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, 2023

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, 2023 (the last business day of the registrant's most recently completed second quarter) as reported by Nasdaq Global Market on that date was approximately $1.1 billion.

The number of shares of the registrant's common stock, par value $0.001 per share, outstanding as of February 15, 2024 was 50,505,683.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2023 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, 2023, are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein.

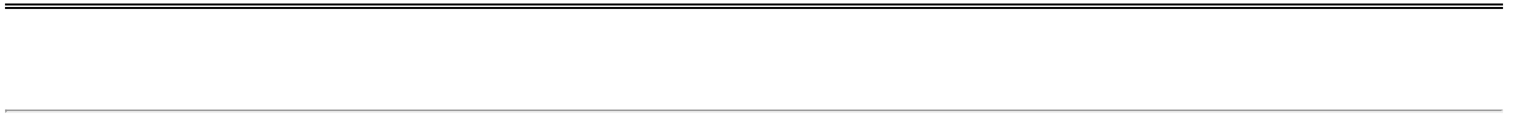

Table of Contents

		Page
PART I		
Item 1.	Business	3
Item 1A.	Risk Factors	21
Item 1B.	Unresolved Staff Comments	60
Item 1C.	Cybersecurity	60
Item 2.	Properties	63
Item 3.	Legal Proceedings	63
Item 4.	Mine Safety Disclosures	63
PART II		
Item 5.	Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	64
Item 6.	[Reserved]	65
Item 7.	Management’s Discussion and Analysis of Financial Condition and Results of Operations	66
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	75
Item 8.	Financial Statements and Supplementary Data	76
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	103
Item 9A.	Controls and Procedures	103
Item 9B.	Other Information	103
Item 9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	103
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	105
Item 11.	Executive Compensation	105
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	105
Item 13.	Certain Relationships and Related Transactions, and Director Independence	105
Item 14.	Principal Accounting Fees and Services	105
PART IV		
Item 15.	Exhibits, Financial Statement Schedules	106
Item 16	Form 10-K Summary	106

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 and revenue growth rate, cost of revenues, operating expenses, gross margin, capital expenditures, cash position, cash burn and our ability to achieve and maintain future profitability;
- 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;
- our expectations regarding the market sizes and growth potential for Tablo, including our estimates of annual spending on dialysis and the number of people affected by kidney failure in the United States, and the total addressable market opportunities for Tablo in the acute care and home settings;
- our planned expansion within the home dialysis market and our assumptions about the home market, including expected drivers of home dialysis adoption;
- any ongoing impact of macroeconomic factors on our business and results of operations, and on our customers and suppliers;
- continued execution of our various initiatives designed to expand gross margins, including by reducing production costs, continuing to sell Tablo cartridges, services and accessories for Tablo console, and reducing the cost of service
- our plans to expand our in-house manufacturing capabilities, and leverage and optimize our sales and marketing infrastructure, to support our growth;
- 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 reduce the cost and complexity of dialysis. 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 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 serve as a dialysis clinic on wheels. 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 by up to 80% in the intensive care unit (ICU). 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 in September 2014. We have invested in growing our economic and clinical evidence, built veteran 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. We plan to continue leveraging our commercial infrastructure, including our sales, field service and marketing teams, to broaden our installed base in the acute care market, as well as driving utilization and fleet expansion with our existing customers.

Tablo is also utilized for home-based dialysis. In March 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 penetrate this market successfully, we continue to make investments in, and focus on refining our home distribution, logistics, service and support systems to help ensure they continue to scale. We are also working with providers, patients and payors to increase awareness and adoption of transitional care units (TCUs) as a bridge to home based therapy. 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. In 2022, we introduced TabloCart with storage drawer, an accessory for Tablo that has 360° wheels for maneuverability and additional storage.
- 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 growing 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 more than 500,000 machine performance data points during every treatment, which is 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.

The real-time nature of TabloDash allows our FSEs to troubleshoot and adjust a device remotely during a call with a customer and avoid the need to send FSEs to a site unnecessarily. If it is necessary to dispatch an FSE, we can use TabloDash to help ensure they arrive with the correct parts to complete the repair and are able to address any preventive maintenance predicted by our algorithms, all during the same visit. TabloDash is the linchpin that helps us optimize the cost of service while increasing the quality of service by reducing unnecessary visits, time spent on-site, and 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 in the United States, Europe and Asia. Notable competitors in the United States include Fresenius Medical Care AG & Co. KGaA (Fresenius), Baxter International, Inc. (Baxter) and B. Braun. Medical Inc. (B. Braun). In addition, Quanta Dialysis Technologies Ltd's (Quanta) dialysis system received FDA 510(k) clearance for use in acute and/or chronic 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. Additionally, companies with dialysis machine development programs include Medtronic plc (Medtronic). With the exception of Quanta, our 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 build the commercial infrastructure necessary to effectively demonstrate the value of Tablo, maintain and improve product quality and feature functionality, build the infrastructure to support the operating needs of the business and achieve cost reductions.

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 that can provide clinical versatility and improve operational efficiency. In the acute care setting, the dialysis machine manufacturers that we compete with include Fresenius, Baxter and B. Braun. We compete primarily on the basis that Tablo is designed to drive operational efficiency through ease of use and cost reduction by reducing infrastructure and supplies cost.

Further, hospital customers in this market have generally outsourced their dialysis services to third party providers, for example, Fresenius, rather than offering on-site inpatient dialysis services on their own. We may also compete against these outsourced dialysis providers. In such instances, we believe our ability to compete effectively will depend 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). 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, 2023, we had 22 issued U.S. patents, as well as 7 pending U.S. patent applications. We had an aggregate of 39 issued patents in Australia, Canada, China, France, Germany, Hong Kong, Japan, Spain, Sweden and the United Kingdom, as well as 35 pending patent applications in Australia, Brazil, Canada, China, the European Patent Office, Hong Kong, Japan, Saudi Arabia, United Arab Emirates and under the Patent Cooperation Treaty. 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 October 2025 and December 2039. 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 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 portion of Tablo cartridges through two contract manufacturing partners, Providien Medical (Providien), part of Carlisle Companies Incorporated, a contract manufacturer with a facility in Mexico, and Infus Medical Co. Ltd. (Infus), a contract manufacturer with two facilities in Thailand. We intend to continue to increase the quantity of Tablo cartridges produced in-house at our manufacturing facility in Mexico, while continuing to rely on one or more of our contract manufacturers as additional sources for cartridge production.

The number of suppliers required for Tablo console production is in excess of 200 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 approximately 30 different single-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, 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 and Tablo Cartridge 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) application 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) application. In late July 2022, the FDA cleared this 510(k) application 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 October 2022,we submitted a 510(k) notification to the

FDA seeking clearance of a new software version intended to offer new commercial features and enhancements designed to improve the reliability and serviceability of Tablo, as well as other previously implemented modifications. In June 2023, the FDA cleared this 510(k) application.

In May 2022, the FDA published a Letter to Healthcare Providers entitled "Potential Risk of Exposure to Toxic Compounds When Using Certain Hemodialysis Machines Manufactured by Fresenius Medical Care – Letter to Health Care Providers." In that communication, the agency stated that it is evaluating the potential risk of exposure to non-dioxin-like (NDL) polychlorinated biphenyl acids (PCBAs) and NDL polychlorinated biphenyls (PCBs) with certain hemodialysis machines marketed in the United States. The FDA stated that the source of the NDL PCBAs and NDL PCBs is from the silicone tubing used as a part of the hydraulics in those machines and the dialysate lines. Although Tablo was not the subject of the FDA's Letter to Healthcare Providers, the FDA reached out to Outset regarding the tubing used in Tablo. In a series of discussions with the FDA, the agency requested that we conduct a targeted analysis and a screening analysis on the tubing currently used in Tablo. After aligning with the FDA on testing and screening protocols, we are concluding our analysis of the data. In parallel, we filed a 510(k) application, and received subsequent 510(k) clearance from the FDA for, PCB-free silicone tubing in December 2023. During the first quarter of 2024, we intend to proactively initiate a workstream to replace the remaining few silicone segments in new and existing Tablo consoles with the new, PCB-free, silicone tubing. While we intend to continue to partner with the FDA on next steps and take appropriate action with respect to this matter, there is no assurance that the FDA will not publish a safety notice specific to Tablo, classify this action as a recall, require us to conduct a recall of previously marketed products, or subject us to other enforcement actions, any of which could damage our reputation and harm our business.

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 and have since completed the associated remediation workstreams to fully address these observations. We continue to provide the FDA with monthly updates as to the status of these 483-related workstreams. Although we believe we are in material compliance with the QSR and have addressed the observations identified in the Form-483, 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 asserts 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 asserts that TabloCart with Prefiltration requires prior 510(k) clearance for marketing authorization. TabloCart with Prefiltration is an accessory to Tablo launched in the third quarter of 2022. We believe the concern raised by the first observation regarding CRRT promotion has been effectively addressed through a thorough review of existing promotional materials and practices. We believe the concern raised by the second observation regarding TabloCart with Prefiltration has been effectively addressed with two actions. First, 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. Second, we submitted to the FDA a 510(k) application for TabloCart with Prefiltration in September 2023, and have been engaged in constructive interactive review with the FDA reviewing team. In addition, we have provided monthly updates to the FDA as to the status of these Warning Letter-related workstreams since July 2023 and believe we have taken appropriate measures to resolve the matters raised in the Warning Letter. While we remain committed to fully cooperating with the FDA to expeditiously and completely resolve the Warning Letter, we cannot guarantee that the FDA will be satisfied with our response or the remedial measures we have taken, nor can we give any assurances as to the timing of the resolution of such matters, including the clearance of the 510(k) application and our resumption of distribution of TabloCart with Prefiltration.

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 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 under the statute, additional civil penalties and treble damages under the 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 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 to allow innocuous or beneficial arrangements 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 is no exception or safe harbor for many common business activities like the provision of meals, educational grants or reimbursement support programs, among others. Given that the 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, which currently set at $13,946 up to $27,894 per false claim or statement for penalties assessed after January 15, 2024. 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 healthcare fraud statute, which was added by HIPAA. The federal 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 the physicians described above and their immediate family members. 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 often 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, 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 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 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. Finally, 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. 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, 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 could result 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. 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 largely goes 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 and 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'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. As 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 clinics. 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 6, 2023, CMS published the final rule for Calendar Year (CY) 2024, which increased the base reimbursement rate per dialysis treatment to $271.02, an increase of $5.45 over the CY 2023 base rate of $265.57. 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.

Additionally, 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.

Beginning January 1, 2021, more dialysis patients enrolled in coverage under a Medicare Advantage plan when changes from the 21st Century Cures Act went into effect. 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 is no longer eligible for, and providers will no longer receive, TPNIES as of 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 Affordable Care Act 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 acute kidney failure (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 initiative implemented in the future could impact our revenue from the sale of our products.

The implementation of the Affordable Care Act 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 Affordable Care Act, 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 Affordable Care Act encouraged expanded 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 Affordable Care Act, as well as efforts to modify certain aspects of the Affordable Care Act. For example, Congress eliminated, starting January 1, 2019, the tax penalty for not complying with the Affordable Care Act'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 Affordable Care Act'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. It is unclear if efforts to challenge, or modify, or alter the implementation or interpretation of the Affordable Care Act will affect our business, financial condition and results of operations.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act 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 July 1, 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 six 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, an executive order signed in July 2019 directed the Secretary of HHS to develop, among other things, Medicare payment models designed to identify and treat at-risk populations earlier in disease development, and in connection with the executive order, HHS announced a goal of having 80% of new ESRD patients in 2025 either receive dialysis at home or receive a transplant. CMS subsequently published a final rule on September 29, 2020, among other things, to implement the End-Stage Renal Disease Treatment Choices (ETC) Model. The ETC Model is a mandatory payment model that adjusts certain Medicare payments to selected ESRD facilities, nephrologists, and other clinicians managing beneficiaries with ESRD starting January 1, 2021 and continuing through June 30, 2027. Specifically, the ETC Model adjusts certain ESRD facilities' treatment base rates under the ESRD Prospective Payment System and managing clinicians' monthly Medicare capitation payments to incentivize greater use of home dialysis and kidney transplants. CMS continues to propose modifications to the ETC Model as it evaluates the model against the agency's stated goals for the program. 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. 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, 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.

Other actions by the Biden administration, the Congress, state governments, third-party payors, and others could impact our business in ways that are difficult to predict but that 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. Current and future healthcare reform legislation and policies could also have a material adverse effect on our business and financial condition.

Human Capital Resources

As of December 31, 2023, we had 480 full-time employees, with 48% in our field sales and service teams and 52% in the rest of the company. Our workforce hails from across industries, including technology, medical devices, life sciences and retail management.

As of December 31, 2023, our manufacturing facility in Tijuana, Mexico had 300 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.

There are no unions represented within our employee base and no members of our workforce are covered under collective bargaining agreements.

Additional information about our human capital programs and initiatives can be found in our most recent Environmental, Social & Governance (ESG) Report, which is available on our website. Nothing contained on or accessible through our website, including our ESG Report or sections thereof, shall be deemed incorporated by reference into this Annual Report.

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. We have a principle that "everyone is a recruiter" and often hold crowd recruiting sessions to identify candidates collectively.

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, a broad-based 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 and Engagement

We have a structured approach for employee performance management, development and growth. Managers generally have two key performance conversations per year with their team members. Our year-end performance conversation is focused on evaluating the success and learning of the past year. Our 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, including programs taught by internal leaders or external speakers, a management development program, and access to on-demand learning resources.

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 annually to monitor employee engagement and identify areas of focus for our human capital management program. Information on the results of these surveys is included in our ESG Report.

Diversity, Equity and Inclusion Strategy

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. We embrace diversity and equal opportunity in an intentional way. We are committed to building a team that represents a variety of backgrounds, perspectives, and skills. We believe that creating an environment where employees feel comfortable to speak up and share ideas means we all do great work.

Our diversity, equity and inclusion strategy includes: broadening the diversity of our talent pools, supporting kidney health and raising awareness of disparity in kidney care access across different demographics, and elevating community volunteering opportunities. Our diversity, equity and inclusion strategy and related initiatives are overseen by our People Operations team, with

active participation from our executive team. Our Board and/or Compensation Committee receive periodic updates at least annually on our diversity, equity and inclusion efforts. Additional information on our diversity, equity and inclusion strategy, including data regarding our U.S. workforce and new hire demographics by gender and ethnicity, are publicly disclosed in our ESG Report.

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 directors as of the date of this Annual Report:

Name	Age	Position(s)
Executive Officers		
Leslie Trigg	53	President, Chief Executive Officer and Chair of the Board
Nabeel Ahmed	48	Chief Financial Officer
John L. Brottem	50	General Counsel and Secretary
Marc Nash	35	Senior Vice President, Operations and R&D
Jean-Olivier Racine	42	Chief Technology Officer
Steve Williamson	51	Chief Commercial Officer

Leslie Trigg

Leslie Trigg has served as our President and Chief Executive Officer and a member of our board of directors 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 Adaptive Biotechnologies Corporation, a biotechnology company, since March 2021, and on the board of directors of ARYA Sciences Acquisition Corp IV, a special purpose acquisition company, since March 2021. Ms. Trigg also serves as the Chair of the board of directors of the Medical Device Manufacturers Association. Ms. Trigg holds a B.S. degree from Northwestern University and an M.B.A. from The Haas School of Business, UC Berkeley.

Nabeel Ahmed

Nabeel Ahmed has served as our Chief Financial Officer since August 2021. Mr. Ahmed joined the Company in May 2020 as Vice President, Controller, was named Vice President, Finance in May 2021, and was appointed as Interim Chief Financial Officer effective July 2021. Prior to joining the Company, Mr. Ahmed served as Vice President, Finance at 8x8, Inc., a communications platform provider, from April 2019 through January 2020, and as Vice President, Finance at Vocera Communications, Inc., a provider of clinical communication and workflow solutions, from December 2014 through April 2019. Prior to that, he held various leadership positions in accounting and finance, including as CFO at Wanderful Media from 2013 to 2014, as well as Vice President, Finance and then CFO at MarketTools, Inc. from 2009 to 2012. Earlier in his career, Mr. Ahmed held various positions of increasing responsibility

at Ernst & Young LLP from 1997 to 2004 and at eBay, Inc. from 2004 to 2008. Mr. Ahmed holds a Bachelor of Commerce degree from Laurentian University and an M.B.A. from The Wharton School, University of Pennsylvania.

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 Senior Vice President, Operations and R&D since July 2023. Mr. Nash joined the Company in December 2019 as Senior Director of Operations and was named Vice President, Manufacturing in March 2021. 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.

Jean-Olivier Racine

Jean-Olivier Racine has served as our Chief Technology Officer since June 2021. Mr. Racine joined the Company from Amazon.com, Inc., an electronic commerce and cloud computing company, where he served in a number of roles: as Head of Engineering and Science, AWS Health AI from June 2020 to June 2021, Head of Cloud Services and Alexa, Halo (a health wearable device) from October 2018 to June 2020, as Head of Digital Media Catalog Services, Fire TV from January 2013 to October 2018, and as Fluidity and Performance Lead, Fire Tablet, Launcher and Platform from November 2011 to February 2013. Prior to that, Mr. Racine was a Senior Programmer-Analyst at the Montréal Exchange from January 2011 to November 2011, and a Projects Leader at NexGen Ergonomics, Inc. from January 2008 to January 2011. Mr. Racine holds a B.Eng. degree and a M.Eng. degree from École de Technologie Supérieure.

Steve Williamson

Steve Williamson has served as our Chief Commercial Officer since November 2020. Prior to joining the Company, Mr. Williamson was Worldwide President, Peripheral Intervention at Becton, Dickinson and Company, a medical technology company, from January 2018 to November 2020, and President, Peripheral Vascular at C.R. Bard (now part of Becton, Dickinson and Company) from August 2012 to December 2017. Prior to that, he was Senior Vice President and General Manager, Gyn Surgical Products from December 2009 to August 2012 and Vice President of Sales and Marketing, Gyn Surgical Products from October 2007 to December 2009 with Hologic, Inc., a medical technology company. Mr. Williamson holds a B.B.A. from University of Massachusetts Amherst and an M.B.A. from Bentley University.

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 reduce 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 hemodialysis market and the expansion of the home hemodialysis market itself
- Risks associated with our international manufacturing operations
- Our reliance on third-party suppliers, including single source suppliers and contract manufacturers, and our ability to overcome any manufacturing or supply chain disruptions
- 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 the recent pandemic, 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
- Potential litigation, including product liability claims, and the expense and potential unavailability of insurance coverage for any liabilities resulting from Tablo
- Risks related to our credit agreements, including interest rate risk and our ability to access additional capital and/or meet certain covenants

Risks Related to Government Regulation

- Our ability to recover from disruptions to our business and operations as a result of the prior shipment hold on Tablo for home use
- Our compliance with FDA and other medical device regulations applicable to our products and operations, including our ability to: resolve the warning letter we recently received from the FDA, comply with the post-market surveillance order recently issued by the FDA for Tablo and resume our distribution of TabloCart with Prefiltration pending the FDA's review and clearance of the submitted 510(k) application; 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
- 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
- Influence of principal stockholders and management over matters subject to stockholder approval
- 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
- 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 $172.8 million, $163.0 million and $131.9 million for the years ended December 31, 2023, 2022, and 2021, respectively. As of December 31, 2023, we had $206.7 million in cash, cash equivalents, restricted cash and short-term investments, and an accumulated deficit of $961.7 million. Based on our current planned operations, we expect our existing cash, cash equivalents and short-term investments, cash generated from revenues from our products and services, and proceeds received from the debt financing described in Note 7, Term Loans, to our audited financial statements included in this Annual Report, 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 recent commercial introduction, Tablo currently has 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.

Over time, we expect that our cost of service, sales and marketing, research and development, regulatory and other expenses will continue to increase as we expand our marketing efforts to increase adoption of Tablo, expand existing relationships with our customers, obtain regulatory clearances or approvals for future product enhancements to Tablo, and conduct clinical trials on Tablo. In addition, we expect our general and administrative expenses to increase over the long-term due to the additional costs associated with scaling our business operations and continuing to operate as a public company, including due to legal, accounting, insurance, exchange listing and SEC compliance, investor relations and other expenses. As a result, we expect to continue to incur operating losses and may never achieve profitability. We will need to generate significant additional revenue in order to achieve and sustain profitability. Even if we 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 reduce the cost of producing our products. Over the past three years, we have moved the production of Tablo consoles and a majority of Tablo cartridges in-house at 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. 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 the recent 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.

Moreover, 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. 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.

Lastly, 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.

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

Our success will depend, in part, on the 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 throughout the United States in 2018 and began the process to commercialize Tablo for home-based dialysis in 2020. Our relatively limited commercialization experience makes it more difficult to evaluate our current business and predict our future prospects. It is difficult to predict how quickly, if at all, providers and patients will accept Tablo or, if accepted, how frequently it will be used. These constituents must believe that Tablo offers benefits over traditional machines. The degree of market acceptance of Tablo 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 over traditional machines;
- the potential and perceived advantages of Tablo relative to our customers' other capital and operating purchase requirements;
- the cost of treatment, maintenance and upkeep using Tablo in relation to traditional machines;

- the cost of treatment, and convenience and ease of use of Tablo in the acute setting relative to outsourcing dialysis services to third-party providers;
- the convenience and ease of use of Tablo relative to traditional machines;
- the effectiveness of our sales and marketing efforts for Tablo;
- 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 the 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
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Additionally, even if Tablo achieves widespread market acceptance, it may not maintain that market acceptance over time if competing products or technologies, which are more cost effective or received more favorably, are introduced. Failure to achieve or maintain 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 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 consumables could adversely affect our business, financial condition and results of operation.

Our customers are facing financial pressures including capital budget constraints, staffing shortages and increased costs, that have had, and may continue to have, a negative impact on our revenue.

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 for the second half of 2023, and we expect these negative impacts to continue into 2024. During 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. If our customers continue to face prolonged periods of rising interest rates, capital budget constraints, volatility, uncertainty, staffing shortages, rising costs and other financial pressures, whether due to general macroeconomic conditions or otherwise, 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.

In 2022, we launched a pilot clinical and administrative services program designed to help bridge our healthcare provider customers, particularly those challenged by staffing shortages, as they transition from using an outsourced inpatient dialysis provider to offering on-site inpatient dialysis services on their own. In return for a fair market value service fee, we assign members of our own employed nurses on a temporary basis to support participating providers to launch and manage an inpatient dialysis program using Tablo and, as full-time staff is hired, to help train and onboard those nurses. However, our pilot clinical and administrative services program may not be successful in achieving the objectives we intend and anticipate, may fail to meet our customers' expectations, may not generate sufficient returns to justify our investment, or may result in unanticipated costs, which could harm our reputation and customer relationships and adversely impact our operating margins and results of operations.

Our ability to generate revenue from home-based dialysis is subject to certain risks and uncertainties, including around the use of Tablo in the home setting.

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 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 Tablo console, associated consumables and support and maintenance, which could adversely affect our business, financial condition and results of operations.

Our 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. Moreover, given the home dialysis market remains a relatively novel one 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 located outside of the United States, we may experience manufacturing 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 majority of Tablo cartridges, at our manufacturing facility in Tijuana, Mexico which we operate in collaboration with our outsourced business administration service provider, TACNA, and we intend to continue to increase the quantity of Tablo cartridges produced at this facility. 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 recent 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. 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, Mexico's Congress is considering proposals to amend Mexico's federal labor law, including a reduction in maximum workweek hours from 48 to 40 hours. These proposed 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 rely on contract manufacturing partners in Mexico and Southeast Asia, for the production of a portion of our Tablo cartridges. If either of our contract manufacturing partners' facilities were disrupted, by labor disputes, work stoppages, public health crises such as the recent COVID-19 pandemic, riots, terrorism, vandalism, cyber security attacks, natural disaster, regulatory action or otherwise, it could cause substantial delays in our operations and result in our having insufficient Tablo cartridge in inventory to fulfill orders. For example, in late 2021, supply chain disruptions exacerbated by COVID-19 outbreaks and protocols escalated, and we faced increased supply constraints, which increased freight costs associated with the transportation of Tablo cartridges. Further, to the extent we seek to renew or renegotiate our arrangements with either of our contract manufacturing partners, and cannot agree to the terms and conditions of future contract manufacturing arrangements, or if either of our contract manufacturing partners terminate existing agreements with us, our ability to produce and sell Tablo cartridges could be delayed until

we are able to ramp our own in-house manufacturing capabilities to meet demand, or until an alternative manufacturing partner or arrangement is identified, a new contract manufacturing agreement is negotiated and new production lines are established.

We depend upon third-party suppliers, including contract manufacturers 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 in excess of 200 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, our suppliers, including single source suppliers. Moreover, while we manufacture a majority of Tablo cartridges in-house, we rely on contract manufacturers for the production of a portion of Tablo cartridges. Many of our suppliers and contract manufacturers 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 manufacturers 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 manufacturers may encounter problems during manufacturing for a variety of reasons, including as a result of public health crises such as the recent 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 manufacturers may cease producing the components we purchase from them or otherwise decide to cease doing business with us. Further, we maintain limited volumes of inventory from most of our suppliers and contract manufacturers. 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 manufacturers, we may be required to change suppliers or contract manufacturers. While we believe replacement suppliers exist for 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. We faced increased supply chain constraints during late 2021, resulting in increased transportation and related costs associated with delivering adequate supply of Tablo treatments to our customers from our contract manufacturing partner in Southeast Asia. During 2023, we saw moderation in these costs. Moreover, we believe that localizing production of a majority of Tablo cartridges in Mexico (to our Mexico-based contract manufacturer and, more recently, 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.

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 and revenues, and 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. In addition, with our relatively recent transition to manufacturing Tablo consoles and a majority of Tablo cartridges at our facility in Mexico operated in collaboration with TACNA, we are more exposed to risks relating to

product quality and reliability as we continue to refine our manufacturing processes. Like all transitions of this nature, they could increase our costs in the near-term and accordingly adversely affect our business, financial condition and results of operations.

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 in the United States, Europe and Asia. Notable competitors in the United States include Fresenius Medical Care AG & Co. KGaA (Fresenius), Baxter International, Inc. (Baxter) and B. Braun Medical Inc. (B. Braun). In addition, Quanta Dialysis Technologies Ltd's (Quanta) dialysis system received FDA 510(k) clearance for use in acute and/or chronic 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. Fresenius, Baxter and B. Braun all supply machines and supplies in both the acute and home care settings. With the exception of Quanta, all of these organizations are currently significantly larger with greater financial and personnel resources than us, enjoy significantly greater market share than ours and have greater resources than we do. As a consequence, they are able to spend more on product development, marketing, sales and other product initiatives than we can. Additionally, companies with dialysis machine development programs include Medtronic. Some of our competitors have:

- substantially greater name recognition;
- broader, deeper or longer-term relations with healthcare professionals, customers and third-party payors;
- more established distribution networks;
- additional lines of products and the ability to offer rebates or bundle products to offer greater discounts or other incentives to gain a competitive advantage;
- greater experience in conducting research and development, manufacturing, clinical trials, marketing and obtaining regulatory clearance or approval for products; and
- greater financial and human resources for product development, sales and marketing and patent litigation.

Further, we may compete with third party providers of outsourced dialysis services, including Fresenius. These organizations are significantly larger with greater financial, personnel and other resources than us and enjoy significantly greater market share and name recognition than us. As a result, these competitors may be able to adopt more aggressive pricing policies and devote greater resources to the promotion, marketing and sales of their services.

Our continued success depends on our ability to:

- 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;
- increase adoption of Tablo in the chronic outpatient facility setting via transitional care programs within existing dialysis clinics;
- demonstrate Tablo's economic, clinical, compliance and operational benefits relative to outsourcing dialysis services; and
- overcome the adverse impact in the field from the Warning Letter and our 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 April 2023, Medtronic and DaVita launched a new independent company focused on kidney care, and in August 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 January 2023, Baxter announced its plans to spin off its renal care business unit into a new independent company.

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 acquisition 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. 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 smishing 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. 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.

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

As of December 31, 2023, we had 480 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 31,2023, our largest customer accounted for 13% 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 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 largest customers terminates its 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, 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, potential disruption in our supply chain from regional or global public health crises such as the recent 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 recent 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 and in recent years implemented 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 recent 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 recent 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 or the resurgence of it, 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 recent 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 Tablo or products of our competitors or broader industry trends;
- the impact, if any, that public health crises such as the recent 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 leverage and optimize our existing sales force, and the speed at which any newly hired salespeople become effective, and the cost and level of investment therein;
- 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 subsequent pause on the distribution of 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, as well as inflationary pressures (such as current inflation related to global supply chain 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.

We expect to continue to incur net losses for the next several years and we may require substantial additional capital to finance our planned operations, which may include future equity and debt financings. This additional capital may not be available to us on acceptable terms or at all. Our 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.

We may require additional financing to fund working capital and pay our obligations. While we entered into two senior secured credit facilities on November 3, 2022, which provide for (i) up to $250.0 million of term loans (the SLR Term Loan Facility) pursuant to a loan and security agreement with certain lenders and SLR Investment Corp., as agent (the SLR Loan Agreement) and (ii) up to a $50.0 million asset-based revolving credit facility (the SLR Revolver, together with the SLR Term Loan Facility, the SLR Credit Facilities) pursuant to a credit agreement with Gemino Healthcare Finance, LLC d/b/a SLR Healthcare ABL, as lender (the SLR Revolving Credit Agreement, together with the SLR Loan Agreement, the SLR Credit Facility Agreements), we have already borrowed $200.0 million of term loans and the additional $100.0 million borrowings under the SLR Credit Facilities is subject to us achieving certain net revenue milestones and obtaining lenders' credit approval. 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 net revenue milestones and obtaining lenders' credit approval.

We entered into the SLR Credit Facilities on November 3, 2022, which provide for (i) up to $250.0 million of term loans pursuant to the SLR Loan Agreement and (ii) up to a $50.0 million asset-based revolving credit facility pursuant to the SLR Revolving Credit Agreement. We have already borrowed $200.0 million of term loans and the additional $100.0 million of borrowings under the SLR Credit Facilities is subject to us achieving certain net revenue milestones and obtaining lenders' credit approval. If we achieve a certain net revenue milestone, calculated on a trailing six-month basis (First Revenue Milestone), on or before June 30, 2024 and the additional tranche under the SLR Revolver has been approved, we will be permitted to borrow up to an additional $50.0 million under the SLR Credit Facilities. If we achieve a subsequent additional net revenue milestone, calculated on a trailing six-month basis (Second Revenue Milestone, and together with First Revenue Milestone, the Revenue Milestones), on or before June 30, 2025 and obtain lenders' credit approval, we will be permitted to further borrow up to an additional $50.0 million under the SLR Credit Facilities. If we fail to achieve either or both of these Revenue Milestones or obtain lenders' credit approval, we will not be able to access the remaining $100.0 million of borrowings under the SLR Credit Facilities. The SLR Credit Facilities are secured by substantially all of our assets, including all of our intellectual property, subject to certain exceptions. The SLR Credit Facility Agreements contain a number of restrictive covenants, and 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. In addition, as principal amounts outstanding under each of the SLR Term Loan Facility and the SLR Revolver accrue interest at variable interest rates tied to SOFR, any borrowings under the facilities will be subject to interest rate risk. An adverse change in interest rates for our borrowings could increase our future 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 – SLR Debt Financing."

The SLR Credit Facility Agreements contain customary representations and warranties and affirmative covenants and also contain certain restrictive covenants, including, among others, limitations on: the incurrence of additional debt, liens on property, acquisitions and investments, loans and guarantees, mergers, consolidations, liquidations and dissolutions, asset sales, dividends and other payments in respect of our capital stock, prepayments of certain debt, transactions with affiliates and changes to our type of business, management of the business, control of the business or business locations. The SLR Credit Facility Agreements also include a financial covenant that, beginning with the fiscal quarter ending December 31, 2023, requires us to either (i) maintain certain levels of cash and cash equivalents in accounts subject to control agreements in favor of Agent and ABL Lender of at least the sum of (a) 50% of the outstanding obligations under the SLR Term Loan Facility and (b) the amount of the Company's accounts payable that have not been paid within 120 days from the invoice date thereof or (ii) generate net product and product related revenue in excess of specified amounts and maintain gross profit margins in excess of specified percentages, in each case, for applicable measuring periods. The SLR Credit Facility Agreements also contain customary events of default. If we fail to comply with such covenants, payments or other terms of either SLR Credit Facility Agreement, our agent or lender, as applicable, could declare an event of default, which would give it the right to declare all borrowings outstanding, together with accrued and unpaid interest and fees, to be immediately due and payable. In addition, our agent or lender, as applicable, would have the right to proceed against the assets we provided as collateral pursuant to the SLR Loan Agreement or SLR Revolving Credit Agreement, as applicable. If the debt under either SLR Credit Facility 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. For example, in late 2021, surges and shifts in consumer demand as the economy reopened, further exacerbated by COVID-19 outbreaks and protocols, strained the global freight network and placed significant stress on air, ocean and freight ground carriers, resulting in increased freight costs associated with our transportation of Tablo cartridges. 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.

If we fail to retain our sales and marketing personnel, fail to increase our sales and marketing capabilities or develop broad awareness of Tablo in a cost-effective manner, we may not be able to generate revenue growth.

We have limited experience marketing and selling Tablo. We currently rely on our direct sales force to sell Tablo in the United States, and any failure to maintain, leverage and optimize our direct sales force will negatively affect our business, financial condition and results of operations. The members of our direct sales force are highly trained and possess substantial technical expertise, which we believe is critical in increasing adoption of Tablo. The members of our U.S. sales force are at-will employees. The loss of these personnel to competitors, or otherwise, will negatively affect our business, financial condition and results of operations. If we are unable to retain our direct sales force personnel or replace them with individuals of equivalent technical expertise and qualifications, or if we are unable to successfully instill such technical expertise in replacement personnel, it may negatively affect our business, financial condition and results of operations. In addition, our services revenue is dependent in part on our FSEs, and any failure to maintain, or adequately train, our team of FSEs could negatively impact our services revenue.

In order to generate future growth, we plan to leverage and optimize our sales and marketing infrastructure to increase the number of customers that adopt Tablo. In addition, identifying and recruiting qualified sales and marketing personnel and training them on Tablo, on applicable federal and state laws and regulations and on our internal policies and procedures requires significant time, expense and attention. It often takes several months or more before a sales representative is fully trained and productive. Our sales force may subject us to higher fixed costs than those of companies with competing techniques or products that utilize independent third parties, which could place us at a competitive disadvantage. It will negatively affect our business, financial condition and results of operations if our efforts to expand and train our sales force do not generate a corresponding increase in revenue, and our higher fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for Tablo. In addition, our ability to generate revenue growth depends on the success of our efforts to further evolve our commercial infrastructure and sales processes to support the growth of our business in the home and acute markets. Any failure to hire, develop and retain talented sales personnel, to achieve desired productivity levels in a reasonable period of time or timely reduce fixed costs, or to evolve and scale our commercial infrastructure and sales processes, could negatively affect our business, financial condition and results of operations. Our ability to increase our customer base and achieve broader market acceptance of Tablo will depend to a significant extent on our ability to expand our marketing efforts. We plan to dedicate significant resources to our marketing programs. It will negatively affect our business, financial condition and results of operations if our marketing efforts and expenditures do not generate a corresponding increase in revenue. In addition, we believe that developing and maintaining broad awareness of Tablo in a cost-effective manner is critical to achieving broad acceptance of Tablo. Promotion activities may not generate patient or physician awareness or increase revenue, and even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain and protect our brand, we may fail to attract or retain the physician acceptance necessary to realize a sufficient return on our brand building efforts, or to achieve the level of brand awareness that is critical for broad adoption of Tablo.

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 class action 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 July 8, 2022, a purported stockholder class action lawsuit was filed against the Company, our Chief Executive Officer, Chief Financial Officer and former 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 regarding the Company's regulatory studies of Tablo for at home use and the Company's prospects related to the sale of the system for at home use. On September 7, 2022, the plaintiff filed a notice of voluntary dismissal of this action without prejudice, and this action is now concluded. 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, 2023, we had U.S. federal and state net operating loss (NOL) carryforwards of $643.4 million and $380.2 million, respectively. If not utilized, our U.S. federal NOLs generated in taxable years beginning before 2018 will begin to expire in 2024 and our state NOLs began to expire in 2024. Deductibility of U.S. federal NOLs generated in taxable years beginning after 2017 and used in taxable years beginning after 2020 do not expire but are limited to 80% of our taxable income before the deduction of such NOLs. As of December 31, 2023, we also had U.S. federal and state research and development credits of $8.8 million and $7.5 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 over a three-year period, is subject to limitations on its ability to utilize its pre-change net operating losses 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 NOLs 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 NOLs 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

We are subject to risks related to the warning letter we recently received from the FDA and the pause we recently implemented on the distribution of TabloCart with Prefiltration.

In July 2023, we received a warning letter (the "Warning Letter") from the FDA that raised two observations. The first observation asserts that certain content reviewed by the FDA and found on our website promotes CRRT, a modality outside of the current indications for Tablo. The second observation asserts that TabloCart with Prefiltration requires prior 510(k) clearance for marketing authorization. TabloCart with Prefiltration is an accessory to Tablo launched in the third quarter of 2022.

We believe the concern raised by the first observation regarding CRRT promotion has been effectively addressed through a thorough review of existing promotional materials and practices. We believe the concern raised by the second observation regarding TabloCart with Prefiltration has been effectively addressed with two actions. First, 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. Second, we submitted to the FDA a 510(k) application for TabloCart with Prefiltration in September 2023, and have been engaged in constructive interactive review with the FDA reviewing team. In addition, we have provided monthly updates to the FDA as to the status of these Warning Letter-related workstreams since July 2023, and believe we have taken appropriate measures to resolve the matters raised in the Warning Letter.

While we remain committed to fully cooperating with the FDA to expeditiously and completely resolve the Warning Letter, we cannot guarantee that the FDA will be satisfied with our response or the remedial measures we have taken, nor can we give any assurances as to the timing of the resolution of such matters, including the clearance of the 510(k) application and our resumption of distribution of TabloCart with Prefiltration. Failure to promptly and fully address the matters raised in the Warning Letter to the FDA's satisfaction or to comply with FDA regulations in general could result in further regulatory and enforcement actions being initiated by the FDA.

These actions may include, among other things, additional inspections, requirements to implement additional remedial measures, recommending or requiring that we cease manufacturing or producing TabloCart with Prefiltration or that we withdraw or recall the product from the marketplace, until clearance is obtained (which may not happen in a timely manner or at all), as well as product seizures, injunctions, civil monetary penalties, fines, or criminal prosecution. In addition, although we have paused distribution of TabloCart with Prefiltration pending the FDA's review and clearance of the submitted 510(k) application, the FDA could specifically mandate that we do so, which would result in the resumption of such distribution being outside of our sole control. Any such actions could materially and adversely disrupt and harm our business, reputation, financial condition, results of operations and future growth.

In addition, while we have submitted a 510(k) application for TabloCart with Prefiltration, we cannot predict with certainty when the FDA will complete its review of our application, whether the FDA will ultimately grant clearance of our application, or when we will resume distribution of the product. Based on the results of the FDA's review, we may be required to take additional actions, which may include making changes to the product, temporarily withdrawing or recalling TabloCart with Prefiltration until clearance 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, any of which could materially and adversely disrupt and harm our business and future growth.

Moreover, even if we are able to expeditiously and definitively resolve the Warning Letter, we will continue to incur incremental expenses relating to doing so, and we have experienced and expect to continue to experience related disruptions to our business, including reputational harm, customer uncertainty regarding the matters addressed in the Warning Letter and diversion of management's time and attention. Furthermore, our business and operations have experienced and may continue to experience disruptions as a result of our pause on the distribution of TabloCart with Prefiltration, including reputational harm and adverse impacts on our bookings and revenues, and may experience further disruptions which could include adverse impacts on our backlog, our ability to expand customer relationships or attract new customers, as well as reduced demand for TabloCart and/or, potentially, Tablo. Any of these factors could materially and adversely affect our results of operations, financial condition and growth prospects. For example, beginning in the third quarter of 2023, we observed more customers than we anticipated choosing to defer their Tablo console purchasing and installation until TabloCart with Prefiltration becomes available again, and we also experienced marketplace confusion in relation to the Warning Letter (exacerbated, we believe, in some cases by our competitors), particularly regarding Tablo's use in the ICU. These factors, combined with other macroeconomic factors, served to elongate our sales cycle and the timing of delivery and installations which, in turn, had an adverse impact on our bookings and revenues for the second half of 2023. We anticipate that the negative impacts from the Warning Letter and our distribution pause will continue into 2024. Moreover, these risks

and adverse impacts will be exacerbated if the FDA's review of our pending 510(k) application for TabloCart with Prefiltration and the current distribution pause (or any mandated distribution pause by the FDA) continues for an extended period of time, or if the FDA ultimately does not grant clearance of our 510(k) application.

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) 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) application 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) application. In late July 2022, the FDA cleared this 510(k) application 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 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. For example, on November 6, 2023, CMS issued a final rule updating the PPS to, among other things, increase the base rate from $265.57 to $271.02, an increase that CMS projects will increase the total payments to all ESRD facilities by 2.1% in CY 2024. 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.

Additionally, federal regulations provide for transitional add-on payment adjustments under the Medicare ESRD PPS for certain TPNIES. For home dialysis equipment, CMS provided a pathway for 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 with CY 2022. However, our TPNIES approval, which temporarily increased provider reimbursement, expired on December 31, 2023. We cannot fully assess the impact of the expiration of our TPNIES approval on our financial performance.

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.

Although most ESRD patients are currently covered by traditional Medicare, beginning January 1, 2021, when changes from the 21st Century Cures Act entered into effect, more dialysis patients were eligible to enroll in Medicare Advantage managed care plans. 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. In March 2023, CMS released the Announcement of CY 2024 Medicare Advantage Capitation Rates and Payment Policies. Among other changes, this announcement includes information about future Medicare Advantage rate increases and updates certain policies associated with risk adjustments.

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 Affordable Care Act 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. Specifically, 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.

We cannot anticipate what the impact of the Court's decision will be on our business, including whether adverse ESRD coverage actions may be taken by health plans or whether regulatory guidance or new legislation may be issued limiting 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 Affordable Care Act 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 Affordable Care Act, as well as efforts by both the executive and legislative branches of the federal government to modify certain aspects of the Affordable Care Act. It is unclear how these and other efforts to challenge or modify, or alter the implementation or interpretation of the Affordable Care Act 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 ETC 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 (such as the Warning Letter we received in July 2023), 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.

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 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 and have since completed the associated remediation workstreams to fully address these observations. We continue to provide the FDA with monthly updates as to the status of these 483-related workstreams. Although we believe we are in material compliance with the QSR and have addressed the observations identified in the Form-483, 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. For example, in May 2022, the FDA published a Letter to Healthcare Providers entitled "Potential Risk of Exposure to Toxic Compounds When Using Certain Hemodialysis Machines Manufactured by Fresenius Medical Care – Letter to Health Care Providers." In that communication, the agency stated that it is evaluating the potential risk of exposure to NDL PCBA and NDL PCBs with certain hemodialysis machines marketed in the United States. The FDA stated that the source of the NDL PCBAs and NDL PCBs is from the silicone tubing used as a part of the hydraulics in those machines and the dialysate lines. Although Tablo was not the subject of the FDA's Letter to Healthcare Providers, the FDA reached out to Outset regarding the tubing used in Tablo. In a series of discussions with the FDA, the agency requested that we conduct a targeted analysis and a screening analysis on the tubing currently used in Tablo. After aligning with the FDA on testing and screening protocols, we are concluding our analysis of the data. In parallel, we filed a 510(k) application, and received subsequent 510(k) clearance from the FDA for, PCB-free silicone tubing in December 2023. During the first quarter of 2024, we intend to proactively initiate a workstream to replace the remaining few silicone segments in new and existing Tablo consoles with the new, PCB-free, silicone tubing. While we intend to continue to partner with the FDA on next steps and take appropriate action with respect to this matter, there is no assurance that the FDA will not publish a safety notice specific to Tablo, classify this action as a recall, require us to conduct a recall of previously marketed products, or subject us to other enforcement actions, any of which could damage our reputation and harm our business.

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. For example, in January 2022 we proactively initiated a recall to replace a component in Tablo consoles at customer sites due to the possibility of heat-related damage to the device as a result of the component. 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, even if they are not reportable to the FDA.

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, one of the observations raised in the Warning Letter we received in July 2023 asserted that certain content reviewed by the FDA and found on our website promotes CRRT, a modality outside of the current indications for Tablo. We believe this concern has been effectively addressed through a thorough review of existing promotional materials and practices, 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. Specifically, the FDA recently finalized new cybersecurity guidance for medical device manufacturers, which we anticipate may necessitate additional time and cost for product development, submission and approval or clearance.

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.

Changes in funding or disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new product applications to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, the U.S. government could shut down causing certain regulatory agencies, including the FDA, to furlough critical employees and stop critical activities. Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of foreign and domestic manufacturing facilities. Although inspections have resumed to near pre-pandemic levels, the FDA could amend its priorities with respect to inspections at any time, and those changes could have a material effect on our regulatory submissions and on our business.

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.

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 OIG 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 (for example, the Warning Letter we received in July 2023 and our subsequent pause on the distribution of TabloCart with Prefiltration);
- 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, 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, and uncertainty surrounding the development of such new technologies, drugs and other treatments may drive volatility in our stock price. For example, in October 2023, a pharmaceutical manufacturer announced the early termination of its study, which sought to demonstrate the effectiveness of its 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. The release of further information on GLP-1 receptor agonists and their potential application to kidney care, or the release of other information regarding current or future new or innovative technologies, drugs and other treatments may continue to drive volatility in our stock price.

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. If we were to become involved in securities litigation, it 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 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 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 in the future will be at the discretion of our board of directors. In addition, the terms of the SLR Credit Facility Agreements 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 December 31, 2023, our executive officers, directors and 5% stockholders beneficially owned approximately 59% of the outstanding shares of capital stock. In addition, as of December 31, 2023, our executive officers and directors held options to purchase an aggregate of 1,470,776 shares of our common stock at a weighted-average exercise price of $12.41 per share, and 1,049,341 restricted stock units, which would give our officers and directors ownership of approximately 6% of our outstanding common stock as of December 31, 2023 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 this ownership 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 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. 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 current conflict between Russia and Ukraine and related economic and other retaliatory measures taken by the United States, European Union and others or the ongoing conflict between Israel and Hamas and in the Red Sea as well as the potential escalation or geographic expansion of such conflicts), pandemics (such as the recent COVID-19 pandemic), 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, the restructuring of our organization which we substantially completed in the fourth quarter of 2023, and any future restructurings intended to improve operational efficiencies and operating expenses, 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.

If our internal control over financial reporting or our disclosure controls and procedures are not effective, we may not be able to accurately report our financial results, prevent fraud or file our periodic reports in a timely manner, which may cause investors to lose confidence in our reported financial information.

We are a “large accelerated filer” under the Exchange Act, which requires us to comply with the requirements of Section 404 of the Sarbanes-Oxley Act. Section 404 of the Sarbanes-Oxley Act requires that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluations, document our controls and perform testing of our key controls over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. We have incurred significant expense and devoted substantial management effort to complying with the requirements of Section 404 of the Sarbanes-Oxley Act, which we

expect will continue. We may hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge, or incur expense associated with consultants, to support future growth. If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act or if we encounter difficulties in the timely and accurate reporting of our financial results, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, our investors could lose confidence in our reported financial information, the market price of our stock may decline and we could be subject to lawsuits, sanctions or investigations by regulatory authorities, which would require additional financial and management resources.

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 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 November 2022, we entered into the SLR Credit Facility Agreements 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.

There is increasing focus from certain investors, customers and other stakeholders 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. Third party providers of ESG ratings and reports on companies have increased in number to meet growing investor demand for measurement of ESG performance, resulting in varied and in some cases inconsistent standards. In addition, the criteria by which companies' ESG practices are assessed are evolving, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Alternatively, if we elect not to or are unable to satisfy such new criteria, some investors may conclude that our policies with respect ESG matters are inadequate. We may face reputational damages in the event that our ESG procedures or standards do not meet the standards set by various constituencies. Furthermore, if our competitors' ESG performance is perceived to be better than ours, potential or current investors may elect to invest with our competitors instead.

Further, increased public awareness and concern regarding ESG factors may result in new or enhanced legal requirements. For example, new regulations relating to ESG matters, including human capital, diversity, sustainability, climate change and cybersecurity, are under consideration or being adopted. Such regulations may impose additional reporting obligations and increase our compliance costs. In addition, climate change initiatives and legislation could also disrupt our operations by impacting the availability and cost of materials within our supply chain, and could also increase our operating costs.

In addition, from time to time, we communicate certain initiatives and goals related to ESG matters. For example, in June 2023, we published our second full ESG Report, including updates on our ESG programs, priorities, initiatives, goals and performance. We could fail, or be perceived to fail, in our achievement of such initiatives or goals, or we could fail in fully and accurately reporting our progress on such initiatives and goals. In addition, we could be criticized for the scope of such initiatives or goals or perceived as not acting responsibly in connection with these matters. Our business could be negatively impacted by such matters. If we fail to satisfy the ESG-related expectations of investors, customers and other stakeholders or our initiatives or goals are not executed or achieved as planned, our reputation and financial results could be materially and adversely affected.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity

At Outset, we strive to protect the confidentiality, integrity and availability of the personal 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 COMMITTEE OVERSIGHT	
BOARD: 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 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

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.	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 Chief Technology Officer manages our information security program.	
Executive leadership	Our Chief Technology Officer and the information security team periodically present information about the Company's information security program, including program goals and actions, 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 management engagement	We have established a committee comprised of leaders from key functions across the Company including, but not limited to, information security, IT, engineering, legal, regulatory, medical affairs, finance, research and development, operations, supply chain, marketing and people operations. This committee generally meets quarterly and is responsible for promoting a culture of awareness and accountability related to, among other things, information security. The committee also provides cross-functional input to facilitate the development, articulation, implementation and operation of information security risk management programs.
Governance of information security risks	We have also established a risk governance committee, which generally meets on a monthly basis. This committee, which is sponsored by the Chief Technology Officer, is comprised of Company associates from information security, information technology (IT), engineering, 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 information security 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 currently consult with third party firms to assist with our annual penetration testing for the Tablo device, Tablo cloud and IT infrastructure. In addition, 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. We also used a third-party firm to assist us with the National Institute of Standards and Technology (NIST) Federal Information Processing Standards (FIPS) 140-3 certification we are pursuing.

- **VENDOR ASSESSMENT:** We leverage a third-party risk assessment tool to help us identify cybersecurity 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. 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 recently 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, we are in the process of pursuing NIST FIPS 140-3 certification, and we are working to align our processes, protocols and software with the FDA's recent cybersecurity guidance finalized in September 2023. 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 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.
- **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 training as part of the new employee onboarding process and refresher training is assigned annually. Our IT team also conducts continuous automated phishing 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, defend against, and respond to cyber and other security threats to our networks and other information security 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 security 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, 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. 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.

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 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.

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

As of February 15, 2024, there were 102 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.

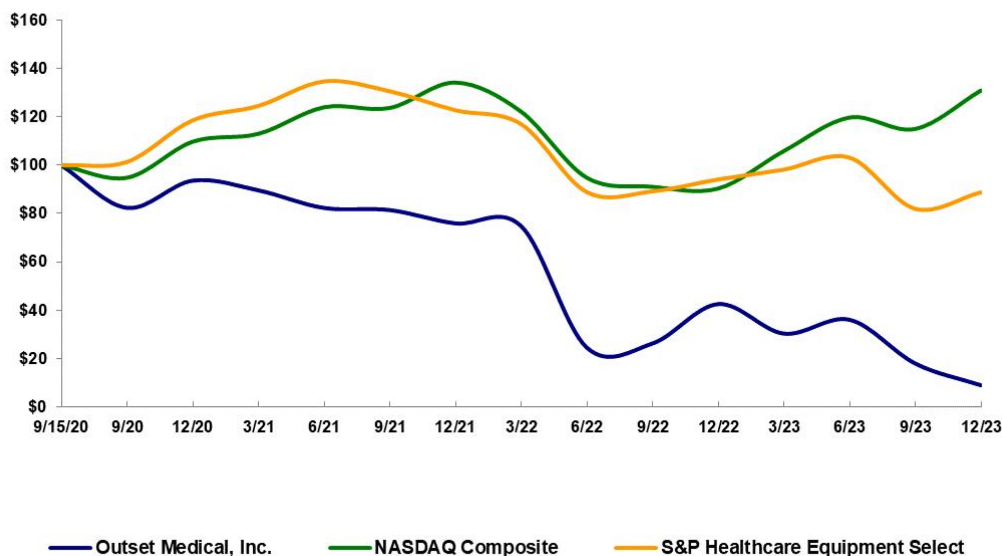
Dividend Policy

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 September 15, 2020 (the first day of trading of our common stock) through December 31, 2023. The graph assumes an investment of $100 on September 15, 2020 and its relative performance is tracked through December 31, 2023. 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. The offering price of our common stock in our initial public offering (IPO), which had a closing stock price of $60.68 on September 15, 2020, was $27.00 per share. Note that historic stock price performance is not necessarily indicative of future stock price performance.



Recent Sales of Unregistered Securities

None.

Issuer Purchases or Equity Securities

None.

Item 6. [Reserved].

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, 2022 for reference to discussion of the year ended December 31, 2022, 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, 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 serve as a dialysis clinic on wheels. 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 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. 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 by up to 80% in the intensive care unit. 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. We plan to continue leveraging our commercial infrastructure to broaden our installed base in the acute care market, 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 continue to focus on refining our home distribution, logistics and support systems to help ensure they are ready for scale. We are also working with providers, patients, and payors to increase awareness and adoption of TCUs as a bridge to home-based therapy. To demonstrate the cost advantages of Tablo in the home setting, we are continuing to collect additional patient clinical experience and outcomes data.

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, 2023, 2022, and 2021, sales of our consoles, which includes Tablo consoles and accessories, accounted for 47%, 56% and 63% 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, 2023, 2022, and 2021, sales of our consumables accounted for 32%, 25% and 19% of our revenue, respectively, and sales of service and other accounted for 21%, 19% and 18% 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 48% of our total full-time employees as of December 31, 2023. 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.

Recent Developments

In May 2022, 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 a 510(k) application we submitted for changes made since the device's original March 2020 clearance. In late July 2022, the FDA cleared our 510(k) application of Tablo for patient use in the home and we resumed marketing and shipping Tablo for home use.

In July 2023, we received a warning letter (the "Warning Letter") from the FDA that raised two observations. The first observation asserts that certain content reviewed by the FDA and found on our website promotes CRRT, a modality outside of the current indications for Tablo. The second observation asserts that TabloCart with Prefiltration requires prior 510(k) clearance for marketing authorization. TabloCart with Prefiltration is an accessory to Tablo launched in the third quarter of 2022. We believe the concern raised by the first observation regarding CRRT promotion has been effectively addressed through a thorough review of existing promotional materials and practices. We believe the concern raised by the second observation regarding TabloCart with Prefiltration has been effectively addressed with two actions. First, 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. Second, we submitted to the FDA a 510(k) application for TabloCart with Prefiltration in September 2023. In addition, we have provided monthly updates to the FDA as to the status of these Warning Letter-related workstreams since July 2023, and believe we have taken appropriate measures to resolve the matters raised in the Warning Letter. We have not identified any safety issues with TabloCart with Prefiltration. While we remain committed to fully cooperating with the FDA to expeditiously and completely resolve the Warning Letter, we cannot guarantee that the FDA will be satisfied with our response or the remedial measures we have taken, nor can we give any assurances as to the timing of the resolution of such matters, including the clearance of the 510(k) application and our resumption of distribution of TabloCart with Prefiltration.

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 IDNs and health systems, sub-acute long-term acute care hospitals (LTACHs) and skilled nursing facilities (SNFs). 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 our ability to expeditiously resolve the Warning Letter, overcome the adverse impact in the field from the Warning Letter and our distribution pause on TabloCart with Prefiltration, as well as the success of our efforts to further evolve our commercial infrastructure and sales processes to support the growth of our business in the acute care market.

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 our ability to further evolve our commercial 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 reduce the cost of Tablo consoles; second, our ability to continue to sell Tablo cartridges, services, and accessories for Tablo consoles; and third, our ability to reduce the cost of service. Over the past three years, we have moved the production of Tablo consoles and a majority of Tablo cartridges in-house at 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. Further, we will continue to utilize our cloud-based data system, as well as enhanced product performance, to better support our field service team and drive down service costs per console. In addition, 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 expand gross margins depends on our ability to successfully execute these strategies.

Impacts of Macroeconomic Factors

Global macroeconomic conditions, including inflationary pressures, rising interest rates, increased labor costs, labor 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 for the second half of 2023, and we expect these negative impacts to continue into 2024. During 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. We have generally seen some stabilization in these challenging labor market dynamics for healthcare providers in 2023 as compared to the prior year. Moreover, we believe Tablo offers automation and ease-of-use benefits over traditional machines that can enhance our existing and potential customers' ability to support their patient populations despite staffing shortages. However, if our customers continue to face prolonged periods of rising interest rates, capital budget constraints, volatility, uncertainty, staffing shortages, rising costs and other financial pressures, whether due to general macroeconomic conditions or otherwise, 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.

In 2022, we launched a pilot clinical and administrative services program designed to help bridge our healthcare provider customers, particularly those challenged by staffing shortages, as they transition from using an outsourced inpatient dialysis provider to offering on-site inpatient dialysis services on their own. In return for a fair market value service fee, we assign members of our own employed nurses on a temporary basis to support participating providers to launch and manage an inpatient dialysis program using Tablo and, as full-time staff is hired, to help train and onboard those nurses. However, our pilot clinical and administrative services program may not be successful in achieving the objectives we intend and anticipate, may fail to meet our customers' expectations, may not generate sufficient returns to justify our investment, or may result in unanticipated costs, which could harm our reputation and customer relationships, and adversely impact our operating margins and results of operations.

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 faced increased supply chain constraints during late 2021, resulting in increased transportation and related costs associated with delivering adequate supply of Tablo treatments to our customers from our contract manufacturing partner in Southeast Asia. During 2023, we saw moderation in these costs. Moreover, we believe that localizing production of a majority of Tablo cartridges in Mexico (to our Mexico-based contract manufacturer and, more recently, 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.

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, enhance existing products and develop new products and service offerings and expect research and development expenses to vary over time, depending on the level and timing of the enhancement of the existing products and new product or service development 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, government affairs, 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. Additionally, we will continue to invest in infrastructure to support our growth. As a result, we expect sales and marketing expenses to increase in absolute dollars in future periods. As a percentage of revenue, however, we expect sales and marketing expenses 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, employee recruiting and training costs, 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 increase in absolute dollars 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 SVB Term Loan in November 2022, which included early prepayment and exit 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, 2023 compared to the year ended December 31, 2022.

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

	Years Ended December 31,		
	2023	2022	2021
Revenue:			
Product revenue	$ 103,537	$ 93,388	$ 84,312
Service and other revenue	26,839	21,987	18,290
Total revenue	130,376	115,375	102,602
Cost of revenue:			
Cost of product revenue	74,454	82,510	84,639
Cost of service and other revenue	26,922	15,032	10,355
Total cost of revenue	101,376	97,542	94,994
Gross profit	29,000	17,833	7,608
Operating expenses:			
Research and development	57,307	48,855	36,741
Sales and marketing	96,232	89,482	65,070
General and administrative	45,231	40,515	36,316
Total operating expenses	198,770	178,852	138,127
Loss from operations	(169,770)	(161,019)	(130,519)
Interest income and other income, net	10,171	3,291	498
Interest expense	(12,675)	(3,566)	(1,715)
Loss on extinguishment of term loan	—	(1,367)	—
Loss before provision for income taxes	(172,274)	(162,661)	(131,736)
Provision for income taxes	523	295	199
Net loss	$ (172,797)	$ (162,956)	$ (131,935)

Revenue

	Years Ended December 31,		Change	
(dollars in thousands)	2023	2022	$	%
Revenue:				
Product revenue	$ 103,537	$ 93,388	$ 10,149	11 %
Service and other revenue	26,839	21,987	4,852	22 %
Total revenue	$ 130,376	$ 115,375	15,001	13 %

Product revenue increased by $10.1 million, or 11%, for the year ended December 31, 2023 as compared to the prior year. The increase was primarily due to a $13.4 million increase in consumables revenue attributable to the growth in our console installed base. This increase was partially offset by a $3.3 million decrease in console revenue which was primarily comprised of a $1.7 million decrease in console leasing revenue due to the expiration of certain lease agreements and lower number of consoles sold in the current year as compared to the prior year.

Service and other revenue increased by $4.9 million, or 22%, for the year ended December 31, 2023 as compared to the prior year. The increase was primarily due to services associated with the growth in our console installed base, which was partially offset by a $4.1 million decrease in service revenue from leased consoles due to the expiration of certain lease agreements.

Gross Profit and Gross Margin

	Years Ended December 31,		Change	
(dollars in thousands)	2023	2022	$	%
Gross profit and gross margin:				
Gross profit	$ 29,000	$ 17,833	$ 11,167	63 %
Gross margin	*22.2* %	*15.5* %		

Gross profit increased by $11.2 million, or 63%, for the year ended December 31, 2023 as compared to the prior year. The gross margin percentage improved by 6.7 percentage points for the year ended December 31, 2023 as compared to the prior year. This improvement in gross margin was primarily driven by the impact of cost reduction activities and a higher average selling price for both consoles and consumables. Such improvement was partially offset by the impact from the expiration of certain lease agreements.

Operating Expenses

Years Ended December 31,	Change

(dollars in thousands)	2023	2022	$	%
Operating expenses:				
Research and development	$ 57,307	$ 48,855	$ 8,452	17 %
Sales and marketing	96,232	89,482	6,750	8 %
General and administrative	45,231	40,515	4,716	12 %
Total operating expenses	$ 198,770	$ 178,852	19,918	11 %

Research and development expenses increased by $8.5 million, or 17%, for the year ended December 31, 2023 as compared to the prior year. This increase was primarily due to compensation-related and stock-based compensation expense, supplies and materials used to support our research and development efforts, and infrastructure costs to support our growth. These increases were partially offset by lower consulting expenses.

Sales and marketing expenses increased by $6.8 million, or 8% for the year ended December 31, 2023 as compared to the prior year. The increase was primarily driven by compensation-related and stock-based compensation expense and infrastructure costs to support our growth. In addition, there were higher freight and marketing expenses due to an increase in sales and marketing activities. These increases were partially offset by lower travel and consulting expenses.

General and administrative expenses increased by $4.7 million, or 12%, for the year ended December 31, 2023 as compared to the prior year. The increase was primarily driven by compensation-related and stock-based compensation expense and consulting expenses. These increases were partially offset by lower insurance expense and lower supplies and materials.

Other Income (Expenses), Net

	Years Ended December 31,		Change	
(dollars in thousands)	2023	2022	$	%
Other income (expenses), net:				
Interest income and other income, net	$ 10,171	$ 3,291	$ 6,880	209 %
Interest expense	(12,675)	(3,566)	(9,109)	255 %
Loss on extinguishment of term loan	—	(1,367)	1,367	*
Total other expenses, net	$ (2,504)	$ (1,642)	(862)	52 %

The increase in interest income and other income, net, for the year ended December 31, 2023 as compared to the prior year was driven by higher interest rates.

The increase in interest expense for the year ended December 31, 2023 as compared to the prior year was due to the increase in interest rate and a full year of outstanding balance under the SLR Term Loan Facility in 2023 as compared to only two months of outstanding balance of such facility in 2022.

The loss on extinguishment of term loan of $1.4 million in 2022 was recognized for the repayment of the SVB Term Loan, which included early prepayment and exit fees.

Liquidity and Capital Resources

Sources of Liquidity

As of December 31, 2023, we had a total cash, cash equivalents, restricted cash and short-term investments balance of $206.7 million. In January 2024, we borrowed and received $66.5 million under the SLR Term Loan Facility (see the section entitled "Debt Obligations" below).

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 redeemable convertible preferred stock and common stock, revenue from sales, debt financings, and proceeds from employee exercises of stock options and employee stock purchase plan purchases.

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. We may raise additional capital through the issuance of additional equity financing, debt financings, including through refinancing 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 reevaluate 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. If we raise additional capital through debt financing (including through our existing debt), we will be subject to an increase in our interest expense which may negatively affect our cash flow. 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. 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 – SLR Debt Financing", 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,		
	2023	2022	2021
Net cash (used in) provided by:			
Operating activities	$ (131,373)	$ (145,729)	$ (130,264)
Investing activities	83,026	(66,295)	(142,507)
Financing activities	43,652	72,898	160,147
Net decrease in cash, cash equivalents and restricted cash	$ (4,695)	$ (139,126)	$ (112,624)

Operating Activities

Net cash used in operating activities of $131.4 million for the year ended December 31, 2023 was due to a net loss of $172.8 million and a net cash outflow from the change in our operating assets and liabilities of $0.8 million, partially adjusted by the primary non-cash adjustments for stock-based compensation expense of $38.6 million, amortization of premium on investments of $6.4 million, depreciation and amortization of $5.8 million, non-cash interest expense of $1.8 million, and non-cash lease expense of $1.3 million. The net cash outflow from operating assets and liabilities was primarily due to an increase in accounts receivable due to timing of collections and billings, a decrease in accrued expenses and other current liabilities, a decrease in accrued compensation and related benefits, and a decrease in operating lease liabilities. The net cash outflow from operating assets and liabilities was partially offset by an increase in accounts payable due to timing of vendor payments, an increase in deferred revenue due to the growth in service agreements and a decrease in inventories.

Net cash used in operating activities of $145.7 million for the year ended December 31, 2022 was due to a net loss of $163.0 million and a net cash outflow from the change in our operating assets and liabilities of $21.1 million, partially offset by the primary non-cash adjustments for stock-based compensation expense of $27.2 million, depreciation and amortization of $5.2 million, provision for inventories of $2.6 million, loss on extinguishment of term loan of $1.4 million, non-cash lease expense of $1.1 million, accretion of discount on investments of $0.4 million, and non-cash interest expense of $0.4 million. The net cash outflow from operating assets and liabilities was primarily due to an increase in inventories due to the timing of inventory purchases including advance purchases of inventory to mitigate supply chain disruptions, a decrease in accrued compensation and related benefits, an increase in accounts receivable due to timing of collections, a decrease in accounts payable due to timing of vendor payments, an increase in prepaid expenses and other assets, and a decrease in 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 an increase in accrued expenses and other current liabilities.

Investing Activities

Net cash provided by investing activities of $83.0 million for the year ended December 31, 2023 was due to the maturities of investment securities of $258.8 million, partially offset by purchases of investment securities of $172.3 million and purchases of property and equipment of $3.4 million.

Net cash used in investing activities of $66.3 million for the year ended December 31, 2022 was due primarily to purchases of investment securities of $261.2 million and purchases of property and equipment of $8.3 million, partially offset by the maturities of investment securities of $203.2 million.

Financing Activities

Net cash provided by financing activities of $43.7 million for the year ended December 31, 2023 was due primarily to the net proceeds of $33.2 million from borrowings under the SLR Term Loan Facility and the proceeds of $10.4 million from employee exercises of stock options and employee stock purchase plan purchases.

Net cash provided by financing activities of $72.9 million for the year ended December 31, 2022 was due primarily to the net proceeds of $96.1 million from borrowings under the SLR Term Loan Facility and the proceeds of $8.0 million from employee exercises of stock options and employee stock purchase plan purchases, partially offset by the cash outflow of $31.2 million in repayment of the SVB Term Loan which included early prepayment and exit fees.

Debt Obligations

SLR Debt Financing

On November 3, 2022 (the Closing Date), we entered into two senior secured credit facilities, which collectively provide 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 (Agent), the lenders from time to time party thereto (the Term Loan Lenders) and us (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 (ABL Lender), and us (the SLR Revolver, together with the SLR Term Loan Facility, the SLR Credit Facilities).

The maximum amount we are permitted to borrow under the SLR Credit Facilities is subject to certain overall borrowing limitations. As described in further detail below, we have already borrowed $200.0 million of term loans. If we achieve a certain net revenue milestone, calculated on a trailing six-month basis (First Revenue Milestone), on or before June 30, 2024 and the Additional Tranche (as defined below) under the SLR Revolver has been approved, we will be permitted to borrow up to an additional $50.0 million under the SLR Credit Facilities (i.e., a maximum amount of $250.0 million). If we achieve a subsequent additional net revenue milestone, calculated on a trailing six-month basis (Second Revenue Milestone), on or before June 30, 2025 and obtain lenders' credit approval, we will be permitted to further borrow up to an additional $50.0 million under the SLR Credit Facilities (i.e., a maximum amount of $300.0 million).

Under the SLR Loan Agreement, as subsequently amended on December 11, 2023, the Term Loan Lenders agreed to extend term loans to us in an aggregate principal amount of up to $250.0 million, comprised of (i) a term loan of $100.0 million (the Term A Loan), (ii) term loans in an aggregate principal amount of up to $100.0 million that was provided for in two increments, one of $33.5 million (the Term B-1 Loan) and one of $66.5 million (the Term B-2 Loan) and (iii) one or more term loans in an aggregate principal amount of up to $50.0 million (the Term C Loans). As of December 31, 2023, we had an outstanding principal amount of $133.5 million under the Term A and B-1 Loans, which were funded in November 2022 and December 2023, respectively. Subsequently, we borrowed and received $66.5 million under the Term B-2 Loan in January 2024. As a result, the outstanding principal amount under the SLR Term Loan Facility is $200.0 million as of the date of this Annual Report. The Term C Loans are available subject to lenders' credit approval and the achievement of the Second Revenue Milestone on or before June 30, 2025. The Term C Loans will remain available for funding until one business day prior to November 1, 2027.

The SLR Revolving Credit Agreement provides for an asset-based revolving credit facility with aggregate revolving commitments of $25.0 million (the Initial Revolver Commitment). We may request to increase the aggregate revolving commitments by $25.0 million (the Additional Tranche) to an aggregate amount of $50.0 million, subject to ABL Lender's approval. Amounts available to be drawn under the SLR Revolver are equal to the lesser of (i) outstanding revolving commitments under the SLR Revolving Credit Agreement and (ii) a borrowing base (the Borrowing Base) equal to the sum of (a) 85% of eligible accounts receivable, plus (b) 25% of eligible inventory (not to exceed the lesser of 50% of the Borrowing Base and $5.0 million), minus (c) customary reserves, minus (d) unposted cash. No amounts were outstanding under the SLR Revolver as of December 31, 2023.

SVB Term Loan

We entered into the SVB Loan and Security Agreement with SVB in July 2020, which provides for a $30.0 million term loan (the SVB Term Loan). In November 2022, we terminated the SVB Term Loan and repaid in full all amounts due under such loan, including the early repayment fee of $0.3 million and the final payment of $2.0 million, using a portion of the proceeds of the SLR Credit Facilities.

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 policy 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 judgement. 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. When SSP is not directly observable for a performance obligation, we utilize the residual method to allocate revenue. 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, 2023, we had $133.5 million in variable rate debt outstanding under the SLR Term Loan Facility. Subsequently, we borrowed and received an additional $66.5 million in January 2024. The SLR Term Loan Facility bears interest at a rate per annum equal to one-month term Secured Overnight Financing Rate (term SOFR) (subject to a 2.75% floor), plus 5.15%. The SLR Term Loan Facility matures on November 1, 2027. On an annualized basis, a 100-basis point change in the term SOFR rate would change our interest expense by $2.0 million based upon our debt outstanding balance of $200 million as of January 31, 2024 (including the $66.5 million received in January 2024).

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 held 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

	Page
Report of Independent Registered Public Accounting Firm	77
Balance Sheets	79
Statements of Operations	80
Statements of Comprehensive Loss	81
Statements of Stockholders’ Equity	82
Statements of Cash Flows	83
Notes to Financial Statements	85

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, 2023 and 2022, the related statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2023, and the related notes (collectively, the financial statements). We also have audited the Company's internal control over financial reporting as of December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2023, 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, 2023 based on criteria established in *Internal 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 matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter 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 matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Sufficiency of audit evidence over Tablo console revenue

As discussed in Note 2 to the financial statements, 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. The Company allocates the contracted transaction price to each distinct performance obligation based upon the standalone selling price.

We identified the evaluation of the sufficiency of audit evidence over Tablo console revenue as a critical audit matter. Challenging auditor judgment was required to assess the Company’s manual determination of Tablo console revenue, including the timing of the revenue recognized.

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 manual determination of Tablo console revenue, including the timing of the revenue recognized. We evaluated the design and tested the operating effectiveness of certain internal controls over the Company's Tablo console revenue process, including controls over the Company's manual determination and timing of revenue recognized. For a sample of Tablo console revenue transactions, we evaluated the amount and timing of revenue recognized by comparing it to the Company’s manual determination, the underlying contract, and other supporting documentation. In addition, we evaluated the overall sufficiency of audit evidence obtained over Tablo console 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 21, 2024

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

	December 31,	
	2023	**2022**
Assets		
Current assets:		
Cash and cash equivalents	$ 68,509	$ 73,222
Short-term investments	134,815	214,280
Accounts receivable, net	32,980	28,070
Inventories	49,215	51,476
Prepaid expenses and other current assets	5,700	6,597
Total current assets	291,219	373,645
Restricted cash	3,329	3,311
Property and equipment, net	13,273	15,876
Operating lease right-of-use assets	5,375	6,117
Other assets	605	1,166
Total assets	$ 313,801	$ 400,115
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,827	$ 603
Accrued compensation and related benefits	19,005	21,519
Accrued expenses and other current liabilities	13,459	16,227
Accrued warranty liability	3,712	3,620
Deferred revenue, current	11,727	8,662
Operating lease liabilities, current	1,593	1,318
Total current liabilities	55,323	51,949
Accrued interest	896	113
Deferred revenue	101	151
Operating lease liabilities	4,482	5,576
Term loans	130,113	96,336
Total liabilities	190,915	154,125
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, 2023 and 2022	—	—
Common stock, $0.001 par value; 300,000 shares authorized as of December 31, 2023 and 2022; 50,317 and 48,465 shares issued and outstanding as of December 31, 2023 and 2022, respectively	50	48
Additional paid-in capital	1,084,515	1,035,456
Accumulated other comprehensive loss	68	(564)
Accumulated deficit	(961,747)	(788,950)
Total stockholders' equity	122,886	245,990
Total liabilities and stockholders' equity	$ 313,801	$ 400,115

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,		
	2023	**2022**	**2021**
Revenue:			
Product revenue	$ 103,537	$ 93,388	$ 84,312
Service and other revenue	26,839	21,987	18,290
Total revenue	130,376	115,375	102,602
Cost of revenue:			
Cost of product revenue	74,454	82,510	84,639
Cost of service and other revenue	26,922	15,032	10,355
Total cost of revenue	101,376	97,542	94,994
Gross profit	29,000	17,833	7,608
Operating expenses:			
Research and development	57,307	48,855	36,741
Sales and marketing	96,232	89,482	65,070
General and administrative	45,231	40,515	36,316
Total operating expenses	198,770	178,852	138,127
Loss from operations	(169,770)	(161,019)	(130,519)
Interest income and other income, net	10,171	3,291	498
Interest expense	(12,675)	(3,566)	(1,715)
Loss on extinguishment of term loan	—	(1,367)	—
Loss before provision for income taxes	(172,274)	(162,661)	(131,736)
Provision for income taxes	523	295	199
Net loss	$ (172,797)	$ (162,956)	$ (131,935)
Net loss per share, basic and diluted	$ (3.48)	$ (3.38)	$ (2.89)
Shares used in computing net loss per share, basic and diluted	49,588	48,161	$ 45,589

The accompanying notes are an integral part of these financial statements

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

	Years Ended December 31,		
	2023	**2022**	**2021**
Net loss	$ (172,797)	$ (162,956)	$ (131,935)
Other comprehensive income (loss):			
Unrealized gain (loss) on available-for-sale securities	632	(380)	(185)
Comprehensive loss	$ (172,165)	$ (163,336)	$ (132,120)

The accompanying notes are an integral part of these financial statements

Outset Medical, Inc.
Statements of Stockholders' Equity
(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders Equity
	Shares	Amount				
Balance as of December 31, 2020	42,722	$ 43	$ 822,624	$ 1	$ (494,059)	$ 328,609
Issuance of common stock upon follow-on public offering, net of issuance costs	2,946	3	149,082	—	—	149,085
Issuance of common stock through employee stock purchase plan	116	—	3,434	—	—	3,434
Issuance of common stock for settlement of RSUs	19	—	—	—	—	—
Stock option exercises	1,438	1	7,627	—	—	7,628
Stock-based compensation expense	—	—	17,445	—	—	17,445
Unrealized loss on available-for-sale securities	—	—	—	(185)	—	(185)
Net loss	—	—	—	—	(131,935)	(131,935)
Balance as of December 31, 2021	47,241	$ 47	$ 1,000,212	$ (184)	$ (625,994)	$ 374,081
Issuance of common stock through employee stock purchase plan	193	—	4,202	—	—	4,202
Issuance of common stock for settlement of RSUs	241	—	—	—	—	—
Stock option exercises	790	1	3,839	—	—	3,840
Stock-based compensation expense	—	—	27,203	—	—	27,203
Unrealized loss on available-for-sale securities	—	—	—	(380)	—	(380)
Net loss	—	—	—	—	(162,956)	(162,956)
Balance as of December 31, 2022	48,465	$ 48	$ 1,035,456	$ (564)	$ (788,950)	$ 245,990
Issuance of common stock through employee stock purchase plan	559	1	7,509	—	—	7,510
Issuance of common stock for settlement of RSUs	708	—	—	—	—	—
Stock option exercises	585	1	2,916	—	—	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	50,317	$ 50	$ 1,084,515	$ 68	$ (961,747)	$ 122,886

The accompanying notes are an integral part of these financial statements

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

	Years Ended December 31,		
	2023	2022	2021
Cash flows from operating activities:			
Net loss	$ (172,797)	$ (162,956)	$ (131,935)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	38,634	27,203	17,445
Depreciation and amortization	5,810	5,169	5,162
Non-cash lease expense	1,271	1,114	1,022
Non-cash interest expense	1,828	381	569
Accretion (amortization) of discount (premium) on investments, net	(6,369)	449	1,972
Provision for inventories	733	2,610	1,023
Other non-cash items	290	76	81
Loss on extinguishment of term loan	—	1,367	—
Changes in operating assets and liabilities:			
Accounts receivable	(5,094)	(2,506)	(19,137)
Inventories	1,647	(14,730)	(22,042)
Prepaid expenses and other assets	739	(1,215)	1,860
Accounts payable	5,312	(1,281)	(3,066)
Accrued compensation and related benefits	(2,515)	(3,428)	8,103
Accrued expenses and other current liabilities	(2,621)	1,811	5,889
Accrued warranty liability	91	(83)	791
Deferred revenue	3,015	2,161	2,881
Operating lease liabilities	(1,347)	(1,150)	(882)
Accrued interest	—	(721)	—
Net cash used in operating activities	(131,373)	(145,729)	(130,264)
Cash flows from investing activities:			
Purchases of property and equipment	(3,440)	(8,325)	(3,108)
Purchases of investment securities	(172,284)	(261,154)	(178,432)
Maturities of investment securities	258,750	203,184	39,033
Net cash provided by (used in) investing activities	83,026	(66,295)	(142,507)
Cash flows from financing activities:			
Proceeds from stock option exercises and ESPP purchases	10,427	8,042	11,062
Proceeds from issuance of term loans, net of issuance costs	33,225	96,059	—
Repayment of term loan and extinguishment costs	—	(31,203)	—
Proceeds from issuance of common stock upon the follow-on public offering, net of issuance costs	—	—	149,085
Net cash provided by financing activities	43,652	72,898	160,147
Net decrease in cash, cash equivalents and restricted cash	(4,695)	(139,126)	(112,624)
Cash, cash equivalents and restricted cash as of beginning of period	76,533	215,659	328,283
Cash, cash equivalents and restricted cash as of end of period	$ 71,838	$ 76,533	$ 215,659
Supplemental cash flow disclosures:			
Cash paid for income taxes	$ 491	$ 385	$ 83
Cash paid for interest	$ 10,847	$ 3,185	$ 1,146
Cash paid for amounts included in the measurement of operating lease liabilities	$ 1,347	$ 1,150	$ 882

The accompanying notes are an integral part of these financial statements

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

	Years Ended December 31,		
	2023	2022	2021
Supplemental non-cash investing and financing activities:			
Capital expenditures included in accounts payable and accrued expenses	$ 159	$ 167	$ 121
Right-of-use assets obtained in exchange for operating lease liabilities	$ 528	$ —	$ —
Transfer of inventories to property and equipment	$ 119	$ 28	$ 1,410
Deferred financing costs included in accrued expenses	$ —	$ 750	$ —
Transfer of property and equipment to inventories	$ —	$ 199	$ 1,192

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 reduce the cost and complexity of dialysis. Tablo® Hemodialysis System, cleared by the 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 serve as a dialysis clinic on wheels. 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.

Liquidity

Since inception, the Company has incurred net losses and negative cash flows from operations. The Company incurred net losses of $172.8 million, $163.0 million and $131.9 million for the years ended December 31, 2023, 2022, and 2021, respectively. As of December 31, 2023, the Company had an accumulated deficit of $961.7 million.

As of December 31, 2023, the Company had a total cash, cash equivalents, restricted cash, and short-term investments balance of $206.7 million. In January 2024, the Company received $66.5 million under the SLR Term Loan Facility (see Notes 7 and 12 for further details). The Company is subject to certain covenants limiting or restricting its ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Management expects to continue to incur significant expenses for the foreseeable future and 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, cash generated from sales, and proceeds received from the debt financing described in Note 7, 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, 2023, 2022 and 2021, the Company's largest customer accounted for 13%, 14% and 30% of revenues, respectively. For the year ended December 31, 2021, another customer accounted for 15% of revenues.

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. As a result, the Company believes that its accounts receivable credit risk exposure is limited. 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. One customer accounted for 14% of accounts receivable as of December 31, 2023. Another customer accounted for 13% of accounts receivable as of December 31, 2022.

The Company manufactures Tablo consoles, and a 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 recent 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 the Company's best estimate of the amount of credit losses in customer accounts. The Company regularly reviews the allowance by considering factors such as existing contractual payment terms, historical experience, credit quality, the age of the accounts receivable balances, and current economic conditions that may affect a customer's ability to pay. The allowance for credit losses was not significant as of December 31, 2023 and 2022.

Available-for-sale debt securities. The Company primarily holds U.S. government-sponsored enterprises debt securities, corporate debt securities, commercial paper, U.S. Treasury securities and money market funds. 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 and U.S. government-sponsored enterprises debt 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 investments in corporate debt securities 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 and U.S. government-sponsored enterprises debt securities.

The Company primarily holds U.S. government-sponsored enterprises debt securities, corporate debt securities, commercial paper, and U.S. Treasury securities, 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, 2023 and 2022.

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.

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 judgement. 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. When SSP is not directly observable for a performance obligation, the Company utilizes the residual method to allocate revenue. 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.

Operating Lease Arrangements

The Company enters into operating lease arrangements that contain both lease and non-lease elements. The lease element includes Tablo consoles, while non-lease elements include consumables, services and training. Revenue related to such arrangements is allocated to lease and non-lease elements based on their relative SSP. Revenue for the lease element, net of any taxes collected from customers, is recognized on a straight-line basis as product revenue over the lease term, generally one month to one year, in the statements of operations. The costs of the leased Tablo consoles are included in property and equipment, net on the balance sheets and amortized to cost of product revenue.

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 options with performance and market-based vesting conditions, 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. For all service-based stock options granted, the Company calculates the expected term using the simplified method for "plain vanilla" stock option awards. The Company had no publicly available stock price information prior to the IPO and limited available stock price information subsequent to the IPO; therefore, the Company has used the historical volatility of the stock price of similar publicly traded peer companies. 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.

For stock options with performance- and market-based vesting conditions, stock-based compensation expense begins to be recognized over the remaining service period when it is considered probable that the performance vesting condition will be satisfied. Stock-based compensation expense related to these options is recognized using the accelerated attribution method as the performance-based vesting condition and not reversed if the achievement of the market condition does not occur. The fair value of these stock options is estimated using the Monte Carlo simulation model.

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, 2023, 2022, and 2021 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 is authorized to make matching contributions but did not make such contributions for the year ended December 31, 2021. Effective January 1, 2022, the Company began to match 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 $1.7 million and $1.4 million for the years ended December 31, 2023 and 2022, respectively.

Segment

The Company operates as a single operating segment. The Company's chief operating decision maker, its Chief Executive Officer, reviews financial information on an aggregate basis for the purposes of allocating resources and evaluating financial performance. 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 $9.8 million as of December 31, 2023.

Recently Adopted Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board (FASB) issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326) Measurement of Credit Losses on Financial Instruments* (ASU 2016-13), which requires an entity to utilize a new impairment model known as the current expected credit loss (CECL) model to estimate its lifetime "expected credit loss" and record an allowance that, when deducted from the amortized cost basis of the financial assets and certain other instruments, including but not limited to available-for-sale debt securities. Credit losses relating to available-for-sale debt securities will be recorded through an allowance for credit losses rather than as a direct write-down to the security. ASU 2016-13 requires a cumulative effect adjustment to the balance sheet as of the beginning of the first reporting period in which the guidance is effective. The Company adopted ASU 2016-13 as of January 1, 2023. The adoption did not have a material impact on the Company's financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* (ASU 2023-07), which requires that an entity disclose significant segment expenses impacting profit and loss that are regularly provided to the chief operating decision maker. The update is required to be applied retrospectively to prior periods presented, based on the significant segment expense categories identified and disclosed in the period of adoption. This ASU is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company is currently evaluating the impact of the adoption of ASU 2023-07 on its financial statements.

In December 2023, the FASB issued 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. This ASU is effective for fiscal years beginning after December 15, 2024. The Company does not expect the adoption of ASU 2023-09 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,		
	2023	2022	2021

Consoles	$ 61,331	$ 64,590	$ 65,133
Consumables	42,206	28,798	19,179
Total product revenue	103,537	93,388	84,312
Service and other revenue	26,839	21,987	18,290
Total revenue	$ 130,376	$ 115,375	$ 102,602

For the years ended December 31, 2023, 2022 and 2021, $0.3 million, $2.0 million and $4.7 million, respectively, of consoles revenue were from console operating lease arrangements.

Remaining Performance Obligations and Contract Liabilities

As of December 31, 2023, the aggregate amount of the transaction price allocated to the remaining performance obligations related to service agreements that are unsatisfied or partially unsatisfied was $11.8 million, which is recorded as deferred revenue on the Company's balance sheet. Of that amount, $11.7 million will be recognized as revenue during the year ended December 31, 2024 and $0.1 million thereafter.

The contract liabilities consist of deferred revenue which represents payments received in advance of revenue recognition. During the years ended December 31, 2023, 2022 and 2021, the Company recognized $8.7 million, $6.3 million, and $3.2 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, 2023			
	Valuation Hierarchy	Amortized Costs	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Assets:					
Cash equivalents:					
Money market funds	Level 1	$ 44,883	$ —	$ —	$ 44,883
Short-term investments:					
U.S. Treasury securities	Level 1	53,790	58	(32)	53,816
U.S. government-sponsored enterprises debt securities	Level 2	29,645	24	(38)	29,631
Corporate debt	Level 2	33,214	56	—	33,270
Commercial paper	Level 2	18,097	5	(4)	18,098
Total cash equivalents and short-term investments		$ 179,629	$ 143	$ (74)	$ 179,698

		December 31, 2022			
	Valuation Hierarchy	Amortized Costs	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Assets:					
Cash equivalents:					
Money market funds	Level 1	$ 42,834	$ —	$ —	$ 42,834
U.S. government-sponsored enterprises debt securities	Level 2	7,965	—	—	7,965
Short-term investments:					
U.S. Treasury securities	Level 1	133,473	9	(447)	133,035
U.S. government-sponsored enterprises debt securities	Level 2	26,404	42	(14)	26,432
Corporate debt	Level 2	29,831	—	(154)	29,677
Commercial paper	Level 2	25,136	—	—	25,136
Total cash equivalents and short-term investments		$ 265,643	$ 51	$ (615)	$ 265,079

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 following tables present the breakdown of the available-for-sale debt securities with unrealized losses as of December 31, 2023 and 2022 (in thousands):

	December 31, 2023					
	Unrealized losses less than 12 months		Unrealized losses 12 months or greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
U.S. Treasury securities	$ 8,416	$ (16)	17,925	(16)	$ 26,341	$ (32)
U.S. government-sponsored enterprises	18,757	(22)	8,488	(16)	27,245	(38)
Corporate debt	11,291	(4)	—	—	11,291	(4)
Total	$ 38,464	$ (42)	$ 26,413	$ (32)	$ 64,877	$ (74)

	December 31, 2022					
	Unrealized losses less than 12 months		Unrealized losses 12 months or greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
U.S. Treasury securities	$ 95,499	$ (343)	$ 12,895	$ (103)	$ 108,394	$ (446)
U.S. government-sponsored enterprises	16,464	(14)	—	—	16,464	(14)
Corporate debt	21,480	(142)	8,196	(13)	29,676	(155)
Total	$ 133,443	$ (499)	$ 21,091	$ (116)	$ 154,534	$ (615)

The unrealized losses on the Company’s available-for-sale debt securities were caused by interest rate increases. The contractual terms of those investments do not permit the issuer to settle the securities at a price less than the amortized cost basis of the investments. As of December 31,2023, the Company does not intend to sell the investments, and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost basis, which may be at maturity. Additional factors considered in determining the treatment of unrealized losses include the 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. For the years ended December 31, 2023 and 2022, the Company did not recognize credit loss related to available-for-sales debt securities.

As of December 31, 2023, the remaining contractual maturities for short-term investments were as follows (in thousands):

	Aggregate Fair Value
Due within one year	$ 112,333
After one but within five years	22,482
Total	$ 134,815

The estimated fair value of the term loans as of December 31, 2023 and 2022 was $141.3 million and $100 million, respectively. The fair value of term loans is based on quoted market prices for the same or similar issues or on the current rates offered for loan of similar maturities.

5. Balance Sheet Components

Cash, Cash Equivalents and Restricted Cash

As of December 31, 2023 and 2022, the restricted cash balance of $3.3 million was related to collateral for the Company's building leases in San Jose, CA and Tijuana, Mexico (see Note 6). As of December, 31, 2021, the restricted cash balance of $33.3 million included the contractual obligations under the SVB Loan and Security Agreement (see Note 7) in addition to the collateral for the building leases.

The following table provides a reconciliation of cash, cash equivalents and restricted cash that sum to the total of the amounts shown in the statements of cash flows (in thousands):

	December 31,		
	2023	2022	2021
Cash and cash equivalents	$ 68,509	$ 73,222	$ 182,348
Restricted cash	3,329	3,311	33,311
Total cash, cash equivalents and restricted cash	$ 71,838	$ 76,533	$ 215,659

Inventories

Inventories consist of the following (in thousands):

	December 31,	
	2023	2022
Raw materials	$ 18,706	$ 20,623
Work in process	8,728	9,086
Finished goods	21,781	21,767
Total inventories	$ 49,215	$ 51,476

Property and Equipment, net

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

	December 31,	
	2023	2022
Tablos under operating leases	$ 522	$ 714
Computers and software	5,148	4,021
Furniture and fixtures	1,983	1,768
Machinery and equipment	11,602	10,367
Leasehold improvements	9,621	5,040
Construction in progress	769	4,773
Total property and equipment	$ 29,645	$ 26,683
Less: accumulated depreciation and amortization	(16,372)	(10,807)
Property and equipment, net	$ 13,273	$ 15,876

Total depreciation and amortization expense for the years ended December 31, 2023, 2022 and 2021, was $5.8 million, $5.2 million, and $5.2 million, respectively.

Accrued Expenses and Other Current Liabilities

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

	December 31,	
	2023	2022
Inventory	$ 3,395	$ 5,585
Research and development expenses	1,050	908
Professional services	1,153	1,261
Customer rebates	2,100	1,364
Other	5,761	7,109
Total accrued expenses and other current liabilities	$ 13,459	$ 16,227

Accrued Warranty Liability

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

	December 31,	
	2023	2022
Balance as of December 31, 2022	$ 3,620	$ 3,704
Additions charged to cost of product revenue	5,172	5,748
Consumption	(5,080)	(5,832)
Balance as of December 31, 2023	$ 3,712	$ 3,620

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 and will expire in August 2026. 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 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 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.

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

	Years ended December 31,		
	2023	2022	2021
Operating lease costs	$ 1,837	$ 1,759	$ 1,759
Variable lease costs	435	329	375
Short-term lease costs	94	170	180
Total lease costs	$ 2,366	$ 2,258	$ 2,314

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

	December 31,	
	2023	2022
Weighted-average remaining lease term (in years)	3.4	4.3
Weighted-average discount rate	8.8%	8.7%

The maturity of the Company's operating lease liabilities as of December 31, 2023 were as follows (in thousands):

Years Ending December 31:	
2024	$ 2,049
2025	2,107
2026	1,952
Thereafter	901
Total lease payments	7,009
Less: imputed interest	(934)
Present value of operating lease liabilities	$ 6,075
Operating lease liabilities, current	$ 1,593
Operating lease liabilities, noncurrent	$ 4,482

Purchase Commitments

The Company's commitments as of December 31, 2023 were $59.5 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

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. The Company is not presently a party to any legal proceedings that, if determined adversely to the Company, would individually or taken together have a material adverse effect on its business, results of operations, financial condition or cash flows.

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,	
	2023	2022
Principal of term loans	$ 133,476	$ 100,000
Unamortized debt discount	(3,363)	(3,664)
Term loans, noncurrent	$ 130,113	$ 96,336

SVB Loan and Security Agreement

On July 2, 2020, the Company entered into a senior secured term loan facility with Silicon Valley Bank (SVB) (the SVB Loan and Security Agreement), which provided for a $30.0 million term loan (the SVB Term Loan).

The SVB Term Loan was scheduled to mature on November 1, 2025. Payments under the SVB Term Loan were for interest only through May 2023, and then 30 monthly principal and interest payments from June 2023 until maturity. The SVB Term Loan bore interest at the greater of (A) 0.50% above the Prime Rate as reported in the Wall Street Journal and (B) 3.75%. The Company was obligated to maintain a restricted cash balance greater or equal to the outstanding principal balance of $30.0 million of the SVB Term Loan.

In November 2022, the Company entered into new senior secured credit facilities (the SLR Credit Facilities, as described below) and repaid in full all amounts due under the SVB Loan and Security Agreement, including the early repayment fee of $0.3 million and the final payment of $2.0 million, using a portion of the proceeds of the SLR Credit Facilities. The repayment of the SVB Term Loan was accounted for as a debt extinguishment, which resulted in a loss on extinguishment of $1.4 million recorded in the statement of operations for the year ended December 31, 2022.

SLR Credit Facilities

On November 3, 2022 (the Closing Date), the Company entered into two senior secured credit facilities, which collectively provide 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 (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 (ABL Lender), and the Company (the SLR Revolver, together with the SLR Term Loan Facility, the SLR Credit Facilities).

The maximum amount the Company is permitted to borrow under the SLR Credit Facilities is subject to certain overall borrowing limitations. With the outstanding principal amount of $133.5 million as of December 31, 2023 and the $66.5 million borrowed and received in January 2024 under the SLR Term Loan Facility (see further detailed discussion below), the Company has borrowed $200.0 million of term loans as of the date of this Annual Report. If the Company achieves a certain net revenue milestone, calculated on a trailing six-month basis (First Revenue Milestone), on or before June 30, 2024 and the Additional Tranche (as defined below) under the SLR Revolver has been approved, the Company will be permitted to borrow up to an additional $50.0 million under the SLR Credit Facilities (i.e., a maximum amount of $250.0 million). If the Company achieves a subsequent additional net revenue milestone, calculated on a trailing six-month basis (Second Revenue Milestone), on or before June 30, 2025 and obtains lenders' credit approval, the Company will be permitted to further borrow up to an additional $50.0 million under the SLR Credit Facilities (i.e., a maximum amount of $300.0 million).

SLR Term Loan Facility

Under the SLR Loan Agreement, as subsequently amended on December 11, 2023, the Term Loan Lenders agreed to extend term loans to the Company in an aggregate principal amount of up to $250.0 million, comprised of (i) a term loan of $100.0 million (the Term A Loan), (ii) term loans in an aggregate principal amount of up to $100.0 million that was provided for in two increments, one of $33.5 million (the Term B-1 Loan) and one of $66.5 million (the Term B-2 Loan) and (iii) one or more term loans in an aggregate principal amount of up to $50.0 million (Term C Loans). Each Term A Loan, Term B Loan and Term C Loan is referred to single as a Term Loan and are referred to collectively as the Term Loans. As of December 31, 2023, the Company had an outstanding principal amount of $133.5 million under the Term A and B-1 Loans, which were funded in November 2022 and December 2023, respectively. Subsequently, the Company borrowed and received $66.5 million under the Term B-2 Loan in January 2024 (see Note 12 for further details). The Term C Loans are available subject to lenders' credit approval and the achievement of the Second Revenue Milestone on or before June 30, 2025. The Term C Loans will remain available for funding until one business day prior to November 1, 2027.

Any principal amount outstanding under the Term Loans will accrue interest at a rate per annum equal to one-month term Secured Overnight Financing Rate (term SOFR) (subject to a 2.75% floor), plus 5.15% (10.46% as of December 31,2023), payable monthly in arrears. The Company is permitted to make interest-only payments on the Term Loans through November 30, 2026, which may be extended at the Company's option to May 31, 2027; provided that the Company meets the First Revenue Milestone. Any principal amounts outstanding under the Term Loans, if not repaid sooner, are due and payable on November 1, 2027 (the Maturity Date). The Company is obligated to pay Agent (i) a non-refundable facility fee in the amount of $750,000 in respect of the Term A Loan, (ii) a non-refundable facility fees in the aggregate amount of $750,000 in respect of the Term B-1 and B-2 Loans and (iii) a non-refundable facility fee in the amount of $375,000 in respect of the Term C Loan, to be due and payable upon the earliest to occur of (a) the funding of the first Term C Loan, (b) one day prior to the Maturity Date and (c) the prepayment of the Term Loans. In addition, the Company is obligated to pay a final fee equal to 4.75% of the aggregate amount of the Term Loans funded, such final fee to be due and payable upon the earliest to occur of (i) the Maturity Date, (ii) the acceleration of the Term Loans and (iii) the prepayment of the Term Loans. The Company may voluntarily prepay the outstanding Term Loans, subject to a prepayment premium of (i) 3.0% of the principal amount of the Term Loan, if prepaid prior to or on the first anniversary of the Closing Date, (ii) 2.0% of the principal amount of the Term Loan, if prepaid after the first anniversary of the Closing Date through and including the second anniversary of the Closing Date, or (iii) 1.0% of the principal amount of the Term Loan if prepaid after the second anniversary of the Closing Date and prior to the Maturity Date.

SLR Revolver

The SLR Revolving Credit Agreement provides for an asset-based revolving credit facility with aggregate revolving commitments of $25.0 million (the Initial Revolver Commitment). The Company may request to increase the aggregate revolving commitments by $25.0 million (the Additional Tranche) to an aggregate amount of $50.0 million, subject to ABL Lender's approval. Amounts available to be drawn under the SLR Revolver are equal to the lesser of (i) outstanding revolving commitments under the SLR Revolving Credit Agreement and (ii) a borrowing base (the Borrowing Base) equal to the sum of (a) 85% of eligible accounts receivable, plus (b) 25% of eligible inventory (not to exceed the lesser of 50% of the Borrowing Base and $5.0 million), minus
(c) customary reserves, minus (d) unposted cash. No amounts were outstanding under the SLR Revolver as of December 31, 2023.

Any principal amount outstanding under the SLR Revolver will accrue interest at a rate per annum equal to one-month term SOFR (subject to a 2.75% floor), plus 3.20%, payable monthly in arrears. Interest on any borrowing is payable monthly. The Company is obligated to pay Lender (i) a non-refundable facility fee in the amount of $187,500 in respect of the Initial Revolver Commitment, (ii) a non-refundable facility fee in the amount of $187,500 in respect of the Additional Tranche, to be due and payable upon activation of the Additional Tranche, (iii) a commitment fee of 0.50% per annum of the average daily unused portion of the then commitment amount, payable monthly and (iv) a collateral monitoring fee of 0.10% per month of the average daily Borrowing Base during the prior month, payable monthly. The Company may terminate the SLR Revolver at any time, subject to a termination fee of (i) 2.0% of the aggregate revolving commitments then in effect, if terminated prior to or on the first anniversary of the Closing Date, (ii) 1.0% of the aggregate revolving commitments then in effect, if terminated after the first anniversary of the Closing Date through and including the second anniversary of the Closing Date, or (iii) 0.5% of the aggregate revolving commitments then in effect, if terminated after the second anniversary of the Closing Date through and including the third anniversary of the Closing Date. Such termination fee is waived if the SLR Revolver is terminated after the third anniversary of the Closing Date and prior to the Maturity Date.

Subject to customary exceptions and restrictions, the Company may borrow, repay and reborrow varying amounts under the SLR Revolver at any time. If at any time the outstanding amount under the SLR Revolver exceeds the lesser of (i) the aggregate revolving commitments then in effect and (ii) the Borrowing Base then in effect, the Company will be required to prepay outstanding amounts under the SLR Revolver.

The SLR Revolver shall expire on November 1, 2027.

Other Terms of the SLR Credit Facilities

As security for its obligations under the SLR Credit Facilities, the Company granted Agent, for the benefit of the Term Loan Lenders, and ABL Lender a security interest in substantially all of the assets of the Company, including the Company's intellectual property, subject to certain exceptions.

The SLR Credit Facility Agreements contain 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 agreements also include a financial covenant that, beginning with the fiscal quarter ending December 31, 2023, the Company must either (i) maintain certain levels of cash and cash equivalents in accounts subject to control agreements in favor of Agent and ABL Lender of at least 50% of the sum of (a) the outstanding obligations under the Term Loans (as defined below) and (b) the amount of the Company's accounts payable that have not been paid within 120 days from the invoice date thereof or (ii) generate net product and product related revenue in excess of specified amounts and maintain gross profit margins in excess of specified percentages, in each case, for applicable measuring periods.

In addition, the SLR Credit Facility Agreements contain customary events of default that entitle Agent, under the SLR Loan Agreement, and ABL Lender, under the SLR Revolving Credit Agreement, to cause the Company's indebtedness under the SLR Loan Agreement or SLR Revolving Credit Agreement, as applicable, to become immediately due and payable, and to exercise remedies against the Company and the collateral securing the obligations owed under the applicable SLR Credit Facility Agreement. Under the SLR Credit Facility Agreements, an event of default will occur if, among other things, the Company fails to make payments under either SLR Credit Facility Agreement, the Company breaches covenants under either SLR Credit Facility Agreement, subject to specified cure periods with respect to certain breaches, the Agent or ABL Lender, as applicable, determine that a material adverse change has occurred under the SLR Loan Agreement or SLR Revolving Credit Agreement, as applicable, 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 SLR Credit Facility Agreements.

As of December 31, 2023, the Company borrowed an aggregate principal amount of $133.5 million under the Term A and B-1 Loans. The debt issuance costs and the facility fees related to the Term A and B Loans were recorded as a direct deduction from the term loans balance on the balance sheets and are being recognized as non-cash interest expense over the term of the loans using the effective interest method, along with the final payment fee. The facility fees related to the Initial Revolver Commitment were recorded as deferred financing costs and are being recognized as non-cash interest expense over their respective commitment period using straight-line method.

The annual principal annual payments, excluding interest payments and the final fee, due on the term loans as of December 31, 2023 were as follows (in thousands):

Years Ending December 31:		
2024	$	—
2025		—
2026		11,123
2027		122,353
Total principal payments		133,476
Less: unamortized debt discount		(3,363)
Total term loans, net of debt discount	$	130,113

8. 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 IPO. 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 3,665,000 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. As of December 31, 2023, 4,768,000 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 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, 2022	2,602	$ 13.97		
Granted	—	—		
Exercised	(585)	$ 4.99		
Forfeited and expired	(82)	$ 40.10		
Outstanding as of December 31, 2023	1,935	$ 15.58	5.27	$ 1,406
Exercisable as of December 31, 2023	1,777	$ 13.22	5.10	$ 1,406

The weighted average grant date fair value of options granted to employees was $18.56 and $24.74 per share during the years ended December 31, 2022 and 2021, respectively. The total intrinsic value of options exercised during the years ended December 31, 2023, 2022 and 2021 was $9.9 million, $22.2 million and $61.0 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, 2023, 2022 and 2021 was $3.6 million, $6.1 million and $24.5 million, respectively. As of December 31, 2023, the total unrecognized stock-based compensation expense related to the stock options was $3.3 million, which will be recognized over a weighted-average period of 1.15 years.

For the year ended December 31, 2021, the Company recorded stock-based compensation expense of $4.3 million related to stock options with performance- and market-based vesting conditions that were fully vested in 2021.

The fair value of each stock option grant is estimated on the date of grant using the following assumptions for the periods indicated:

	Years Ended December 31,	
	2022	2021
Expected term (in years)	6.08	5.95 – 6.08
Expected volatility	55.0%	53.9% – 55.3%
Risk-free interest rate	1.74%	0.66% – 1.36%
Dividend yield	0%	0%

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 our 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. RSUs with a service-based vesting condition granted to a grantee prior to February 2022 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.

In 2022 and 2023, the Company issued 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. These PSUs are earned and vest over performance and vesting periods extending through the end of the third year from the grant year (Year 3) based on achievement against two metrics: (1) an operational metric tied to the number of patients treating at home on Tablo as of the end of the second year from the grant year (Year 2), with 50% of earned units vesting after certification of the achievement level following the end of Year 2 and the remaining 50% of earned units vesting at the end of Year 3 (performance-based vesting conditions, referred to as the Home PSUs) and (2) the Company's relative total stockholder return (relative TSR) over a two-year performance period as compared to companies in a pre-determined index of medical device companies, with 100% of earned units vesting at the end of Year 3 (market-based vesting conditions, referred to as the Relative TSR PSUs). The number of units earned at the end of the Year 2 will vary, based on actual performance, from 0% to 200% (to 250% for the CEO) of the target number of the Home PSUs granted. The number of units earned at the end of the two-year period will vary, based on actual performance, from 75% to 150% (to 250% for the CEO) of the target number of the Relative TSR PSUs granted.

The grant date for these Home PSUs is 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. The 2024 target for the Home PSUs granted in 2023 (2023 Home PSUs) was not determined and approved by the Compensation Committee of the Board until February 2024. Therefore, no expense was recognized for these 2023 Home PSUs in 2023. The 2023 target for the Home PSUs granted in 2022 (2022 Home PSUs) was determined in January 2023 and achieved and earned at 123.4% as of December 31, 2023. The stock-based compensation expense related to 2022 Home PSUs was adjusted based on the achievement and a cumulative catch up was recognized in 2023.

During 2021 and 2020, the Company issued PSUs that vest upon the achievement of specified revenue targets (performance-based vesting conditions) or specified market stock prices (market-based vesting conditions) and continued performance of services. Certain PSUs with performance-based vesting conditions vest in a range between 0% and 200% of the units approved based on the performance relative to specified revenue targets.

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, 2022	1,593	239	$ 34.75	$ 26.50
Granted	2,321	266	$ 18.09	$ 11.06
Vested	(708)	—	$ 35.22	—
Forfeited	(612)	(73)	$ 27.02	$ 32.31
Outstanding as of December 31, 2023	2,594	432	$ 21.54	$ 22.50

The total grant date fair value of restricted stock vested for the years ended December 31, 2023, 2022 and 2021 were $24.9 million, $9.9 million, and $1.0 million, respectively. As of December 31, 2023, the total unrecognized stock-based compensation expense related to the restricted stock was $45.7 million, which will be recognized over a weighted-average period of 1.78 years.

Employees Stock Purchase Plan (ESPP)

In 2020, the Company adopted the ESPP. The Company initially reserved 687,000 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) 687,000 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. As of December 31, 2023, 1,204,000 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 15% 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 6-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,		
	2023	2022	2021
Expected term (in years)	0.49 – 2.00	0.49 – 2.00	0.50
Expected volatility	53.3% – 61.6%	41.1% – 58.0%	41.0% – 43.8%
Risk-free interest rate	4.81% – 5.4%	0.6% – 3.48%	0.06% – 0.07%
Dividend yield	0%	0%	0%
Grant Date Fair Value	$3.25–$8.27	$4.89 – $16.23	$13.25–$13.95

As of December 31, 2023, the total unrecognized stock-based compensation expense related to the ESPP was $5.3 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,		
	2023	2022	2021
Cost of revenue	$ 1,805	$ 701	$ 269
Research and development	10,538	6,845	3,809
Sales and marketing	12,419	10,269	5,897
General and administrative	13,872	9,388	7,470
Total stock-based compensation expense	$ 38,634	$ 27,203	$ 17,445

9. Income Taxes

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

	Years Ended December 31,		
	2023	2022	2021
Domestic	$ (158,095)	$ (153,226)	$ (128,400)
Foreign	(14,179)	(9,435)	(3,336)
Loss before provision for income taxes	$ (172,274)	$ (162,661)	$ (131,736)

The provision for income taxes were $0.5 million, $0.3 million, and $0.2 million for the years ended December 31, 2023, 2022 and 2021, 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 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,		
	2023	2022	2021
Federal statutory income tax rate	21.0 %	21.0 %	21.0 %
State taxes	3.2	4.2	1.3
Change in valuation allowance	(22.0)	(26.1)	(22.8)
Federal and state tax credits	1.3	1.4	1.2
Stock-based compensation expense	(2.0)	1.2	8.1
Non-deductible permanent expenses	(0.7)	(0.2)	(0.1)
Effect of deferred tax adjustment	—	0.2	(0.7)
Non-deductible compensation	(1.0)	(1.9)	(8.2)
Effective income tax rate	(0.2) %	(0.2) %	(0.2) %

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,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 161,189	$ 131,705
Tax credits	16,343	14,172
Accrual and reserves	4,907	4,509
Tangible and intangible assets	2,894	2,143
Stock-based compensation expense	4,596	4,686
Capitalized research costs	29,663	25,730
Other deferred tax asset	3,812	2,876
Gross deferred tax assets	223,404	185,821
Valuation allowance	(222,061)	(184,298)
Net deferred tax assets	$ 1,343	$ 1,523

	December 31,	
	2023	2022
Deferred tax liabilities:		
Right-of-use assets	$ (1,343)	$ (1,523)
Gross deferred tax liabilities	$ (1,343)	$ (1,523)

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, 2023 and 2022. The change in the valuation allowance during the years ended December 31, 2023, 2022 and 2021 was an increase of $37.8 million, $42.6 million, and $30.7 million, respectively.

Starting in 2022, changes to Internal Revenue Code Section 174 made by the Tax Cuts and Jobs Act of 2017 (the TCJA) no longer permit an immediate deduction for research and development expenditures in the tax year that such costs are incurred. As a result, the Company capitalized such costs in its 2023 and 2022 income tax provisions, resulting in an increase in deferred tax assets.

Net Operating Loss and Tax Credit Carryforwards

As of December 31, 2023, the Company had a net operating loss carryforward for U.S. federal income tax purposes of $643.4 million. Federal net operating losses of $515.6 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 2024 and continue to expire through 2037. The Company had a total U.S. state net operating loss carryforward of $380.2 million. State net operating losses of $108.3 million do not expire. The remaining state net operating loss carryforward of $271.9 million will begin to expire in 2024 and continue to expire through 2043.

As of December 31, 2023, the Company had federal research and development credits of $8.8 million, which will begin to expire in 2030 and state research and development credits of $7.5 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, 2023 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,	
	2023	2022
Balance, beginning of year	$ 3,027	$ 2,190
Increase related to prior years positions	—	37
Decrease related to current year positions	—	—
Increase related to current year positions	754	800
Balance, end of year	$ 3,781	$ 3,027

The Company does not have any material accrued interest or penalties associated with unrecognized tax benefits. The Company does not believe it is reasonably possible that its unrecognized tax benefits will significantly change within the next twelve months.

The Company files income tax returns in the United States, various U.S. states and Mexico. The Company is currently under Texas franchise tax audit. The Company is not under examination by income tax authorities in federal, other states with the exception of Texas, 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.

10. 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,		
	2023	2022	2021
Stock options to purchase common stock	1,935	2,602	3,533
Restricted stock units	2,593	1,593	581
Performance stock units	197	47	17
Shares committed under ESPP	318	90	37
Warrant to purchase common stock	63	63	63
Total	5,106	4,395	4,231

11. Restructuring

Early in the fourth quarter of 2023, the Company began restructuring its organization to better align its talent, organizational design and spending in support of its most critical strategies while also streamlining its overall cost structure. The restructuring plan was substantially completed as of December 31, 2023. As a result, we recognized restructuring charges of $2.5 million for severance costs, all of which were paid or will be paid in cash. As of December 31, 2023, $0.9 million of restructuring costs were recorded in accrued compensation and related benefits on the balance sheet.

Restructuring costs are recorded in the statements of operations as follows (in thousands):

	Year Ended December 31, 2023
Cost of revenue	$ 129
Research and development	739
Sales and marketing	1,294
General and administrative	370
Total	$ 2,532

12. Subsequent Event

On January 2, 2024, the Company borrowed and received $66.5 million under the SLR Term Loan Facility (the Term B-2 Loan). After giving effect to such borrowing and the recent borrowing the Company made in December 2023, the outstanding principal amount under the SLR Term Loan Facility is $200.0 million as of the date of this Annual Report.

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, 2023.

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, 2023.

The effectiveness of our internal control over financial reporting as of December 31, 2023 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, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

During the three months ended December 31, 2023, 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.

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.

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 2024 Annual Meeting of Stockholders within 120 days of our fiscal year ended December 31, 2023 (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	Form of Amended and Restated Certificate of Incorporation of Outset Medical, Inc.	S-1/A	333-248225	3.1	September 9, 2020
3.2	Form of Amended and Restated Bylaws of Outset Medical, Inc.	S-1/A	333-248225	3.2	September 9, 2020
4.1	Form of Common Stock Certificate	S-1/A	333-248225	4.1	September 9, 2020
4.2	Amended and Restated Registration Rights Agreement	S-1	333-248225	4.2	August 21, 2020
4.3	Form of Series A Warrant Agreement #1	S-1	333-248225	4.3	August 21, 2020
4.4	Form of Series A Warrant Agreement #2	S-1	333-248225	4.4	August 21, 2020
4.5	Description of Outset Medical, Inc.'s Securities Registered Pursuant to Section 12 of the Exchange Act	10-K	001-39513	4.5	March 22, 2021
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				
10.5†	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-Q	001-39513	10.3	November 9, 2022
10.10†	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
10.11*	Form of Amended and Restated Change in Control and Severance Agreement for Chief Executive Officer				
10.12*	Form of Amended and Restated Change in Control and Severance Agreement for non-Chief Executive Officer executive officers				
10.13#	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
10.14#	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
10.15#	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
10.16#	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
10.17#	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

10.18#	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
10.19#	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
10.20#	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
10.21#	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
10.22#	Supply Agreement by and between Carlisle Interconnect Technologies, Inc. and Outset Medical, Inc., dated January 12, 2021	10-K	001-39513	10.30	March 22, 2021
10.22	Loan and Security Agreement by and between SLR Investment Corp., the lenders from time to time party thereto and Outset Medical, Inc. dated as of November 3, 2022	10-Q	001-39513	10.1	November 9, 2022
10.24	Credit Agreement by and between Gemino Healthcare Finance, LLC d/b/a SLR Healthcare ABL and Outset Medical, Inc. dated as of November 3, 2022	10-Q	001-39513	10.2	November 9, 2022
10.25*	First Amendment to Loan and Security Agreement by and among SLR Investment Corp., as collateral agent, the lenders party thereto and Outset Medical, Inc. dated as of December 11, 2023				
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				
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 21, 2024

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 Nabeel Ahmed, 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 21, 2024
/s/ Nabeel Ahmed Nabeel Ahmed	Chief Financial Officer (*Principal Financial Officer and Principal Accounting Officer*)	February 21, 2024
/s/ D. Keith Grossman D. Keith Grossman	Lead Independent Director	February 21, 2024
/s/ Karen Drexler Karen Drexler	Director	February 21, 2024
/s/ Patrick T. Hackett Patrick T. Hackett	Director	February 21, 2024
/s/ Jim Hinrichs Jim Hinrichs	Director	February 21, 2024
/s/ Dale Jones Dale Jones	Director	February 21, 2024
/s/ Andrea L. Saia Andrea L. Saia	Director	February 21, 2024
/s/ Catherine Szyman Catherine Szyman	Director	February 21, 2024

.Outset

Exhibit 10.4

OUTSET MEDICAL, INC.

2020 EQUITY INCENTIVE PLAN

ADOPTED BY THE BOARD OF DIRECTORS: SEPTEMBER 2, 2020
APPROVED BY THE STOCKHOLDERS: SEPTEMBER 7, 2020
AMENDED AND RESTATED : JANUARY 1, 2024
TERMINATION DATE: SEPTEMBER 2, 2030

I. INTRODUCTION

1.1 PURPOSES. The purposes of the Outset Medical, Inc. 2020 Equity Incentive Plan (this "***Plan***") are (i) to align the interests of the Company's stockholders and the recipients of awards under this Plan by increasing the proprietary interest of such recipients in the Company's growth and success, (ii) to advance the interests of the Company by attracting and retaining Non-Employee Directors, officers, other employees, consultants, independent contractors and agents and (iii) to motivate such persons to act in the long-term best interests of the Company and its stockholders.

1.2 CERTAIN DEFINITIONS.

"***Agreement***" means the written or electronic agreement evidencing an award hereunder between the Company and the recipient of such award.

"***Board***" means the Board of Directors of the Company.

"***Change in Control***" has the meaning set forth in Section 5.8(a).

"***Code***" means the Internal Revenue Code of 1986, as amended.

"***Committee***" means the Compensation Committee of the Board, or a subcommittee thereof, or such other committee designated by the Board, in each case, consisting of two or more members of the Board, each of whom is intended to be (i) a "Non-Employee Director" within the meaning of Rule 16b-3 under the Exchange Act and (ii) "independent" within the meaning of the rules of NASDAQ or, if the Common Stock is not listed on NASDAQ, within the meaning of the rules of the principal stock exchange on which the Common Stock is then traded.

"***Common Stock***" means the common stock, par value $0.001 per share, of the Company, and all rights appurtenant thereto.

"***Company***" means Outset Medical, Inc., a Delaware corporation, or any successor thereto.

"***Exchange Act***" means the Securities Exchange Act of 1934, as amended.

"***Exchange Act Person***" means any natural person, entity, or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act), except that "Exchange Act Person" does not include: (i) the Company or any Subsidiary; (ii) any employee benefit plan of the Company or any Subsidiary or any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary; (iii) an underwriter temporarily holding securities pursuant to an offering of such securities; (iv) an entity owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of stock of the Company; or (v) any natural person, entity, or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act) that, as of the effective date of this Plan, is the owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company's then outstanding securities.

"***Fair Market Value***" means the closing transaction price of a share of Common Stock as reported on NASDAQ on the date as of which such value is being determined or, if the Common Stock is not listed on NASDAQ,

the closing transaction price of a share of Common Stock on the principal national stock exchange on which the Common Stock is traded on the date as of which such value is being determined or, if there shall be no reported transactions for such date, on the next preceding date for which transactions were reported; *provided*, *however*, that (i) the Company may in its discretion use the closing transaction price of a share of Common Stock on the day preceding the date as of which such value is being determined to the extent the Company determines such method is more practical for administrative purposes, such as for purposes of tax withholding and (ii) if the Common Stock is not listed on a national stock exchange or if Fair Market Value for any date cannot be so determined, Fair Market Value shall be determined by the Committee by whatever means or method as the Committee, in the good faith exercise of its discretion, shall at such time deem appropriate and in compliance with Section 409A of the Code.

"*Free-Standing SAR*" means a SAR which is not granted in tandem with, or by reference to, an option, which entitles the holder thereof to receive, upon exercise, shares of Common Stock (which may be Restricted Stock) or, to the extent set forth in the applicable Agreement, cash or a combination thereof, with an aggregate value equal to the excess of the Fair Market Value of one share of Common Stock on the date of exercise over the base price of such SAR, multiplied by the number of such SARs that are exercised.

"*Incentive Stock Option*" means an option to purchase shares of Common Stock that meets the requirements of Section 422 of the Code, or any successor provision, which is intended by the Committee to constitute an Incentive Stock Option.

"*Incumbent Director*" has the meaning set forth in Section 5.8(a)(5).

"*Non-Employee Director*" means any member of the Board who is not an officer or employee of the Company or any Subsidiary.

"*Nonstatutory Stock Option*" means an option to purchase shares of Common Stock which is not an Incentive Stock Option.

"*Other Stock Award*" means an award granted pursuant to Section 3.4 of the Plan.

"*Performance Award*" means a right to receive an amount of cash, Common Stock, or a combination of both, contingent upon the attainment of specified Performance Measures within a specified Performance Period.

"*Performance Measures*" means the criteria and objectives, established by the Committee, which shall be satisfied or met (i) as a condition to the grant or exercisability of all or a portion of an option or SAR or (ii) during the applicable Restriction Period or Performance Period as a condition to the vesting of the holder's interest, in the case of a Restricted Stock Award, of the shares of Common Stock subject to such award, or, in the case of a Restricted Stock Unit Award, Other Stock Award or Performance Award, to the holder's receipt of the shares of Common Stock subject to such award or of payment with respect to such award. Such criteria and objectives may include one or more of the following corporate-wide or Subsidiary, division, operating unit, line of business, project, geographic or individual measures: the attainment by a share of Common Stock of a specified Fair Market Value for a specified period of time; increase in stockholder value; earnings per share; return on or net assets; return on equity; return on investments; return on capital or invested capital; total stockholder return; earnings or income of the Company before or after taxes and/or interest; earnings before interest, taxes, depreciation and amortization ("EBITDA"); EBITDA margin; operating income; revenues; operating expenses, attainment of expense levels or cost reduction goals; market share; cash flow, cash flow per share, cash flow margin or free cash flow; interest expense; economic value created; gross profit or margin; operating profit or margin; net cash provided by operations; price-to-earnings growth; and strategic business criteria, consisting of one or more objectives based on meeting specified goals relating to market penetration, customer acquisition, business expansion, cost targets, customer satisfaction, reductions in errors and omissions, reductions in lost business, management of employment practices and employee benefits, supervision of litigation, supervision of information technology, quality and quality audit scores, efficiency, acquisitions or divestitures, publication, clinical or regulatory milestones, research and development achievements, coverage decisions, licenses, collaborations, joint ventures or promotional arrangements and such other goals as the Committee may determine whether or not listed herein, or any combination of the foregoing. Each such goal may be expressed on an absolute or relative basis and may include comparisons based on current internal targets, the past performance of the Company (including the performance of one or more Subsidiaries, divisions, or operating units) or the past or

current performance of other companies or market indices (or a combination of such past and current performance). In addition to the ratios specifically enumerated above, performance goals may include comparisons relating to capital (including, but not limited to, the cost of capital), shareholders' equity, shares outstanding, assets or net assets, sales, or any combination thereof. The applicable performance measures may be applied on a pre- or post-tax basis and may be adjusted to include or exclude components of any performance measure, including, without limitation, foreign exchange gains and losses, asset writedowns, acquisitions and divestitures, change in fiscal year, unbudgeted capital expenditures, special charges such as restructuring or impairment charges, debt refinancing costs, extraordinary or noncash items, unusual, infrequently occurring, nonrecurring or one-time events affecting the Company or its financial statements or changes in law or accounting principles ("Adjustment Events"). In the sole discretion of the Committee, the Committee may amend or adjust the Performance Measures or other terms and conditions of an outstanding award in recognition of any Adjustment Events. Performance goals shall be subject to such other special rules and conditions as the Committee may establish at any time.

"***Performance Period***" means any period designated by the Committee during which (i) the Performance Measures applicable to an award shall be measured and (ii) the conditions to vesting applicable to an award shall remain in effect.

"***Prior Plan***" means the Outset Medical, Inc. 2019 Equity Incentive Plan and each other equity plan maintained by the Company under which awards are outstanding as of the effective date of the Plan.

"***Restricted Stock***" means shares of Common Stock which are subject to a Restriction Period and which may, in addition thereto, be subject to the attainment of specified Performance Measures within a specified Performance Period.

"***Restricted Stock Award***" means an award of Restricted Stock under this Plan.

"***Restricted Stock Unit***" means a right to receive one share of Common Stock or, in lieu thereof and to the extent set forth in the applicable Agreement, the Fair Market Value of such share of Common Stock in cash, which shall be contingent upon the expiration of a specified Restriction Period and which may, in addition thereto, be contingent upon the attainment of specified Performance Measures within a specified Performance Period.

"***Restricted Stock Unit Award***" means an award of Restricted Stock Units under this Plan.

"***Restriction Period***" means any period designated by the Committee during which either (i) the Common Stock subject to a Restricted Stock Award may not be sold, transferred, assigned, pledged, hypothecated or otherwise encumbered or disposed of, except as provided in this Plan or the Agreement relating to such award, or (ii) the conditions to vesting applicable to a Restricted Stock Unit Award or Other Stock Award shall remain in effect.

"***SAR***" means a stock appreciation right, which may be a Free-Standing SAR or a Tandem SAR.

"***Stock Award***" means a Restricted Stock Award, Restricted Stock Unit Award or Other Stock Award.

"***Subject Person***" has the meaning set forth in Section 5.8(a)(1).

"***Subsidiary***" means any corporation, limited liability company, partnership, joint venture, or similar entity in which the Company owns, directly or indirectly, an equity interest possessing more than 50% of the combined voting power of the total outstanding equity interests of such entity.

"***Substitute Award***" means an award granted under this Plan upon the assumption of, or in substitution for, outstanding equity awards previously granted by a company or other entity in connection with a corporate transaction, including a merger, combination, consolidation, or acquisition of property or stock; *provided*, *however*, that in no event shall the term "Substitute Award" be construed to refer to an award made in connection with the cancellation and repricing of an option or SAR.

"***Tandem SAR***" means an SAR which is granted in tandem with, or by reference to, an option (including a Nonstatutory Stock Option granted prior to the date of grant of the SAR), which entitles the holder thereof to receive, upon exercise of such SAR and surrender for cancellation of all or a portion of such option, shares of Common Stock (which may be Restricted Stock) or, to the extent set forth in the applicable Agreement, cash or a combination thereof, with an aggregate value equal to the excess of the Fair Market Value of one share of Common Stock on the date of exercise over the base price of such SAR, multiplied by the number of shares of Common Stock subject to such option, or portion thereof, which is surrendered.

"***Tax Date***" has the meaning set forth in Section 5.5.

"***Ten Percent Holder***" has the meaning set forth in Section 2.1(a).

1.3 Administration. This Plan shall be administered by the Committee. Any one or a combination of the following awards may be made under this Plan to eligible persons: (i) options to purchase shares of Common Stock in the form of Incentive Stock Options or Nonstatutory Stock Options; (ii) SARs in the form of Tandem SARs or Free-Standing SARs; (iii) Stock Awards in the form of Restricted Stock, Restricted Stock Units or Other Stock Awards; and (iv) Performance Awards. The Committee shall, subject to the terms of this Plan, select eligible persons for participation in this Plan and determine the form, amount and timing of each award to such persons and, if applicable, the number of shares of Common Stock subject to an award, the number of SARs, the number of Restricted Stock Units, the dollar value subject to a Performance Award, the purchase price or base price associated with the award, the time and conditions of exercise or settlement of the award, and all other terms and conditions of the award, including, without limitation, the form of the Agreement evidencing the award. The Committee may, in its sole discretion and for any reason at any time, take action such that (i) any or all outstanding options and SARs shall become exercisable in part or in full, (ii) all or a portion of the Restriction Period applicable to any outstanding awards shall lapse, (iii) all or a portion of the Performance Period applicable to any outstanding awards shall lapse and (iv) the Performance Measures (if any) applicable to any outstanding awards shall be deemed to be satisfied at the target, maximum or any other level. The Committee shall, subject to the terms of this Plan, interpret this Plan and the application thereof, establish rules and regulations it deems necessary or desirable for the administration of this Plan, and may impose, incidental to the grant of an award, conditions with respect to the award, such as limiting competitive employment or other activities. All such interpretations, rules, regulations and conditions shall be conclusive and binding on all parties.

The Committee may delegate some or all of its power and authority hereunder to the Board (or any members thereof) or, subject to applicable law, to a subcommittee of the Board, a member of the Board, the Chief Executive Officer or other executive officer of the Company as the Committee deems appropriate; *provided*, *however*, that the Committee may not delegate its power and authority to a member of the Board, the Chief Executive Officer or other executive officer of the Company with regard to the selection for participation in this Plan of an officer, director or other person subject to Section 16 of the Exchange Act or decisions concerning the timing, pricing or amount of an award to such an officer, director or other person.

No member of the Board or Committee, and neither the Chief Executive Officer nor any other executive officer to whom the Committee delegates any of its power and authority hereunder, shall be liable for any act, omission, interpretation, construction or determination made in connection with this Plan in good faith, and the members of the Board and the Committee and the Chief Executive Officer or other executive officer shall be entitled to indemnification and reimbursement by the Company in respect of any claim, loss, damage or expense (including attorneys' fees) arising therefrom to the full extent permitted by law (except as otherwise may be provided in the Company's Certificate of Incorporation and/or By-laws) and under any directors' and officers' liability insurance that may be in effect from time to time.

1.4 Eligibility. Participants in this Plan shall consist of such officers, other employees, Non-Employee Directors, consultants, independent contractors, agents, and persons expected to become officers, other employees, Non-Employee Directors, consultants, independent contractors and agents of the Company and its Subsidiaries as the Committee in its sole discretion may select from time to time. The Committee's selection of a person to participate in this Plan at any time shall not require the Committee to select such person to participate in this Plan at any other time. Except as otherwise provided for in an Agreement, for purposes of this Plan, references to employment by the

Company shall also mean employment by a Subsidiary, and references to employment shall include service as a Non-Employee Director, consultant, independent contractor or agent. The Committee shall determine, in its sole discretion, the extent to which a participant shall be considered employed during an approved leave of absence. Notwithstanding anything herein to the contrary, the aggregate value of cash compensation to be paid and the grant date fair value of equity awards that may be granted during any fiscal year of the Company to any Non-Employee Director shall not exceed $400,000, increased to $800,000 with respect to the fiscal year of a Non-Employee Director's initial service as a Non-Employee Director.

1.5 Shares Available. Subject to adjustment as provided in Section 5.7 and to all other limits set forth in this Plan, 3,665,167 shares of Common Stock shall initially be available for all awards under this Plan, other than Substitute Awards. Subject to adjustment as provided in Section 5.7, no more than 9,162,917 shares of Common Stock in the aggregate may be issued under the Plan in connection with Incentive Stock Options. The number of shares of Common Stock available under the Plan shall increase annually 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 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 Board. The number of shares of Common Stock that remain available for future grants under this Plan shall be reduced by the sum of the aggregate number of shares of Common Stock that become subject to outstanding options, outstanding Free-Standing SARs, outstanding Stock Awards and outstanding Performance Awards denominated in shares of Common Stock.

To the extent that shares of Common Stock subject to an outstanding option, SAR, Stock Award or Performance Award granted under the Plan or the Prior Plan, other than Substitute Awards, are not issued or delivered by reason of (i) the expiration, termination, cancellation or forfeiture of such award (excluding shares subject to an option cancelled upon settlement in shares of a related Tandem SAR or shares subject to a Tandem SAR cancelled upon exercise of a related option) or (ii) the settlement of such award in cash, then such shares of Common Stock shall again be available under this Plan. In addition, shares of Common Stock subject to an award under this Plan or the Prior Plan shall again be available for issuance under this Plan if such shares are (x) shares that were subject to an option or stock-settled SAR and were not issued or delivered upon the net settlement or net exercise of such option or SAR or (y) shares delivered to or withheld by the Company to pay the purchase price or the withholding taxes related to an outstanding award. Notwithstanding anything herein to the contrary, shares repurchased by the Company on the open market with the proceeds of an option exercise shall not again be available under this Plan.

The number of shares of Common Stock available for awards under this Plan shall not be reduced by (i) the number of shares of Common Stock subject to Substitute Awards or (ii) available shares under a stockholder approved plan of a company or other entity which was a party to a corporate transaction with the Company (as appropriately adjusted to reflect such corporate transaction) which become subject to awards granted under this Plan (subject to applicable stock exchange requirements).

Shares of Common Stock to be delivered under this Plan shall be made available from authorized and unissued shares of Common Stock, or authorized and issued shares of Common Stock reacquired and held as treasury shares or otherwise or a combination thereof.

II. Stock Options and Stock Appreciation Rights

2.1 Stock Options. The Committee may, in its discretion, grant options to purchase shares of Common Stock to such eligible persons as may be selected by the Committee. Each option, or portion thereof, that is not an Incentive Stock Option, shall be a Nonstatutory Stock Option. To the extent that the aggregate Fair Market Value (determined as of the date of grant) of shares of Common Stock with respect to which options designated as Incentive Stock Options are exercisable for the first time by a holder during any calendar year (under this Plan or any other plan of the Company, or any parent or Subsidiary) exceeds the amount (currently $100,000) established by the Code, such options shall constitute Nonstatutory Stock Options.

Options shall be subject to the following terms and conditions and shall contain such additional terms and conditions, not inconsistent with the terms of this Plan, as the Committee shall deem advisable:

(a) **Number of Shares and Purchase Price.** The number of shares of Common Stock subject to an option and the purchase price per share of Common Stock purchasable upon exercise of the option shall be determined by the Committee; *provided*, *however*, that the purchase price per share of Common Stock purchasable upon exercise of an option shall not be less than 100% of the Fair Market Value of a share of Common Stock on the date of grant of such option; *provided further*, that if an Incentive Stock Option shall be granted to any person who, at the time such option is granted, owns capital stock possessing more than 10% of the total combined voting power of all classes of capital stock of the Company (or of any parent or Subsidiary) (a "***Ten Percent Holder***"), the purchase price per share of Common Stock shall not be less than the price (currently 110% of Fair Market Value) required by the Code in order to constitute an Incentive Stock Option.

Notwithstanding the foregoing, in the case of an option that is a Substitute Award, the purchase price per share of the shares subject to such option may be less than 100% of the Fair Market Value per share on the date of grant, provided, that the excess of: (a) the aggregate Fair Market Value (as of the date such Substitute Award is granted) of the shares subject to the Substitute Award, over (b) the aggregate purchase price thereof does not exceed the excess of: (x) the aggregate fair market value (as of the time immediately preceding the transaction giving rise to the Substitute Award, such fair market value to be determined by the Committee) of the shares of the predecessor company or other entity that were subject to the grant assumed or substituted for by the Company, over (y) the aggregate purchase price of such shares.

(b) **Option Period and Exercisability.** The period during which an option may be exercised shall be determined by the Committee; *provided*, *however*, that no option may be exercised later than ten years after its date of grant; *provided further*, that if an Incentive Stock Option shall be granted to a Ten Percent Holder, such option may not be exercised later than five years after its date of grant. The Committee may, in its discretion, establish Performance Measures which shall be satisfied or met as a condition to the grant of an option or to the exercisability of all or a portion of an option. The Committee shall determine whether an option shall become exercisable in cumulative or non-cumulative installments and in part or in full at any time. An exercisable option, or portion thereof, may be exercised only with respect to whole shares of Common Stock.

(c) **Method of Exercise.** An option may be exercised (i) by giving written notice to the Company specifying the number of whole shares of Common Stock to be purchased and accompanying such notice with payment therefor in full (or arrangement made for such payment to the Company's satisfaction) either: (A) in cash; (B) by delivery (either actual delivery or by attestation procedures established by the Company) of shares of Common Stock having a Fair Market Value, determined as of the date of exercise, equal to the aggregate purchase price payable by reason of such exercise; (C) authorizing the Company to withhold whole shares of Common Stock which would otherwise be delivered having an aggregate Fair Market Value, determined as of the date of exercise, equal to the amount necessary to satisfy such obligation; (D) in cash by a broker-dealer acceptable to the Company to whom the holder has submitted an irrevocable notice of exercise; (E) in any other form of legal consideration that may be acceptable to the Committee and specified in the Agreement; or (F) a combination of (A), (B), (C) and (E), in each case to the extent set forth in the Agreement relating to the option; (ii) if applicable, by surrendering to the Company any Tandem SARs which are cancelled by reason of the exercise of the option; and (iii) by executing such documents as the Company may reasonably request. Any fraction of a share of Common Stock which would be required to pay such purchase price shall be disregarded and the remaining amount due shall be paid in cash by the holder. No shares of Common Stock shall be issued and no certificate representing Common Stock shall be delivered until the full purchase price therefor and any withholding taxes thereon, as described in Section 5.5, have been paid (or arrangement made for such payment to the Company's satisfaction).

2.2 Stock Appreciation Rights. The Committee may, in its discretion, grant SARs to such eligible persons as may be selected by the Committee. The Agreement relating to an SAR shall specify whether the SAR is a Tandem SAR or a Free-Standing SAR.

SARs shall be subject to the following terms and conditions and shall contain such additional terms and conditions, not inconsistent with the terms of this Plan, as the Committee shall deem advisable:

(a) **Number of SARs and Base Price.** The number of SARs subject to an award shall be determined by the Committee. Any Tandem SAR related to an Incentive Stock Option shall be granted at the same time that such

Incentive Stock Option is granted. The base price of a Tandem SAR shall be the purchase price per share of Common Stock of the related option. The base price of a Free-Standing SAR shall be determined by the Committee; *provided*, *however*, that such base price shall not be less than 100% of the Fair Market Value of a share of Common Stock on the date of grant of such SAR (or, if earlier, the date of grant of the option for which the SAR is exchanged or substituted).

Notwithstanding the foregoing, in the case of an SAR that is a Substitute Award, the base price per share of the shares subject to such SAR may be less than 100% of the Fair Market Value per share on the date of grant, provided, that the excess of: (a) the aggregate Fair Market Value (as of the date such Substitute Award is granted) of the shares subject to the Substitute Award, over (b) the aggregate base price thereof does not exceed the excess of: (x) the aggregate fair market value (as of the time immediately preceding the transaction giving rise to the Substitute Award, such fair market value to be determined by the Committee) of the shares of the predecessor company or other entity that were subject to the grant assumed or substituted for by the Company, over (y) the aggregate base price of such shares.

(b) **Exercise Period and Exercisability.** The period for the exercise of an SAR shall be determined by the Committee; *provided*, *however*, that (i) no Tandem SAR may be exercised later than the expiration, cancellation, forfeiture or other termination of the related option and (ii) no Free-Standing SAR may be exercised later than ten years after its date of grant. The Committee may, in its discretion, establish Performance Measures which shall be satisfied or met as a condition to the grant of an SAR or to the exercisability of all or a portion of an SAR. The Committee shall determine whether an SAR may be exercised in cumulative or non-cumulative installments and in part or in full at any time. An exercisable SAR, or portion thereof, may be exercised, in the case of a Tandem SAR, only with respect to whole shares of Common Stock and, in the case of a Free-Standing SAR, only with respect to a whole number of SARs. If an SAR is exercised for shares of Restricted Stock, a certificate or certificates representing such Restricted Stock shall be issued in accordance with Section 3.2(c), or such shares shall be transferred to the holder in book entry form with restrictions on the shares duly noted, and the holder of such Restricted Stock shall have such rights of a stockholder of the Company as determined pursuant to Section 3.2(d). Prior to the exercise of a stock-settled SAR, the holder of such SAR shall have no rights as a stockholder of the Company with respect to the shares of Common Stock subject to such SAR.

(c) **Method of Exercise.** A Tandem SAR may be exercised by (i) giving written notice to the Company specifying the number of whole SARs which are being exercised, (ii) surrendering to the Company any options which are cancelled by reason of the exercise of the Tandem SAR and (iii) executing such documents as the Company may reasonably request. A Free-Standing SAR may be exercised by (A) giving written notice to the Company specifying the whole number of SARs which are being exercised and (B) executing such documents as the Company may reasonably request. No shares of Common Stock shall be issued and no certificate representing Common Stock shall be delivered until any withholding taxes thereon, as described in Section 5.5, have been paid (or arrangement made for such payment to the Company's satisfaction).

2.3 Termination of Employment or Service. All of the terms relating to the exercise, cancellation or other disposition of an option or SAR (i) upon a termination of employment with or service to the Company of the holder of such option or SAR, as the case may be, whether by reason of disability, retirement, death, or any other reason; or (ii) during a paid or unpaid leave of absence, shall be determined by the Committee and set forth in the applicable Agreement.

2.4 No Repricing. The Committee shall not, without the approval of the stockholders of the Company, (i) reduce the purchase price or base price of any previously granted option or SAR, (ii) cancel any previously granted option or SAR in exchange for another option or SAR with a lower purchase price or base price or (iii) cancel any previously granted option or SAR in exchange for cash or another award if the purchase price of such option or the base price of such SAR exceeds the Fair Market Value of a share of Common Stock on the date of such cancellation, in each case, other than in connection with a Change in Control or the adjustment provisions set forth in Section 5.7.

2.5 No Dividend Equivalents. Notwithstanding anything in an Agreement to the contrary, the holder of an option or SAR shall not be entitled to receive dividend equivalents with respect to the number of shares of Common Stock subject to such option or SAR.

III. STOCK AWARDS

3.1 STOCK AWARDS. The Committee may, in its discretion, grant Stock Awards to such eligible persons as may be selected by the Committee. The Agreement relating to a Stock Award shall specify whether the Stock Award is a Restricted Stock Award, a Restricted Stock Unit Award or, in the case of an Other Stock Award, the type of award being granted.

3.2 TERMS OF RESTRICTED STOCK AWARDS. Restricted Stock Awards shall be subject to the following terms and conditions and shall contain such additional terms and conditions, not inconsistent with the terms of this Plan, as the Committee shall deem advisable.

(a) **Number of Shares and Other Terms.** The number of shares of Common Stock subject to a Restricted Stock Award and the Restriction Period, Performance Period (if any) and Performance Measures (if any) applicable to a Restricted Stock Award shall be determined by the Committee.

(b) **Vesting and Forfeiture.** The Agreement relating to a Restricted Stock Award shall provide, in the manner determined by the Committee, in its discretion, and subject to the provisions of this Plan, for the vesting of the shares of Common Stock subject to such award (i) if the holder of such award remains continuously in the employment of the Company during the specified Restriction Period and (ii) if specified Performance Measures (if any) are satisfied or met during a specified Performance Period, and for the forfeiture of the shares of Common Stock subject to such award (x) if the holder of such award does not remain continuously in the employment of the Company during the specified Restriction Period or (y) if specified Performance Measures (if any) are not satisfied or met during a specified Performance Period.

(c) **Stock Issuance.** During the Restriction Period, the shares of Restricted Stock shall be held by a custodian in book entry form with restrictions on such shares duly noted or, alternatively, a certificate or certificates representing a Restricted Stock Award shall be registered in the holder's name and may bear a legend, in addition to any legend which may be required pursuant to Section 5.6, indicating that the ownership of the shares of Common Stock represented by such certificate is subject to the restrictions, terms and conditions of this Plan and the Agreement relating to the Restricted Stock Award. All such certificates shall be deposited with the Company, together with stock powers or other instruments of assignment (including a power of attorney), each endorsed in blank with a guarantee of signature if deemed necessary or appropriate, which would permit transfer to the Company of all or a portion of the shares of Common Stock subject to the Restricted Stock Award in the event such award is forfeited in whole or in part. Upon termination of any applicable Restriction Period (and the satisfaction or attainment of applicable Performance Measures), subject to the Company's right to require payment of any taxes in accordance with Section 5.5, the restrictions shall be removed from the requisite number of any shares of Common Stock that are held in book entry form, and all certificates evidencing ownership of the requisite number of shares of Common Stock shall be delivered to the holder of such award.

(d) **Rights with Respect to Restricted Stock Awards.** Unless otherwise set forth in the Agreement relating to a Restricted Stock Award, and subject to the terms and conditions of a Restricted Stock Award, the holder of such award shall have all rights as a stockholder of the Company, including, but not limited to, voting rights, the right to receive dividends and the right to participate in any capital adjustment applicable to all holders of Common Stock; *provided, however*, that (i) a distribution with respect to shares of Common Stock, other than a regular cash dividend, and (ii) a regular cash dividend with respect to shares of Common Stock that are subject to performance-based vesting conditions, in each case, shall be deposited with the Company and shall be subject to the same restrictions as the shares of Common Stock with respect to which such distribution was made.

3.3 TERMS OF RESTRICTED STOCK UNIT AWARDS. Restricted Stock Unit Awards shall be subject to the following terms and conditions and shall contain such additional terms and conditions, not inconsistent with the terms of this Plan, as the Committee shall deem advisable.

(a) **Number of Shares and Other Terms.** The number of shares of Common Stock subject to a Restricted Stock Unit Award, including the number of shares that are earned upon the attainment of any specified

Performance Measures, and the Restriction Period, Performance Period (if any) and Performance Measures (if any) applicable to a Restricted Stock Unit Award shall be determined by the Committee.

(b) **Vesting and Forfeiture.** The Agreement relating to a Restricted Stock Unit Award shall provide, in the manner determined by the Committee, in its discretion, and subject to the provisions of this Plan, for the vesting of such Restricted Stock Unit Award (i) if the holder of such award remains continuously in the employment of the Company during the specified Restriction Period and (ii) if specified Performance Measures (if any) are satisfied or met during a specified Performance Period, and for the forfeiture of the shares of Common Stock subject to such award (x) if the holder of such award does not remain continuously in the employment of the Company during the specified Restriction Period or (y) if specified Performance Measures (if any) are not satisfied or met during a specified Performance Period.

(c) **Settlement of Vested Restricted Stock Unit Awards.** The Agreement relating to a Restricted Stock Unit Award shall specify (i) whether such award may be settled in shares of Common Stock or cash or a combination thereof and (ii) whether the holder thereof shall be entitled to receive dividend equivalents, and, if determined by the Committee, interest on, or the deemed reinvestment of, any deferred dividend equivalents, with respect to the number of shares of Common Stock subject to such award. Any dividend equivalents with respect to Restricted Stock Units that are subject to performance-based vesting conditions shall be subject to the same restrictions as such Restricted Stock Units. Prior to the settlement of a Restricted Stock Unit Award, the holder of such award shall have no rights as a stockholder of the Company with respect to the shares of Common Stock subject to such award.

3.4 Other Stock Awards. Subject to the limitations set forth in the Plan, the Committee is authorized to grant other awards that may be denominated or payable in, valued in whole or in part by reference to, or otherwise based on, or related to, shares of Common Stock, including without limitation shares of Common Stock granted as a bonus and not subject to any vesting conditions, dividend equivalents, deferred stock units, stock purchase rights and shares of Common Stock issued in lieu of obligations of the Company to pay cash under any compensatory plan or arrangement, subject to such terms as shall be determined by the Committee. The Committee shall determine the terms and conditions of such awards, which may include the right to elective deferral thereof, subject to such terms and conditions as the Committee may specify in its discretion.

3.5 Termination of Employment or Service. All of the terms relating to the satisfaction of Performance Measures and the termination of the Restriction Period or Performance Period relating to a Stock Award, or any forfeiture and cancellation of such award (i) upon a termination of employment with or service to the Company of the holder of such award, whether by reason of disability, retirement, death, or any other reason; or (ii) during a paid or unpaid leave of absence, shall be determined by the Committee and set forth in the applicable Agreement.

IV. Performance Awards

4.1 Performance Awards. The Committee may, in its discretion, grant Performance Awards to such eligible persons as may be selected by the Committee.

4.2 Terms of Performance Awards. Performance Awards shall be subject to the following terms and conditions and shall contain such additional terms and conditions, not inconsistent with the terms of this Plan, as the Committee shall deem advisable.

(a) **Value of Performance Awards and Performance Measures.** The method of determining the value of the Performance Award and the Performance Measures and Performance Period applicable to a Performance Award shall be determined by the Committee.

(b) **Vesting and Forfeiture.** The Agreement relating to a Performance Award shall provide, in the manner determined by the Committee, in its discretion, and subject to the provisions of this Plan, for the vesting of such Performance Award if the specified Performance Measures are satisfied or met during the specified Performance

Period and for the forfeiture of such award if the specified Performance Measures are not satisfied or met during the specified Performance Period.

(c) **Settlement of Vested Performance Awards.** The Agreement relating to a Performance Award shall specify whether such award may be settled in shares of Common Stock (including shares of Restricted Stock) or cash or a combination thereof. If a Performance Award is settled in shares of Restricted Stock, such shares of Restricted Stock shall be issued to the holder in book entry form or a certificate or certificates representing such Restricted Stock shall be issued in accordance with Section 3.2(c) and the holder of such Restricted Stock shall have such rights as a stockholder of the Company as determined pursuant to Section 3.2(d). Any dividends or dividend equivalents with respect to a Performance Award subject to performance-based vesting conditions shall be subject to the same restrictions as such Performance Award. Prior to the settlement of a Performance Award in shares of Common Stock, including Restricted Stock, the holder of such award shall have no rights as a stockholder of the Company.

4.3 Termination of Employment or Service. All of the terms relating to the satisfaction of Performance Measures and the termination of the Performance Period relating to a Performance Award, or any forfeiture and cancellation of such award (i) upon a termination of employment with or service to the Company of the holder of such award, whether by reason of disability, retirement, death, or any other reason; or (ii) during a paid or unpaid leave of absence, shall be determined by the Committee and set forth in the applicable Agreement.

V. General

5.1 Effective Date and Term of Plan. This Plan was approved by the stockholders of the Company and became effective on September 7, 2020. This Plan shall terminate on the tenth anniversary of Board approval of the Plan, unless terminated earlier by the Board. Termination of this Plan shall not affect the terms or conditions of any award granted prior to termination. Awards hereunder may be made at any time prior to the termination of this Plan, provided that no Incentive Stock Option may be granted later than ten years after the date on which the Plan was approved by the Board.

5.2 Amendments. The Board may amend this Plan as it shall deem advisable; *provided*, *however*, that no amendment to the Plan shall be effective without the approval of the Company's stockholders if (i) stockholder approval is required by applicable law, rule or regulation, including any rule of NASDAQ or any other stock exchange on which the Common Stock is then traded, or (ii) such amendment seeks to modify the Non-Employee Director compensation limit set forth in Section 1.4 or the terms of Section 2.4 hereof; *provided further*, that no amendment may materially impair the rights of a holder of an outstanding award without the consent of such holder.

5.3 Agreement. The Company may condition an award holder's right (a) to exercise, vest or settle the award and (b) to receive delivery of shares, on the execution and delivery to the Company of an Agreement and the completion of other requirements, including, but not limited to, the execution of a nonsolicitation agreement by the recipient and delivery thereof to the Company. Notwithstanding anything contained herein to the contrary, the Committee may approve an Agreement that, upon the termination of an award holder's employment or service, provides that (i) any or all outstanding options and SARs shall become exercisable in part or in full, (ii) all or a portion of the Restriction Period applicable to any outstanding awards shall lapse, (iii) all or a portion of the Performance Period applicable to any outstanding awards shall lapse and (iv) the Performance Measures (if any) applicable to any outstanding awards shall be deemed to be satisfied at the target, maximum or any other level.

5.4 Non-Transferability. No award shall be transferable other than by will, the laws of descent and distribution or pursuant to beneficiary designation procedures approved by the Company or, to the extent expressly permitted in the Agreement relating to such award, to the holder's family members, a trust or entity established by the holder for estate planning purposes, a charitable organization designated by the holder or pursuant to a domestic relations order, in each case, without consideration. Except to the extent permitted by the foregoing sentence or the Agreement relating to an award, each award may be exercised or settled during the holder's lifetime only by the holder or the holder's legal representative or similar person. Except as permitted by the second preceding sentence, no award may be sold, transferred, assigned, pledged, hypothecated, encumbered or otherwise disposed of (whether by operation

of law or otherwise) or be subject to execution, attachment or similar process. Upon any attempt to so sell, transfer, assign, pledge, hypothecate, encumber or otherwise dispose of any award, such award and all rights thereunder shall immediately become null and void.

5.5 Tax Withholding. The Company shall have the right to require, prior to the issuance or delivery of any shares of Common Stock or the payment of any cash pursuant to an award made hereunder, payment by the holder of such award of any federal, state, local or other taxes which may be required to be withheld or paid in connection with such award. An Agreement may provide that (i) the Company shall withhold whole shares of Common Stock which would otherwise be delivered to a holder, having an aggregate Fair Market Value determined as of the date the obligation to withhold or pay taxes arises in connection with an award (the "***Tax Date***"), or withhold an amount of cash which would otherwise be payable to a holder, in the amount necessary to satisfy any such obligation or (ii) the holder may satisfy any such obligation by any of the following means: (A) a cash payment to the Company; (B) delivery (either actual delivery or by attestation procedures established by the Company) to the Company of previously owned whole shares of Common Stock having an aggregate Fair Market Value, determined as of the Tax Date, equal to the amount necessary to satisfy any such obligation; (C) authorizing the Company to withhold whole shares of Common Stock which would otherwise be delivered having an aggregate Fair Market Value, determined as of the Tax Date, or withhold an amount of cash which would otherwise be payable to a holder, in either case equal to the amount necessary to satisfy any such obligation; (D) a cash payment by a broker-dealer acceptable to the Company; or (E) any combination of (A), (B), and (C), in each case to the extent set forth in the Agreement relating to the award. Shares of Common Stock to be delivered or withheld may not have an aggregate Fair Market Value in excess of the amount determined by applying the minimum statutory withholding rate (or, if permitted by the Company, such other rate as shall not cause adverse accounting consequences under the accounting rules then in effect, and is permitted under applicable IRS withholding rules). Any fraction of a share of Common Stock which would be required to satisfy such an obligation shall be disregarded and the remaining amount due shall be paid in cash by the holder.

5.6 Restrictions on Shares. Each award made hereunder shall be subject to the requirement that if at any time the Company determines that the listing, registration or qualification of the shares of Common Stock subject to such award upon any securities exchange or under any law, or the consent or approval of any governmental body, or the taking of any other action is necessary or desirable as a condition of, or in connection with, the delivery of shares thereunder, such shares shall not be delivered unless such listing, registration, qualification, consent, approval or other action shall have been effected or obtained, free of any conditions not acceptable to the Company. The Company may require that certificates evidencing shares of Common Stock delivered pursuant to any award made hereunder bear a legend indicating that the sale, transfer or other disposition thereof by the holder is prohibited except in compliance with the Securities Act of 1933, as amended, and the rules and regulations thereunder.

5.7 Adjustment. In the event of any equity restructuring (within the meaning of Financial Accounting Standards Board Accounting Standards Codification Topic 718, Compensation—Stock Compensation or any successor or replacement accounting standard) that causes the per share value of shares of Common Stock to change, such as a stock dividend, stock split, spinoff, rights offering, or recapitalization through an extraordinary cash dividend, the number and class of securities available under this Plan, the terms of each outstanding option and SAR (including the number and class of securities subject to each outstanding option or SAR and the purchase price or base price per share), the terms of each outstanding Stock Award (including the number and class of securities subject thereto), and the terms of each outstanding Performance Award (including the number and class of securities subject thereto, if applicable) shall be appropriately adjusted by the Committee, such adjustments to be made in the case of outstanding options and SARs in accordance with Section 409A of the Code. In the event of any other change in corporate capitalization, including a merger, consolidation, reorganization, or partial or complete liquidation of the Company, such equitable adjustments described in the foregoing sentence may be made as determined to be appropriate and equitable by the Committee to prevent dilution or enlargement of rights of participants. In either case, the decision of the Committee regarding any such adjustment shall be final, binding and conclusive.

5.8 Change in Control.

(a) For purposes of this Plan, "***Change in Control***" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(1) any Exchange Act Person becomes the owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company's then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change in Control shall not be deemed to occur (A) on account of the acquisition of securities of the Company directly from the Company, (B) on account of the acquisition of securities of the Company by an investor, any affiliate thereof or any other Exchange Act Person that acquires the Company's securities in a transaction or series of related transactions the primary purpose of which is to obtain financing for the Company through the issuance of equity securities or (C) solely because the level of ownership held by any Exchange Act Person (the "***Subject Person***") exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities owned by the Subject Person over the designated percentage threshold, then a Change in Control shall be deemed to occur;

(2) there is consummated a merger, consolidation, or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation, or similar transaction, the stockholders of the Company immediately prior thereto do not own, directly or indirectly, either (A) outstanding voting securities representing more than 50% of the combined outstanding voting power of the surviving entity in such merger, consolidation or similar transaction or (B) more than 50% of the combined outstanding voting power of the parent of the surviving entity in such merger, consolidation, or similar transaction, in each case in substantially the same proportions as their ownership of the outstanding voting securities of the Company immediately prior to such transaction;

(3) there is consummated a sale, lease, exclusive license, or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, license, or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an entity, more than 50% of the combined voting power of the voting securities of which are owned by stockholders of the Company in substantially the same proportions as their ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, license, or other disposition;

(4) the stockholders of the Company approve or the Board approves a plan of complete dissolution or liquidation of the Company, or a complete dissolution or liquidation of the Company shall otherwise occur, except for a liquidation into a parent corporation; or

(5) during any twenty-four (24) month period, individuals who, as of the beginning of such period, constitute the Board (the "*Incumbent Directors*") cease for any reason to constitute at least a majority of the Board; provided that any Person becoming a director subsequent to the beginning of such period whose election or nomination for election was approved by a vote of at least a majority of the Incumbent Directors then on the Board (either by a specific vote or by approval of the proxy statement of the Company in which such Person is named as a nominee for director, without written objection to such nomination) shall be an Incumbent Director; provided, however, that no individual initially elected or nominated as a director of the Company as a result of an actual or threatened election contest with respect to directors or as a result of any other actual or threatened solicitation of proxies by or on behalf of any Person other than the Board shall be deemed to be an Incumbent Director. For purposes of this clause (5), "*Person*" shall have the meaning given in Section 3(a)(9) of the Exchange Act, as modified and used in Sections 13(d) and 14(d) thereof, except that such term shall not include (w) the Company or any of its Affiliates, within the meaning of Rule 12b-2 under Section 12 of the

Exchange Act; (x) a trustee or other fiduciary holding securities under an employee benefit plan of the Company or any of its Subsidiaries; (y) an underwriter temporarily holding securities pursuant to an offering of such securities; or (z) a corporation owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of stock of the Company.

Notwithstanding the foregoing definition or any other provision of this Plan, (A) the term Change in Control shall not include a sale of assets, merger, or other transaction effected exclusively for the purpose of changing the domicile of the Company and (B) with respect to any nonqualified deferred compensation that becomes payable on account of the Change in Control, the transaction or event described in clause (1), (2), (3), (4) or (5) shall also constitute a "change in control event," as defined in Treasury Regulation § 1.409A-3(i)(5) if required in order for the payment not to violate Section 409A of the Code.

(b) Subject to the terms of the applicable Agreements, in the event of a Change in Control, the Board, as constituted prior to the Change in Control, may, in its discretion:

(1) require that (i) some or all outstanding options and SARs shall become exercisable in full or in part, either immediately or upon a subsequent termination of employment, (ii) the Restriction Period applicable to some or all outstanding Stock Awards shall lapse in full or in part, either immediately or upon a subsequent termination of employment, (iii) the Performance Period applicable to some or all outstanding awards shall lapse in full or in part, and (iv) the Performance Measures applicable to some or all outstanding awards shall be deemed to be satisfied at the target, maximum or any other level;

(2) require that shares of capital stock of the corporation resulting from or succeeding to the business of the Company pursuant to such Change in Control, or a parent corporation thereof, or other property be substituted for some or all of the shares of Common Stock subject to an outstanding award, with an appropriate and equitable adjustment to such award as determined by the Board in accordance with Section 5.7; and/or

(3) require outstanding awards, in whole or in part, to be surrendered to the Company by the holder, and to be immediately cancelled by the Company, and to provide for the holder to receive (i) a cash payment in an amount equal to (A) in the case of an option or an SAR, the aggregate number of shares of Common Stock then subject to the portion of such option or SAR surrendered, whether or not vested or exercisable, multiplied by the excess, if any, of the Fair Market Value of a share of Common Stock as of the date of the Change in Control, over the purchase price or base price per share of Common Stock subject to such option or SAR, (B) in the case of a Stock Award or a Performance Award denominated in shares of Common Stock, the number of shares of Common Stock then subject to the portion of such award surrendered to the extent the Performance Measures applicable to such award have been satisfied or are deemed satisfied pursuant to Section 5.8(a)(1), whether or not vested, multiplied by the Fair Market Value of a share of Common Stock as of the date of the Change in Control, and (C) in the case of a Performance Award denominated in cash, the value of the Performance Award then subject to the portion of such award surrendered to the extent the Performance Measures applicable to such award have been satisfied or are deemed satisfied pursuant to Section 5.8(a)(1); (ii) shares of capital stock of the corporation resulting from or succeeding to the business of the Company pursuant to such Change in Control, or a parent corporation thereof, or other property having a fair market value not less than the amount determined under clause (i) above; or (iii) a combination of the payment of cash pursuant to clause (i) above or the issuance of shares or other property pursuant to clause (ii) above.

5.9 Deferrals. The Committee may determine that the delivery of shares of Common Stock or the payment of cash, or a combination thereof, upon the settlement of all or a portion of any award made hereunder shall be deferred, or the Committee may, in its sole discretion, approve deferral elections made by holders of awards. Deferrals shall be

for such periods and upon such terms as the Committee may determine in its sole discretion, subject to the requirements of Section 409A of the Code.

5.10 No Right of Participation, Employment or Service. Unless otherwise set forth in an employment agreement, no person shall have any right to participate in this Plan. Neither this Plan nor any award made hereunder shall confer upon any person any right to continued employment by or service with the Company, any Subsidiary or any affiliate of the Company or affect in any manner the right of the Company, any Subsidiary or any affiliate of the Company to terminate the employment or service of any person at any time without liability hereunder.

5.11 Rights as Stockholder. No person shall have any right as a stockholder of the Company with respect to any shares of Common Stock or other equity security of the Company which is subject to an award hereunder unless and until such person becomes a stockholder of record with respect to such shares of Common Stock or equity security.

5.12 Designation of Beneficiary. To the extent permitted by the Company, a holder of an award may file with the Company a written designation of one or more persons as such holder's beneficiary or beneficiaries (both primary and contingent) in the event of the holder's death or incapacity. To the extent an outstanding option or SAR granted hereunder is exercisable, such beneficiary or beneficiaries shall be entitled to exercise such option or SAR pursuant to procedures prescribed by the Company. Each beneficiary designation shall become effective only when filed in writing with the Company during the holder's lifetime on a form prescribed by the Company. The spouse of a married holder domiciled in a community property jurisdiction shall join in any designation of a beneficiary other than such spouse. The filing with the Company of a new beneficiary designation shall cancel all previously filed beneficiary designations. If a holder fails to designate a beneficiary, or if all designated beneficiaries of a holder predecease the holder, then each outstanding award held by such holder, to the extent vested or exercisable, shall be payable to or may be exercised by such holder's executor, administrator, legal representative or similar person.

5.13 Awards Subject to Clawback. The awards granted under this Plan and any cash payment or shares of Common Stock delivered pursuant to such an award are subject to forfeiture, recovery by the Company or other action pursuant to the applicable Agreement or any clawback or recoupment policy which the Company may adopt from time to time, including without limitation the policy adopted by the Company under the Dodd-Frank Wall Street Reform and Consumer Protection Act and implementing rules and regulations thereunder, or as otherwise required by law.

5.14 Governing Law. This Plan, each award hereunder and the related Agreement, and all determinations made and actions taken pursuant thereto, to the extent not otherwise governed by the Code or the laws of the United States, shall be governed by the laws of the State of Delaware and construed in accordance therewith without giving effect to principles of conflicts of laws.

5.15 Compliance with Section 409A of the Code. To the extent that the Board determines that any award granted hereunder is subject to Section 409A of the Code, the Plan and applicable Agreement will be interpreted in accordance with Section 409A of the Code. Notwithstanding anything to the contrary in the Plan (and unless the Agreement specifically provides otherwise), if the shares of Common Stock are publicly traded, and if a holder holding an award that constitutes "deferred compensation" under Section 409A of the Code is a "specified employee" for purposes of Section 409A of the Code, no distribution or payment of any amount that is due because of a "separation from service" (as defined in Section 409A of the Code without regard to alternative definitions thereunder) will be issued or paid before the date that is six months following the date of such holder's "separation from service" (as defined in Section 409A of the Code without regard to alternative definitions thereunder) or, if earlier, the date of the holder's death, unless such distribution or payment can be made in a manner that complies with Section 409A of the Code, and any amounts so deferred will be paid in a lump sum on the day after such six month period elapses, with the balance paid thereafter on the original schedule.

5.16 Foreign Employees. Without amending this Plan, the Committee may grant awards to eligible persons who are foreign nationals and/or reside outside of the United States on such terms and conditions different from those specified in this Plan as may in the judgment of the Committee be necessary or desirable to foster and promote achievement of the purposes of this Plan and, in furtherance of such purposes the Committee may make such

modifications, amendments, procedures, subplans and the like as may be necessary or advisable to comply with provisions of laws in other countries or jurisdictions in which the Company or its Subsidiaries operates or has employees.

Exhibit 10.11

OUTSET MEDICAL, INC.

AMENDED AND RESTATED

CHANGE IN CONTROL AND SEVERANCE AGREEMENT

This Amended and Restated Change in Control and Severance Agreement (the "**Agreement**") is made between Outset Medical, Inc. (the "**Company**") and Leslie Trigg (the "**Executive**"), effective as of [ ], 2024 (the "**Effective Date**").

The Company and the Executive entered into a Change in Control and Severance Agreement, dated as of September 10, 2020 (the "**Prior Agreement**"). The Company desires to offer the Executive an amendment of the terms and conditions of the Prior Agreement, which is embodied in the terms and conditions of this Agreement as provided herein. This Agreement provides certain protections to the Executive in connection with a change in control of the Company or in connection with the involuntary termination of the Executive's employment under the circumstances described in this Agreement and replaces the Prior Agreement in its entirety.

The Company and the Executive agree as follows:

1. Term of Agreement. This Agreement will have an initial term of three (3) years commencing on the Effective Date (the "**Initial Term**"). On the third (3rd) anniversary of the Effective Date, this Agreement will renew automatically for additional, one (1) year terms (each, an "**Additional Term**") unless either party provides the other party with written notice of nonrenewal at least one (1) year prior to the date of automatic renewal. Notwithstanding the foregoing, if a Change in Control occurs (a) when there are fewer than twelve (12) months remaining during the Initial Term or (b) during an Additional Term, the term of this Agreement will extend automatically through the date that is twelve (12) months following the date of the Change in Control. If the Executive becomes entitled to the benefits under Section 3 of this Agreement, then the Agreement will not terminate until all of the obligations of the parties hereto with respect to this Agreement have been satisfied.

2. At-Will Employment. The Company and the Executive acknowledge that the Executive's employment is and will continue to be at-will, as defined under applicable law.

3. Severance Benefits.

(a) Qualifying Non-CIC Termination. On a Qualifying Non-CIC Termination (as defined below), the Executive will be eligible to receive the following payments and benefits from the Company:

(i) Salary Severance. A single, lump sum payment equal to twelve (12) months of the Executive's Salary (as defined below), less applicable withholdings.

(ii) COBRA Coverage. Subject to Section 3(d), the Company will pay the premiums for coverage under COBRA (as defined below) for the Executive and the Executive's eligible dependents, if any, at the rates then in effect, subject to any subsequent changes in rates that are generally applicable to the Company's active employees (the "**COBRA Coverage**"), until the earliest of (A) a period of twelve (12) months from the date of the Executive's termination of employment, (B) the date upon which the Executive (and the Executive's eligible dependents, as applicable) becomes covered under similar plans, or (C) the date upon which the Executive ceases to be eligible for coverage under COBRA.

(b) Qualifying CIC Termination. On a Qualifying CIC Termination, the Executive will be eligible to receive the following payments and benefits from the Company:

(i) Salary Severance. A single, lump sum payment, less applicable withholdings, equal to twenty-four (24) months of the Executive's Salary (such total number of months, the "**Severance Period**").

(ii) Bonus Severance. A single, lump sum payment equal to 200% of the Executive's target annual bonus as in effect for the fiscal year in which the Qualifying CIC Termination occurs, less applicable withholdings.

(iii) COBRA Coverage. Subject to Section 3(d), the Company will provide COBRA Coverage until the earliest of (A) eighteen (18) months from the date of the Executive's termination of employment, (B) the date upon which the Executive (and the Executive's eligible dependents, as applicable) becomes covered under similar plans, or (C) the date upon which the Executive ceases to be eligible for coverage under COBRA.

(iv) Equity Vesting Acceleration. Vesting acceleration (and exercisability, as applicable) as to 100% of the then-unvested shares subject to each of the Executive's then-outstanding Company equity awards. In the case of an equity award with performance-based vesting, unless the applicable equity award agreement governing such award provides for more favorable treatment, all performance goals and other vesting criteria will be deemed achieved at target. For the avoidance of doubt, in the event of the Executive's Qualifying Pre-CIC Termination (as defined below), any unvested portion of the Executive's then-outstanding equity awards will remain outstanding until the earlier of (x) three (3) months following the Qualifying Termination or (y) the occurrence of a Change in Control, solely so that any benefits due on a Qualifying Pre-CIC Termination can be provided if a Change in Control occurs within the three (3) month period following the Qualifying Termination (provided that in no event will the Executive's stock options or similar equity awards remain outstanding beyond the equity award's maximum term to expiration). If no Change in Control occurs within the three (3) month period following a Qualifying Termination, any unvested portion of the Executive's equity awards automatically and permanently will be forfeited on the three (3) month anniversary following the date of the Qualifying Termination without having vested.

(c) Termination Other Than a Qualifying Termination. If the termination of the Executive's employment with the Company Group is not a Qualifying Termination, then the Executive will not be entitled to receive severance or other benefits.

(d) Conditions to Receipt of COBRA Coverage. The Executive's receipt of COBRA Coverage is subject to the Executive electing COBRA continuation coverage within the time period prescribed pursuant to COBRA for the Executive and the Executive's eligible dependents, if any. If the Company determines in its sole discretion that it cannot provide the COBRA Coverage without potentially violating, or being subject to an excise tax under, applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then in lieu of any COBRA Coverage, the Company will provide to the Executive a taxable monthly payment payable on the last day of a given month (except as provided by the immediately following sentence), in an amount equal to the monthly COBRA premium that the Executive would be required to pay to continue his or her group health coverage in effect on the date of his or her Qualifying Termination (which amount will be based on the premium rates applicable for the first month of COBRA Coverage for the Executive and any of eligible dependents of the Executive) (each, a "**COBRA Replacement Payment**"), which COBRA Replacement Payments will be made regardless of whether the Executive elects COBRA continuation coverage and will end on the earlier of (x) the date upon which the Executive obtains other employment or (y) the date the Company has paid an amount totaling the number of COBRA Replacement Payments equal to the number of months in the applicable COBRA Coverage period. For the avoidance of doubt, the COBRA Replacement Payments may be used for any purpose, including, but not limited to continuation coverage under COBRA, and will be subject to any applicable withholdings. Notwithstanding anything to the contrary under this Agreement, if the Company determines in its sole discretion at any time that it cannot provide the COBRA Replacement Payments without violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Executive will not receive the COBRA Replacement Payments or any further COBRA Coverage.

(e) Non-Duplication of Payment or Benefits. For purposes of clarity, in the event of a Qualifying Pre-CIC Termination, any severance payments and benefits to be provided to the Executive under Section 3(b) will be reduced by any amounts that already were provided to the Executive under Section 3(a). Notwithstanding any provision of this Agreement to the contrary, if the Executive is entitled to any cash severance, continued health coverage benefits, or vesting acceleration of any equity awards (other than under this Agreement) by operation of applicable law or under a plan, policy, contract, or arrangement sponsored by or to which any member of the Company Group is a party ("**Other Benefits**"), then the corresponding severance payments and benefits under this Agreement will be reduced by the amount of Other Benefits paid or provided to the Executive.

(f) Death of the Executive. In the event of the Executive's death before all payments or benefits the Executive is entitled to receive under this Agreement have been provided, the unpaid amounts will be provided to the Executive's designated beneficiary, if living, or otherwise to the Executive's personal representative in a single lump sum as soon as possible following the Executive's death.

(g) Transfer Between Members of the Company Group. For purposes of this Agreement, if the Executive is involuntarily transferred from one member of the Company Group to another, the transfer will not be a termination without Cause but may give the Executive the ability to resign for Good Reason.

(h) Exclusive Remedy. In the event of a termination of the Executive's employment with the Company Group, the provisions of this Agreement are intended to be and are exclusive and in lieu of any other rights or remedies to which the Executive may otherwise be entitled, whether at law, tort or contract, or in equity. The Executive will be entitled to no benefits, compensation or other payments or rights upon termination of employment other than those benefits expressly set forth in this Agreement.

4. Accrued Compensation. On any termination of the Executive's employment with the Company Group, the Executive will be entitled to receive all accrued but unpaid vacation, expense reimbursements, wages, and other benefits due to the Executive under any Company-provided plans, policies, and arrangements.

5. Conditions to Receipt of Severance.

(a) Separation Agreement and Release of Claims. The Executive's receipt of any severance payments or benefits upon the Executive's Qualifying Termination under Section 3 is subject to the Executive signing and not revoking the Company's then-standard separation agreement and release of claims (which may include an agreement not to disparage any member of the Company Group, non-solicit provisions, an agreement to assist in any litigation matters, and other standard terms and conditions) (the "**Release**" and that requirement, the "**Release Requirement**"), which must become effective and irrevocable no later than the sixtieth (60th) day following the Executive's Qualifying Termination (the "**Release Deadline**"). If the Release does not become effective and irrevocable by the Release Deadline, the Executive will forfeit any right to severance payments or benefits under Section 3.

(b) Payment Timing. Any lump sum Salary or bonus payments under Sections 3(a)(i), 3(b)(i) and 3(b)(ii) will be provided on the first regularly scheduled payroll date of the Company following the date the Release becomes effective and irrevocable (the "**Severance Start Date**"), subject to any delay required by Section 5(d) below. Any taxable installments of any COBRA-related severance benefits that otherwise would have been made to the Executive on or before the Severance Start Date will be paid on the Severance Start Date, and any remaining installments thereafter will be provided as specified in the Agreement. Any restricted stock units, performance shares, performance units, and/or similar full value awards that accelerate vesting under Section 3(b)(iv) will be settled (x) on a date no later than ten (10) days following the date the Release becomes effective and irrevocable, or (y) if later, in the event of a Qualifying Pre-CIC Termination, on a date no later than the Change in Control.

(c) Return of Company Property. The Executive's receipt of any severance payments or benefits upon the Executive's Qualifying Termination under Section 3 is subject to the Executive returning all documents and other property provided to the Executive by any member of the Company Group (with the exception of a copy of the Company employee handbook and personnel documents specifically relating to the Executive), developed or obtained by the Executive in connection with his or her employment with the Company Group, or otherwise belonging to the Company Group.

(d) Section 409A. The Company intends that all payments and benefits provided under this Agreement or otherwise are exempt from, or comply with, the requirements of Section 409A of the Code and any guidance promulgated under Section 409A of the Code (collectively, "**Section 409A**") so that none of the payments or benefits will be subject to the additional tax imposed under Section 409A, and any ambiguities in this Agreement will be interpreted in accordance with this intent. No payment or benefits to be paid to the Executive, if any, under this Agreement or otherwise, when considered together with any other severance payments or separation benefits that are considered deferred compensation under Section 409A (together, the "**Deferred Payments**") will be paid or otherwise provided until the Executive has a "separation from service" within the meaning of Section 409A. If, at the time of the Executive's termination

of employment, the Executive is a "specified employee" within the meaning of Section 409A, then the payment of the Deferred Payments will be delayed to the extent necessary to avoid the imposition of the additional tax imposed under Section 409A, which generally means that the Executive will receive payment on the first payroll date that occurs on or after the date that is 6 months and 1 day following the Executive's termination of employment (or, if earlier, the date of the Executive's death). Notwithstanding any other provision in this Agreement, each Deferred Payment which is conditioned upon Executive's execution of the Release and which is to be paid or provided during a designated period that begins in one taxable year and ends in a second taxable year, shall be paid or provided in the later of the two taxable years. The Company reserves the right to amend this Agreement as it considers necessary or advisable, in its sole discretion and without the consent of the Executive or any other individual, to comply with any provision required to avoid the imposition of the additional tax imposed under Section 409A or to otherwise avoid income recognition under Section 409A prior to the actual payment of any benefits or imposition of any additional tax. Each payment, installment, and benefit payable under this Agreement is intended to constitute a separate payment for purposes of U.S. Treasury Regulation Section 1.409A-2(b)(2). In no event will any member of the Company Group reimburse, indemnify, or hold harmless the Executive for any taxes, penalties and interest that may be imposed, or other costs that may be incurred, as a result of Section 409A.

(e) Resignation of Officer and Director Positions. The Executive's receipt of any severance payments or benefits upon the Executive's Qualifying Termination under Section 3 is subject to the Executive resigning from all officer and director positions with all members of the Company Group and the Executive executing any documents the Company may require in connection with the same.

6. Limitation on Payments.

(a) Reduction of Severance Benefits. If any payment or benefit that the Executive would receive from any Company Group member or any other party whether in connection with the provisions in this Agreement or otherwise (the "**Payment**") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "**Excise Tax**"), then the Payment will be equal to the Best Results Amount. The "**Best Results Amount**" will be either (x) the full amount of the Payment or (y) a lesser amount that would result in no portion of the Payment being subject to the Excise Tax, whichever of those amounts, taking into account the applicable federal, state and local employment taxes, income taxes and the Excise Tax, results in the Executive's receipt, on an after-tax basis, of the greater amount. If a reduction in payments or benefits constituting parachute payments is necessary so that the Payment equals the Best Results Amount, reduction will occur in the following order: (A) reduction of cash payments in reverse chronological order (that is, the cash payment owed on the latest date following the occurrence of the event triggering the Excise Tax will be the first cash payment to be reduced); (B) cancellation of equity awards that were granted "contingent on a change in ownership or control" within the meaning of Section 280G of the Code in the reverse order of date of grant of the awards (that is, the most recently granted equity awards will be cancelled first); (C) reduction of the accelerated vesting of equity awards in the reverse order of date of grant of the awards (that is, the vesting of the most recently granted equity awards will be cancelled first); and (D) reduction of employee benefits in reverse chronological order (that is, the benefit owed on the latest date following the occurrence of the event triggering the Excise Tax will be the first benefit to be reduced). In no event will the Executive have any discretion with respect to the ordering of Payment reductions. The Executive will be solely responsible for the payment of all personal tax liability, including the Excise Tax, that is incurred as a result of the payments and benefits received under this Agreement, and the Executive will not be reimbursed, indemnified, or held harmless by any member of the Company Group for any of those payments of personal tax liability.

(b) Determination of Excise Tax Liability. Unless the Company and the Executive otherwise agree in writing, the Company will select a professional services firm (the "**Firm**") to make all determinations required under this Section 6, which determinations will be conclusive and binding upon the Executive and the Company for all purposes. For purposes of making the calculations required by this Section 6, the Firm may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. The Company and the Executive will furnish to the Firm such information and documents as the Firm reasonably may request in order to make determinations under this Section 6. The Company will bear the costs and make all payments for the Firm's services in connection with any calculations contemplated by this Section 6. The Company will have no liability to the Executive for the determinations of the Firm.

7. Definitions. The following terms referred to in this Agreement will have the following meanings:

(a) "**Board**" means the Company's Board of Directors.

(b) "**Cause**" means: (i) the Executive's conviction of, or plea of guilty or nolo contendere to, a felony or a crime involving moral turpitude; (ii) the Executive's admission or conviction of, or plea of guilty or nolo contendere to, an intentional act of fraud, embezzlement or theft in connection with your duties or in the course of employment with the Company Group; (iii) the Executive's intentional wrongful damage to property of the Company Group; (iv) intentional unauthorized or wrongful use or disclosure of secret processes or of proprietary or confidential information of the Company Group (or any other party to whom the Executive owes an obligation of nonuse or nondisclosure as a result of the Executive's employment relationship with the Company), including but not limited to trade secrets and customer lists; (iv) the Executive's violation of any agreement not to compete with the Company Group or to solicit either its customers or employees on behalf of competitors while remaining employed with the Company Group; (v) the Executive's intentional violation of any policy or policies regarding ethical conduct; (vi) an act of dishonesty made by the Executive in connection with the Executive's responsibilities as an employee which materially harms the Company Group, or (vii) the Executive's intentional or continued failure to perform the Executive's duties with the Company Group, as determined in good faith by the Company after being provided with notice of such failure, such notice specifying in reasonable detail the tasks which must be accomplished and a timeline for the accomplishment to avoid termination for Cause, and an opportunity to cure within thirty (30) days of receipt of such notice.

(c) "**Change in Control**" means the occurrence of any of the following events:

(i) A change in the ownership of the Company which occurs on the date that any one person, or more than one person acting as a group ("**Person**"), acquires ownership of the stock of the Company that, together with the stock held by such Person, constitutes more than 50% of the total voting power of the stock of the Company; provided, however, that for purposes of this subsection, (A) the acquisition of additional stock by any one Person, who is considered to own more than 50% of the total voting power of the stock of the Company will not be considered a Change in Control, and (B) if the stockholders of the Company immediately before such change in ownership continue to retain immediately after the change in ownership, in substantially the same proportions as their ownership of shares of the Company's voting stock immediately prior to the change in ownership, the direct or indirect beneficial ownership of 50% or more of the total voting power of the stock of the Company or of the ultimate parent entity of the Company, such event will not be considered a Change in Control under this subsection (i). For this purpose, indirect beneficial ownership will include, without limitation, an interest resulting from ownership of the voting securities of one or more corporations or other business entities which own the Company, as the case may be, either directly or through one or more subsidiary corporations or other business entities; or

(ii) A change in the effective control of the Company which occurs on the date that a majority of members of the Board is replaced during any twelve (12) month period by members of the Board whose appointment or election is not endorsed by a majority of the members of the Board prior to the date of the appointment or election. For purposes of this subsection (ii), if any Person is considered to be in effective control of the Company, the acquisition of additional control of the Company by the same Person will not be considered a Change in Control; or

(iii) A change in the ownership of a substantial portion of the Company's assets which occurs on the date that any Person acquires (or has acquired during the twelve (12) month period ending on the date of the most recent acquisition by such person or persons) assets from the Company that have a total gross fair market value equal to or more than 50% of the total gross fair market value of all of the assets of the Company immediately prior to such acquisition or acquisitions; provided, however, that for purposes of this subsection (iii), the following will not constitute a change in the ownership of a substantial portion of the Company's assets: (A) a transfer to an entity that is controlled by the Company's stockholders immediately after the transfer, or (B) a transfer of assets by the Company to: (1) a stockholder of the Company (immediately before the asset transfer) in exchange for or with respect to the Company's stock, (2) an entity, 50% or more of the total value or voting power of which is owned, directly or indirectly, by the Company, (3) a Person, that owns, directly or indirectly, 50% or more of the total value or voting power of all the outstanding stock of the Company, or (4) an entity, at least 50% of the total value or voting power of which is owned, directly or indirectly, by a Person described in this subsection (iii)(B)(3). For purposes of this subsection (iii), gross fair market value means the value of the assets of the Company, or the value of the assets being disposed of, determined without regard to any liabilities associated with such assets.

For purposes of this definition, persons will be considered to be acting as a group if they are owners of a corporation that enters into a merger, consolidation, purchase or acquisition of stock, or similar business transaction with the Company.

Notwithstanding the foregoing, to the extent required to comply with Section 409A, a transaction will not be deemed a Change in Control unless the transaction qualifies as a change in control event within the meaning of Section 409A.

Further and for the avoidance of doubt, a transaction will not constitute a Change in Control if: (i) its sole purpose is to change the state of the Company's incorporation, or (ii) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction.

(d) "**Change in Control Period**" means the period beginning three (3) months prior to a Change in Control and ending twelve (12) months following a Change in Control.

(e) "**COBRA**" means the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended.

(f) "**Code**" means the Internal Revenue Code of 1986, as amended.

(g) "**Company Group**" means the Company and its subsidiaries.

(h) "**Confidentiality Agreement**" means the At-Will Employment, Confidential Information, Invention Assignment, Nonsolicitation, and Arbitration Agreement.

(i) "**Disability**" means a total and permanent disability as defined in Section 22(e)(3) of the Code.

(j) "**Good Reason**" means the termination of the Executive's employment with the Company Group by the Executive in accordance with the next sentence after the occurrence of one or more of the following events without the Executive's express written consent: (i) a material reduction of the Executive's duties, authorities, or responsibilities relative to the Executive's duties, authorities, or responsibilities in effect immediately prior to the reduction; (ii) a reduction by a Company Group member in the Executive's rate of annual base salary by more than 10%; (iii) a material change in the geographic location of the Executive's primary work facility or location by more than thirty-five (35) miles from the Executive's then present location; provided, that a relocation to a location that is within 35 miles from the Executive's then-present primary residence will not be considered a material change in geographic location, or (iv) failure of a successor corporation to assume the obligations under this Agreement as contemplated by Section 8. In order for the termination of the Executive's employment with a Company Group member to be for Good Reason, the Executive must not terminate employment without first providing written notice to the Company of the acts or omissions constituting the grounds for "Good Reason" within sixty (60) days of the initial existence of the grounds for "Good Reason" and a cure period of thirty (30) days following the date of written notice (the "**Cure Period**"), the grounds must not have been cured during that time, and the Executive must terminate the Executive's employment within thirty (30) days following the Cure Period.

(k) "**Qualifying Pre-CIC Termination**" means a Qualifying CIC Termination that occurs prior to the date of the Change in Control.

(l) "**Qualifying Termination**" means a termination of the Executive's employment either (i) by a Company Group member without Cause (excluding by reason of Executive's death or Disability) or (ii) by the Executive for Good Reason, in either case, during the Change in Control Period (a "**Qualifying CIC Termination**") or outside of the Change in Control Period (a "**Qualifying Non-CIC Termination**").

(m) "**Salary**" means the Executive's annual base salary as in effect immediately prior to the Executive's Qualifying Termination (or if the termination is due to a resignation for Good Reason based on a material reduction in base salary, then the Executive's annual base salary in effect immediately prior to the reduction) or, if the

Executive's Qualifying Termination is a Qualifying CIC Termination and the amount is greater, at the level in effect immediately prior to the Change in Control.

8. Successors. This Agreement will be binding upon and inure to the benefit of (a) the heirs, executors, and legal representatives of the Executive upon the Executive's death, and (b) any successor of the Company. Any such successor of the Company will be deemed substituted for the Company under the terms of this Agreement for all purposes. For this purpose, "successor" means any person, firm, corporation, or other business entity which at any time, whether by purchase, merger, or otherwise, directly or indirectly acquires all or substantially all of the assets or business of the Company. None of the rights of the Executive to receive any form of compensation payable pursuant to this Agreement may be assigned or transferred except by will or the laws of descent and distribution. Any other attempted assignment, transfer, conveyance, or other disposition of the Executive's right to compensation or other benefits will be null and void.

9. Notice.

(a) General. All notices and other communications required or permitted under this Agreement shall be in writing and will be effectively given (i) upon actual delivery to the party to be notified, (ii) upon transmission by email, (iii) twenty-four (24) hours after confirmed facsimile transmission, (iv) 1 business day after deposit with a recognized overnight courier, or (v) three (3) business days after deposit with the U.S. Postal Service by first class certified or registered mail, return receipt requested, postage prepaid, addressed (A) if to the Executive, at the address the Executive shall have most recently furnished to the Company in writing, (B) if to the Company, at the following address:

Outset Medical, Inc.
3052 Orchard Dr., San Jose, CA 95134
Attention: Chief People Officer

(b) Notice of Termination. Any termination by a Company Group member for Cause will be communicated by a notice of termination to the Executive, and any termination by the Executive for Good Reason will be communicated by a notice of termination to the Company, in each case given in accordance with Section 9(a) of this Agreement. The notice will indicate the specific termination provision in this Agreement relied upon, will set forth in reasonable detail the facts and circumstances claimed to provide a basis for termination under the provision so indicated, and will specify the termination date (which will be not more than thirty (30) days after the later of (i) the giving of the notice or (ii) the end of any applicable cure period).

10. Resignation. The termination of the Executive's employment for any reason will also constitute, without any further required action by the Executive, the Executive's voluntary resignation from all officer and/or director positions held at any member of the Company Group, and at the Board's request, the Executive will execute any documents reasonably necessary to reflect the resignations.

11. Miscellaneous Provisions.

(a) No Duty to Mitigate. The Executive will not be required to mitigate the amount of any payment contemplated by this Agreement, nor will any payment be reduced by any earnings that the Executive may receive from any other source except as specified in Section 3(e).

(b) Waiver; Amendment. No provision of this Agreement will be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by an authorized officer of the Company (other than the Executive) and by the Executive. No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party will be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) Headings. All captions and section headings used in this Agreement are for convenient reference only and do not form a part of this Agreement.

(d) Entire Agreement. This Agreement constitutes the entire agreement of the parties and supersedes in their entirety all prior representations, understandings, undertakings or agreements (whether oral or written and whether expressed or implied) of the parties with respect to the subject matter of this Agreement, including, for the avoidance of doubt, any other employment letter or agreement, severance policy or program, or equity award agreement.

(e) Protected Rights. Nothing in this Agreement or any other agreement with a member of the Company Group shall prohibit or impede Executive from communicating, cooperating or filing a complaint with any U.S. federal, state or local governmental or law enforcement branch, agency or entity (collectively, a "Governmental Entity") with respect to possible violations of any U.S. federal, state or local law or regulation, or otherwise making disclosures to any Governmental Entity, in each case, that are protected under the whistleblower provisions of any such law or regulation, provided that in each case such communications and disclosures are consistent with applicable law. Executive understands and acknowledges that an individual shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that is made (i) in confidence to a federal, state, or local government official or to an attorney solely for the purpose of reporting or investigating a suspected violation of law, or (ii) in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. Executive understands and acknowledges further that an individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual files any document containing the trade secret under seal; and does not disclose the trade secret, except pursuant to court order. Moreover, Executive is not required to give prior notice to (or get prior authorization from) the Company regarding any such communication or disclosure. Notwithstanding the foregoing, under no circumstance will Executive be authorized to disclose any information covered by attorney-client privilege or attorney work product of any member of the Company Group without prior written consent of Company's General Counsel or other officer designated by the Company. Participant does not need the prior authorization of (or to give notice to) any member of the Company Group regarding any communication, disclosure, or activity permitted by this paragraph.

(f) Choice of Law. This Agreement will be governed by the laws of the State of California without regard to California's conflicts of law rules that may result in the application of the laws of any jurisdiction other than California. To the extent that any lawsuit is permitted under this Agreement, Employee hereby expressly consents to the personal and exclusive jurisdiction and venue of the state and federal courts located in California for any lawsuit filed against the Executive by the Company.

(g) Arbitration. Any and all controversies, claims, or disputes with anyone under this Agreement (including the Company and any employee, officer, director, stockholder or benefit plan of the Company in their capacity as such or otherwise) arising out of, relating to, or resulting from the Executive's employment with the Company Group, shall be subject to arbitration in accordance with the provisions of the Confidentiality Agreement.

(h) Severability. The invalidity or unenforceability of any provision or provisions of this Agreement will not affect the validity or enforceability of any other provision of this Agreement, which will remain in full force and effect.

(i) Withholding. All payments and benefits under this Agreement will be paid less applicable withholding taxes. The Company is authorized to withhold from any payments or benefits all federal, state, local, and/or foreign taxes required to be withheld from the payments or benefits and make any other required payroll deductions. No member of the Company Group will pay the Executive's taxes arising from or relating to any payments or benefits under this Agreement.

(j) Counterparts. This Agreement may be executed in counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

[Signature page follows.]

By its signature below, each of the parties signifies its acceptance of the terms of this Agreement, in the case of the Company by its duly authorized officer.

COMPANY OUTSET MEDICAL, INC.

By: ________

Name: _

Title: __

Date: __

EXECUTIVE By: ____________

Name: Leslie Trigg

Date: __

Exhibit 10.12

OUTSET MEDICAL, INC.

AMENDED AND RESTATED

CHANGE IN CONTROL AND SEVERANCE AGREEMENT

This Amended and Restated Change in Control and Severance Agreement (the "**Agreement**") is made between Outset Medical, Inc. (the "**Company**") and [ ] (the "**Executive**"), effective as of [_______], 2024 (the "**Effective Date**").

The Company and the Executive entered into a Change in Control and Severance Agreement, dated as of [______], 202[_] (the "**Prior Agreement**"). The Company desires to offer the Executive an amendment of the terms and conditions of the Prior Agreement, which is embodied in the terms and conditions of this Agreement as provided herein. This Agreement provides certain protections to the Executive in connection with a change in control of the Company or in connection with the involuntary termination of the Executive's employment under the circumstances described in this Agreement and replaces the Prior Agreement in its entirety.

The Company and the Executive agree as follows:

1. Term of Agreement. This Agreement will have an initial term of three (3) years commencing on the Effective Date (the "**Initial Term**"). On the third (3rd) anniversary of the Effective Date, this Agreement will renew automatically for additional, one (1) year terms (each, an "**Additional Term**") unless either party provides the other party with written notice of nonrenewal at least one (1) year prior to the date of automatic renewal. Notwithstanding the foregoing, if a Change in Control occurs (a) when there are fewer than twelve (12) months remaining during the Initial Term or (b) during an Additional Term, the term of this Agreement will extend automatically through the date that is twelve (12) months following the date of the Change in Control. If the Executive becomes entitled to the benefits under Section 3 of this Agreement, then the Agreement will not terminate until all of the obligations of the parties hereto with respect to this Agreement have been satisfied.

2. At-Will Employment. The Company and the Executive acknowledge that the Executive's employment is and will continue to be at-will, as defined under applicable law.

3. Severance Benefits.

(a) Qualifying Non-CIC Termination. On a Qualifying Non-CIC Termination (as defined below), the Executive will be eligible to receive the following payments and benefits from the Company:

(i) Salary Severance. A single, lump sum payment equal to nine (9) months of the Executive's Salary (as defined below), less applicable withholdings.

(ii) COBRA Coverage. Subject to Section 3(d), the Company will pay the premiums for coverage under COBRA (as defined below) for the Executive and the Executive's eligible dependents, if any, at the rates then in effect, subject to any subsequent changes in rates that are generally applicable to the Company's active employees (the "**COBRA Coverage**"), until the earliest of (A) a period of nine (9) months from the date of the Executive's termination of employment, (B) the date upon which the Executive (and the Executive's eligible dependents, as applicable) becomes covered under similar plans, or (C) the date upon which the Executive ceases to be eligible for coverage under COBRA.

(b) Qualifying CIC Termination. On a Qualifying CIC Termination, the Executive will be eligible to receive the following payments and benefits from the Company:

(i) Salary Severance. A single, lump sum payment, less applicable withholdings, equal to twelve (12) months of the Executive's Salary (such total number of months, the "**Severance Period**").

(ii) Bonus Severance. A single, lump sum payment equal to 100% of the Executive's target annual bonus as in effect for the fiscal year in which the Qualifying CIC Termination occurs, less applicable withholdings.

(iii) COBRA Coverage. Subject to Section 3(d), the Company will provide COBRA Coverage until the earliest of (A) a period of months from the date of the Executive's termination of employment equal to the Severance Period, (B) the date upon which the Executive (and the Executive's eligible dependents, as applicable) becomes covered under similar plans, or (C) the date upon which the Executive ceases to be eligible for coverage under COBRA.

(iv) Equity Vesting Acceleration. Vesting acceleration (and exercisability, as applicable) as to 100% of the then-unvested shares subject to each of the Executive's then-outstanding Company equity awards. In the case of an equity award with performance-based vesting, unless the applicable equity award agreement governing such award provides for more favorable treatment, all performance goals and other vesting criteria will be deemed achieved at target. For the avoidance of doubt, in the event of the Executive's Qualifying Pre-CIC Termination (as defined below), any unvested portion of the Executive's then-outstanding equity awards will remain outstanding until the earlier of (x) three (3) months following the Qualifying Termination or (y) the occurrence of a Change in Control, solely so that any benefits due on a Qualifying Pre-CIC Termination can be provided if a Change in Control occurs within the three (3) month period following the Qualifying Termination (provided that in no event will the Executive's stock options or similar equity awards remain outstanding beyond the equity award's maximum term to expiration). If no Change in Control occurs within the three (3) month period following a Qualifying Termination, any unvested portion of the Executive's equity awards automatically and permanently will be forfeited on the three (3) month anniversary following the date of the Qualifying Termination without having vested.

(c) Termination Other Than a Qualifying Termination. If the termination of the Executive's employment with the Company Group is not a Qualifying Termination, then the Executive will not be entitled to receive severance or other benefits.

(d) Conditions to Receipt of COBRA Coverage. The Executive's receipt of COBRA Coverage is subject to the Executive electing COBRA continuation coverage within the time period prescribed pursuant to COBRA for the Executive and the Executive's eligible dependents, if any. If the Company determines in its sole discretion that it cannot provide the COBRA Coverage without potentially violating, or being subject to an excise tax under, applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then in lieu of any COBRA Coverage, the Company will provide to the Executive a taxable monthly payment payable on the last day of a given month (except as provided by the immediately following sentence), in an amount equal to the monthly COBRA premium that the Executive would be required to pay to continue his or her group health coverage in effect on the date of his or her Qualifying Termination (which amount will be based on the premium rates applicable for the first month of COBRA Coverage for the Executive and any of eligible dependents of the Executive) (each, a "**COBRA Replacement Payment**"), which COBRA Replacement Payments will be made regardless of whether the Executive elects COBRA continuation coverage and will end on the earlier of (x) the date upon which the Executive obtains other employment or (y) the date the Company has paid an amount totaling the number of COBRA Replacement Payments equal to the number of months in the applicable COBRA Coverage period. For the avoidance of doubt, the COBRA Replacement Payments may be used for any purpose, including, but not limited to continuation coverage under COBRA, and will be subject to any applicable withholdings. Notwithstanding anything to the contrary under this Agreement, if the Company determines in its sole discretion at any time that it cannot provide the COBRA Replacement Payments without violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Executive will not receive the COBRA Replacement Payments or any further COBRA Coverage.

(e) Non-Duplication of Payment or Benefits. For purposes of clarity, in the event of a Qualifying Pre-CIC Termination, any severance payments and benefits to be provided to the Executive under Section 3(b) will be reduced by any amounts that already were provided to the Executive under Section 3(a). Notwithstanding any provision of this Agreement to the contrary, if the Executive is entitled to any cash severance, continued health coverage benefits, or vesting acceleration of any equity awards (other than under this Agreement) by operation of applicable law or under a plan, policy, contract, or arrangement sponsored by or to which any member of the Company Group is a party ("**Other Benefits**"), then the corresponding severance payments and benefits under this Agreement will be reduced by the amount of Other Benefits paid or provided to the Executive.

(f) Death of the Executive. In the event of the Executive's death before all payments or benefits the Executive is entitled to receive under this Agreement have been provided, the unpaid amounts will be provided to the Executive's designated beneficiary, if living, or otherwise to the Executive's personal representative in a single lump sum as soon as possible following the Executive's death.

(g) Transfer Between Members of the Company Group. For purposes of this Agreement, if the Executive is involuntarily transferred from one member of the Company Group to another, the transfer will not be a termination without Cause but may give the Executive the ability to resign for Good Reason.

(h) Exclusive Remedy. In the event of a termination of the Executive's employment with the Company Group, the provisions of this Agreement are intended to be and are exclusive and in lieu of any other rights or remedies to which the Executive may otherwise be entitled, whether at law, tort or contract, or in equity. The Executive will be entitled to no benefits, compensation or other payments or rights upon termination of employment other than those benefits expressly set forth in this Agreement.

4. Accrued Compensation. On any termination of the Executive's employment with the Company Group, the Executive will be entitled to receive all accrued but unpaid vacation, expense reimbursements, wages, and other benefits due to the Executive under any Company-provided plans, policies, and arrangements.

5. Conditions to Receipt of Severance.

(a) Separation Agreement and Release of Claims. The Executive's receipt of any severance payments or benefits upon the Executive's Qualifying Termination under Section 3 is subject to the Executive signing and not revoking the Company's then-standard separation agreement and release of claims (which may include an agreement not to disparage any member of the Company Group, non-solicit provisions, an agreement to assist in any litigation matters, and other standard terms and conditions) (the "**Release**" and that requirement, the "**Release Requirement**"), which must become effective and irrevocable no later than the sixtieth (60th) day following the Executive's Qualifying Termination (the "**Release Deadline**"). If the Release does not become effective and irrevocable by the Release Deadline, the Executive will forfeit any right to severance payments or benefits under Section 3.

(b) Payment Timing. Any lump sum Salary or bonus payments under Sections 3(a)(i), 3(b)(i) and 3(b)(ii) will be provided on the first regularly scheduled payroll date of the Company following the date the Release becomes effective and irrevocable (the "**Severance Start Date**"), subject to any delay required by Section 5(d) below. Any taxable installments of any COBRA-related severance benefits that otherwise would have been made to the Executive on or before the Severance Start Date will be paid on the Severance Start Date, and any remaining installments thereafter will be provided as specified in the Agreement. Any restricted stock units, performance shares, performance units, and/or similar full value awards that accelerate vesting under Section 3(b)(iv) will be settled (x) on a date no later than ten (10) days following the date the Release becomes effective and irrevocable, or (y) if later, in the event of a Qualifying Pre-CIC Termination, on a date no later than the Change in Control.

(c) Return of Company Property. The Executive's receipt of any severance payments or benefits upon the Executive's Qualifying Termination under Section 3 is subject to the Executive returning all documents and other property provided to the Executive by any member of the Company Group (with the exception of a copy of the Company employee handbook and personnel documents specifically relating to the Executive), developed or obtained by the Executive in connection with his or her employment with the Company Group, or otherwise belonging to the Company Group.

(d) Section 409A. The Company intends that all payments and benefits provided under this Agreement or otherwise are exempt from, or comply with, the requirements of Section 409A of the Code and any guidance promulgated under Section 409A of the Code (collectively, "**Section 409A**") so that none of the payments or benefits will be subject to the additional tax imposed under Section 409A, and any ambiguities in this Agreement will be interpreted in accordance with this intent. No payment or benefits to be paid to the Executive, if any, under this Agreement or otherwise, when considered together with any other severance payments or separation benefits that are considered deferred compensation under Section 409A (together, the "**Deferred Payments**") will be paid or otherwise provided until the Executive has a "separation from service" within the meaning of Section 409A. If, at the time of the Executive's termination

of employment, the Executive is a "specified employee" within the meaning of Section 409A, then the payment of the Deferred Payments will be delayed to the extent necessary to avoid the imposition of the additional tax imposed under Section 409A, which generally means that the Executive will receive payment on the first payroll date that occurs on or after the date that is 6 months and 1 day following the Executive's termination of employment (or, if earlier, the date of the Executive's death). Notwithstanding any other provision in this Agreement, each Deferred Payment which is conditioned upon Executive's execution of the Release and which is to be paid or provided during a designated period that begins in one taxable year and ends in a second taxable year, shall be paid or provided in the later of the two taxable years. The Company reserves the right to amend this Agreement as it considers necessary or advisable, in its sole discretion and without the consent of the Executive or any other individual, to comply with any provision required to avoid the imposition of the additional tax imposed under Section 409A or to otherwise avoid income recognition under Section 409A prior to the actual payment of any benefits or imposition of any additional tax. Each payment, installment, and benefit payable under this Agreement is intended to constitute a separate payment for purposes of U.S. Treasury Regulation Section 1.409A-2(b)(2). In no event will any member of the Company Group reimburse, indemnify, or hold harmless the Executive for any taxes, penalties and interest that may be imposed, or other costs that may be incurred, as a result of Section 409A.

(e) Resignation of Officer and Director Positions. The Executive's receipt of any severance payments or benefits upon the Executive's Qualifying Termination under Section 3 is subject to the Executive resigning from all officer and director positions with all members of the Company Group and the Executive executing any documents the Company may require in connection with the same.

6. Limitation on Payments.

(a) Reduction of Severance Benefits. If any payment or benefit that the Executive would receive from any Company Group member or any other party whether in connection with the provisions in this Agreement or otherwise (the "**Payment**") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "**Excise Tax**"), then the Payment will be equal to the Best Results Amount. The "**Best Results Amount**" will be either (x) the full amount of the Payment or (y) a lesser amount that would result in no portion of the Payment being subject to the Excise Tax, whichever of those amounts, taking into account the applicable federal, state and local employment taxes, income taxes and the Excise Tax, results in the Executive's receipt, on an after-tax basis, of the greater amount. If a reduction in payments or benefits constituting parachute payments is necessary so that the Payment equals the Best Results Amount, reduction will occur in the following order: (A) reduction of cash payments in reverse chronological order (that is, the cash payment owed on the latest date following the occurrence of the event triggering the Excise Tax will be the first cash payment to be reduced); (B) cancellation of equity awards that were granted "contingent on a change in ownership or control" within the meaning of Section 280G of the Code in the reverse order of date of grant of the awards (that is, the most recently granted equity awards will be cancelled first); (C) reduction of the accelerated vesting of equity awards in the reverse order of date of grant of the awards (that is, the vesting of the most recently granted equity awards will be cancelled first); and (D) reduction of employee benefits in reverse chronological order (that is, the benefit owed on the latest date following the occurrence of the event triggering the Excise Tax will be the first benefit to be reduced). In no event will the Executive have any discretion with respect to the ordering of Payment reductions. The Executive will be solely responsible for the payment of all personal tax liability, including the Excise Tax, that is incurred as a result of the payments and benefits received under this Agreement, and the Executive will not be reimbursed, indemnified, or held harmless by any member of the Company Group for any of those payments of personal tax liability.

(b) Determination of Excise Tax Liability. Unless the Company and the Executive otherwise agree in writing, the Company will select a professional services firm (the "**Firm**") to make all determinations required under this Section 6, which determinations will be conclusive and binding upon the Executive and the Company for all purposes. For purposes of making the calculations required by this Section 6, the Firm may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. The Company and the Executive will furnish to the Firm such information and documents as the Firm reasonably may request in order to make determinations under this Section 6. The Company will bear the costs and make all payments for the Firm's services in connection with any calculations contemplated by this Section 6. The Company will have no liability to the Executive for the determinations of the Firm.

7. Definitions. The following terms referred to in this Agreement will have the following meanings:

(a) "**Board**" means the Company's Board of Directors.

(b) "**Cause**" means: (i) the Executive's conviction of, or plea of guilty or nolo contendere to, a felony or a crime involving moral turpitude; (ii) the Executive's admission or conviction of, or plea of guilty or nolo contendere to, an intentional act of fraud, embezzlement or theft in connection with your duties or in the course of employment with the Company Group; (iii) the Executive's intentional wrongful damage to property of the Company Group; (iv) intentional unauthorized or wrongful use or disclosure of secret processes or of proprietary or confidential information of the Company Group (or any other party to whom the Executive owes an obligation of nonuse or nondisclosure as a result of the Executive's employment relationship with the Company), including but not limited to trade secrets and customer lists; (iv) the Executive's violation of any agreement not to compete with the Company Group or to solicit either its customers or employees on behalf of competitors while remaining employed with the Company Group; (v) the Executive's intentional violation of any policy or policies regarding ethical conduct; (vi) an act of dishonesty made by the Executive in connection with the Executive's responsibilities as an employee which materially harms the Company Group, or (vii) the Executive's intentional or continued failure to perform the Executive's duties with the Company Group, as determined in good faith by the Company after being provided with notice of such failure, such notice specifying in reasonable detail the tasks which must be accomplished and a timeline for the accomplishment to avoid termination for Cause, and an opportunity to cure within thirty (30) days of receipt of such notice.

(c) "**Change in Control**" means the occurrence of any of the following events:

(i) A change in the ownership of the Company which occurs on the date that any one person, or more than one person acting as a group ("Person"), acquires ownership of the stock of the Company that, together with the stock held by such Person, constitutes more than 50% of the total voting power of the stock of the Company; provided, however, that for purposes of this subsection, (A) the acquisition of additional stock by any one Person, who is considered to own more than 50% of the total voting power of the stock of the Company will not be considered a Change in Control, and (B) if the stockholders of the Company immediately before such change in ownership continue to retain immediately after the change in ownership, in substantially the same proportions as their ownership of shares of the Company's voting stock immediately prior to the change in ownership, the direct or indirect beneficial ownership of 50% or more of the total voting power of the stock of the Company or of the ultimate parent entity of the Company, such event will not be considered a Change in Control under this subsection (i). For this purpose, indirect beneficial ownership will include, without limitation, an interest resulting from ownership of the voting securities of one or more corporations or other business entities which own the Company, as the case may be, either directly or through one or more subsidiary corporations or other business entities; or

(ii) A change in the effective control of the Company which occurs on the date that a majority of members of the Board is replaced during any twelve (12) month period by members of the Board whose appointment or election is not endorsed by a majority of the members of the Board prior to the date of the appointment or election. For purposes of this subsection (ii), if any Person is considered to be in effective control of the Company, the acquisition of additional control of the Company by the same Person will not be considered a Change in Control; or

(iii) A change in the ownership of a substantial portion of the Company's assets which occurs on the date that any Person acquires (or has acquired during the twelve (12) month period ending on the date of the most recent acquisition by such person or persons) assets from the Company that have a total gross fair market value equal to or more than 50% of the total gross fair market value of all of the assets of the Company immediately prior to such acquisition or acquisitions; provided, however, that for purposes of this subsection (iii), the following will not constitute a change in the ownership of a substantial portion of the Company's assets: (A) a transfer to an entity that is controlled by the Company's stockholders immediately after the transfer, or (B) a transfer of assets by the Company to: (1) a stockholder of the Company (immediately before the asset transfer) in exchange for or with respect to the Company's stock, (2) an entity, 50% or more of the total value or voting power of which is owned, directly or indirectly, by the Company, (3) a Person, that owns, directly or indirectly, 50% or more of the total value or voting power of all the outstanding stock of the Company, or (4) an entity, at least 50% of the total value or voting power of which is owned, directly or indirectly, by a Person described in this subsection (iii)(B)(3). For purposes of this subsection (iii), gross fair market value means the value of the assets of the Company, or the value of the assets being disposed of, determined without regard to any liabilities associated with such assets.

For purposes of this definition, persons will be considered to be acting as a group if they are owners of a corporation that enters into a merger, consolidation, purchase or acquisition of stock, or similar business transaction with the Company.

Notwithstanding the foregoing, to the extent required to comply with Section 409A, a transaction will not be deemed a Change in Control unless the transaction qualifies as a change in control event within the meaning of Section 409A.

Further and for the avoidance of doubt, a transaction will not constitute a Change in Control if: (i) its sole purpose is to change the state of the Company's incorporation, or (ii) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction.

(d) "**Change in Control Period**" means the period beginning three (3) months prior to a Change in Control and ending twelve (12) months following a Change in Control.

(e) "**COBRA**" means the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended.

(f) "**Code**" means the Internal Revenue Code of 1986, as amended.

(g) "**Company Group**" means the Company and its subsidiaries.

(h) "**Confidentiality Agreement**" means the At-Will Employment, Confidential Information, Invention Assignment, Nonsolicitation, and Arbitration Agreement.

(i) "**Disability**" means a total and permanent disability as defined in Section 22(e)(3) of the Code.

(j) "**Good Reason**" means the termination of the Executive's employment with the Company Group by the Executive in accordance with the next sentence after the occurrence of one or more of the following events without the Executive's express written consent: (i) a material reduction of the Executive's duties, authorities, or responsibilities relative to the Executive's duties, authorities, or responsibilities in effect immediately prior to the reduction; (ii) a reduction by a Company Group member in the Executive's rate of annual base salary by more than 10%; (iii) a material change in the geographic location of the Executive's primary work facility or location by more than thirty-five (35) miles from the Executive's then present location; provided, that a relocation to a location that is within 35 miles from the Executive's then-present primary residence will not be considered a material change in geographic location, or (iv) failure of a successor corporation to assume the obligations under this Agreement as contemplated by Section 8. In order for the termination of the Executive's employment with a Company Group member to be for Good Reason, the Executive must not terminate employment without first providing written notice to the Company of the acts or omissions constituting the grounds for "Good Reason" within sixty (60) days of the initial existence of the grounds for "Good Reason" and a cure period of thirty (30) days following the date of written notice (the "**Cure Period**"), the grounds must not have been cured during that time, and the Executive must terminate the Executive's employment within thirty (30) days following the Cure Period.

(k) "**Qualifying Pre-CIC Termination**" means a Qualifying CIC Termination that occurs prior to the date of the Change in Control.

(l) "**Qualifying Termination**" means a termination of the Executive's employment either (i) by a Company Group member without Cause (excluding by reason of Executive's death or Disability) or (ii) by the Executive for Good Reason, in either case, during the Change in Control Period (a "**Qualifying CIC Termination**") or outside of the Change in Control Period (a "**Qualifying Non-CIC Termination**").

(m) "**Salary**" means the Executive's annual base salary as in effect immediately prior to the Executive's Qualifying Termination (or if the termination is due to a resignation for Good Reason based on a material reduction in base salary, then the Executive's annual base salary in effect immediately prior to the reduction) or, if the

Executive's Qualifying Termination is a Qualifying CIC Termination and the amount is greater, at the level in effect immediately prior to the Change in Control.

8. Successors. This Agreement will be binding upon and inure to the benefit of (a) the heirs, executors, and legal representatives of the Executive upon the Executive's death, and (b) any successor of the Company. Any such successor of the Company will be deemed substituted for the Company under the terms of this Agreement for all purposes. For this purpose, "successor" means any person, firm, corporation, or other business entity which at any time, whether by purchase, merger, or otherwise, directly or indirectly acquires all or substantially all of the assets or business of the Company. None of the rights of the Executive to receive any form of compensation payable pursuant to this Agreement may be assigned or transferred except by will or the laws of descent and distribution. Any other attempted assignment, transfer, conveyance, or other disposition of the Executive's right to compensation or other benefits will be null and void.

9. Notice.

(a) General. All notices and other communications required or permitted under this Agreement shall be in writing and will be effectively given (i) upon actual delivery to the party to be notified, (ii) upon transmission by email, (iii) twenty-four (24) hours after confirmed facsimile transmission, (iv) 1 business day after deposit with a recognized overnight courier, or (v) three (3) business days after deposit with the U.S. Postal Service by first class certified or registered mail, return receipt requested, postage prepaid, addressed (A) if to the Executive, at the address the Executive shall have most recently furnished to the Company in writing, (B) if to the Company, at the following address:

Outset Medical, Inc.
3052 Orchard Dr., San Jose, CA 95134
Attention: Chief People Officer

(b) Notice of Termination. Any termination by a Company Group member for Cause will be communicated by a notice of termination to the Executive, and any termination by the Executive for Good Reason will be communicated by a notice of termination to the Company, in each case given in accordance with Section 9(a) of this Agreement. The notice will indicate the specific termination provision in this Agreement relied upon, will set forth in reasonable detail the facts and circumstances claimed to provide a basis for termination under the provision so indicated, and will specify the termination date (which will be not more than thirty (30) days after the later of (i) the giving of the notice or (ii) the end of any applicable cure period).

10. Resignation. The termination of the Executive's employment for any reason will also constitute, without any further required action by the Executive, the Executive's voluntary resignation from all officer and/or director positions held at any member of the Company Group, and at the Board's request, the Executive will execute any documents reasonably necessary to reflect the resignations.

11. Miscellaneous Provisions.

(a) No Duty to Mitigate. The Executive will not be required to mitigate the amount of any payment contemplated by this Agreement, nor will any payment be reduced by any earnings that the Executive may receive from any other source except as specified in Section 3(e).

(b) Waiver; Amendment. No provision of this Agreement will be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by an authorized officer of the Company (other than the Executive) and by the Executive. No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party will be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) Headings. All captions and section headings used in this Agreement are for convenient reference only and do not form a part of this Agreement.

(d) Entire Agreement. This Agreement constitutes the entire agreement of the parties and supersedes in their entirety all prior representations, understandings, undertakings or agreements (whether oral or written and whether expressed or implied) of the parties with respect to the subject matter of this Agreement, including, for the avoidance of doubt, any other employment letter or agreement, severance policy or program, or equity award agreement.

(e) Protected Rights. Nothing in this Agreement or any other agreement with a member of the Company Group shall prohibit or impede Executive from communicating, cooperating or filing a complaint with any U.S. federal, state or local governmental or law enforcement branch, agency or entity (collectively, a "Governmental Entity") with respect to possible violations of any U.S. federal, state or local law or regulation, or otherwise making disclosures to any Governmental Entity, in each case, that are protected under the whistleblower provisions of any such law or regulation, provided that in each case such communications and disclosures are consistent with applicable law. Executive understands and acknowledges that an individual shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that is made (i) in confidence to a federal, state, or local government official or to an attorney solely for the purpose of reporting or investigating a suspected violation of law, or (ii) in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. Executive understands and acknowledges further that an individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual files any document containing the trade secret under seal; and does not disclose the trade secret, except pursuant to court order. Moreover, Executive is not required to give prior notice to (or get prior authorization from) the Company regarding any such communication or disclosure. Notwithstanding the foregoing, under no circumstance will Executive be authorized to disclose any information covered by attorney-client privilege or attorney work product of any member of the Company Group without prior written consent of Company's General Counsel or other officer designated by the Company. Participant does not need the prior authorization of (or to give notice to) any member of the Company Group regarding any communication, disclosure, or activity permitted by this paragraph.

(f) Choice of Law. This Agreement will be governed by the laws of the State of California without regard to California's conflicts of law rules that may result in the application of the laws of any jurisdiction other than California. To the extent that any lawsuit is permitted under this Agreement, Employee hereby expressly consents to the personal and exclusive jurisdiction and venue of the state and federal courts located in California for any lawsuit filed against the Executive by the Company.

(g) Arbitration. Any and all controversies, claims, or disputes with anyone under this Agreement (including the Company and any employee, officer, director, stockholder or benefit plan of the Company in their capacity as such or otherwise) arising out of, relating to, or resulting from the Executive's employment with the Company Group, shall be subject to arbitration in accordance with the provisions of the Confidentiality Agreement.

(h) Severability. The invalidity or unenforceability of any provision or provisions of this Agreement will not affect the validity or enforceability of any other provision of this Agreement, which will remain in full force and effect.

(i) Withholding. All payments and benefits under this Agreement will be paid less applicable withholding taxes. The Company is authorized to withhold from any payments or benefits all federal, state, local, and/or foreign taxes required to be withheld from the payments or benefits and make any other required payroll deductions. No member of the Company Group will pay the Executive's taxes arising from or relating to any payments or benefits under this Agreement.

(j) Counterparts. This Agreement may be executed in counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

[Signature page follows.]

By its signature below, each of the parties signifies its acceptance of the terms of this Agreement, in the case of the Company by its duly authorized officer.

COMPANY OUTSET MEDICAL, INC.

By: _________

Name: __

Title: ___

Date: ___

EXECUTIVE By: _____________

Name: __

Date: ___

Exhibit 10.25

FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS **FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT** (this "**Amendment**"), dated as of December 11, 2023 (the "**Amendment Effective Date**"), is made among SLR Investment Corp., a Maryland corporation with an office located at 500 Park Avenue, 3rd Floor, New York, NY 10022 ("**SLR**"), as collateral agent (in such capacity, together with its successors and assigns in such capacity, "**Collateral Agent**"), and the Lenders listed on Schedule 1.1 (as amended herein) of the Loan and Security Agreement (as defined below) or otherwise a party hereto from time to time including SLR in its capacity as a Lender (each a "**Lender**" and collectively, the "**Lenders**"), and Outset Medical, Inc., a Delaware corporation with an office located at 3052 Orchard Drive, San Jose, CA 95134 ("**Borrower**").

The Borrower, the Lenders and Collateral Agent are parties to a Loan and Security Agreement dated as of November 3, 2022 (as amended, restated or modified from time to time, the "**Loan and Security Agreement**"). The Borrower has requested that the Lenders agree to certain amendments to the Loan and Security Agreement. The Lenders have agreed to such request, subject to the terms and conditions hereof.

Accordingly, the parties hereto agree as follows:

SECTION 1Definitions; Interpretation.

(a) **Terms Defined in Loan and Security Agreement**. All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan and Security Agreement.

(b) **Interpretation**. The rules of interpretation set forth in Section 1.1 of the Loan and Security Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

SECTION 2Amendments to the Loan and Security Agreement.

(a) The Loan and Security Agreement shall be amended as follows effective as of the Amendment Effective Date:

(i) Section 2.2(a)(ii). Section 2.2(a)(ii) is hereby amended and restated as follows:

"Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, during the Second Draw Period, to make term loans to Borrower in an aggregate principal amount of up to One Hundred Million Dollars ($100,000,000.00) , consisting of Term B-1 Loans according to each Lender's Term B-1 Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a "**Term B-1 Loan**", and collectively as the "**Term B-1 Loans**") and of Term B-2 Loans according to each Lender's Term B-2 Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a "**Term B-2 Loan**", and collectively as the "**Term B-2 Loans**", and together with the Term B-1 Loans, referred to singly as a "**Term B Loan**", and collectively as the "**Term B Loans**"). After repayment, no Term B Loan may be re-borrowed."

(ii) Lenders and Commitments. Schedule 1.1 of the Loan and Security Agreement, the Schedules of Lenders and Commitments, is hereby amended and restated in its entirety with Annex A hereto.

(b) **References Within Loan and Security Agreement**. Each reference in the Loan and Security Agreement to "this Agreement" and the words "hereof," "herein," "hereunder," or words of like import, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment.

SECTION 3Conditions of Effectiveness. The effectiveness of Section 2 of this Amendment shall be subject to the satisfaction of each of the following conditions precedent:

(a) **[Reserved].**

(b) **This Amendment**. Collateral Agent shall have received this Amendment, executed by Collateral Agent, the Lenders and the Borrower.

(c) **[Reserved].**

SECTION 4[Reserved].

SECTION 5Miscellaneous.

(a) **Loan Documents Otherwise Not Affected; Reaffirmation**. Except as expressly amended pursuant hereto or referenced herein, the Loan and Security Agreement and the other Loan Documents shall remain unchanged and in full force and effect and are hereby ratified and confirmed in all respects. The Lenders' and Collateral Agent's execution and delivery of, or acceptance of, this Amendment shall not be deemed to create a course of dealing or otherwise create any express or implied duty by any of them to provide any other or further amendments, consents or waivers in the future. The Borrower hereby reaffirms the grant of security under Section 4.1 of the Loan and Security Agreement and hereby reaffirms that such grant of security in the Collateral secures all Obligations under the Loan and Security Agreement, including without limitation any Term Loans funded on or after the Amendment Effective Date, as of the date hereof.

(b) **Conditions**. For purposes of determining compliance with the conditions specified in Section 3, each Lender that has signed this Amendment shall be deemed to have consented to, approved or accepted or to be satisfied with, each document or other matter required thereunder to be consented to or approved by or acceptable or satisfactory to a Lender unless Collateral Agent shall have received notice from such Lender prior to the Amendment Effective Date specifying its objection thereto.

(c) **[Reserved].**

(d) **No Reliance**. The Borrower hereby acknowledges and confirms to Collateral Agent and the Lenders that the Borrower is executing this Amendment on the basis of its own investigation and for its own reasons without reliance upon any agreement, representation, understanding or communication by or on behalf of any other Person.

(e) **[Reserved].**

(f) **Binding Effect**. This Amendment binds and is for the benefit of the successors and permitted assigns of each party.

(g) **Governing Law and Jurisdiction**. THIS AMENDMENT, THE OTHER LOAN DOCUMENTS (EXCLUDING THOSE LOAN DOCUMENTS THAT BY THEIR OWN TERMS ARE EXPRESSLY GOVERNED BY THE LAWS OF ANOTHER JURISDICTION) AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER AND THEREUNDER SHALL IN ALL RESPECTS BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK (WITHOUT REGARD TO THE CONFLICT OF LAWS PRINCIPLES THAT WOULD RESULT IN THE APPLICATION OF ANY LAW OTHER THAN THE LAW OF SUCH STATE), INCLUDING ALL MATTERS OF CONSTRUCTION, VALIDITY AND PERFORMANCE, REGARDLESS OF THE LOCATION OF THE COLLATERAL, PROVIDED, HOWEVER, THAT IF THE LAWS OF ANY JURISDICTION OTHER THAN NEW YORK SHALL GOVERN IN REGARD TO THE VALIDITY, PERFECTION OR EFFECT OF PERFECTION OF ANY LIEN OR IN REGARD TO PROCEDURAL MATTERS AFFECTING ENFORCEMENT OF ANY LIENS IN COLLATERAL, SUCH LAWS OF SUCH OTHER JURISDICTIONS SHALL CONTINUE TO APPLY TO THAT EXTENT.

(h) **Complete Agreement; Amendments**. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents.

(i) **Severability of Provisions.** Each provision of this Amendment is severable from every other provision in determining the enforceability of any provision.

(j) **Counterparts**. This Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Amendment. Delivery of an executed counterpart of a signature page of this Amendment by facsimile, portable document format (.pdf) or other electronic transmission will be as effective as delivery of a manually executed counterpart hereof.

(k) **Loan Documents**. This Amendment and the documents related thereto shall constitute Loan Documents.

[Balance of Page Intentionally Left Blank; Signature Pages Follow]

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment, as of the date first above written.

BORROWER:

OUTSET MEDICAL, INC.

By /s/ Nabeel Ahmed
Name: Nabeel Ahmed
Title: Chief Financial Officer

[Signature Page to First Amendment to Loan and Security Agreement]

COLLATERAL AGENT AND LENDER:

SLR INVESTMENT CORP.

By /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

LENDERS:

SUNS SPV LLC

By /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SCP PRIVATE CREDIT INCOME FUND SPV, LLC

By /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SCP PRIVATE CREDIT INCOME BDC SPV LLC

By /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SCP PRIVATE CORPORATE LENDING FUND SPV LLC

By /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SCP CAYMAN DEBT MASTER FUND SPV LLC

By /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SLR CP SF DEBT FUND SPV LLC

By /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SLR HC FUND SPV, LLC

By /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SLR HC BDC SPV LLC

By /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SCP PRIVATE CREDIT INCOME FUND L.P.

By /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SCP PRIVATE CREDIT INCOME BDC LLC

By /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SCP PRIVATE CORPORATE LENDING FUND L.P.

By /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SCP SF DEBT FUND L.P

By /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SLR HC ONSHORE FUND L.P.

By /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SLR HC BDC LLC

By /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SLR 1818 L.P.

By /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SLR PRIVATE CREDIT FUND II L.P.

By /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SLR PRIVATE CREDIT BDC II LLC

By /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

SLR PRIVATE CORPORATE LENDING FUND II L.P.

By /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

CRPTF-SLR CREDIT PARTNERSHIP L.P.

By /s/ Anthony Storino
Name: Anthony Storino
Title: Authorized Signatory

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 and 333-269746) on Form S-8 of our report dated February 21, 2024, 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 21, 2024

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 21, 2024

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, Nabeel Ahmed, 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 21, 2024

By: /s/ Nabeel Ahmed
Nabeel Ahmed
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, 2023, 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 21, 2024 By: /s/ Leslie Trigg
Leslie Trigg
Chief Executive Officer
(*Principal Executive Officer*)

Date: February 21, 2024 By: /s/ Nabeel Ahmed
Nabeel Ahmed
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.

Exhibit 97.1

OUTSET MEDICAL, INC.
POLICY ON RECOUPMENT OF INCENTIVE COMPENSATION

Introduction

The Board of Directors (the "***Board***") of Outset Medical, Inc. (the "***Company***") has adopted this Policy on Recoupment of Incentive Compensation (this "***Policy***"), which provides for the recoupment of compensation in certain circumstances in the event of a restatement of financial results by the Company. This Policy is intended to comply with the requirements of Securities and Exchange Commission rules and Nasdaq Stock Market ("***Nasdaq***") listing standards implementing Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (the "***Dodd-Frank Act***").

Administration

This Policy shall be administered by the Compensation Committee of the Board (the "***Compensation Committee***"). Any determinations made by the Compensation Committee shall be final and binding on all affected individuals. The Compensation Committee is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate or advisable for the administration of this Policy, in all cases consistent with the Dodd-Frank Act. The Board or Compensation Committee may amend this Policy from time to time in its discretion.

Covered Executives

This Policy applies to any current or former "executive officer," within the meaning of Rule 10D-1 under the Securities Exchange Act of 1934, as amended, who was employed by the Company or a subsidiary of the Company (each such individual, an "***Executive***") during the applicable Recovery Period, as defined below. This Policy shall be binding and enforceable against all Executives and their beneficiaries, executors, administrators, and other legal representatives.

Recoupment Upon Financial Restatement

If the Company is required to prepare an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (a "***Financial Restatement***"), the Compensation Committee shall cause the Company to recoup from each Executive, as promptly as reasonably possible, any erroneously awarded Incentive-Based Compensation, as defined below.

No-Fault Recovery

Recoupment under this Policy shall be required regardless of whether the Executive or any other person was at fault or responsible for accounting errors that contributed to the need for the Financial Restatement or engaged in any misconduct.

Compensation Subject to Recovery; Enforcement

This Policy applies to all compensation granted, earned or vested based wholly or in part upon the attainment of any financial reporting measure, including stock price and total shareholder return ("***TSR***"), including but not limited to performance-based cash, stock, options or other equity-based awards paid or granted to the Executive ("***Incentive-Based Compensation***"). Compensation that is granted, vests or is earned based solely upon the occurrence of non-financial events, such as base salary, restricted stock or options with time-based vesting, or a bonus awarded solely at the discretion of the Board or Compensation Committee and not based on the attainment of any financial measure is not subject to this Policy.

In the event of a Financial Restatement, the amount to be recovered will be the excess of (i) the Incentive-Based Compensation received by the Executive during the three completed fiscal years immediately preceding the date on which the Company is required to prepare the Financial Restatement, as determined in accordance with the last sentence of this paragraph (the "***Recovery Period***"), based on the erroneous data and calculated without regard to any taxes paid or withheld, over (ii) the Incentive-Based Compensation that would have been received by the Executive had it been calculated based on the restated financial information, as determined by the Compensation Committee. For this purpose, Incentive-Based Compensation is considered to have been received by an Executive in the fiscal year during which the applicable financial reporting measure was attained or purportedly attained, regardless of when the payment or grant of such Incentive-Based Compensation occurs. The date on which the Company is required to prepare a Financial Restatement is the earlier to occur of (A) the date the Board or a Board committee (or authorized officers of the Company if Board action is not required) concludes, or reasonably should have concluded, that the Company is required to prepare a Financial Restatement or (B) the date a court, regulator, or other legally authorized body directs the Company to prepare a Financial Restatement.

For Incentive-Based Compensation based on stock price or TSR, where the amount of erroneously awarded compensation is not subject to mathematical recalculation directly from the information in the Financial Restatement, the Compensation Committee shall determine the amount to be recovered based on a reasonable estimate of the effect of the Financial Restatement on the stock price or TSR upon which the Incentive-Based Compensation was received and the Company shall document the determination of that reasonable estimate and provide it to Nasdaq.

The Company may use any legal or equitable remedies that are available to the Company to recoup any erroneously awarded Incentive-Based Compensation, including but not limited to by collecting from the Executive a cash payment or shares of Company common stock or by forfeiting any amounts that the Company owes to the Executive.

No Indemnification

The Company shall not indemnify any Executive or pay or reimburse the premium for any insurance policy to cover any losses incurred by such Executive under this Policy.

Exceptions

The compensation recouped under this Policy shall not include Incentive-Based Compensation received by an Executive (i) prior to beginning service as an Executive or (ii) if he or she did not serve as an Executive at any time during the applicable Recovery Period. The Compensation Committee (or a majority of independent directors serving on the Board) may determine not to seek recovery from an Executive in whole or part to the extent it determines in its sole discretion that such recovery would be impractical because (A) the direct expense paid to a third party to assist in enforcing recovery would exceed the recoverable amount (after having made a reasonable attempt to recover the erroneously awarded Incentive-Based Compensation and providing corresponding documentation of such attempt to Nasdaq), (B) recovery would violate the home country law that was in effect prior to November 28, 2022, as determined by an opinion of counsel licensed in the applicable jurisdiction that is provided to Nasdaq, or (C) recovery would likely cause the Company's 401(k) plan or any other tax-qualified retirement plan to fail to meet the requirements of Section 401(a)(13) or Section 411(a) of the Internal Revenue Code of 1986, as amended.

Other Remedies Not Precluded

The exercise by the Compensation Committee of any rights pursuant to this Policy shall be without prejudice to any other rights or remedies that the Company, the Board or the Compensation Committee may have with respect to any Executive subject to this Policy.

Effective Date

This Policy has been adopted by the Board, effective as of April 25, 2023 (the "***Effective Date***") and shall apply to any Incentive-Based Compensation that is received by an Executive on or after the Effective Date.