 8,190	21%
Gross margin	*39.1* %	*33.9* %		

The gross margin percentage improved by 5.2 percentage points for the year ended December 31, 2025 as compared to the prior year. This improvement in gross margin was primarily driven by a higher console gross margin resulting from a lower cost per unit as well as a higher average selling price, a higher consumable gross margin mainly resulting from a higher average selling price, and a higher service gross margin.

(dollars in thousands)	Years Ended December 31, 2025	2024	Change $	Change %
Operating expenses:				
Research and development	$ 21,235	$ 38,397	$ (17,162)	(45)%
Sales and marketing	54,361	70,044	(15,683)	(22)%
General and administrative	37,864	43,498	(5,634)	(13)%
Total operating expenses	$ 113,460	$ 151,939	(38,479)	(25)%

The decrease in research and development expenses was primarily due to an overall decrease in compensation-related and stock-based compensation expenses, infrastructure costs and consulting expense resulting from our cost reduction efforts.

The decrease in sales and marketing expenses was primarily driven by an overall decrease in compensation-related and stock-based compensation expenses, travel and freight expenses resulting from our cost reduction efforts. These decreases were partially offset by higher marketing expenses due to an increase in marketing activities and higher consulting expense.

The decrease in general and administrative expenses was primarily driven by an overall decrease in compensation-related and stock-based compensation expenses resulting from our cost reduction efforts. These decreases were partially offset by increases in the allowance for credit losses and legal fees related to the stockholder class action and related derivative lawsuits.

Other Income (Expenses), Net

(dollars in thousands)	Years Ended December 31, 2025	2024	Change $	Change %
Other income (expenses), net:				
Interest income and other income, net	$ 7,408	$ 9,761	$ (2,353)	(24)%
Interest expense	(13,952)	(23,871)	9,919	(42)%
Loss on extinguishment of term loan	(7,685)	—	(7,685)	*
Total other expenses, net	$ (14,229)	$ (14,110)	(119)	1%

** Not meaningful*

The decrease in interest income and other income, net, for the year ended December 31, 2025 as compared to the prior year was driven by the changes in interest rates and a lower average short-term investment balance in 2025.

The decrease in interest expense for the year ended December 31, 2025 as compared to the prior year was due to a lower outstanding term loan balance in 2025.

The loss on extinguishments of term loan of $7.7 million was recognized for the repayment of the SLR Term Loan in 2025, which included final payment and termination fees.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred net losses and negative cash flows from operations. To date, we have financed our operations and capital expenditures primarily through sales of equity securities, revenue from sales, debt financings, and proceeds from employee exercises of stock options and employee stock purchase plan purchases.

As of December 31, 2025, we had a total cash, cash equivalents, restricted cash and short-term investments balance of $172.8 million.

In addition, in January 2025, we entered into a credit agreement and guaranty (the Perceptive Credit Agreement) with Perceptive Credit Holdings IV, LP, as administrative agent (Agent) and the lenders from time to time party thereto, which provided a $100 million 5-year term loan at closing and will provide an additional term loan of up to $25 million at our election, which is available for funding until July 14, 2027, subject to achievement of a specified revenue milestone and other customary conditions.

We are required to comply with certain covenants under the Perceptive Credit Agreement, including, among others, requirements as to financial reporting, restrictions on our ability to incur additional indebtedness and to pay any dividends or other distributions on capital stock, maintenance of a minimum cash balance, and achievement of certain specified trailing twelve-month net revenue targets. If we fail to comply with any covenants, payments or other terms of the Perceptive Credit Agreement and such failure constitutes an event of default thereunder, such event of default would give Agent the right to declare all borrowings outstanding, together with accrued and unpaid interest and fees, to be immediately due and payable (see the section entitled “Debt Obligations” below).

While we have taken actions to reduce operating expenses and working capital to align with anticipated revenue growth including implementing restructuring plans to streamline our overall organizational structure and renegotiating commitments with suppliers to reduce inventory, we expect to continue to incur operating losses in the near term while we make investments to support our anticipated growth. We may raise additional capital through the issuance of additional equity financing, debt financings, which may require refinancing or amending the terms of our existing debt, or other sources. If this financing is not available to us at adequate levels or on acceptable terms, we may need to further evaluate our operating plans. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights. We are subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through debt financing (including through our existing debt), we may be subject to an increase in our interest expense which may negatively affect our cash flow.

We believe that our existing cash, cash equivalents and short-term investments, cash generated from sales, and proceeds received from the debt financing described below under "Debt Obligations – Perceptive Credit Agreement" as well as proceeds received from the Private Placement described in Note 8 to the financial statements will be sufficient to meet our anticipated needs for at least the next 12 months from the issuance date of this Annual Report.

Cash Flows Summary

The following table summarizes the cash flows for each of the periods indicated (in thousands):

	Years Ended December 31,	
	2025	**2024**
Net cash (used in) provided by:		
Operating activities	$ (46,327)	$ (116,303)
Investing activities	(97,684)	103,938
Financing activities	55,503	67,870
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (88,508)	$ 55,505

Operating Activities

Net cash used in operating activities of $46.3 million for the year ended December 31, 2025 was due to a net loss of $81.7 million, and amortization of premium on investments of $2.3 million, partially adjusted by the primary non-cash adjustments for stock-based compensation expense of $15.6 million, loss on extinguishment of term loan of $7.7 million, depreciation and amortization of $4.3 million, change in provision for credit losses of $3.5 million, non-cash interest expense of $2.8 million, a net cash inflow from the change in our operating assets and liabilities of $2.2 million, and non-cash lease expense of $1.6 million. The net cash inflow from operating assets and liabilities was primarily due to a decrease in inventories, a decrease in accounts receivable due to timing of collections and billings, an increase in accrued expenses and other current liabilities, and an increase in deferred revenue due to the growth in service agreements. The net cash inflow from operating assets and liabilities was partially offset by decreases in accrued compensation and related benefits, accounts payable, accrued interest, operating lease liabilities and accrued warranty liabilities, and an increase in prepaid expenses and other assets.

Net cash used in operating activities of $116.3 million for the year ended December 31, 2024 was due to a net loss of $128.0 million, a net cash outflow from the change in our operating assets and liabilities of $25.7 million, and amortization of premium on investments of $4.7 million, partially adjusted by the primary non-cash adjustments for stock-based compensation expense of $29.4 million, depreciation and amortization of $5.7 million, non-cash interest expense of $2.6 million, change in provision for credit losses of $2.4 million, and non-cash lease expense of $1.4 million. The net cash outflow from operating assets and liabilities was primarily due to an increase in inventories, a decrease in accrued expenses and other current liabilities, an increase in accounts receivable due to timing of collections and billings, decreases in accounts payable, accrued compensation and related benefits, accrued warranty liabilities, and operating lease liabilities. The net cash outflow from operating assets and liabilities was partially offset by an increase in deferred revenue due to the growth in service agreements and a decrease in prepaid expenses and other assets.

Investing Activities

Net cash used in investing activities of $97.7 million for the year ended December 31, 2025 was due to purchases of investment securities of $222.0 million and purchases of property and equipment of $0.8 million, partially offset by the sales and maturities of investment securities of $125.1 million.

Net cash provided by investing activities of $103.9 million for the year ended December 31, 2024 was due to the sales and maturities of investment securities of $261.4 million, partially offset by purchases of investment securities of $156.6 million and purchases of property and equipment of $0.9 million.

Financing Activities

Net cash provided by financing activities of $55.5 million for the year ended December 31, 2025 was due to net proceeds of $161.5 million from the issuance of Series A Convertible Preferred Stock, net proceeds of $98.3 million from borrowings under the Perceptive Term Loan Facility, and proceeds from ESPP purchases, partially offset by cash outflow of $205.0 million in repayment of the SLR Term Loan which included final payment and termination fees.

Net cash provided by financing activities of $67.9 million for the year ended December 31, 2024 was due primarily to the net proceeds of $66.5 million from borrowings under the SLR Term Loan Facility and the proceeds of $2.3 million from employee exercises of stock options and employee stock purchase plan purchases. These cash inflow was partially offset by the payment of deferred financing costs.

Debt Obligations

Perceptive Credit Agreement

On January 3, 2025, we entered into a senior secured credit facility for borrowings up to an aggregate principal amount of $125.0 million pursuant to the Perceptive Credit Agreement among Perceptive Credit Holdings IV, LP, as Agent, the lenders from time to time party thereto and the Company.

Pursuant to the terms and conditions of the Perceptive Credit Agreement, the lenders agreed to extend term loans to us in an aggregate principal amount of up to $125.0 million, comprised of (i) a term loan of $100.0 million (the Initial Term Loan), which was funded at the closing of the Perceptive Credit Agreement on January 8, 2025, and (ii) a delayed draw term loan of up to $25.0 million (the Delayed Draw Loan, together with the Initial Term Loan, the Perceptive Term Loan). The Delayed Draw Loan is available for funding until July 14, 2027, subject to the achievement of certain revenue milestone and other customary conditions.

Critical Accounting Estimates

Our financial statements have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses incurred during the reporting periods. The estimates are based on historical experience and on various other factors that are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

While the significant accounting policies are more fully described in Note 2 to our audited financial statements included elsewhere in this Annual Report, we believe that the following critical accounting estimate is most important to understanding and evaluating our reported financial results.

Revenue Recognition

Our contracts with customers often include multiple performance obligations, such as products and services. We determine the standalone sale prices (SSP) based upon the facts and circumstances of each performance obligation (product or services), which often requires management's judgment. We use an observable price to estimate SSP for items that are sold separately, including service agreements. In instances where SSP is not directly observable, such as when we do not sell the product or service separately, we determine the SSP using information that may include market conditions and other observable inputs and allocate the contracted transaction price to each distinct performance obligation based upon the relative SSP. We may offer additional goods or services to customers at the inception of customer contracts at prices not at SSP. If such contracts result in a material right, we allocate part of the transaction price to that right and recognize the associated revenue when those future goods and services are transferred to the customer. SSP is assigned based on the estimated value of the material right. We establish SSP ranges for our products and services and reassess them periodically.

Recent Accounting Pronouncements

Refer to Note 2, "Summary of Significant Accounting Policies" in our audited financial statements included in Part II, Item 8 of this Annual Report for a discussion of recent accounting pronouncements that may impact us.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

Our cash, cash equivalents, restricted cash and short-term investments are held in bank deposits, money market funds, U.S. Treasury and debt securities. Such interest-earning instruments carry a degree of interest rate risk. The goals of our investment policy are liquidity and capital preservation; we do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate exposure. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short-term nature of our cash, cash equivalents and short-term investments.

As of December 31, 2025, we had $101.5 million in variable rate debt outstanding under the Perceptive Term Loan. The Perceptive Term Loan bears interest at a rate per annum equal to one-month term Secured Overnight Financing Rate (term SOFR) (subject to a 4.00% floor), plus 8.00%. The Perceptive Term Loan matures in January 2030. On an annualized basis, a 100-basis point change in the term SOFR rate would change our interest expense by $1.0 million based upon our debt outstanding balance of $101.5 million as of December 31, 2025.

Foreign Currency Exchange Risk

Our expenses are generally denominated in USD. However, as certain of our Mexico-based manufacturing operations incur costs that are denominated in MXN and we hold cash in MXN, we are exposed to the risk of currency fluctuations between USD and MXN. To date, foreign currency transaction gains and losses have not been material to our financial statements.

Unfavorable changes in foreign exchange rates versus USD could increase our product costs, thus reducing our gross profit. We have not engaged in the hedging of foreign currency transactions to date, although we may choose to do so in the future. We do not believe that an immediate 10% increase or decrease in the relative value of USD to other currencies would have a material effect on operating results or financial condition.

Item 8. Financial Statements and Supplementary Data.

Outset Medical, Inc.

Index to Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Outset Medical, Inc.:

Opinions on the Financial Statements and Internal Control Over Financial Reporting

We have audited the accompanying balance sheets of Outset Medical, Inc. (the Company) as of December 31, 2025 and 2024, the related statements of operations, comprehensive loss, convertible preferred stock and stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2025, and the related notes (collectively, the financial statements). We also have audited the Company's internal control over financial reporting as of December 31, 2025, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2025, in conformity with U.S. generally accepted accounting principles. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2025 based on criteria established in I*nternal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Basis for Opinions

The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's financial statements and an opinion on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the financial statements included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matter

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material

to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Sufficiency of audit evidence over Tablo console revenue and service agreement revenue

As discussed in Note 2 to the financial statements, the Company derives revenue primarily from the sales of its products and services. Product revenue consists primarily of sales of Tablo consoles and related consumables, including Tablo cartridges and accessories. Service and other revenue consists primarily of revenue generated from service agreements and other revenue from shipping and handling charged to customers. The Company's contracts with customers often include multiple performance obligations, such as products and services. The Company determines the amount and timing of revenue recorded for each performance obligation.

We identified the evaluation of the sufficiency of audit evidence over Tablo console revenue and service agreement revenue as a critical audit matter. Challenging auditor judgment was required to evaluate the sufficiency of audit evidence due to the automated nature of the process and the information technology (IT) system used in the Company's determination of Tablo console revenue and service agreement revenue, including the timing of the revenue recognized. Involvement of IT professionals with specialized skills and knowledge was required to assist in the performance of certain procedures over the IT system used in the revenue process.

The following are the primary procedures we performed to address this critical audit matter. We applied auditor judgment to determine the nature and extent of procedures to be performed over the Company's determination of Tablo console revenue and service agreement revenue, including the timing of the revenue recognized. We evaluated the design and tested the operating effectiveness of certain internal controls related to the Company's process to determine Tablo console revenue and service agreement revenue. This included controls over the Company's determination and timing of revenue recognized. We involved IT professionals with specialized skills and knowledge who assisted in testing certain general IT and application controls used in the Company's determination of Tablo console revenue and service agreement revenue. For samples of Tablo console revenue transactions and service agreement revenue transactions, we evaluated the amount and timing of revenue recognized by comparing it to the underlying contract, and/or other supporting documentation, and recalculating the Company's determination of revenue recognized. In addition, we evaluated the overall sufficiency of audit evidence obtained over Tablo console revenue and service agreement revenue by assessing the results of procedures performed, including the appropriateness of the nature and extent of audit effort.

/s/ KPMG LLP

We have served as the Company's auditor since 2011.

San Francisco, California
February 13, 2026

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

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 35,006	$ 124,014
Short-term investments	133,940	34,671
Accounts receivable, net	28,329	35,619
Inventories	47,609	59,387
Prepaid expenses and other current assets	5,999	4,530
Total current assets	250,883	258,221
Restricted cash	3,829	3,329
Property and equipment, net	4,670	8,133
Operating lease right-of-use assets	4,797	3,940
Other assets	317	2,172
Total assets	$ 264,496	$ 275,795
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 554	$ 3,862
Accrued compensation and related benefits	10,735	16,821
Accrued expenses and other current liabilities	9,433	8,205
Accrued warranty liability	1,374	1,938
Deferred revenue, current	13,795	12,753
Operating lease liabilities, current	1,739	1,799
Total current liabilities	37,630	45,378
Accrued interest	—	2,695
Deferred revenue	406	844
Operating lease liabilities	3,271	2,684
Term loans	96,237	197,375
Total liabilities	137,544	248,976
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred Stock, $0.001 par value; 5,000 shares authorized, and no shares issued and outstanding as of December 31, 2025 and 2024	—	—
Common stock, $0.001 par value; 300,000 shares authorized as of December 31, 2025 and 2024; 18,169 and 3,530 shares issued and outstanding as of December 31, 2025 and 2024, respectively	18	4
Additional paid-in capital	1,298,138	1,116,496
Accumulated other comprehensive income	172	42
Accumulated deficit	(1,171,376)	(1,089,723)
Total stockholders' equity	126,952	26,819
Total liabilities and stockholders' equity	$ 264,496	$ 275,795

The accompanying notes are an integral part of these financial statements

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

	Years Ended December 31,		
	2025	**2024**	**2023**
Revenue:			
Product revenue	$ 84,808	$ 80,977	$ 103,537
Service and other revenue	34,668	32,712	26,839
Total revenue	119,476	113,689	130,376
Cost of revenue:			
Cost of product revenue	43,765	46,449	74,454
Cost of service and other revenue	28,957	28,676	26,922
Total cost of revenue	72,722	75,125	101,376
Gross profit	46,754	38,564	29,000
Operating expenses:			
Research and development	21,235	38,397	57,307
Sales and marketing	54,361	70,044	96,232
General and administrative	37,864	43,498	45,231
Total operating expenses	113,460	151,939	198,770
Loss from operations	(66,706)	(113,375)	(169,770)
Interest income and other income, net	7,408	9,761	10,171
Interest expense	(13,952)	(23,871)	(12,675)
Loss on extinguishment of term loan	(7,685)	—	—
Loss before provision for income taxes	(80,935)	(127,485)	(172,274)
Provision for income taxes	718	491	523
Net loss	$ (81,653)	$ (127,976)	$ (172,797)
Net loss per share, basic and diluted	$ (5.37)	$ (36.96)	$ (52.28)
Shares used in computing net loss per share, basic and diluted	15,211	3,463	$ 3,305

The accompanying notes are an integral part of these financial statements

Outset Medical, Inc.
Statements of Comprehensive Loss
(in thousands)

	Years Ended December 31,		
	2025	**2024**	**2023**
Net loss	$ (81,653)	$ (127,976)	$ (172,797)
Other comprehensive income:			
Unrealized gain (loss) on available-for-sale securities	130	(26)	632
Comprehensive loss	$ (81,523)	$ (128,002)	$ (172,165)

The accompanying notes are an integral part of these financial statements

Outset Medical, Inc.
Statements of Convertible Preferred Stock and Stockholders' Equity
(in thousands)

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital			
Balance as of December 31, 2022	—	$ —	3,231	$ 3	$ 1,035,501	$ (564)	$ (788,950)	$ 245,990
Issuance of common stock through employee stock purchase plan	—	—	37	—	7,510	—	—	7,510
Issuance of common stock for settlement of RSUs	—	—	47	—	—	—	—	—
Stock option exercises	—	—	39	—	2,917	—	—	2,917
Stock-based compensation expense	—	—	—	—	38,634	—	—	38,634
Unrealized gain on available-for-sale securities	—	—	—	—	—	632	—	632
Net loss	—	—	—	—	—	—	(172,797)	(172,797)
Balance as of December 31, 2023	—	$ —	3,354	$ 3	$ 1,084,562	$ 68	$ (961,747)	$ 122,886
Issuance of common stock through employee stock purchase plan	—	—	70	1	2,200	—	—	2,201
Issuance of common stock for settlement of RSUs	—	—	101	—	295	—	—	295
Stock option exercises	—	—	5	—	83	—	—	83
Stock-based compensation expense	—	—	—	—	29,356	—	—	29,356
Unrealized loss on available-for-sale securities	—	—	—	—	—	(26)	—	(26)
Net loss	—	—	—	—	—	—	(127,976)	(127,976)
Balance as of December 31, 2024	—	$ —	3,530	$ 4	$ 1,116,496	$ 42	$ (1,089,723)	$ 26,819
Issuance of Series A convertible preferred stock, net of issuance costs	863	161,071	—	—	—	—	—	—
Conversion of convertible preferred stock to common stock	(863)	(161,071)	14,389	14	161,057	—	—	161,071
Issuance of common stock warrant, net of issuance costs	—	—	—	—	4,330	—	—	4,330
Issuance of common stock through employee stock purchase plan	—	—	87	—	639	—	—	639
Issuance of common stock for settlement of RSUs	—	—	163	—	—	—	—	—
Stock option exercises	—	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	15,616	—	—	15,616
Unrealized gain on available-for-sale securities	—	—	—	—	—	130	—	130
Net loss	—	—	—	—	—	—	(81,653)	(81,653)
Balance as of December 31, 2025	—	$ —	18,169	$ 18	$ 1,298,136	$ 172	$ (1,171,376)	$ 126,952

The accompanying notes are an integral part of these financial statements

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

	Years Ended December 31,		
	2025	**2024**	**2023**
Cash flows from operating activities:			
Net loss	$ (81,653)	$ (127,976)	$ (172,797)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	15,616	29,356	38,634
Depreciation and amortization	4,341	5,728	5,810
Non-cash lease expense	1,583	1,435	1,271
Non-cash interest expense	2,758	2,574	1,828
Amortization of premium on investments, net	(2,253)	(4,720)	(6,369)
Change in provision for inventories	(124)	561	733
Change in provision for credit losses	3,515	2,374	184
Loss on disposal of property and equipment	5	53	106
Loss on extinguishment of term loan	7,685	—	—
Changes in operating assets and liabilities:			
Accounts receivable	3,775	(5,012)	(5,094)
Inventories	11,793	(10,857)	1,647
Prepaid expenses and other assets	(940)	784	739
Accounts payable	(3,293)	(1,948)	5,312
Accrued compensation and related benefits	(6,086)	(1,889)	(2,515)
Accrued expenses and other current liabilities	1,519	(5,168)	(2,621)
Accrued warranty liability	(564)	(1,774)	91
Deferred revenue	604	1,769	3,015
Operating lease liabilities	(1,913)	(1,593)	(1,347)
Accrued interest	(2,695)	—	—
Net cash used in operating activities	(46,327)	(116,303)	(131,373)
Cash flows from investing activities:			
Purchases of property and equipment	(798)	(912)	(3,440)
Purchases of investment securities	(221,969)	(156,584)	(172,284)
Sales and maturities of investment securities	125,083	261,434	258,750
Net cash (used in) provided by investing activities	(97,684)	103,938	83,026
Cash flows from financing activities:			
Proceeds from stock option exercises and ESPP purchases	639	2,284	10,427
Proceeds from issuance of term loans, net of issuance costs	98,270	66,524	33,225
Repayment of term loan and extinguishment costs	(204,954)	—	—
Proceeds from issuance of Series A convertible preferred stock, net of issuance costs	161,548	—	—
Payment of deferred financing costs	—	(938)	—
Net cash provided by financing activities	55,503	67,870	43,652
Net (decrease) increase in cash, cash equivalents and restricted cash	(88,508)	55,505	(4,695)
Cash, cash equivalents and restricted cash as of beginning of period	127,343	71,838	76,533
Cash, cash equivalents and restricted cash as of end of period	$ 38,835	$ 127,343	$ 71,838
Summary of cash, cash equivalents and restricted cash reported within the balance sheets:			
Cash and cash equivalents	$ 35,006	$ 124,014	$ 68,509
Restricted cash	3,829	3,329	3,329
Total cash, cash equivalents and restricted cash	$ 38,835	$ 127,343	$ 71,838

The accompanying notes are an integral part of these financial statements

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

	Years Ended December 31,		
	2025	**2024**	**2023**
Supplemental cash flow disclosures:			
Cash paid for income taxes	$ 447	$ 593	$ 491
Cash paid for interest	$ 15,634	$ 20,685	$ 10,847
Cash paid for amounts included in the measurement of operating lease liabilities	$ 1,913	$ 1,593	$ 1,347
Supplemental non-cash investing and financing activities:			
Transfer of inventories to property and equipment	$ 109	$ 148	$ 119
Right-of-use assets obtained in exchange for operating lease liabilities	$ 2,441	$ —	$ 528
Fair value of common stock warrant	$ 4,367	$ —	$ —
Issuance costs included in accrued expenses	$ —	$ 266	$ —
Capital expenditures included in accounts payable and accrued expenses	$ —	$ 31	$ 159

The accompanying notes are an integral part of these financial statements

Notes to Financial Statements

1. Description of Business

Outset Medical, Inc. (the Company) is a medical technology company pioneering a first-of-its-kind technology to improve clinical outcomes in dialysis with less cost and complexity. Tablo® Hemodialysis System (Tablo), cleared by the U.S. Food and Drug Administration (FDA) for use from the hospital to the home, represents a significant technological advancement designed to transform the dialysis experience for patients and operationally simplify it for providers. Tablo serves as a single enterprise solution designed to be utilized across the continuum of care, allowing dialysis to be delivered anytime, anywhere, and by virtually anyone. The integration of water purification and on-demand dialysate production in a single 35-inch compact console enables Tablo to provide clinical and operational flexibility to customers. With a simple-to-use touchscreen interface, two-way wireless data transmission and a proprietary data analytics platform, Tablo is a new holistic approach to dialysis care. The Company's headquarters are located in San Jose, CA.

Reverse Stock Split

In March 2025, the Company's board of directors and shareholders approved a Certificate of Amendment to the Company's Amended and Restated Certificate of Incorporation to effect a reverse split of shares of the Company's common stock on a 15-for-one basis (the Reverse Stock Split), which became effective as of March 20, 2025. The number of authorized shares and the par values of the common stock and preferred stock were not adjusted as a result of the Reverse Stock Split. In connection with the Reverse Stock Split, the conversion ratio for the Company's outstanding convertible preferred stock was proportionately adjusted such that the common stock issuable upon conversion of such preferred stock was decreased in proportion to the Reverse Stock Split. Also, any outstanding common stock warrants were adjusted such that the common stock issuable upon exercise of such warrants were decreased in proportion to the Reverse Stock Split. In addition, the number of shares of common stock available for issuance under the Company's equity incentive plans and issuable upon the exercise of stock options, warrants and restricted stock units outstanding prior to the Reverse Stock Split were proportionately adjusted. No fractional shares were distributed as a result of the Reverse Stock Split and stockholders were entitled to a cash payment in lieu of fractional shares.

All common stock share and per share amounts and information presented herein have been retroactively adjusted to reflect the effect of the Reverse Stock Split for all periods presented.

Liquidity

Since inception, the Company has incurred net losses and negative cash flows from operations. For the years ended December 31, 2025, 2024, and 2023, the Company incurred net losses of $81.7 million, $128.0 million and $172.8 million, respectively, and cash outflow from operating activities of $46.3 million, $116.3 million and $131.4 million, respectively. As of December 31, 2025, the Company had an accumulated deficit of $1.2 billion.

As of December 31, 2025, the Company had a total cash, cash equivalents, restricted cash, and short-term investments balance of $172.8 million.

In addition, in January 2025, the Company entered into a credit agreement and guaranty (the Perceptive Credit Agreement) with Perceptive Credit Holdings IV, LP, as administrative agent (Agent) and the lenders from time to time party thereto, which provided a $100 million 5-year term loan at closing and will provide an additional term loan of up to $25 million at our election, which is available for funding until July 14, 2027, subject to the achievement of certain revenue milestone and other customary conditions (the Perceptive Term Loan). The Company is required to comply with certain covenants under the Perceptive Credit Agreement including, among others, requirements as to financial reporting, restrictions on its ability to incur additional indebtedness and to pay any dividends or other distributions on capital stock, maintenance of a minimum cash balance, and achievement of certain specified trailing twelve-month net revenue targets. If the Company fails to comply with any covenants, payments or other terms of the Perceptive Credit Agreement and such failure constitutes an event of default, such event of default would give Agent the right to declare all borrowings outstanding, together with accrued and unpaid interest and fees, to be immediately due and payable. Further details of obligations under the Perceptive Credit Agreement are described in Note 7.

While the Company has taken actions to reduce operating expenses and working capital to align with anticipated revenue growth including implementing restructuring plans to streamline its overall organizational structure and renegotiating commitments with suppliers to reduce inventory, management expects to continue to incur operating losses in the near term while the Company makes investments to support its anticipated growth.

Management believes that the Company's existing cash, cash equivalents, short-term investments, and cash generated from sales will be sufficient to meet its anticipated needs for at least the next 12 months from the issuance date of the accompanying financial statements.

Basis of Presentation

The financial statements have been prepared in accordance with U.S. GAAP. All share amounts disclosed in the notes to the financial statements are rounded to the nearest thousand except for per share amounts.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of the financial statements in conformity with U.S. GAAP requires management to make judgments, estimates, and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenue and expenses. These judgments, estimates and assumptions are used for, but not limited to, revenue recognition, allowance for credit losses, inventory valuation and write-downs, warranty obligations, the fair value of equity awards, the valuation of investments, recoverability of the Company's net deferred tax assets, and certain accrued expenses. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results may differ from those estimates under different assumptions or conditions and the differences may be material.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents, restricted cash, short-term investments, and accounts receivable. Substantially all the Company's cash and cash equivalents, restricted cash, and investments are held at one financial institution in the United States that management believes is of high credit quality. Such investments may, at times, exceed federally insured limits or may not be covered by deposit insurance at all.

For the year ended December 31, 2025, 2024 and 2023, the Company's largest customer accounted for 15%, 16%, and 13% of revenues, respectively.

Accounts receivable are unsecured; however, the Company does assess the collectability of accounts receivable based on a number of factors, including past transaction history with, and the creditworthiness of, the customer. Accordingly, the Company is exposed to credit risk associated with accounts receivable. To reduce risk, the Company closely monitors the amounts due from its customers and assesses the financial strength of its customers through a variety of methods that include, but are not limited to, engaging directly with customer operations and leadership personnel, visiting customer locations to observe operating activities, and assessing customer longevity and reputation in the marketplace. A material default in payment or a material reduction in purchases from these or any other large customers could have a material adverse impact on the Company's financial condition, results of operations, and liquidity. Two customers accounted for 11% and 10% of accounts receivable as of December 31, 2025. One customer accounted for 16% of accounts receivable as of December 31, 2024.

The Company manufactures Tablo consoles, and a substantial majority of Tablo cartridges, at its manufacturing facility in Tijuana, Mexico which it operates in collaboration with its outsourced business administration service provider, TACNA. The Company is subject to a number of risks associated with operating its Mexico-based manufacturing facility, and many of these risks may heighten to the extent the Company continues to ramp its cartridge manufacturing capabilities and increase its dependence on the Mexico-based manufacturing operations. The Company may experience strikes, work stoppages, work slowdowns, high personnel turnover, grievances, complaints, claims of unfair labor practices, other collective bargaining disputes or other labor disputes at its facility. The manufacturing operations at the facility may also suffer disruptions from global or regional public health crises such as the COVID-19 pandemic, natural disasters, cyber security attacks, vandalism, terrorism or other political hostilities. Any such occurrences could negatively impact the Company's ability to produce Tablo consoles and cartridges. The Company is also subject to a variety of foreign laws and regulations, including trade and labor restrictions and laws relating to importation, exportation and taxation of goods, and U.S. laws and regulations relating to foreign operations. In addition, because certain of its Mexico-based manufacturing operations incur costs that are denominated in MXN, the Company is exposed to additional risk of currency fluctuations between USD and MXN, which could increase its product and labor costs, thus reducing its gross profit. To date, foreign currency transaction gains and losses have not been material to the Company's financial statements.

Fair Value of Financial Instruments

The Company determines the fair value of an asset or liability based on the assumptions that market participants would use in pricing the asset or liability in an orderly transaction between market participants at the measurement date. The identification of market participant assumptions provides a basis for determining what inputs are to be used for pricing each asset or liability.

The Company classifies financial instruments using a three-tiered fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

The Company's cash and cash equivalents, restricted cash, accounts receivable, accounts payable and accrued liabilities approximate their fair value due to their short maturities.

Credit Losses

Accounts receivable. Accounts receivable are recorded at invoice value, net of any allowance for credit losses. The allowance for credit losses is based on the Company's assessment of its best estimate of the amount of receivables that will not be collected over the estimated life of the assets. The allowance is calculated by considering previous loss history, delinquency of receivables balances, current and anticipated future economic conditions that may affect a customer's ability to pay. To the extent an individual customer's credit quality deteriorates, the Company measures an allowance based on the risk characteristics of the individual customer. Once a receivable is deemed to be uncollectible, such balance is charged against the allowance. The allowance is calculated at each reporting period with changes recorded to general and administrative expense in the statements of operations.

The Company writes off accounts receivable when the Company has exhausted collection efforts without success, and payments subsequently received on such receivables are credited to the allowance in the period the payment is received.

Available-for-sale debt securities. The Company primarily holds money market funds, U.S. Treasury securities, corporate debt securities, commercial paper, and foreign entity bonds. The Company regularly reviews the securities in an unrealized loss position and evaluates the current expected credit loss by considering factors such as historical experience, market data, financial condition and near-term prospects of the investee, the extent of the loss related to the credit of the issuer, and the expected cash flows from the security. The Company segments its portfolio based on the underlying risk profiles of the securities and has a zero-loss expectation for U.S. Treasury securities. The basis for this assumption is that these securities have consistently high credit ratings by rating agencies, have a long history with no credit losses, are explicitly guaranteed by a sovereign entity, which can print its own currency, and are denominated in a currency that is routinely held by central banks, used in international commerce, and commonly viewed as a reserve currency. Additionally, all of the Company's other investments are in securities with high-quality credit ratings, which have historically experienced low rates of default.

Cash Equivalents and Short-Term Investments

The Company considers all highly liquid investments with an original maturity of three months or less from the date of purchase to be cash equivalents. Cash equivalents are stated at fair value and consist primarily of amounts invested in money market funds.

The Company primarily holds U.S. Treasury securities, corporate debt securities, commercial paper, and foreign entity bonds, and has the ability, if necessary, to liquidate any of its investments to meet its liquidity needs in the next 12 months, without significant penalty. Accordingly, those investments with contractual maturities greater than one year from the date of purchase are classified as short-term investments on the accompanying balance sheets. Short-term investments have been classified as available-for-sale at the time of purchase. The Company evaluates the appropriate classification of its investments as of each balance sheet date.

The Company's investment securities are recorded at fair value based on the fair value hierarchy. Money market funds and U.S. Treasury securities are classified within Level 1 of the fair value hierarchy. Other securities are classified within Level 2 of the fair value hierarchy. Unrealized gains and losses, deemed temporary in nature, are reported as a separate component of accumulated other comprehensive income (loss).

A decline in the fair value of any security below cost that is deemed other than temporary results in a charge to earnings and the corresponding establishment of a new cost basis for the security. Premiums (discounts) are amortized (accreted) into interest income over the life of the related security as an adjustment to yield using the straight-line interest method. Dividend and interest income are recognized when earned. Realized gains and losses are included in earnings and are derived using the specific identification method for determining the cost of securities sold.

Inventories

Inventory is stated at the lower of cost or net realizable value, with approximate costs determined on a first-in, first-out basis. Inventory costs include direct materials, direct labor, and normal manufacturing overhead. The carrying value of inventories is reduced for any products that are considered excessive or obsolete based upon assumptions about future demand and market conditions. Any write-down of its inventory to net realizable value establishes a new cost basis and will be maintained even if certain circumstances suggest that the inventory is recoverable in subsequent periods. Costs associated with the write-down of inventory are recorded to cost of revenue on the statements of operations.

Property and Equipment, Net

Property and equipment, net is stated at cost, net of accumulated depreciation. Depreciation is generally computed using the straight-line method based on the estimated useful lives of the assets, which is generally two to five years. Leasehold improvements

are amortized using the straight-line method over the shorter of the assets estimated useful lives or the remaining term of the lease. Maintenance and repairs are charged to expense as incurred. Significant improvements that substantially enhance the useful life of an asset are capitalized and depreciated. When assets are retired or disposed of, the cost together with related accumulated depreciation is removed from the balance sheet and any resulting gain or loss is reflected in the statements of operations in the period realized.

Long-lived assets, such as property and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If circumstances require a long-lived asset or asset group to be tested for possible impairment, the Company first compares undiscounted cash flows expected to be generated by that asset or asset group to its carrying value. If the carrying value of the long-lived asset or asset group is not recoverable on an undiscounted cash flow basis, an impairment is recognized to the extent that the carrying value exceeds its fair value. Fair value is determined through various valuation techniques including discounted cash flow models, quoted market values and third-party independent appraisals, as considered necessary. There were no such impairment losses as of December 31, 2025 and 2024.

Leases

The Company determines if an arrangement is a lease at inception by assessing whether the arrangement contains an identified asset and whether it has the right to control the identified asset. Right-of-use (ROU) assets represent the Company's right to use an underlying asset for the lease term. Operating lease liabilities represent the Company's obligation to make lease payments arising from the lease. Lease liabilities are recognized at the lease commencement date based on the present value of future lease payments over the lease term. ROU assets are based on the measurement of the lease liability and also include any lease payments made prior to or on lease commencement and exclude lease incentives and initial direct costs incurred, as applicable.

As the implicit rate in the Company's leases is generally unknown, the Company uses its incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. The lease terms may include options to extend or terminate the lease when the Company is reasonably certain it will exercise such options. Lease costs for the Company's operating leases are recognized on a straight-line basis over the reasonably assured lease term. Variable lease payments include lease operating expenses.

The Company has elected to not separate lease and non-lease components for any leases within its existing classes of assets and, as a result, accounts for any lease and non-lease components as a single lease component. The Company has also elected to not apply the recognition requirement to any leases within its existing classes of assets with a term of 12 months or less and does not include an option to purchase the underlying asset that the Company is reasonably certain to exercise.

Accrued Warranty Liability

The Company generally provides a one-year warranty for defective parts and workmanship on its Tablo consoles, commencing upon the transfer of title and risk of loss to the customer. The Company accrues the estimated cost of product warranties when it invoices the customer, based on historical experience and expected results. Should actual product failure rates and material usage costs differ from these estimates, revisions to the estimated warranty liability would be required. The Company periodically assesses the adequacy of its recorded product warranty liabilities and adjusts the balance as required. Warranty expense is recorded as a component of cost of product revenue in the statements of operations.

Contract Liabilities - Deferred Revenue

The timing of revenue recognition may differ from the timing of invoicing to customers. The Company records deferred revenue when revenue is recognized subsequent to invoicing. For service agreements, the Company generally invoices customers annually at the beginning of each annual coverage period. Deferred revenue that will be recognized during the 12 months following the balance sheet date is recorded as the current portion of deferred revenue and the remaining portion is recorded as noncurrent.

Common Stock Warrant

The Company has accounted for its freestanding warrants to purchase shares of the Company's common stock as equity at fair value upon issuance primarily because the warrants are indexed to the Company's own common stock. The Company estimated the fair value of these warrants using the Black-Scholes option pricing model, which is considered to be a Level 3 fair value measurement. Assumptions used in the pricing model were based on the individual characteristics of the warrants on the valuation date, as well as assumptions for expected volatility, expected term, and risk-free interest rate.

Revenue

The Company generates revenue primarily from the sale of its products and services. Product revenue consists primarily of sales of Tablo consoles and related consumables, including Tablo cartridges and accessories. Service and other revenue consists primarily of revenue generated from service agreements and other revenue from shipping and handling charged to customers.

Each customer contract defines our distinct performance obligations and the associated transaction price for each obligation. Tablo consoles and consumables are generally sold without the right of return. Revenue is recognized when a performance obligation is satisfied. Revenue from product sales is recognized at a point in time when management has determined that control has transferred to the customer, which is generally when legal title has transferred to the customer. Revenue from service agreements is recognized over time as the service is performed, typically evenly over the service period. Certain contracts include variable consideration such as rebates, revenue for such contracts is recognized only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Revenue is recognized net of any taxes collected from customers, which are subsequently remitted to governmental authorities.

The Company's contracts with customers often include multiple performance obligations, such as products and services. The Company determines the SSP based upon the facts and circumstances of each performance obligation (product or services), which often requires management's judgment. The Company uses an observable price to estimate SSP for items that are sold separately, including service agreements. In instances where SSP is not directly observable, such as when the Company does not sell the product or service separately, the Company determines the SSP using information that may include market conditions and other observable inputs and allocates the contracted transaction price to each distinct performance obligation based upon the relative SSP. The Company may offer additional goods or services to customers at the inception of customer contracts at prices not at SSP. If such contracts result in a material right, the Company allocates part of the transaction price to that right and recognizes the associated revenue when those future goods and services are transferred to the customer. SSP is assigned based on the estimated value of the material right. The Company establishes SSP ranges for its products and services and reassesses them periodically.

Costs associated with product sales include commissions. The Company applies the practical expedient to expense the commissions as incurred as the expected amortization period is one year or less. Commissions are recorded as sales and marketing expenses in the statements of operations.

Shipping and Handling Costs

Shipping and handling charged to customers are recorded as revenue. Shipping and handling costs are expensed as incurred and are included in sales and marketing expenses.

Stock-Based Compensation Expense

Stock-based compensation expense relates to stock options with a service-based vesting condition, stock purchase rights under the ESPP, Restricted Stock Units (RSUs) and Performance Stock Units (PSUs) with performance or market-based vesting conditions. Stock-based compensation expense for the Company's stock-based awards is based on their grant date fair value.

The fair value of stock options with a service condition and stock purchase rights under the ESPP on the grant date is estimated using the Black-Scholes option-pricing model. The fair value of these awards is recognized as compensation expense on a straight-line basis over the requisite service period in which the awards are expected to vest and forfeitures are recognized as they occur.

The Black-Scholes model considers several variables and assumptions in estimating the fair value of service-based stock options and stock purchase rights under the ESPP. These variables include the per share fair value of the underlying common stock, exercise price, expected term, risk-free interest rate, expected annual dividend yield and expected stock price volatility over the expected term. The risk-free interest rate is based on the yield available on U.S. Treasury zero-coupon issues similar in duration to the expected term on the equity settled award.

The fair value of RSUs and PSUs with a service- or performance-based vesting condition is based on the market price of the Company's common stock on the date of grant. The determination of the stock-based compensation expense related to PSUs to be recognized in the statements of operations requires the use of certain estimates and assumptions. At each reported period, the Company reassesses the probability of the achievement of corporate performance goals to estimate the number of shares to be released. Any increase or decrease in stock-based compensation expense resulting from an adjustment in the estimated shares to be released is treated as a cumulative catch-up in the period of adjustment. If any of the assumptions or estimates used change significantly, stock-based compensation expense may differ materially from what the Company has recorded in the current period. The fair value of PSUs with a market-based vesting condition is estimated using the Monte Carlo simulation model. Stock-based compensation expense related to these PSUs is recognized using the accelerated attribution method and not reversed if the achievement of the market conditions does not occur.

Research and Development

The Company expenses all research and development costs as incurred. These expenses include the costs of proprietary research and development efforts, quality engineering, clinical studies and trials, and regulatory affairs. Costs primarily consist of

compensation and personnel costs, regulatory fees, consulting services, laboratory supplies and materials expenses, and infrastructure costs including facilities, depreciation, and information technology.

Advertising Costs

Advertising costs are expensed as incurred. The advertising costs for years ended December 31, 2025, 2024, and 2023 were not significant.

Income Taxes

The Company accounts for income taxes under the liability method. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax reporting bases of assets and liabilities and remeasured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain.

The Company utilizes a two-step approach to recognize and measure uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained upon tax authority examination, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement.

The Company includes any penalties and interest expense related to income taxes as a component of other expense, net, as necessary.

Net Loss per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period, without consideration for potential dilutive securities.

Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares and common share equivalents of potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, awards under the Company's equity compensation plan and warrants are considered to be potentially dilutive securities. For periods in which the Company reports net losses, basic net loss per share is the same as diluted net loss per share because the effects of potentially dilutive securities are antidilutive.

Employee Benefit Plan

The Company has a defined contribution retirement savings plan under Section 401(k) of the Internal Revenue Code. This plan allows eligible employees to defer a portion of their eligible compensation on a pre- or post-tax basis. The Company matches 100% of each employee's contributions up to a maximum matching contribution equal to 2% of such employee's eligible compensation, subject to the terms and limitations of the 401(k) plan and applicable law. The Company's matching contributions were $1.0 million, $1.5 million and $1.7 million for the years ended December 31, 2025, 2024, and 2023, respectively.

Segment

The Company generates revenue primarily from the sale of its products and services. Product revenue consists primarily of sales of Tablo consoles and related consumables, including Tablo cartridges and accessories. Service and other revenue consists primarily of revenue generated from service agreements and other revenue from shipping and handling charged to customers. Tablo is a single enterprise solution that can be utilized in both the acute and home care settings. The Company derives revenue primarily in the United States and operates a manufacturing facility in Mexico. As the Company manages its business activities on a consolidated basis, the Company has one reportable segment. The Company's chief operating decision maker (CODM), its Chief Executive Officer, reviews financial information on an aggregate basis for the purposes of allocating resources and evaluating financial performance.

Recently Adopted Accounting Pronouncement

In December 2023, the Financial Accounting Standards Board (FASB) issued Accounting Standards Updated (ASU) No. 2023-09, *Improvements to Income Tax Disclosures* (ASU 2023-09), which requires that an entity disclose specific categories in the effective tax rate reconciliation as well as provide additional information for reconciling items that meet a quantitative threshold. Further, the ASU requires certain disclosures of state versus federal income tax expense and taxes paid. The Company adopted ASU 2023-09 for the year ended December 31, 2025 on a prospective basis. The adoption did not have a material impact on the Company's financial statements. See Note 9 for additional information.

Recently Issued Accounting Pronouncements Not Yet Adopted

In March 2024, the SEC adopted rules intended to enhance and standardize climate-related disclosures in registration statements and annual reports. The new rules will require disclosure of material climate-related risks, including the material impacts of these risks to the Company, the quantification of material impacts to the Company as a result of severe weather events and other natural conditions and Board of Directors' oversight and risk management activities. The new rules follow a compliance phase-in timeline based on a company's filing status. Large accelerated filers and accelerated filers (other than smaller reporting companies) are required to first incorporate such disclosures for fiscal years 2025 and 2026, respectively, followed by greenhouse gas-related disclosures, if material, for fiscal years 2026 and 2027, respectively. In April 2024, the SEC determined to voluntarily stay the final rules pending certain legal challenges. In March 2025, the SEC voted to end its legal defense of the final rules in U.S. Court of Appeals for the Eighth Circuit. The Eighth Circuit has suspended the litigation until the SEC informs the court whether it intends to reconsider the rules under administrative procedures or whether the SEC will renew its defense of the rules. The Company is monitoring the judicial process for resolution of the legal challenges and impacts on the disclosure requirements.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* (ASU 2024-03), which requires additional disclosures about the nature of expenses included in the income statement, such as purchases of inventory, employee compensation and depreciation. ASU 2024-03 will be effective for fiscal years beginning after December 15, 2026, and interim periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact of adopting this standard on its financial statements and related disclosures.

In July 2025, the FASB issued ASU 2025-05, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses for Accounts Receivable and Contract Assets* (ASU 2025-05), which permits entities to elect a practical expedient to assume current conditions as of the balance sheet date will not change for the remaining life of accounts receivable and contract assets when developing forecasts as part of estimating expected credit losses. The amendments in ASU 2025-05 will be effective for fiscal years beginning after December 15, 2025, and interim periods within those fiscal years, with early adoption permitted. The amendments should be applied prospectively. The Company is currently evaluating this practical expedient and does not expect it to have a material impact on its financial statements.

In September 2025, the FASB issued ASU 2025-06, *Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software (*ASU 2025-06), which removes all references to software development project stages and requires entities to start capitalizing software costs when both of the following occur: (i) management has authorized and committed to funding the software project and (ii) it is probable that the project will be completed and the software will be used to perform the function intended. The amendments in ASU 2025-06 will be effective for fiscal years beginning after December 15, 2027, and interim periods within those fiscal years, with early adoption permitted as of the beginning of a fiscal year. The amendments can be applied prospectively, retrospectively, or via a modified prospective transition method. The Company is currently evaluating the impact of adopting this standard on its financial statements.

On December 8, 2025, the FASB issued ASU 2025-11, *Interim Reporting (Topic 270): Narrow-Scope Improvements* (ASU 2025-11) which is intended to improve the navigability of the guidance in ASC 270, *Interim Reporting*, and clarify when it applies. Under the amendments, an entity is subject to ASC 270 if it provides interim financial statements and notes in accordance with GAAP. ASU 2025-11 also addresses the form and content of such financial statements, interim disclosures requirements, and establishes a principle under which an entity must disclose events since the end of the last annual reporting period that have a material impact on the entity. ASU 2025-11 is effective for interim reporting periods within annual reporting periods beginning after December 15, 2027, and early adoption is permitted. The Company is currently evaluating the impact of adopting this standard and does not expect it to have a material impact on its financial statements.

3. Revenue from Contracts with Customers

Disaggregation of Revenue

Revenue by source consisted of the following (in thousands):

	Years Ended December 31,		
	2025	**2024**	**2023**
Consoles	$ 30,733	$ 29,832	$ 61,331
Consumables	54,075	51,145	42,206
Total product revenue	84,808	80,977	103,537
Service and other revenue	34,668	32,712	26,839
Total revenue	$ 119,476	$ 113,689	$ 130,376

Remaining Performance Obligations and Contract Liabilities

As of December 31, 2025, the aggregate amount of the transaction price allocated to the remaining performance obligations related to service agreements that are unsatisfied or partially unsatisfied was $14.2 million, which is recorded as deferred revenue on the Company's balance sheet. Of that amount, $13.8 million will be recognized as revenue during the year ended December 31, 2026 and $0.4 million thereafter.

The contract liabilities consist of deferred revenue which represents payments received in advance of revenue recognition. During the years ended December 31, 2025, 2024 and 2023, the Company recognized $11.2 million, $11.6 million and $8.7 million, respectively, of previously deferred revenue.

4. Fair Value Measurements

The following tables summarize the Company's financial assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

		December 31, 2025			
	Valuation Hierarchy	Amortized Costs	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Assets:					
Cash equivalents:					
Money market funds	Level 1	$ 24,253	$ —	$ —	$ 24,253
Short-term investments:					
U.S. Treasury securities	Level 1	77,622	109	—	77,731
Corporate debt	Level 2	47,111	56	(1)	47,166
Commercial paper	Level 2	5,909	4	—	5,913
Foreign entity bond	Level 2	3,126	4	—	3,130
Total cash equivalents and short-term investments		$ 158,021	$ 173	$ (1)	$ 158,193

		December 31, 2024			
	Valuation Hierarchy	Amortized Costs	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Assets:					
Cash equivalents:					
Money market funds	Level 1	$ 110,979	$ —	$ —	$ 110,979
Short-term investments:					
Corporate debt	Level 2	34,629	43	(1)	34,671
Total cash equivalents and short-term investments		$ 145,608	$ 43	$ (1)	$ 145,650

The Company's Level 2 debt securities are valued using third-party pricing sources. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities, prepayment/default projections based on historical data and other observable inputs. The Company validates the prices provided by its third-party pricing services by understanding the models used, obtaining market values from other pricing sources and confirming those securities traded in active markets.

The unrealized losses for securities in an unrealized loss position for more than 12 months as of December 31, 2025 and 2024 were immaterial. For the years ended December 31, 2025, 2024, and 2023, the Company did not recognize credit loss related to available-for-sales debt securities.

As of December 31, 2025, the remaining contractual maturities for short-term investments were as follows (in thousands):

	Aggregate Fair Value
Due within one year	$ 124,373
After one but within five years	9,567
Total	$ 133,940

The estimated fair value of the term loans as of December 31, 2025 and 2024 were $104.5 million and $212.1 million, respectively, and were determined using a discounted cash flow calculation with a discount rate at 11.7% and 9.5%, respectively.

5. Balance Sheet Components

Restricted Cash

As of December 31, 2025, the restricted cash balance of $3.8 million was related to collateral for the Company's building leases and a vehicle lease agreement (see Note 6) while the restricted cash balance as of December 31, 2024 was only related to collateral for the building leases.

Accounts Receivable

The following table presents the activity in the Company's allowance for credit losses (in thousands):

	December 31,	
	2025	2024
Balance at beginning of year	$ 2,577	$ 203
Increase in allowance	4,487	2,381
Write-offs	(972)	(7)
Balance at end of year	$ 6,092	$ 2,577

Inventories

Inventories consist of the following (in thousands):

	December 31,	
	2025	2024
Raw materials	$ 27,183	$ 25,703
Work in process	7,316	9,973
Finished goods	13,110	23,711
Total inventories	$ 47,609	$ 59,387

Property and Equipment, net

Property and equipment, net consisted of the following (in thousands):

	December 31,	
	2025	2024
Tablos under operating leases	$ —	$ 238
Computers and software	4,844	4,783
Furniture and fixtures	1,915	1,910
Machinery and equipment	12,707	11,905
Leasehold improvements	9,580	9,685
Construction in progress	523	637
Total property and equipment	$ 29,569	$ 29,158
Less: accumulated depreciation and amortization	(24,899)	(21,025)
Property and equipment, net	$ 4,670	$ 8,133

Total depreciation and amortization expense for the years ended December 31, 2025, 2024 and 2023, was $4.3 million, $5.7 million, and $5.8 million, respectively.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31,	
	2025	2024
Inventory	$ 2,245	$ 2,079
Research and development expenses	159	219
Professional services	1,022	1,084
Customer rebates	1,937	1,733
Other	4,070	3,090
Total accrued expenses and other current liabilities	$ 9,433	$ 8,205

Accrued Warranty Liability

The change in accrued warranty liability is presented in the following table (in thousands):

	December 31,	
	2025	2024
Balance at the beginning of year	$ 1,938	$ 3,712
Warranties issued and adjustments to provisions	903	1,908
Warranty claims	(1,467)	(3,682)
Balance at end of year	$ 1,374	$ 1,938

6. Commitments and Contingencies

Leases

In September 2019, the Company entered into an operating lease agreement for its facility and office space in San Jose, CA that commenced in April 2020 and expires in March 2027. This operating lease contains a free rent period and an escalation clause. The landlord provided the Company with a tenant improvement allowance of up to $2.0 million. The Company issued an irrevocable standby letter of credit in the amount of $0.3 million in lieu of a cash security deposit. The letter of credit is fully secured by cash held at the bank in a restricted account.

In May 2020, the Company entered into an operating lease agreement for its manufacturing facility in Tijuana, Mexico that commenced in May 2020. This operating lease contains a free rent period and an escalation clause. The Company issued an irrevocable standby letter of credit in the amount of $3.0 million, in lieu of a cash security deposit. The letter of credit is fully secured by cash held at the bank in a restricted account. In December 2025, the Company determined that it was reasonably certain that the Company would exercise one of the two five-year renewal options and re-measured the related operating lease liabilities with the adjustment to the ROU assets accordingly. With the expected renewal, the lease will expire in August 2031.

In May 2023, the Company entered into on an operating lease agreement for office space in Tijuana, Mexico for certain research and development and general and administrative activities. The lease will expire in 2028.

All three building leases include renewal options at the election of the Company to renew or extend the lease. The Company evaluates renewal options at lease inception and on an ongoing basis and includes renewal options that it is reasonably certain to exercise in its expected lease terms when classifying leases and measuring lease liabilities.

In December 2025, the Company entered into a master lease agreement for vehicles and expects that the individual underlying vehicle leases will be commenced in 2026. The Company issued an irrevocable standby letter of credit in the amount of $0.5 million in lieu of a cash security deposit. The letter of credit is fully secured by cash held at the bank in a restricted account.

The components of lease costs were as follows (in thousands):

	Years ended December 31,		
	2025	2024	2023
Operating lease costs	$ 1,892	$ 1,892	$ 1,837
Variable lease costs	423	351	435
Short-term lease costs	35	115	94

Total lease costs	$ 2,350	$ 2,358	$ 2,366

The weighted-average remaining lease term and discount rate were as follows:

	December 31,	
	2025	2024
Weighted-average remaining lease term (in years)	4.1	2.4
Weighted-average discount rate	10.4%	8.8%

The maturity of the Company's operating lease liabilities as of December 31, 2025 were as follows (in thousands):

Years Ending December 31:	
2026	$ 2,058
2027	1,503
2028	729
2029	696
2030	717
2031	487
Total lease payments	6,190
Less: imputed interest	(1,180)
Present value of operating lease liabilities	$ 5,010
Operating lease liabilities, current	$ 1,739
Operating lease liabilities, noncurrent	$ 3,271

Purchase Commitments

The Company's commitments as of December 31, 2025 were $38.3 million relating to the Company's open purchase orders and contractual obligations that occur in the ordinary course of business, including commitments with contract manufacturers and suppliers for which the Company has not received the goods or services, commitments for capital expenditures, consulting activities for which the Company has not received the services, and subscription of software services. Although open purchase orders are considered enforceable and legally binding, the terms generally allow the Company the option to cancel within a reasonable period, reschedule, and adjust its requirements based on its business needs prior to the delivery of goods or performance of services.

Litigation

On August 29, 2024, a purported stockholder class action lawsuit (the Porcelli Complaint), Porcelli v. Outset Medical, Inc., et al., 5:24-cv-06124-EJD, was filed in the U.S. District Court for the Northern District of California, against the Company, its Chief Executive Officer, and then-Chief Financial Officer. On October 18, 2024, a second purported stockholder class action lawsuit (the Plymouth Complaint; together with the Porcelli Complaint, the Class Actions), Plymouth County Retirement Association v. Outset Medical, Inc., et al., 5:24-cv-06124-HSG, was filed in the same court. The second lawsuit also named the Company's prior Chief Financial Officer as a defendant (together with the CEO and then-CFO, the Class Defendants). The Porcelli Complaint alleged that, between August 1, 2022 and August 7, 2024, defendants made materially false or misleading statements in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended (Exchange Act) regarding the Company's business, operations, and prospects related to the sale and marketing of the Tablo Hemodialysis System and TabloCart with Prefiltration, including concerning the impact of certain FDA processes for these products on the Company's revenue growth. The Plymouth Complaint alleged similar violations between September 15, 2020 and August 7, 2024. On March 18, 2025, the court consolidated the Class Actions into one action captioned In re Outset Medical, Inc. Securities Litigation, Case No. 5:24-cv-06124-EJD, appointing a Lead Plaintiff and Lead Counsel. The Lead Plaintiff filed its consolidated amended complaint on June 6, 2025. The Class Defendants filed a motion to dismiss the consolidated amended complaint on August 14, 2025, the Lead Plaintiff filed its opposition on October 6, 2025, and the Class Defendants filed their reply in support of the motion to dismiss on November 17, 2025. A hearing on the Class Defendants' motion to dismiss took place on January 22, 2026. The court took the matter under submission and has not yet issued a ruling.

On November 29, 2024, an Outset stockholder purporting to act on behalf of the Company filed an action in the U.S. District Court for the Northern District of California against current and former members of Outset's Board of Directors and certain of its officers (the Derivative Defendants), alleging that the Derivative Defendants breached their fiduciary duties to the Company in connection with the same alleged events and alleged materially false and misleading statements asserted in the Class Actions described above. Three additional substantively duplicative actions were filed in the U.S. District Court for the Northern District of California on April 28, 2025, May 8, 2025, and June 16, 2025. The complaints seek unspecified monetary damages and other relief. On July 17, 2025, the court entered a stay of all derivative actions pending the outcome of the Class Defendants' motion to dismiss the consolidated amended complaint.

The cases are at a very early stage and the Company cannot currently estimate the loss or the range of possible losses it may experience in connection with this litigation.

In addition, from time to time, the Company may become involved in other legal proceedings or investigations, which could have an adverse impact on its reputation, business and financial condition and divert the attention of the Company's management from the operation of the Company's business.

Indemnifications

In the ordinary course of business, the Company often includes standard indemnification provisions in its arrangements with its partners, customers and suppliers. Pursuant to these provisions, the Company may be obligated to indemnify such parties for losses or claims suffered or incurred in connection with its service, breach of representations or covenants, intellectual property infringement or other claims made against such parties. These provisions may limit the time within which an indemnification claim can be made. It is not possible to determine the maximum potential amount under these indemnification obligations due to the limited history of prior indemnification claims and the unique facts and circumstances involved in each particular agreement. To date, the Company has not incurred any material costs as a result of such indemnification obligations and has not accrued any liabilities related to such obligations in these financial statements.

7. Term Loans

Term loans consist of the following (in thousands):

	December 31,	
	2025	**2024**
Principal of term loans	$ 101,502	$ 200,000
Unamortized debt discount	(5,265)	(2,625)
Term loans, noncurrent	$ 96,237	$ 197,375

SLR Credit Facilities

In November 2022, the Company entered into two senior secured credit facilities, which collectively provided for borrowings of up to $300.0 million as follows: (i) up to a $250.0 million term loan facility pursuant to a loan and security agreement (the SLR Loan Agreement) among SLR Investment Corp., as collateral agent (SLR Agent), the lenders from time to time party thereto (the Term Loan Lenders) and the Company (the SLR Term Loan Facility), and (ii) up to a $50.0 million asset-based revolving credit facility pursuant to a credit agreement (the SLR Revolving Credit Agreement, together with the SLR Loan Agreement, the SLR Credit Facility Agreements) among Gemino Healthcare Finance, LLC d/b/a SLR Healthcare ABL, as lender, and the Company (the SLR Revolver, together with the SLR Term Loan Facility, the SLR Credit Facilities).

As of December 31, 2024, $200.0 million was outstanding under the SLR Term Loan Facility and no amounts were outstanding under the SLR Revolver. On January 3, 2025, the Company terminated the SLR Credit Facility Agreements and repaid in full all amounts due, including a final payment of $7.5 million and a termination fee of $0.1 million, using the proceeds from the Perceptive Term Loan as described below, together with cash on hand. The repayment of the SLR Credit Facilities was accounted for as a debt extinguishment, which resulted in a loss on extinguishment of $7.7 million recorded in the accompanying statements of operations for the year ended December 31, 2025.

Perceptive Term Loan

On January 3, 2025, the Company entered into a senior secured credit facility for borrowings up to an aggregate principal amount of $125.0 million pursuant to the Perceptive Credit Agreement with Perceptive Credit Holdings IV, LP (who also participated in the Private Placement). Pursuant to the terms and conditions of the Perceptive Credit Agreement, the lenders agreed to extend term loans to the Company in an aggregate principal amount of up to $125.0 million, comprised of (i) a term loan of $100.0 million (the Initial Term Loan), which was funded on January 8, 2025 (the Closing Date), and (ii) a delayed draw term loan of up to $25.0 million (the Delayed Draw Loan). The Initial Term Loan and the Delayed Draw Loan are referred to collectively as the Perceptive Term Loan. The Delayed Draw Loan is available for funding until July 14, 2027, subject to the achievement of certain revenue milestone and other customary conditions.

The principal amount outstanding under the Loans will accrue interest at a rate per annum equal to (i) the greater of (a) one-month term SOFR or (b) 4.00% per annum, plus (ii) an applicable margin of 8.00%, payable monthly in arrears. During the first two years after the Closing Date, a portion of the accrued interest equal to 1.50% per annum will be paid in kind and added to the principal amount of the Loans on each monthly interest payment date. The outstanding principal amount of the Loans will be due and payable on the five year anniversary of the Closing Date (the Maturity Date).

The Company paid the lenders a non-refundable closing fee in the amount of $1.0 million in respect of the Initial Term Loan on the Closing Date. The Company is obligated to pay the lenders a non-refundable closing fee in the amount of $250,000 in respect of the Delayed Draw Loan, to be due and payable upon the funding of the Delayed Draw Loan.

On the Closing Date, the Company issued to Perceptive Credit Holdings IV, LP as the initial lender a warrant to purchase 375,000 of shares of the Company's common stock (the Closing Date Warrant), at an exercise price equal to $12.00 per share. If the Company draws the Delayed Draw Loan, the Company is required to issue additional warrant(s) to the lenders to purchase 94,000 shares of the Company's common stock (the Delayed Draw Warrant), at an exercise price equal to the average closing price of the Company's common stock for the 5 trading days immediately preceding the issuance date of the Delayed Draw Warrant. Both the Closing Date Warrant and the Delayed Draw Warrant, if issued, are exercisable during the seven years after the date of issuance.

The fair value of the Closing Date Warrant of $4.4 million and the debt issuance costs paid directly to Perceptive Credit Holdings IV, LP along with other debt issuance costs amounting to $6.5 million were accounted for as a direct deduction from the term loan balance on the balance sheets and are being recognized as non-cash interest expense over the term of the loan using the effective interest method.

The Company may voluntarily prepay the outstanding loan(s), subject to a prepayment premium of (i) 10.0% of the principal amount of the prepaid loan(s), if prepaid prior to or on the first anniversary of the Closing Date, (ii) 8.0% of the principal amount of the prepaid Loans, if prepaid after the first anniversary of the Closing Date through and including the second anniversary of the Closing Date, (iii) 4.0% of the principal amount of the prepaid loan(s), if prepaid after the second anniversary of the Closing Date through and including the third anniversary of the Closing Date, (iv) 2.0% of the principal amount of the prepaid Loans, if prepaid after the third anniversary of the Closing Date through and including the fourth anniversary of the Closing Date, and (v) 0.00% of the principal amount of the prepaid loan(s), if prepaid after the fourth anniversary of the Closing Date.

The Perceptive Credit Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among others, requirements as to financial reporting and insurance and restrictions on the Company's ability to dispose of its business or property, to change its line of business, to liquidate or dissolve, to enter into any change in control transaction, to merge or consolidate with any other entity or to acquire all or substantially all the capital stock or property of another entity, to incur additional indebtedness, to incur liens on its property or to pay any dividends or other distributions on capital stock, in each case with certain exceptions. The Company has also agreed to certain financial covenants that require the Company to (i) maintain a minimum cash balance of at least $10.0 million in accounts subject to control agreements in favor of Agent, and (ii) achieve certain trailing twelve-month net revenue targets as set forth in the Perceptive Credit Agreement.

In addition, the Perceptive Credit Agreement contains customary events of default that entitle the Agent to cause the Company's indebtedness under the Perceptive Credit Agreement to become immediately due and payable, and to exercise remedies against the Company and the collateral securing the obligations owed under the Perceptive Credit Agreement. Under the Perceptive Credit Agreement, an event of default will occur if, among other things, the Company fails to make payments under the Perceptive Credit Agreement, the Company breaches certain covenants under the Perceptive Credit Agreement, subject to specified cure periods with respect to certain breaches, a material adverse change or a material regulatory event has occurred under the Perceptive Credit Agreement, or the Company or its assets become subject to certain legal proceedings, such as bankruptcy proceedings. Upon the occurrence and for the duration of an event of default, an additional default interest rate equal to 4.0% per annum will apply to all obligations owed under the Perceptive Credit Agreement.

The annual principal annual payments, excluding interest payments and the final fee, due on the term loan as of December 31, 2025 were as follows (in thousands):

Years Ending December 31:	
2026 – 2029	$ —
2030	103,091
Total estimated principal payments	103,091
Less: estimated interest paid-in-kind	(1,589)
Less: unamortized debt discount	(5,265)
Total term loan, net of debt discount	$ 96,237

8. Convertible Preferred Stock and Stockholders' Equity

Convertible Preferred Stock

The Company is authorized to issue a total of 5,000,000 shares of preferred stock, par value $0.001 per share. In connection with the Private Placement described below, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock with the Delaware Secretary of State on January 7, 2025 (the Certificate of Designation) to set

forth the preferences, rights and limitations of the Series A Convertible Preferred Stock. The Company designated a total of 863,000 shares as Series A Convertible Preferred Stock, which are non-voting and not redeemable.

On January 3, 2025, the Company entered into securities purchase agreements with various investors, including certain of the Company's directors, officers and employees (the Investors) for the issuance and sale by the Company of an aggregate of 863,000 shares of Series A Convertible Preferred Stock, par value $0.001 per share, at a purchase price of $200.00 per share in the Private Placement. The sale of 844,000 shares of Series A Convertible Preferred Stock to institutional investors closed on January 8, 2025, with gross proceeds, before deducting placement agent fees and other offering expenses, of $168.8 million. On March 7, 2025, following stockholder approval of the Company's issuance of shares of Series A Convertible Preferred Stock and shares of the Company's common stock issuable upon the conversion thereof to certain of the Company's directors, officers and employees at the special meeting of stockholders held on March 5, 2025 (the Special Meeting), the Company issued 19,000 shares of Series A Convertible Preferred Stock to certain of the Company's directors, officers and employees, with gross proceeds, before deducting offering expenses, of $3.9 million.

On March 10, 2025, following the stockholder approval of the Company's issuance of common stock in excess of 20% of the Company's then outstanding shares of common stock at the Special Meeting, 842,000 shares of Series A Convertible Preferred Stock were converted into 14,046,000 shares of the Company's common stock at the conversion price of $12.00 per share in accordance with the Certificate of Designation. Following the conversion in March, 21,000 shares of the Series A Convertible Preferred Stock were subsequently converted into 343,000 shares of the Company's common stock in October 2025.

As of December 31, 2025, no shares of Series A Convertible Preferred Stock were outstanding.

Common Stock Warrants

As discussed in Note 7 above, the Company issued a warrant to Perceptive Credit Holdings IV, LP to purchase 375,000 shares of the Company's common stock, at an exercise price equal to $12.00 per share, in January 2025. This warrant is immediately exercisable upon issuance, and expires seven years after the date of issuance, January 2032. This warrant is outstanding and exercisable, and classified as a component of permanent stockholders' equity. The Company determined the fair value using the Black-Scholes option pricing model with the following assumptions on the date of issuance: common stock price of $14.66 per share, expected volatility of 93%, expected term of 7 years, and risk-free interest rate of 4.56%.

9. Stock-Based Compensation

Equity Incentive Plan

In 2019, the Company terminated the 2010 Stock Incentive Plan (the 2010 Plan) and adopted the 2019 Equity Incentive Plan (the 2019 Plan, and together with 2010 Plan, the Prior Plans) for the purpose of providing incentive and non-statutory stock options to employees, directors and certain non-employees.

In 2020, the Company adopted the 2020 Equity Incentive Plan (the 2020 Plan, and together with the Prior Plans, the Plans), which became effective in connection with the Company's initial public offering. As a result, the Company may not grant any additional awards under the Prior Plans. The Prior Plans will continue to govern outstanding equity awards previously granted thereunder. The Company initially reserved 244,000 shares of common stock for the issuance of awards under the 2020 Plan. In addition, the number of shares of common stock available under the 2020 Plan automatically increases on the first day of each fiscal year until (and including) the fiscal year ending December 31, 2030, with such annual increase equal to an amount equal to the lesser of (i) 4% of the number of shares of common stock issued and outstanding on December 31 of the immediately preceding calendar year, and (ii) an amount determined by the Company's board of directors.

At the Company's annual meeting of stockholders held on June 2, 2025 (the 2025 Annual Meeting), the Company's stockholders approved an amendment to the Company's 2020 Plan to increase the number of shares of common stock available for issuance under the plan by 1,950,000 shares. As of December 31, 2025, 1,420,000 shares were reserved for future issuance under the 2020 Plan.

Options under the 2020 Plan have a contractual term of 10 years. The exercise price of an option shall not be less than 100% of the fair market value of the shares on the date of grant.

Stock Options

Subsequent to the first quarter of 2022, the Company no longer grants stock options. Service-based options previously granted to a grantee generally vest at a rate of 25% on the first anniversary of the original vesting date, with the balance vesting monthly over the remaining three years. A summary of the Company's stock option activity under the Plans is set forth below (in thousands, except exercise price and remaining contractual life data):

	Outstanding Options	Weighted-Average Exercise Price	Weighted-Average Remaining Terms (Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2024	92	$ 198.87		
Forfeited and expired	(11)	$ 307.06		
Outstanding as of December 31, 2025	81	$ 183.26	3.61	$ —
Exercisable as of December 31, 2025	81	$ 183.26	3.61	$ —

The total intrinsic value of options exercised during the years ended December 31, 2024 and 2023 was $0.2 million and $9.9 million, respectively. The intrinsic value is the difference between the fair value of the Company's common stock at the time of exercise and the exercise price of the stock option.

The total fair value of options that vested during the years ended December 31, 2025, 2024 and 2023 was $0.5 million, $2.1 million and $3.6 million, respectively. As of December 31, 2025, all stock-based compensation expense related to the stock options was fully recognized.

Restricted Stock

The Company issues RSUs and PSUs, both of which are considered restricted stock. The Company grants restricted stock pursuant to the 2020 Plan and satisfies such grants through the issuance of new shares. RSUs are share awards that, upon vesting, will deliver to the holder shares of the Company's common stock.

RSUs with a service-based vesting condition granted to a grantee, beginning in February 2022, generally vest over a three-year period as follows either: (i) 25% on the first anniversary of the original vesting date, 25% quarterly over the course of the second year, and 50% quarterly over the course of the third year, or (ii) 33% on the first anniversary of the original vesting date, with the balance vesting quarterly over the remaining two years.

Annual RSUs granted to non-executive employees in 2025 vest over one year with 100% vesting on the first anniversary of the grant date while the annual RSUs granted to executives and certain other senior leaders in 2025 vest over a two-year period with 50% vesting on the first anniversary of the vesting commencement date, and the remaining 50% vesting quarterly over the following year.

Annual RSUs granted to non-executive employees in 2024 vest over a two-year period at a rate of 50% on the first anniversary of the original vesting date, with the balance vesting quarterly over the remaining one year.

Prior to February 2022, RSUs with a service-based vesting condition granted to a grantee generally vest at a rate of 25% on the first anniversary of the original vesting date, with the balance vesting quarterly over the remaining three years.

Since 2022, the Company has granted a mix of 50% PSUs and 50% RSUs to its CEO, and a mix of 20% PSUs and 80% RSUs to its other executive officers and certain other senior leaders on an annual basis. These PSUs are earned and vest based on achievement against a performance-based metric and a market-based metric as follows:

- Performance-based vesting conditions:
  - PSUs granted in 2022 through 2024 are earned based on the number of patients treating at home on Tablo as of the end of the second or third year following the grant date (Year 2 or Year 3), with earned units vesting either (i) 50% after certification of achievement following the end of Year 2 and 50% at the end of Year 3 or (ii) 100% after certification of achievement following the end of Year 3 (Home PSUs); or
  - PSUs granted in 2025 are earned based on the Company's three-year non-GAAP cumulative earnings before income tax, depreciation and amortization (EBITDA) at the end of 2027, with 100% of earned units vesting after certification of the achievement level following the end of 2027 (EBITDA PSUs).
- Market-based vesting conditions:
  - PSUs granted in 2022 through 2025 are earned based on the Company's relative total stockholder return (Relative TSR) at the end of a two-year or three-year performance period as compared to companies in a pre-determined index of medical device companies, in each case, with 100% of earned units vesting at the end of Year 3, or after certification of achievement following the end of the three-year performance period (Relative TSR PSUs).

The number of units earned varies based on actual performance as follows: (i) from 0% to 200% (250% for the CEO) of the target number of the Home PSUs and EBITDA PSUs granted, (ii) from 75% to 150% (250% for the CEO) of the target number of

Relative TSR PSUs granted in 2022 and 2023 and (iii) from 0% to 200% (250% for the CEO) of the target number of Relative TSR PSUs granted in 2024 and 2025.

The grant dates for the Home PSUs and EBITDA PSUs are not considered established until the Compensation Committee of the Board approves the target and it is communicated to the award recipients, which then triggers the service inception date, the fair value of the awards, and the associated expense recognition period. Once the grant dates for the Home PSUs and EBITDA PSUs have been established, the related stock-based compensation expense would be recorded based on the forecasted performance, which is reassessed each reporting period based on the probability of achieving the performance conditions.

In 2024, the Company also granted a new type of PSU award to executive officers and certain other senior leaders which is earned and vests based on appreciation of the Company's stock price above pre-determined stock price triggers or achievement of specified operating income targets over a performance period of up to three years.

Restricted stock activity was as follows (in thousands, except per share amounts):

	Restricted Stock Units (RSU)	Performance Stock Units (PSU)	Weighted-Average Grant Date Fair Value Per Share	
			RSU	PSU
Outstanding as of December 31, 2024	229	97	$ 93.97	$ 112.35
Granted	743	162	$ 19.39	$ 11.31
Released	(129)	(33)	$ 102.55	$ 115.52
Forfeited	(134)	(23)	$ 48.25	$ 53.87
Outstanding as of December 31, 2025	709	203	$ 22.86	$ 39.30

The total grant date fair value of restricted stock vested for the years ended December 31, 2025, 2024 and 2023 were $9.4 million, $27.2 million, and $24.9 million, respectively. As of December 31, 2025, the total unrecognized stock-based compensation expense related to the restricted stock was $11.5 million, which will be recognized over a weighted-average period of 1.64 years.

Employees Stock Purchase Plan (ESPP)

In 2020, the Company adopted the ESPP. The Company initially reserved 46,000 shares of common stock for purchase under the ESPP. In addition, the number of shares of common stock available for issuance under the ESPP increases automatically on the first day of each fiscal year until (and including) the fiscal year ending December 31, 2030, with such annual increase equal to the lesser of (i) 46,000 shares, (ii) 1% of the number of common stock issued and outstanding on December 31 of the immediately preceding fiscal year, and (iii) an amount determined by the Company's board of directors.

At the 2025 Annual Meeting, the Company's stockholders approved an amendment to the Company's ESPP to increase the number of shares of common stock available for issuance under the plan by 255,000 shares. As of December 31, 2025, 248,000 shares of common stock were reserved for issuance in connection with the current and future offering periods under the ESPP.

Subject to any limitations contained therein, the ESPP allows eligible participants to contribute, through payroll deductions, up to 10% (15% until August 2025) of their eligible compensation to purchase the Company's common stock at a purchase price equal to 85% of the fair market value of the common stock on the first day of the offering period or purchase date, whichever is lower. The ESPP generally provides for consecutive six-month offering periods. Effective beginning with the offering period commencing on March 1, 2022, the ESPP allows eligible participants to purchase shares pursuant to a cashless exercise program, and the duration for each offering period is a 24-month period consisting of four separate consecutive purchase periods of six months in length. This includes a two-year look-back feature in the ESPP, with a reset feature, which causes the offering period to reset if the fair value of the Company's common stock on the first day of a new offering period is less than that on the original offering date.

The grant date fair value and assumptions used in estimating the fair value of the stock purchase rights under the ESPP were as follows:

	Years Ended December 31,		
	2025	2024	2023
Expected term (in years)	0.49 – 2.00	0.49 – 2.00	0.49 – 2.00
Expected volatility	71.0% – 146.4%	81.7% – 215.2%	53.3% – 61.6%
Risk-free interest rate	3.6% – 4.3%	3.8% – 5.2%	4.8% – 5.4%
Dividend yield	0%	0%	0%
Grant Date Fair Value	$4.18–$7.19	$2.25 – $31.65	48.75–$124.05

As of December 31, 2025, the total unrecognized stock-based compensation expense related to the ESPP was $1.4 million, which will be recognized over a weighted-average period of 0.81 years.

Stock-based Compensation Expense

The following table sets forth stock-based compensation expense included in the statements of operations (in thousands):

	Years Ended December 31,		
	2025	2024	2023
Cost of revenue	$ 583	$ 1,372	$ 1,805
Research and development	3,366	7,291	10,538
Sales and marketing	3,083	6,122	12,419
General and administrative	8,584	14,571	13,872
Total stock-based compensation expense	$ 15,616	$ 29,356	$ 38,634

10. Income Taxes

Loss before provision for income taxes were as follows for the periods indicated (in thousands):

	Years Ended December 31,		
	2025	2024	2023
Domestic	$ (70,397)	$ (116,693)	$ (158,095)
Foreign	(10,538)	(10,792)	(14,179)
Loss before provision for income taxes	$ (80,935)	$ (127,485)	$ (172,274)

The provision for income taxes were $0.7 million, $0.5 million and $0.5 million for the years ended December 31, 2025, 2024 and 2023, respectively, which primarily related to foreign income taxes in Mexico. The Company has incurred net operating losses for all periods presented. The Company has not reflected any benefit of such net operating loss carryforwards in the financial statements. The Company has established a full valuation allowance against its deferred tax assets due to the uncertainty surrounding the realization of such assets.

The following table is a reconciliation of the U.S. federal statutory rate to the Company's effective rate for the year ended December 31, 2025 in accordance with the guidance in ASU No. 2023-09:

	Year Ended December 31, 2025	
U.S. Federal statutory income tax rate	$ (16,997)	21.0 %
State and local income taxes, net of federal	—	—
Foreign tax effects:		
Mexico		
Maquiladora safe harbor profit	3,863	(4.8)
Foreign rate differential	(948)	1.2
Other	16	—
Effect of cross-border tax laws:		
Foreign branch income	(2,360)	2.9
Tax credits	(765)	0.9
Valuation allowances	14,492	(17.9)
Nontaxable or nondeductible items:		
Stock-based compensation	3,536	(4.3)
Other	(120)	0.1
Other adjustment	1	—
Effective income tax rate	$ 718	(0.9) %

As previously disclosed for the years ended December 31, 2024 and 2023, prior to the adoption of ASU 2023-09, the effective tax rate differs from the federal statutory income tax rate applied to the loss before provision for income taxes and tax due to the following:

	Years Ended December 31,	
	2024	2023
Federal statutory income tax rate	21.0 %	21.0 %
State taxes	1.1	3.2
Change in valuation allowance	(17.3)	(22.0)
Federal and state tax credits	1.4	1.3
Stock-based compensation expense	(5.3)	(2.0)
Non-deductible permanent expenses	(0.5)	(0.7)
Effect of deferred tax adjustment	(0.1)	—
Non-deductible compensation	(0.7)	(1.0)
Effective income tax rate	(0.4) %	(0.2) %

Total income taxes paid during the year ended December 31, 2025 were $0.5 million, entirely attributable to foreign income taxes in Mexico.

Deferred tax assets and liabilities

Deferred income taxes reflect the net tax effect of temporary differences between amounts recorded for financial reporting purposes and amounts used for tax purposes. The major components of deferred tax assets and liabilities were as follows as of the dates indicated (in thousands):

	December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 201,253	$ 180,588
Tax credits	19,751	18,163
Accrual and reserves	3,434	3,137
Tangible and intangible assets	1,656	3,534
Stock-based compensation expense	2,091	2,333
Capitalized research costs	22,817	29,014
Other deferred tax asset	9,580	8,386
Gross deferred tax assets	260,582	245,155
Valuation allowance	(259,423)	(244,165)
Net deferred tax assets	$ 1,159	$ 990

	December 31,	
	2025	2024
Deferred tax liabilities:		
Right-of-use assets	$ (1,159)	$ (990)
Gross deferred tax liabilities	$ (1,159)	$ (990)

Realization of the deferred tax assets is dependent upon future taxable income, if any, the amount and timing of which are uncertain. A valuation allowance is provided when it is not more likely than not that some portion of the deferred tax assets will be realized. Management believes that, based on a number of factors, it is more likely than not that the U.S. federal and state net deferred tax assets will not be fully realized, thus a full valuation allowance has been recorded as of December 31, 2025 and 2024. The change in the valuation allowance during the years ended December 31, 2025, 2024 and 2023 was an increase of $15.3 million, $22.1 million, and $37.8 million, respectively.

On July 4, 2025, the One Big Beautiful Bill Act (the OBBBA) was signed into law. The OBBBA contains significant tax law changes, including allowing for the deduction of domestic research and development costs, which were previously required to be capitalized and amortized from 2022 through 2024. Because of the Company's valuation allowance on its deferred tax assets, the change did not impact its financial statements.

Net Operating Loss and Tax Credit Carryforwards

As of December 31, 2025, the Company had a net operating loss carryforward for U.S. federal income tax purposes of $815.1 million. Federal net operating losses of $687.4 million incurred after 2017 do not expire but usage is limited to 80% of taxable

income. The remaining $127.8 million of federal net operating loss carryforward will begin to expire in 2026 and continue to expire through 2037. The Company had a total U.S. state net operating loss carryforward of $453.9 million. State net operating losses of $140.7 million do not expire. The remaining state net operating loss carryforward of $313.2 million will begin to expire in 2026 and continue to expire through 2044.

As of December 31, 2025, the Company had federal research and development credits of $13.4 million, which will begin to expire in 2030 and state research and development credits of $9.2 million which are not currently subject to expiration. Utilization of the operating loss and tax credits may be subject to annual limitation due to the ownership change limitations provided by the Code and similar state provisions. Such an annual limitation could result in the expiration of net operating loss and tax credit carryforwards before utilization.

Federal and state laws impose substantial restrictions on the utilization of net operating loss and tax credit carryforwards in the event of an ownership change for tax purposes, as defined in Section 382 of the Internal Revenue Code. As a result of such ownership changes, the Company's ability to realize the potential future benefit of tax losses and tax credits that existed at the time of the ownership change may be significantly reduced. The Company's deferred tax asset and related valuation allowance would be reduced, as a result. The Company has not performed a Section 382 study to determine the amount of reduction, if any. Unrecognized tax benefits as of December 31, 2025 have been recorded as an offset to federal and state research and development credit carryforwards.

Unrecognized Tax Benefits

A reconciliation of the total unrecognized tax benefits for the periods presented was as follows (in thousands):

	December 31,	
	2025	**2024**
Balance, beginning of year	$ 4,423	$ 3,781
Increase related to prior years positions	—	—
Decrease related to current year positions	—	—
Increase related to current year positions	548	642
Balance, end of year	$ 4,971	$ 4,423

The Company does not have any material accrued interest or penalties associated with unrecognized tax benefits.

The Company files income tax returns in the United States, various U.S. states and Mexico. The Company is not under examination by income tax authorities in federal, other states, or other jurisdictions. All tax returns remain open for examination by federal, state, and foreign authorities for three, four, and five years, respectively, from the date of utilization of any net operating loss or credits.

11. Net Loss per Share

The following outstanding potentially dilutive shares have been excluded from the calculation of diluted net loss per share due to their anti-dilutive effect (in thousands):

	Years Ended December 31,		
	2025	**2024**	**2023**
Stock options to purchase common stock	81	92	129
Restricted stock units	709	229	172
Performance stock units	7	17	13
Shares committed under ESPP	123	44	21
Warrants to purchase common stock	375	4	4
Total	1,295	386	339

12. Segment and Geographic Information

The accounting policies of the Company's reportable segment are the same as those described in the summary of significant accounting policies. The key measure of segment profit or loss that the CODM uses to allocate resources and assess performance is the Company's net loss, as reported on the accompanying statements of operations. Net income is used to monitor budget versus actual results.

There are no intra-entity sales or transfers. All expense categories on the accompanying statements of operations are significant and there are no other expense categories regularly provided to the CODM beyond those disclosed in the accompanying statements of operations. The CODM manages the business using expense information as well as regularly provided budgeted or forecasted expense information for the single operating segment. The measure of segment assets is reported on the balance sheets as total consolidated

assets with particular emphasis on the Company's available liquidity, including its cash, cash equivalents, restricted cash, and short-term investments.

The Company operates a manufacturing facility in Mexico. The Company's long-lived tangible assets, net, as well as the Company's operating lease right-of-use assets recognized on the balance sheets, located in Mexico were $6.0 million as of December 31, 2025.

13. Workforce Reduction

In order to improve operational efficiencies, reduce operating expenses and streamline its overall organizational structure, the Company implemented two organizational restructuring plans to reduce its workforce in the fourth quarter of 2023 and May 2024 and incurred restructuring charges of $2.5 million in fiscal year 2023 and $2.7 million through the first half of fiscal year 2024 for employee severance and other termination benefits.

In connection with steps the Company took to help optimize its commercial organization, and to help improve operational efficiencies and reduce operating expenses to align with anticipated revenue growth, in the third quarter of 2024, the Company completed an additional restructuring plan primarily impacting its commercial organization. The Company incurred restructuring charges of $1.4 million in the third quarter of 2024 for employee severance and other termination benefits associated with this restructuring.

In January 2025, the Company implemented another restructuring plan and, as a result, estimated and recognized restructuring charges of $1.5 million as of December 31, 2024 for employee severance and other termination benefits. Restructuring accruals are based upon management estimates at the time and are subject to change depending upon changes in facts and circumstances subsequent to the date the original liability was recorded.

The following table sets forth severance and related benefits charges included in the statements of operations (in thousands):

	Years Ended December 31,		
	2025	2024	2023
Cost of revenue	$ —	$ 579	$ 129
Research and development	34	2,107	739
Sales and marketing	—	2,149	1,294
General and administrative	(42)	720	370
Total	$ (8)	$ 5,555	$ 2,532

For the year ended December 31, 2025, changes in liabilities resulting from the restructuring accruals, which were recorded in accrued compensation and related benefits on the balance sheet, were as follows (in thousands):

Balance as of December 31, 2024	$ 1,501
Charges	34
Payments and other adjustments	(1,535)
Balance as of December 31, 2025	$ —

14. Related Party Transactions

As discussed in Note 8, certain of the Company's directors, officers and employees purchased 19,000 shares of Series A Convertible Preferred Stock for a total purchase price of $3.9 million in March 2025. These shares of Series A Convertible Preferred Stock were subsequently converted to common stock.

15. Subsequent Event

On January 22, 2026, upon the recommendation of the Company's Compensation Committee, the Company's Board of Directors (the Board) adopted the Outset Medical, Inc. Inducement Plan (the Inducement Plan), effective February 10, 2026. Under the Inducement Plan, 250,000 shares of the Company's common stock, par value $0.001 per share, are reserved for issuance solely to individuals who were not previously employees or directors of the Company, or who are returning to employment following a bona fide period of non-employment, as an inducement material to such individuals' entry into employment with the Company for purposes of Rule 5635(c)(4) of the Nasdaq Stock Market Marketplace Rules (Rule 5635(c)(4)). The Inducement Plan was adopted by the Board without stockholder approval in reliance on Rule 5635(c)(4). The Inducement Plan incorporates the terms and conditions of the Company's stockholder-approved 2020 Equity Incentive Plan, except as otherwise provided in the Inducement Plan and provided that incentive stock options may not be granted under the Inducement Plan.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation and supervision of our Chief Executive Officer and Chief Financial Officer, have evaluated the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Annual Report. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures are also designed to provide reasonable assurance that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of December 31, 2025.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. The rules define internal control over financial reporting as a process designed by, or under the supervision of, the Company's Chief Executive Officer and Chief Financial Officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an assessment of the effectiveness of our internal control over financial reporting based on the framework in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the results of our assessment under the framework in the Internal Control - Integrated Framework (2013), our management concluded that our internal control over financial reporting was effective as of December 31, 2025.

The effectiveness of our internal control over financial reporting as of December 31, 2025 has been audited by an independent registered public accounting firm, as stated in their report, which is included under "Item 8. Financial Statements and Supplementary Data" of this Annual Report.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that occurred during the quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Rule 10b5-1 Trading Arrangements

During the three months ended December 31, 2025, no director or officer of the Company adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

2026 Executive Cash Retention Bonuses

On February 11, 2026, the Compensation Committee (the Compensation Committee) of our Board of Directors of (the Board) approved the payment of one-time special cash retention bonuses for 2026 to certain of our executive officers, namely Renee Gaeta, John L. Brottem and Marc Nash. The retention bonuses are intended to support retention priorities and leadership continuity in key business functions of the Company.

Each of Ms. Gaeta, Mr. Brottem and Mr. Nash will be entitled to receive the one-time cash retention bonus in the amount set forth opposite his or her name in the table below, payable in a lump sum in December 2026, subject to continued employment with the Company through such payment date. These 2026 retention bonuses are in addition to any amounts that may be earned by such executive officers under our regular 2026 annual cash bonus program. The individual retention bonus amounts are as follows:

Name:	Title	2026 Retention Bonus Amount
Renee Gaeta	*Chief Financial Officer*	$66,795
John L. Brottem	*General Counsel and Secretary*	$106,620
Marc Nash	*Executive Vice President, R&D, Operations and Service*	$100,460

2026 Special Performance-Based Retention Bonus for Marc Nash

On February 11, 2026, the Compensation Committee also approved an additional one-time special performance-based cash bonus for Marc Nash. This bonus is intended to support retention priorities and continuity in leadership of the key business functions overseen by Mr. Nash, while incentivizing the achievement during 2026 of specified cost savings initiatives.

Mr. Nash's bonus opportunity is based on the achievement of two cost savings-related performance goals for 2026 relating to service efficiencies and profitability initiatives. At target performance, the bonus payout opportunity for each of the two cost savings performance goals is $95,000 and $105,000, respectively. For each performance goal, (i) no bonus amount will be payable unless the threshold level of at least 90% of the applicable cost savings target is achieved and (ii) payouts will scale linearly from 90% to 100% for achievement between threshold and target levels. In addition, the bonus includes an overachievement opportunity pursuant to which Mr. Nash may earn 15% of incremental cost savings achieved above the applicable cost savings target, subject to a maximum overperformance payout of $100,000 in the aggregate.

Any bonus amount earned by Mr. Nash pursuant to this arrangement will be payable following the conclusion of 2026, subject to certification of achievement levels by the Compensation Committee and Mr. Nash's continued employment with the Company through the payment date. This performance-based retention bonus is in addition to the special cash retention bonus for 2026 described above, as well as any amounts that may be earned by Mr. Nash under our regular 2026 annual cash bonus program.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 with respect to executive officers may be found under the heading "Information About Our Executive Officers" in Part I, Item 1 of this Annual Report.

We have adopted a code of conduct applicable to our principal executive, financial and accounting officers and all persons performing similar functions. A copy of our code of conduct is available on our principal corporate website at www.outsetmedical.com in the Investors section under "Corporate Governance." We intend to post any required disclosures regarding an amendment to, or waiver from, a provision of our code of conduct on the same website.

We have adopted an insider trading policy which sets forth policies and procedures that govern the purchase, sale and other disposition of our securities by directors, officers and employees. We believe these policies and procedures are reasonably designed to promote compliance with insider trading laws, rules and regulations and listing standards applicable to the Company. A copy of our Insider Trading Policy is filed with this Annual Report on Form 10-K as Exhibit 19.1.

The remaining information required by this Item 10 is incorporated by reference from the sections entitled "*Board and Corporate Governance Matters," "Audit Matters"* and "*Delinquent Section 16(a) Reports*" to be included in our definitive proxy statement to be filed with the Securities and Exchange Commission in connection with our 2026 Annual Meeting of Stockholders within 120 days of our fiscal year ended December 31, 2025 (the Proxy Statement).

Item 11. Executive Compensation.

The information required by this Item 11 will be set forth in the sections entitled "*Director Compensation*," "*Executive Compensation,*" "*Compensation Committee Report,*" and "*Compensation Committee Interlocks and Insider Participation*" to be included in the Proxy Statement and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item 12 will be set forth in the section entitled "*Security Ownership of Certain Beneficial Owners and Management*" and "*Equity Plan Information*" to be included in the Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item 13 will be set forth in the sections entitled "*Certain Relationships and Related Party Transactions*" and "*Director Independence*" to be included in the Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

Our independent registered public accounting firm is KPMG LLP, San Francisco, CA, Auditor ID: 185.

The information required by this Item 14 will be set forth in the section entitled "*Audit Matters*" to be included in the Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

We have filed the following documents as part of this Annual Report:

1. Financial Statements: The financial statements included in "Index to Financial Statements" in Part II, Item 8 are filed as part of this Annual Report.
2. Exhibits: The exhibits listed in the accompanying Exhibit Index are filed or incorporated by reference as part of this Annual Report.

Item 16. Form 10-K Summary.

None.

Exhibit Index

Exhibit Number	Description	Incorporation by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of Outset Medical, Inc.	S-1/A	333-248225	3.1	September 9, 2020
3.2	Amended and Restated Bylaws of Outset Medical, Inc.	S-1/A	333-248225	3.2	September 9, 2020
3.3	Amendment No. 1 to Amended and Restated Bylaws of Outset Medical, Inc., dated January 23, 2025	8-K	001-39513	3.1	January 24, 2025
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series A Non-Voting Convertible Preferred Stock	8-K	001-39513	3.1	January 8, 2025
3.5	Certificate of Correction of the Certificate of Designation of Preferences, Rights and Limitations of Series A Non-Voting Convertible Preferred Stock	8-K	001-39513	3.1	March 11, 2025
3.6	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Outset Medical, Inc.	8-K	001-39513	3.1	March 20, 2025
4.1	Form of Common Stock Certificate	S-1/A	333-248225	4.1	September 9, 2020
4.2	Warrant Certificate, dated January 8, 2025, issued by Outset Medical, Inc. to Perceptive Credit Holdings IV, LP	8-K	001-39513	4.1	January 8, 2025
4.3*	Description of Outset Medical, Inc.'s Securities Registered Pursuant to Section 12 of the Exchange Act				
10.1†	Form of Indemnification Agreement	S-1/A	333-248225	10.1	September 9, 2020
10.2†	Outset Medical, Inc. 2010 Equity Incentive Plan and related form agreements	S-1	333-248225	10.2	August 21, 2020
10.3†	Outset Medical, Inc. 2019 Equity Incentive Plan and related form agreements	S-1	333-248225	10.3	August 21, 2020
10.4†	Outset Medical, Inc. 2020 Equity Incentive Plan, as amended and restated	10-Q	001-39513	10.1	August 7, 2025
10.5†	Form of Stock Option Grant Notice and Option Agreement for Outset Medical, Inc. 2020 Equity Incentive Plan	10-K	001-39513	10.5	March 22, 2021
10.6†	Form of Restricted Stock Unit Award Grant Notice and Award Agreement for Outset Medical, Inc. 2020 Equity Incentive Plan	10-K	001-39513	10.6	March 22, 2021
10.7†	Form of Restricted Stock Award Grant Notice and Award Agreement for Outset Medical, Inc. 2020 Equity Incentive Plan	10-K	001-39513	10.7	March 22, 2021
10.8†	Form of Performance Stock Unit Award Grant Notice and Award Agreement for Outset Medical, Inc. 2020 Equity Incentive Plan	10-K	001-39513	10.8	March 22, 2021
10.9†*	Outset Medical, Inc. Employee Stock Purchase Plan, as amended and restated				
10.10†*	Outset Medical, Inc. Inducement Plan				
10.11†	Employment Agreement by and between Outset Medical and Leslie Trigg, dated as of February 23, 2015	S-1	333-248225	10.6	August 21, 2020
10.12†	Offer Letter between Outset Medical, Inc. and Renee Gaeta, dated as of May 31, 2025	10-Q	001-39513	10.3	August 7, 2025
10.13	Form of Amended and Restated Change in Control and Severance Agreement for Chief Executive Officer	10-K	001-39513	10.11	February 21, 2024
10.14	Form of Amended and Restated Change in Control and Severance Agreement for non-Chief Executive Officer executive officers	10-K	001-39513	10.12	February 21, 2024
10.15#	Lease by and between WH Silicon Valley IV LP and Outset Medical, Inc., dated as of September 19, 2019	S-1	333-248225	10.10	August 21, 2020
10.16#	Sublease Agreement by and among Inmobiliaria IAMSA, S.A. de C.V. (Sublessor), Baja Fur S.A. de C.V. (Sublessee) and Outset Medical, Inc. (Guarantor), dated as of May 5, 2020	S-1	333-248225	10.11	August 21, 2020

10.17#	First Amendment Agreement by and among Inmobiliaria IAMSA, S.A. de C.V. (Sublessor), Baja Fur S.A. de C.V. (Sublessee) and Outset Medical, Inc. (Guarantor), dated as of June 26, 2020	S-1	333-248225	10.12	August 21, 2020
10.18#	Guaranty by and between Inmobiliaria IAMSA, S.A. de C.V. and Outset Medical, Inc dated as of May 6, 2020	S-1	333-248225	10.13	August 21, 2020
10.19#	Manufacturing Services Agreement by and between TACNA Services, Inc. and Outset Medical, Inc. dated as of January 15, 2020	S-1	333-248225	10.17	August 21, 2020
10.20#	Amendment to Manufacturing Services Agreement by and between TACNA Services, Inc. and Outset Medical, Inc. effective as of February 12, 2024	10-Q	001-39513	10.2	May 9, 2024
10.21#	Authorized Reseller Agreement by and between SDV Office Systems, LLC dba SDV Medical and Outset Medical, Inc. dated as of October 14, 2019	S-1	333-248225	10.18	August 21, 2020
10.22#	Amendment 1 to the Authorized Reseller Agreement by and between SDV Office Systems, LLC dba SDV Medical and Outset Medical, Inc. dated as of March 26, 2020	S-1	333-248225	10.19	August 21, 2020
10.23#	Amendment 2 to the Authorized Reseller Agreement by and between SDV Office Systems, LLC dba SDV Medical and Outset Medical, Inc. dated as of May 6, 2020	S-1	333-248225	10.20	August 21, 2020
10.24#	Purchasing Agreement by and between HCA Management Services, L.P. and Outset Medical, Inc. dated as of May 1, 2020	S-1	333-248225	10.21	August 21, 2020
10.25#	Credit Agreement and Guaranty, dated as of January 3, 2025, by and among Outset Medical, Inc. as the borrower and Perceptive Credit Holdings IV, LP, as the initial lender and the administrative agent	8-K	001-39513	10.4	January 6, 2025
10.26	Form of Securities Purchase Agreement, dated as of January 3, 2025 between Outset Medical, Inc. and certain of the Investors	8-K	001-39513	10.1	January 6, 2025
10.27	Form of Securities Purchase Agreement, dated as of January 3, 2025 between Outset Medical, Inc. and certain members of management and certain directors	8-K	001-39513	10.2	January 6, 2025
10.28	Form of Registration Rights Agreement, dated as of January 3, 2025 between Outset Medical, Inc. and the Investors	8-K	001-39513	10.3	January 6, 2025
19.1	Outset Medical, Inc. Insider Trading Policy	10-K	001-39513	19.1	February 28, 2025
23.1*	Consent of KPMG LLP, independent registered public accounting firm				
24.1*	Power of Attorney (included on the signature page)				
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
97.1	Outset Medical, Inc. Policy on Recoupment of Incentive Compensation	10-K	001-39513	97.1	February 21, 2024
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH	Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Documents				
104	Cover Page formatted as inline XBRL and contained in Exhibits 101				

* Filed herewith

† Indicates a management contract or compensatory plan or arrangement.

Portions of the exhibit have been or will be excluded because it is both not material and is the type of information that the registrant treats as private or confidential.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Outset Medical, Inc.

Date: February 13, 2026

By: /s/ Leslie Trigg
Leslie Trigg
President and Chief Executive Officer; Chair of the Board

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Leslie Trigg and Renee Gaeta, and each of them, his or her true and lawful agent, proxy and attorney-in-fact, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed below by the following persons on behalf of the registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Leslie Trigg Leslie Trigg	President and Chief Executive Officer; Chair of the Board (*Principal Executive Officer*)	February 13, 2026
/s/ Renee Gaeta Renee Gaeta	Chief Financial Officer (*Principal Financial Officer and Principal Accounting Officer*)	February 13, 2026
/s/ D. Keith Grossman D. Keith Grossman	Lead Independent Director	February 13, 2026
/s/ Karen Drexler Karen Drexler	Director	February 13, 2026
/s/ Patrick T. Hackett Patrick T. Hackett	Director	February 13, 2026
/s/ Brent Lang Brent Lang	Director	February 13, 2026
/s/ Kevin O'Boyle Kevin O'Boyle	Director	February 13, 2026
/s/ Karen Prange Karen Prange	Director	February 13, 2026

Exhibit 4.3

DESCRIPTION OF REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following summary describes the capital stock of Outset Medical, Inc. (the "Company," "we," "us," and "our") and the material provisions of our amended and restated certificate of incorporation and our amended and restated bylaws, the amended and restated registration rights agreement to which we and certain stockholders are parties and of the General Corporation Law of the State of Delaware. Because the following is only a summary, it does not contain all of the information that may be important to you. For a complete description, you should refer to our amended and restated certificate of incorporation, amended and restated bylaws, and amended and restated registration rights agreement, copies of which are incorporated by reference as exhibits to our Annual Report on Form 10-K.

As of December 31, 2025, Outset Medical, Inc. ("Outset") had common stock, $0.001 par value per share, registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

General

Our amended and restated certificate of incorporation authorizes 300,000,000 shares of common stock, $0.001 par value per share, and 5,000,000 shares of preferred stock, $0.001 par value per share. A description of material terms and provisions of our amended and restated certificate of incorporation and amended and restated bylaws, as amended affecting the rights of holders of our capital stock is set forth below. The description is intended as a summary, and is qualified in its entirety by reference to our amended and restated certificate of incorporation and bylaws.

Common Stock

Dividend Rights

Subject to preferences that may apply to shares of preferred stock outstanding at the time, the holders of outstanding shares of our common stock are entitled to receive dividends out of funds legally available if our board of directors, in its discretion, determines to issue dividends and only then at the times and in the amounts that our board of directors may determine.

Voting Rights

The holders of our common stock are entitled to one vote per share. Stockholders do not have the ability to cumulate votes for the election of directors. Our amended and restated certificate of incorporation and bylaws provide for a classified board of directors consisting of three classes of approximately equal size, each serving staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms.

No Preemptive or Similar Rights

Our common stock is not entitled to preemptive rights and is not subject to redemption or sinking fund provisions.

Right to Receive Liquidation Distributions

Upon our liquidation, dissolution or winding-up, the assets legally available for distribution to our stockholders would be distributable ratably among the holders of our common stock and any participating preferred stock outstanding at that time, subject to prior satisfaction of all outstanding debt and liabilities and the preferential rights of and the payment of liquidation preferences, if any, on any outstanding shares of preferred stock.

Preferred Stock

Pursuant to our amended and restated certificate of incorporation, our board of directors is expressly authorized to issue from time to time preferred stock in one or more series pursuant to a resolution or resolutions providing for

such issue duly adopted by the board of directors, without any further vote or action by our stockholders. The board of directors is further authorized, subject to limitations prescribed by law, to fix by resolution or resolutions and to set forth in a certificate of designation filed pursuant to the DGCL the powers, designations, preferences and relative, participating, optional or other special rights, if any, and the qualifications, limitations or restrictions, if any, of any wholly unissued series of preferred stock, and the number of shares constituting any such series and the designation thereof, or any of the foregoing. Our board of directors is also authorized to increase (but not above the total number of authorized shares of the class) or decrease (but not below the number of shares of that series then outstanding) the number of shares of any series of preferred stock, without any further vote or action by our stockholders. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control and might adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. As of December 31, 2025, no shares of preferred stock were outstanding, and we have no present plan to issue any shares of preferred stock

Registration Rights

Pursuant to the terms of our January 2025 registration rights agreement (the "RRA"), we agreed to prepare and file with the SEC a registration statement that permits the resale or other disposition of shares by certain stockholders (the "Investors") of up to 14,389,000 shares of common stock issued upon conversion of the Series A Preferred Stock issued to such Investors pursuant to certain securities purchase agreements entered into in January 2025 and, subject to certain exceptions, use reasonable efforts to keep the registration statement effective under the Securities Act for so long as such securities registered for resale thereunder retain their character as Registrable Securities (as defined in the RRA).

We have also agreed, among other things, to indemnify each Investor and each person who controls each Investor, and each of their respective members, directors, officers, partners, employees, managers, agents, representatives and advisors from certain liabilities and pay all fees and expenses incident to our obligations under the RRA.

Anti-Takeover Provisions

The provisions of the DGCL, our amended and restated certificate of incorporation and our bylaws could have the effect of delaying, deferring or discouraging another person from acquiring control of our company. These provisions, which are summarized below, are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and encourage persons seeking to acquire control of our company to first negotiate with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Section 203 of the DGCL

We are subject to the provisions of Section 203 of the DGCL regulating corporate takeovers. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the date that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction, which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction, which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans in some instances, but not the outstanding voting stock owned by the interested stockholder; or

- at or after the time the stockholder became interested, the business combination was approved by our board and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock, which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance of transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Amended and Restated Certificate of Incorporation and Bylaw Provisions

Our amended and restated certificate of incorporation and our bylaws include a number of provisions that may have the effect of deterring hostile takeovers, or delaying or preventing changes in control of our management team or changes in our board of directors or our governance or policy, including the following:

Board Vacancies

Our amended and restated certificate of incorporation and bylaws authorize generally only our board of directors to fill vacant directorships resulting from any cause or created by the expansion of our board of directors. In addition, the number of directors constituting our board of directors may be set only by resolution adopted by a majority vote of our entire board of directors. These provisions prevent a stockholder from increasing the size of our board of directors and gaining control of our board of directors by filling the resulting vacancies with its own nominees.

Classified Board

Our amended and restated certificate of incorporation and bylaws provide that our board of directors is classified into three classes of directors. The existence of a classified board of directors could delay a successful tender offeror from obtaining majority control of our board of directors, and the prospect of that delay might deter a potential offeror.

Directors Removed Only for Cause

Our amended and restated certificate of incorporation provides that stockholders may remove directors only for cause.

Supermajority Requirements for Amendments of Our Amended and Restated Certificate of Incorporation and Bylaws

Our amended and restated certificate of incorporation further provides that the affirmative vote of holders of at least two-thirds of the voting power of our outstanding common stock is required to amend certain provisions of our amended and restated certificate of incorporation, including provisions relating to the classified board, the size of the

board of directors, removal of directors, special meetings, actions by written consent and designation of our preferred stock. The affirmative vote of holders of at least two-thirds of the voting power of our outstanding common stock is required to amend or repeal our bylaws, although our bylaws may be amended by a simple majority vote of our board of directors.

Stockholder Action; Special Meetings of Stockholders

Our amended and restated certificate of incorporation provides that our stockholders may not take action by written consent, but may only take action at annual or special meetings of our stockholders. As a result, holders of our capital stock are not able to amend our bylaws or remove directors without holding a meeting of our stockholders called in accordance with our bylaws. Our amended and restated certificate of incorporation and our bylaws provide that special meetings of our stockholders may be called only by a majority of our board of directors, the chairperson of our board of directors, our chief executive officer, our president or the lead independent director, thus prohibiting a stockholder from calling a special meeting. These provisions might delay the ability of our stockholders to force consideration of a proposal or for stockholders to take any action, including the removal of directors.

Advance Notice Requirements for Stockholder Proposals and Director Nominations

Our bylaws provide advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders or to nominate candidates for election as directors at our annual meeting of stockholders. To be timely, a stockholder's notice generally must be delivered to us not later than the close of business on the 90th day nor earlier than the close of business on the 120th day prior to the first anniversary of the preceding year's annual meeting of stockholders. Our bylaws also specify certain requirements regarding the form and content of a stockholder's notice. With respect to nominations of persons for election to our board of directors, the notice shall provide information about the nominee, including, among other things, name, age, address, principal occupation, ownership of our capital stock and whether they meet applicable independence requirements. With respect to the proposal of other business to be considered by our stockholders at an annual meeting, the notice shall provide a brief description of the business desired to be brought before the meeting, the text of the proposal or business, the reasons for conducting such business at the meeting and any material interest in such business by such stockholder and any beneficial owners and associated persons on whose behalf the notice is made, or the proposing persons. In addition, a stockholder's notice must set forth certain information related to the proposing persons, including, among other things:

- the name and address of the proposing persons;
- information as to the ownership by the proposing persons of our capital stock and any derivative interest or short interest in any of our securities held by the proposing persons;
- information as to any material relationships and interest between the proposing persons and us, any of our affiliates and any of our principal competitors;
- a representation that the stockholder is a holder of record of our stock entitled to vote at that meeting and that the stockholder intends to appear in person or by proxy at the meeting to propose such nomination or business; and
- a representation whether the proposing persons intend or are part of a group which intends to deliver a proxy statement or form of proxy to holders of at least the percentage of our outstanding capital stock required to elect the nominee or carry the proposal.

These provisions may preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders. We expect that these provisions might also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company.

No Cumulative Voting

The DGCL provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless a corporation's certificate of incorporation provides otherwise. Our amended and restated certificate of incorporation and bylaws do not provide for cumulative voting.

Issuance of Undesignated Preferred Stock

Our board has the authority, without further action by the stockholders, to issue up to 5,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our board of directors. The existence of authorized but unissued shares of preferred stock enables our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise.

Exclusive Forum

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf under Delaware law, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action arising pursuant to any provision of the DGCL or our amended and restated certificate of incorporation or bylaws, (4) any other action asserting a claim that is governed by the internal affairs doctrine or (5) any other action asserting an "internal corporate claim," as defined in Section 115 of the DGCL, shall be the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) in all cases subject to the court having jurisdiction over indispensable parties named as defendants. These exclusive-forum provisions do not apply to claims under the Securities Act or the Exchange Act. Any person or entity purchasing or otherwise acquiring any interest in our securities shall be deemed to have notice of and consented to this provision. Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against us or our directors and officers.

To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. However, our amended and restated certificate of incorporation contains a federal forum provision which provides that unless the Company consents in writing to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Equiniti Trust Company, LLC. The transfer agent's address is Equiniti Trust Company, LLC, 55 Challenger Road, 2nd Floor, Ridgefield Park, NJ 07660, and its telephone number is (800) 937-5449.

Exchange Listing

Our common stock is listed on the Nasdaq Global Select Market under the symbol "OM."

Exhibit 10.9

OUTSET MEDICAL, INC.

EMPLOYEE STOCK PURCHASE PLAN

ADOPTED BY THE BOARD OF DIRECTORS: SEPTEMBER 2, 2020
APPROVED BY THE STOCKHOLDERS: SEPTEMBER 7, 2020
APPROVED BY THE STOCKHOLDERS: JUNE 2, 2025 (IN RESPECT OF AMENDMENT 2025-1)

TERMINATION DATE: SEPTEMBER 2, 2030

(AMENDED AND RESTATED, EFFECTIVE DECEMBER 16, 2025)

1. PURPOSE. The purpose of the Outset Medical, Inc. Employee Stock Purchase Plan (this "Plan") is to provide eligible Employees of the Company and Participating Subsidiaries with a convenient means of acquiring an equity interest in the Company through payroll deductions and other contributions in order to enhance such employees' sense of participation in the affairs of the Company. This Plan is amended and restated as set forth herein and such amendment and restatement shall apply to Offering Periods, in effect as of, and beginning on or after, December 16, 2025.

This Plan includes two components: (a) a component intended to qualify as an "employee stock purchase plan" under Section 423 of the Code (the "423 Component"), the provisions of which shall be construed so as to extend and limit participation in a uniform and nondiscriminatory manner consistent with the requirements of Section 423 of the Code; and (b) a component that does not qualify as an "employee stock purchase plan" under Section 423 of the Code (the "Non-423 Component"), under which options shall be granted pursuant to rules, procedures or sub-plans adopted by the Committee designed to achieve tax, securities laws or other objectives for eligible Employees, the Company and its Participating Subsidiaries. Except as otherwise provided in this Plan, the Non-423 Component will operate and be administered in the same manner as the 423 Component.

2. DEFINITIONS. As used herein, the terms set forth below have the meanings assigned to them in this Section 2 and shall include the plural as well as the singular.

"1933 Act" means the Securities Act of 1933, as amended.

"1934 Act" means the Securities Exchange Act of 1934, as amended.

"Board" means the Board of Directors of Outset Medical, Inc.

"Business Day" shall mean a day on which NASDAQ is open for trading.

"Brokerage Account" means the account in which the Purchased Shares are held.

"Code" means the Internal Revenue Code of 1986, as amended.

"Committee" means the Compensation Committee of the Board, or the designee of the Compensation Committee.

"Company" means Outset Medical, Inc., a Delaware corporation.

"Compensation" means base pay, commissions, overtime, and vacation, holiday and sick pay. Compensation does not include: (1) income related to stock option awards, stock grants and other equity incentive awards, (2) expense reimbursements, (3) relocation-related payments, (4) benefit plan payments (including but not limited to short-term disability pay, long-term disability pay, maternity pay, military pay, tuition reimbursement and adoption assistance), (5) accrued but unpaid compensation for a deceased Participant, (6) income from non-cash and fringe benefits, (7) severance payments, (8) annual, quarterly, monthly and other cash bonuses, and (9) other forms of compensation not specifically listed herein.

"Employee" means any individual who is a common law employee of the Company or any other Participating Subsidiary. For purposes of the Plan, the employment relationship shall be treated as continuing intact while the individual is on sick leave or other leave of absence approved by the Company or the Participating Subsidiary, as appropriate, and only to the extent permitted under Section 423 of the Code with respect to the 423 Component. For purposes of the Plan, an individual who performs services for the Company or a Participating Subsidiary pursuant to an agreement (written or oral) that classifies such individual's relationship with the Company or a Participating Subsidiary as other than a common law employee shall not be considered an "employee" with respect to any period preceding the date on which a court or administrative agency issues a final determination that such individual is an "employee."

"Enrollment Date" means the first Business Day of each Offering Period.

"Exercise Date" means the last Business Day of each Offering Period (or, if determined by the Committee, the Purchase Period if different from the Offering Period).

"Fair Market Value" on or as of any date means the official closing price for a Share as reported on NASDAQ on the relevant valuation date or, if no official closing price is reported on such date, on the preceding day on which an official closing price is reported on NASDAQ was reported; or, if the Shares are no longer listed on NASDAQ, the closing price for Shares as reported on the official website for such other exchange on which the Shares are listed. Notwithstanding the foregoing, if the first Offering Period commences on the first Business Day on or after the date on which the Securities and Exchange Commission declares the Company's Registration Statement to be effective, the Fair Market Value for purposes of the Enrollment Date for such first Offering Period shall be the initial price to the public as set forth in the final prospectus included in the Registration Statement.

"Offering Period" means each six-month period or, effective March 1, 2022, each 24-month period, beginning the first Business Day of March and the first Business Day of September or such other period designated by the Committee; provided that in no event shall an Offering Period exceed 27 months, with the commencement of the first Offering Period to be determined by the Committee. Notwithstanding anything herein to the contrary, the Committee may establish an Offering Period with multiple Purchase Periods within such Offering Period.

"Option" means an option granted under this Plan that entitles a Participant to purchase Shares.

"Participant" means an Employee who satisfies the requirements of Sections 3 and 5 of the Plan.

"Participating Subsidiary" means each Subsidiary other than those that the Committee or the Board has excluded from participation in the Plan.

"Plan" means this Outset Medical, Inc. Employee Stock Purchase Plan, as amended from time to time.

"Purchase Account" means the account used to purchase Shares through the exercise of Options under the Plan.

"Purchase Period" means the period designated by Committee during which payroll deductions and other contributions of the Participants are accumulated under the Plan. A Purchase Period may coincide with an entire Offering Period or there may be multiple Purchase Periods within an Offering Period, as determined by the Committee prior to the commencement of the applicable Offering Period.

"Purchase Price" shall be the lesser of: (i) 85% percent of the Fair Market Value of a Share on the applicable Enrollment Date for an Offering Period and (ii) 85% percent of the Fair Market Value of a Share on the applicable Exercise Date; provided, however, that the Committee may determine a different per share Purchase Price provided that such per share Purchase Price is communicated to Participants prior to the beginning of the Offering Period and provided that in no event shall such per share Purchase Price be less than the lesser of (i) 85% of the Fair Market Value of a Share on the applicable Enrollment Date or (ii) 85% of the Fair Market Value of a Share on the Exercise Date.

"Purchased Shares" means the full Shares issued or delivered pursuant to the exercise of Options under the Plan.

"Registration Statement" means the registration statement on Form S-1 filed with the Securities and Exchange Commission for the initial public offering of the Common Stock.

"Shares" means shares of the common stock of the Company.

"Subsidiary" means an entity, domestic or foreign, of which not less than 50% of the voting equity is held by the Company or a Subsidiary, whether or not such entity now exists or is hereafter organized or acquired by the Company or a Subsidiary; provided such entity is also a "subsidiary" within the meaning of Section 424 of the Code.

"Termination Date" means (i) the date on which a Participant terminates employment or on which the Participant ceases to provide services to the Company or a Subsidiary as an employee or as otherwise required under Section 423 with respect to the 423 Component or (ii) subject to Section 423 of the Code with respect to the 423 Component, the date on which the Participant's employment is determined to have been terminated for purposes of the Plan by the Committee. The Termination Date specifically does not include any period following that date which the Participant may be eligible for or in receipt of other payments from the Company including in lieu of notice or termination or severance pay or as wrongful dismissal damages.

3. Eligibility.

(a) Only Employees of the Company or a Participating Subsidiary (i) whose customary employment is 20 hours or more per week and (ii) whose customary employment is for five months or more in any calendar year shall be eligible to be granted Options under the Plan and, in no event may a Participant be granted an Option under the Plan following his or her Termination Date.

(b) Any provisions of the Plan to the contrary notwithstanding, no Employee shall be granted an Option under the 423 Component of the Plan if (i) immediately after the grant, such Employee (or any other person whose stock would be attributed to such Employee pursuant to Section 424(d) of the Code) would own capital stock of the Company and/or hold outstanding Options or options to purchase stock possessing 5% or more of the total combined voting power or value of all classes of stock of the Company or of any of its Subsidiaries or (ii) such Option would permit his or her rights to purchase stock under all employee stock purchase plans (described in Section 423 of the Code) of the Company and its Subsidiaries to accrue at a rate that exceeds $25,000 of the Fair Market Value of such stock (determined at the time each such Option is granted) for each calendar year in which such Option is outstanding at any time.

(c) Except as otherwise determined by the Committee prior to the commencement of an Offering Period or as otherwise effected pursuant to an amendment that is made to this Plan in accordance with Section 19 hereof, no Participant may purchase more than 5,000 Shares during any Offering Period; provided that beginning with any Offering Period commencing after April 9, 2025, the Committee has determined that (A) no more than 4,000 Shares may be purchased during any such Offering Period, and (B) to the extent there are multiple Purchase Periods within any such Offering Period, the number of Shares that may be purchased with respect to any such Purchase Period shall not exceed the 4,000 Shares described above *divided by* the total number of Purchase Periods within such Offering Period (the "2025 Share Purchase Limit"); provided, further, that beginning with any Purchase Period commencing on or after March 1, 2026 (the "Commencement Date") and pursuant to this Plan as currently amended and restated, the maximum number of Shares that may be purchased by a Participant in respect of such Purchase Period shall not exceed 800 Shares *divided by* the total number of Purchase Periods within the applicable Offering Period (i.e., the Offering Period to which such Purchase Periods relate), including any Offering Period that is in effect as of the Commencement Date (the "2026 Share Purchase Limit"). For clarity, the 2026 Share Purchase Limit is intended to operate as a prospective per-Purchase-Period limitation, such that the maximum number of Shares that may be purchased during any applicable Offering Period shall be reduced solely by application of such per-Purchase-Period limitation, it being understood that pursuant to such per-Purchase-Period limitation, no more than an aggregate of 800 Shares may be purchased by a Participant during any Offering Period commencing on or after the Commencement Date. For the avoidance of doubt, the applicable provisions in the Plan, as set forth in the prior amended and restated versions thereof and relating to the number of Shares that may be purchased by a Participant, shall apply with respect to any Purchase Period that is in effect prior to the Commencement Date.

4. Exercise of an Option. Options shall be exercised on behalf of Participants in the Plan every Exercise Date, using (i) payroll deductions that have accumulated in the Participants' Purchase Accounts during the immediately preceding Purchase Period or that have been retained from a prior Purchase Period pursuant to Section 8 hereof and (ii) additional contributions to the Company made pursuant to the Cashless Participation Program approved by the Committee.

5. Participation.

(a) Unless otherwise determined by the Committee prior to the commencement of an Offering Period and in accordance with Section 423 of the Code with respect to the 423 Component, an Employee shall be eligible to participate on the first Enrollment Date that occurs after such Employee's first date of employment with the Company or a Participating Subsidiary; provided, that such Employee properly completes and submits an election form by the deadline prescribed by the Company.

(b) An Employee who does not become a Participant on the first Enrollment Date on which he or she is eligible may thereafter become a Participant on any subsequent Enrollment Date by properly completing and submitting an election form by the deadline prescribed by the Company.

(c) Payroll deductions for a Participant shall commence on the first payroll date following the Enrollment Date and shall end on the last payroll date in the Purchase Period to which such authorization is applicable, unless sooner terminated by the Participant as provided in Section 12 hereof.

6. Payroll Deductions and Other Contributions.

(a) A Participant shall elect to have payroll deductions made during a Purchase Period equal to no less than 1% of the Participant's Compensation up to a maximum of 15% (or such greater amount as the Committee establishes from time to time). The amount of such payroll deductions shall be in whole percentages. All payroll deductions made by a Participant shall be credited to his or her Purchase Account. In addition to such payroll deductions credited to a Participant's Purchase Account during the Purchase Period, Participants other than executive officers of the Company, within the meaning of the 1934 Act, may elect to purchase Shares pursuant to a cashless participation program approved by the Committee (the "Cashless Participation Program") by designating an additional amount to be contributed to such Participant's Purchase Account at the end of such Purchase Period. In addition, notwithstanding any provisions to the contrary in the Plan, the Committee may allow participants to make other contributions under the Plan via cash, check, or other means instead of payroll deductions if payroll deductions are not permitted under applicable local law, and for any Offering Period under the 423 Component, the Committee determines that such other contributions are permissible under Section 423 of the Code.

(b) Except as otherwise determined by the Committee prior to the commencement of an Offering Period, a Participant may not increase the rate of payroll deductions or other contributions to be made to the Plan during a Purchase Period. A Participant may decrease the rate of payroll deductions during a Purchase Period by properly completing and submitting an election change form in accordance with the procedures prescribed by the Committee and/or any other forms required by the Committee and by following any other procedures as may be established by the Committee, in which case the new rate shall become effective as soon as administratively practicable after the Participant elects such change and shall continue for the remainder of the Offering Period unless changed as described below. Such change in the rate of payroll deductions may be made at any time during a Purchase Period, but not more than one (1) change may be made effective during any Purchase Period, except that a Participant may elect at any time during a Purchase Period, regardless of whether the Participant previously decreased his or her payroll deduction percentage, to reduce his or her contribution percentage to 0% and such change shall become effective as soon as administratively practicable after the Participant elects such change and shall continue for the remainder of the Offering Period unless changed as described below. If a Participant reduces his or her payroll deduction percentage to 0%, then any election to purchase Shares pursuant to the Cashless Participation Program shall automatically terminate. A Participant may change his or her payroll deduction percentage or additional contribution amount under subsection (a) above for any subsequent Purchase Period by properly completing and submitting an election change form in accordance with the procedures prescribed by the Committee. The change in amount shall be effective as of the first Enrollment Date following the date of filing of the election change form. Unless otherwise determined by the Committee prior to the commencement of an Offering Period, a payroll deduction election and additional contribution election will automatically apply to the next Offering Period, unless otherwise cancelled or changed by the Participant prior to the commencement of such Offering Period.

(c) Notwithstanding the foregoing, to the extent necessary to comply with Section 423(b)(8) of the Code and Section 3(b) hereof, a Participant's payroll deduction and additional contribution elections may be decreased to 0% at any time during an Offering Period. Payroll deductions and additional contributions shall recommence at the rate provided in such Participant's election form at the beginning of the first Offering Period which is scheduled to end in the following calendar year, unless terminated by the Participant as provided in Section 12 hereof.

7. Grant of Option. On the applicable Enrollment Date, each Participant in an Offering Period shall be granted an Option to purchase on the applicable Exercise Date a number of full Shares determined by dividing such Participant's payroll deductions and additional contributions accumulated on or before such Exercise Date and retained in the Participant's Purchase Account as of the applicable Exercise Date by the applicable Purchase Price; provided that in no event will a Participant be permitted to purchase during each Offering Period or Purchase Period (as the case may be) more than a fixed number shares of Common Stock in an amount that the Committee may establish from time to time pursuant to Section 3(b) hereof.

8. Exercise of Option. A Participant's Option for the purchase of Shares shall be exercised automatically on the Exercise Date, and the maximum number of Shares subject to the Option shall be purchased for such Participant at the applicable Purchase Price with the accumulated payroll deductions and additional contributions in his or her Purchase Account. If the Fair Market Value of a Share on the first day of the current Offering Period in which a participant is enrolled is higher than the Fair Market Value of a Share on the first day of any subsequent Offering Period, the Company may establish procedures to automatically enroll such participant in the subsequent Offering Period and any funds accumulated in a participant's account prior to the first day of such subsequent Offering Period will be applied to the purchase of shares on the Exercise Date immediately prior to the first day of such subsequent Offering Period. A participant does not need to file any forms with the Company to be automatically enrolled in the subsequent Offering Period.

No fractional Shares shall be purchased; any payroll deductions and other contributions accumulated in a Participant's Purchase Account which are not sufficient to purchase a full Share shall be retained in the Purchase Account for the next subsequent Purchase Period, subject to earlier withdrawal by the Participant as provided in Section 12 hereof. All other payroll deductions and other contributions accumulated in a Participant's Purchase Account and not used to purchase Shares on an Exercise Date shall be distributed to the Participant. During a Participant's lifetime, a Participant's Option is exercisable only by him or her. The Company shall satisfy the exercise of all Participants' Options for the purchase of Shares through (a) the issuance of authorized but unissued

Shares, (b) the transfer of treasury Shares, (c) the purchase of Shares on behalf of the applicable Participants on the open market through an independent broker and/or (d) a combination of the foregoing.

9. **Issuance of Stock.** The Shares purchased by each Participant shall be issued in book entry form and shall be considered to be issued and outstanding to such Participant's credit as of the end of the last day of each Purchase Period. The Committee may permit or require that shares be deposited directly in a Brokerage Account with one or more brokers designated by the Committee or to one or more designated agents of the Company, and the Committee may use electronic or automated methods of share transfer. The Committee may require that Shares be retained with such brokers or agents for a designated period of time and/or may establish other procedures to permit tracking of disqualifying dispositions of such shares, and may also impose a transaction fee with respect to a sale of Shares issued to a Participant's credit and held by such a broker or agent. The Committee may permit Shares purchased under the Plan to participate in a dividend reinvestment plan or program maintained by the Company, and establish a default method for the payment of dividends.

10. **Approval by Stockholders.** Notwithstanding the above, the Plan is expressly made subject to the approval of the stockholders of the Company within 12 months before or after the date the Plan is adopted by the Board. Such stockholder approval shall be obtained in the manner and to the degree required under applicable federal and state law. If the Plan is not so approved by the stockholders within 12 months before or after the date the Plan is adopted by the Board, this Plan shall not come into effect.

11. **Administration.**

(a) Powers and Duties of the Committee. The Plan shall be administered by the Committee. Subject to the provisions of the Plan, Section 423 of the Code and the regulations thereunder with respect to the 423 Component, the Committee shall have the discretionary authority to determine the time and frequency of granting Options, the duration of Offering Periods and Purchase Periods, the terms and conditions of the Options and the number of Shares subject to each Option. The Committee shall also have the discretionary authority to do everything necessary and appropriate to administer the Plan, including, without limitation, interpreting the provisions of the Plan (but any such interpretation shall not be inconsistent with the provisions of Section 423 of the Code with respect to the 423 Component). All actions, decisions and determinations of, and interpretations by the Committee with respect to the Plan shall be final and binding upon all Participants and upon their executors, administrators, personal representatives, heirs and legatees. No member of the Board or the Committee shall be liable for any action, decision, determination or interpretation made in good faith with respect to the Plan or any Option granted hereunder. With respect to the 423 Component, an Offering Period shall be administered so as to ensure that all Participants have the same rights and privileges as provided by Section 423(b)(5) of the Code.

(b) Administrator. The Company, Board or the Committee may engage the services of one or more brokerage firms or other companies to perform certain ministerial and procedural duties under the Plan including, but not limited to, mailing and receiving notices contemplated under the Plan, determining the number of Purchased Shares for each Participant, maintaining or causing to be maintained the Purchase Account and the Brokerage Account, disbursing funds maintained in the Purchase Account or proceeds from the sale of Shares through the Brokerage Account, and filing with the appropriate tax authorities proper tax returns and forms (including information returns) and providing to each Participant statements as required by law or regulation.

(c) Indemnification. Each person who is or shall have been (a) a member of the Board, (b) a member of the Committee, or (c) an officer or employee of the Company to whom authority was delegated in relation to this Plan, shall be indemnified and held harmless by the Company against and from any loss, cost, liability or expense that may be imposed upon or reasonably incurred by him or her in connection with or resulting from any claim, action, suit or proceeding to which he or she may be a party or in which he or she may be involved by reason of any action taken or failure to act under the Plan and against and from any and all amounts paid by him or her in settlement thereof, with the Company's approval, or paid by him or her in satisfaction of any judgment in any such claim, action, suit or proceeding against him or her; provided, however, that he or she shall give the Company an opportunity, at its own expense, to handle and defend the same before he or she undertakes to handle and defend it on his or her own behalf, unless such loss, cost, liability or expense is a result of his or her own willful misconduct or except as expressly provided by statute.

The foregoing right of indemnification shall not be exclusive of any other rights of indemnification to which such persons may be entitled under the Company's certificate of incorporation or bylaws, any contract with the Company, as a matter of law, or otherwise, or of any power that the Company may have to indemnify them or hold them harmless.

12. Withdrawal. A Participant may withdraw from the Plan by properly completing and submitting to the Company a withdrawal form in accordance with the procedures prescribed by the Committee, which must be submitted prior to the date specified by the Committee before the last day of the applicable Offering Period. Upon withdrawal, any payroll deductions credited to the Participant's Purchase Account prior to the effective date of the Participant's withdrawal from the Plan will be returned to the Participant. No further payroll deductions or additional contributions for the purchase of Shares will be made during subsequent Offering Periods, unless the Participant properly completes and submits an election form, by the deadline prescribed by the Company. A Participant's withdrawal from an offering will not have any effect upon his or her eligibility to participate in the Plan or in any similar plan that may hereafter be adopted by the Company.

13. Termination of Employment. On the Termination Date of a Participant for any reason prior to the applicable Exercise Date, whether voluntary or involuntary, and including termination of employment due to retirement, death or as a result of liquidation, dissolution, sale, merger or a similar event affecting the Company or a Participating Subsidiary, the corresponding payroll deductions credited to his or her Purchase Account will be returned to him or her or, in the case of the Participant's death, to the person or persons entitled thereto under Section 16, and his or her Option will be automatically terminated.

14. Interest. No interest shall accrue on the payroll deductions or other contributions of a Participant in the Plan.

15. Stock.

(a) The stock subject to Options shall be common stock of the Company as traded on NASDAQ or on such other exchange as the Shares may be listed.

(b) Subject to adjustment upon changes in capitalization of the Company as provided in Section 18 hereof, the maximum number of Shares which shall be made available for sale under the Plan shall be 45,814 Shares. In addition, subject to adjustments upon changes in capitalization of the Company as provided in Section 18 hereof, the maximum number of Shares which shall be made available for sale under the Plan shall automatically increase on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2021, and continuing until (and including) the fiscal year ending December 31, 2030, with such annual increase equal to the lesser of (i) 45,814 Shares, (ii) 1% of the number of Shares issued and outstanding on December 31 of the immediately preceding fiscal year, and (iii) an amount determined by the Board; provided that, subject to the aforementioned adjustments upon changes in the capitalization of the Company, and effective as of the June 2, 2025 approval date of the stockholders of the Company at the Company's 2025 Annual Meeting of Stockholders, an additional 255,000 Shares shall be available for awards under the Plan. If, on a given Exercise Date, the number of Shares with respect to which Options are to be exercised exceeds the number of Shares then available under the Plan, the Committee shall make a pro rata allocation of the Shares remaining available for purchase in as uniform a manner as shall be practicable and as it shall determine to be equitable.

(c) A Participant shall have no interest or voting right in Shares covered by his or her Option until such Option has been exercised and the Participant has become a holder of record of Shares acquired pursuant to such exercise.

16. Designation of Beneficiary. The Committee may permit Participants to designate beneficiaries to receive any Purchased Shares or payroll deductions, if any, in the Participant's accounts under the Plan in the event of such Participant's death. Beneficiary designations shall be made in accordance with procedures prescribed by the Committee. If no properly designated beneficiary survives the Participant, the Purchased Shares and payroll deductions, if any, will be distributed to the Participant's estate.

17. Assignability of Options. Neither payroll deductions or other contributions credited to a Participant's Purchase Account nor any rights with regard to the exercise of an Option or to receive Shares under the Plan may be assigned, transferred, pledged or otherwise disposed of in any way (other than by will, the laws of descent and distribution or as provided in Section 16 hereof) by the Participant; provided that the Shares acquired pursuant to the terms of the Cashless Participation Program may be pledged and sold pursuant to the terms of the Cashless Participation Program. Any such attempt at assignment, transfer, pledge or other disposition shall be without effect, except that the Company may treat such act as an election to withdraw from an Offering Period in accordance with Section 12 hereof.

18. Adjustment of Number of Shares Subject to Options.

(a) Adjustment. Subject to any required action by the stockholders of the Company, the maximum number of securities available for purchase under the Plan, as well as the price per security and the number of securities covered by each Option under the Plan which has not yet been exercised shall be appropriately adjusted in the event of any a stock split, reverse stock split, stock dividend, combination or reclassification of the common stock of the Company, or any other increase or decrease in the number of Shares effected without receipt of consideration by the Company; provided, however, that conversion of any convertible securities of the Company shall not be deemed to have been "effected without receipt of consideration." Such adjustment shall be made by the Board or the Committee, whose determination in that respect shall be final, binding and conclusive. If any such adjustment would result in a fractional security being available under the Plan, such fractional security shall be disregarded. Except as expressly provided herein, no issuance by the Company of shares of stock of any class, or securities convertible into shares of stock of any class, shall affect, and no adjustment by reason thereof shall be made with respect to, the number or price of Shares subject to an Option. With respect to the 423 Component, the Options granted pursuant to the Plan shall not be adjusted in a manner that causes the Options to fail to qualify as options issued pursuant to an "employee stock purchase plan" within the meaning of Section 423 of the Code.

(b) Dissolution or Liquidation. In the event of the proposed dissolution or liquidation of the Company, any Offering Period then in progress will terminate immediately prior to the consummation of such proposed action, unless otherwise provided by the Board, and the Board may either provide for the purchase of Shares as of the date on which such Offering Period terminates or return to each Participant the payroll deductions credited to such Participant's Purchase Account.

(c) Merger or Asset Sale. In the event of a proposed sale of all or substantially all of the assets of the Company, or the merger of the Company with or into another corporation, each outstanding Option shall be assumed or an equivalent option substituted by the successor corporation or a parent or subsidiary of the successor corporation, unless the Board determines, in the exercise of its sole discretion, that in lieu of such assumption or substitution to either terminate all outstanding Options and return to each Participant the payroll deductions credited to such Participant's Purchase Account or to provide for the Offering Period in progress to end on a date prior to the consummation of such sale or merger.

19. Amendments or Termination of the Plan.

(a) The Board or the Committee may at any time and for any reason amend, modify, suspend, discontinue or terminate the Plan without notice; provided that no Participant's existing rights in respect of existing Options are adversely affected thereby. To the extent necessary to comply with Section 423 of the Code (or any other applicable law, regulation or stock exchange rule), the Company shall obtain stockholder approval in such a manner and to such a degree as required.

(b) Without stockholder consent and without regard to whether any Participant rights may be considered to have been "adversely affected," the Board or the Committee shall be entitled to change the Purchase Price, Offering Periods, Purchase Periods, eligibility requirements, limit or increase the frequency and/or number of changes in the amount withheld during a Purchase Period, establish the exchange ratio applicable to amounts withheld in a currency other than U.S. dollars, permit payroll withholding or other contributions in an amount less than or greater than the amount designated by a Participant in order to adjust for delays or mistakes in the Company's processing of properly completed withholding elections, establish reasonable waiting and adjustment periods and/or accounting and crediting procedures to ensure that amounts applied toward the purchase of Shares for each Participant properly correspond with amounts withheld from the Participant's Compensation, and establish such other limitations or procedures as the Board or the Committee determines in its sole discretion advisable which are consistent with the Plan; provided, however, that changes to (i) the Purchase Price, (ii) the Offering Period, (iii) the Purchase Period, (iv) the maximum percentage of Compensation that may be deducted pursuant to Section 6(a) or (v) the maximum number of Shares that may be purchased in a Purchase Period, shall not be effective until communicated to Participants in a reasonable manner, with the determination of such reasonable manner in the sole discretion of the Board or the Committee.

20. **No Other Obligations.** The receipt of an Option pursuant to the Plan shall impose no obligation upon the Participant to purchase any Shares covered by such Option. Nor shall the granting of an Option pursuant to the Plan constitute an agreement or an understanding, express or implied, on the part of the Company to employ the Participant for any specified period.

21. **Notices and Communication.** Any notice or other form of communication which the Company or a Participant may be required or permitted to give to the other shall be provided through such means as designated by the Committee, including but not limited to any paper or electronic method.

22. **Condition upon Issuance of Shares.**

(a) Shares shall not be issued with respect to an Option unless the exercise of such Option and the issuance and delivery of such Shares pursuant thereto shall comply with all applicable provisions of law, domestic or foreign, including, without limitation, the 1933 Act and the 1934 Act and the rules and regulations promulgated thereunder, and the requirements of any stock exchange upon which the Shares may then be listed, and shall be further subject to the approval of counsel for the Company with respect to such compliance.

(b) As a condition to the exercise of an Option, the Company may require the person exercising such Option to represent and warrant at the time of any such exercise that the Shares are being purchased only for investment and without any present intention to sell or distribute such Shares if, in the opinion of counsel for the Company, such a representation is required by any of the aforementioned applicable provisions of law.

23. **General Compliance.** The Plan will be administered and Options will be exercised in compliance with the 1933 Act, 1934 Act and all other applicable securities laws and Company policies, including without limitation, any insider trading policy of the Company.

24. **Term of the Plan.** The Plan shall become effective upon the earlier to occur of (i) its adoption by the Board and (ii) its approval by the stockholders of the Company (the earlier of such events, the "Effective Date"), and shall continue in effect until the earlier of (A) the termination of the Plan pursuant to Section 19 hereof and (B) the ten-year anniversary of the Effective Date, with no new Offering Periods commencing on or after such ten-year anniversary.

25. **Governing Law.** The Plan and all Options granted hereunder shall be construed in accordance with and governed by the laws of the State of Delaware without reference to choice of law principles and subject in all cases to the Code and the regulations thereunder.

26. **Non-U.S. Participants.** To the extent permitted under Section 423 of the Code, without the amendment of the Plan, the Company may provide for the participation in the Plan by Employees who are subject to the laws of foreign countries or jurisdictions on such terms and conditions different from those specified in the Plan as may in the judgment of the Company be necessary or desirable to foster and promote achievement of the purposes of the Plan and, in furtherance of such purposes the Company may make such modifications, amendments, procedures, subplans and the like as may be necessary or advisable to comply with provisions of laws of other countries or jurisdictions in which the Company or the Participating Subsidiaries operate or have employees. Each subplan shall constitute a separate "offering" under this Plan in accordance with Treas. Reg. §1.423-2(a) and, to the extent inconsistent with the requirements of Section 423, any such subplan shall be considered part of the Non-423 Component, and rights granted thereunder shall not be required by the terms of the Plan to comply with Section 423 of the Code.

27. **Section 409A.** The 423 Component is exempt from the application of Section 409A of the Code, and any ambiguities herein shall be interpreted to so be exempt from Section 409A of the Code. The Non-423 Component is intended to be exempt from the application of Section 409A of the Code under the short-term deferral exception and any ambiguities shall be construed and interpreted in accordance with such intent. In furtherance of the foregoing and notwithstanding any provision in the Plan to the contrary, if the Committee determines that an option granted under the Plan may be subject to Section 409A of the Code or that any provision in the Plan would cause an option under the Plan to be subject to Section 409A, the Committee may amend the terms of the Plan and/or of an outstanding option granted under the Plan, or take such other action the Committee determines is necessary or appropriate, in each case, without the participant's consent, to exempt any outstanding option or future option that may be granted under the Plan from or to allow any such options to comply with Section 409A of the Code, but only to the extent any such amendments or action by the Committee would not violate Section 409A of the Code. Notwithstanding the foregoing, the Company shall have no liability to a participant or any other party if the option under the Plan that is intended to be exempt from or compliant with Section 409A of the Code is not so exempt or compliant or for any action taken by the Committee with respect thereto.

Exhibit 10.10

OUTSET MEDICAL, INC.

INDUCEMENT PLAN

ADOPTED BY THE BOARD OF DIRECTORS: JANUARY 22, 2026
EFFECTIVE AS OF FEBRUARY 10, 2026

1. PURPOSE

The purpose of this Outset Medical, Inc. Inducement Plan (this "***Plan***") of Outset Medical, Inc., a Delaware corporation (the "***Company***"), is to advance the interests of the Company by providing a material inducement for the best available individuals to join the Company and its Subsidiaries as employees by affording such individuals an opportunity to acquire a proprietary interest in the Company.

2. CERTAIN DEFINITIONS.

2.1. "***2020 Plan***" means the Outset Medical, Inc. 2020 Equity Incentive Plan, as amended and restated from time to time.

2.2. "***Approval Date***" has the meaning set forth in Section 5 below.

2.3 "***Company***" has the meaning set forth in Section 1 above.

2.4 "***Effective Date***" has the meaning set forth in Section 5 below.

2.5 "***Eligible Persons***" means such individuals who are expected to become officers and other employees of the Company and its Subsidiaries as the Committee in its sole discretion may select from time to time and who are eligible to receive an award under this Plan pursuant to the Inducement Rules.

2.6 "***Inducement Rules***" has the meaning set forth in Section 3 below.

2.7 "***Plan***" has the meaning set forth in Section 1 above.

2.8 "***Share Limit***" has the meaning set forth in Section 4 below.

2.9 Defined terms not defined herein shall have the meaning set forth in the 2020 Plan.

3. ELIGIBILITY

This Plan shall be reserved solely for awards to Eligible Persons to whom the Company may issue Shares of common stock of the Company, par value $0.001 per share, without stockholder approval pursuant to Rule 5635(c)(4) of the NASDAQ Listing Rules, or any successor rule relating to inducement awards (the "***Inducement Rules****").*

4. SHARES AVAILABLE; GRANT OF AWARDS

The maximum number of Shares that may be delivered pursuant to awards granted to Eligible Persons under this Plan is 250,000 Shares (the "***Share Limit***"), which limit is subject to adjustment as contemplated by Section 5.7 of the 2020 Plan. Notwithstanding any provision in the 2020 Plan to the contrary, only those Shares which are subject to awards that are forfeited, expire, or are canceled without the issuance of Shares or other consideration shall again be available for issuance under the Plan.

5. EFFECTIVE DATE AND TERM OF PLAN

The adoption of this Plan occurred as of January 22, 2026 ("***Approval Date***") and the Plan is effective as of February 10, 2026 (the "***Effective Date***"). Unless earlier terminated by the Board, this Plan shall terminate at the close

of business on the day before the tenth anniversary of the Approval Date. After the termination of this Plan either upon such stated expiration date or its earlier termination by the Board, no additional awards may be granted under this Plan, but previously granted awards (and the authority of the Committee with respect thereto, including the authority to amend such awards to the extent permitted by the Inducement Rules) shall remain outstanding in accordance with their applicable terms and conditions and the terms and conditions of this Plan.

6. Other Terms

Except as expressly set forth herein, the terms of this Plan shall be identical to the terms of the 2020 Plan, and such terms from the 2020 Plan are incorporated by reference into this Plan (with such non-substantive changes as are necessary to reflect their usage in this Plan instead of the 2020 Plan); provided, however, that no Incentive Stock Options shall be awarded under this Plan. In the event of any conflict between the provisions in this Plan and those of the 2020 Plan, the provisions of this Plan shall govern.

* * *

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statements (Nos. 333-248903, 333-262927, 333-269746, 333-277236, 333-285437, and 333-287798) on Form S-8 and (No. 333-284902) on Form S-3 of our report dated February 13, 2026, with respect to the financial statements of Outset Medical, Inc. and the effectiveness of internal control over financial reporting.

/s/ KPMG LLP

San Francisco, California
February 13, 2026

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Leslie Trigg, certify that:

1. I have reviewed this annual report on Form 10-K of Outset Medical, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 13, 2026

By: /s/ Leslie Trigg
Leslie Trigg
Chief Executive Officer
(*Principal Executive Officer*)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Renee Gaeta, certify that:

1. I have reviewed this annual report on Form 10-K of Outset Medical, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 13, 2026

By: /s/ Renee Gaeta
Renee Gaeta
Chief Financial Officer
(*Principal Financial Officer*)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Outset Medical, Inc. (the "Company") on Form 10-K for the period ended December 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned certifies, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to her or his knowledge:

1. The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 13, 2026 By: /s/ Leslie Trigg
Leslie Trigg
Chief Executive Officer
(*Principal Executive Officer*)

Date: February 13, 2026 By: /s/ Renee Gaeta
Renee Gaeta
Chief Financial Officer
(*Principal Financial Officer*)

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.