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, 2022

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, 2022 (the last business day of the registrant's most recently completed second quarter) as reported by Nasdaq Global Market on that date was $709 million.

The number of shares of the registrant's common stock, par value $0.001 per share, outstanding as of February 9, 2023 was 48,637,059.

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, 2022, are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- our future results of operations and financial position, including our expectations and projections regarding our revenues and revenue growth rate, sales into the home market and such sales as a percentage of revenues, cost of revenues, operating expenses (including as a percentage of revenues), gross margin, capital expenditures 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 the recent COVID-19 pandemic and other macroeconomic factors on our business and results of operations, and on our customers and suppliers;
- our intent to explore opportunities for international expansion;
- continued execution of our initiatives designed to reduce the cost of producing and shipping our products, expand gross margins, further secure supply continuity, improve the flexibility of our operations and otherwise mitigate supply chain challenges, and our ability to achieve projected cost reductions and other anticipated benefits from these initiatives at the levels or within the timeframe we estimate;
- our expectations with respect to anticipated benefits of the TPNIES approval;
- our plans to expand our manufacturing capabilities to support our growth, including by expanding our manufacturing workforce;
- our plans to continue to invest in our research and development efforts to enhance existing products and develop new products;
- our plans to invest in continued expansion of our sales and marketing infrastructure;
- 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 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.

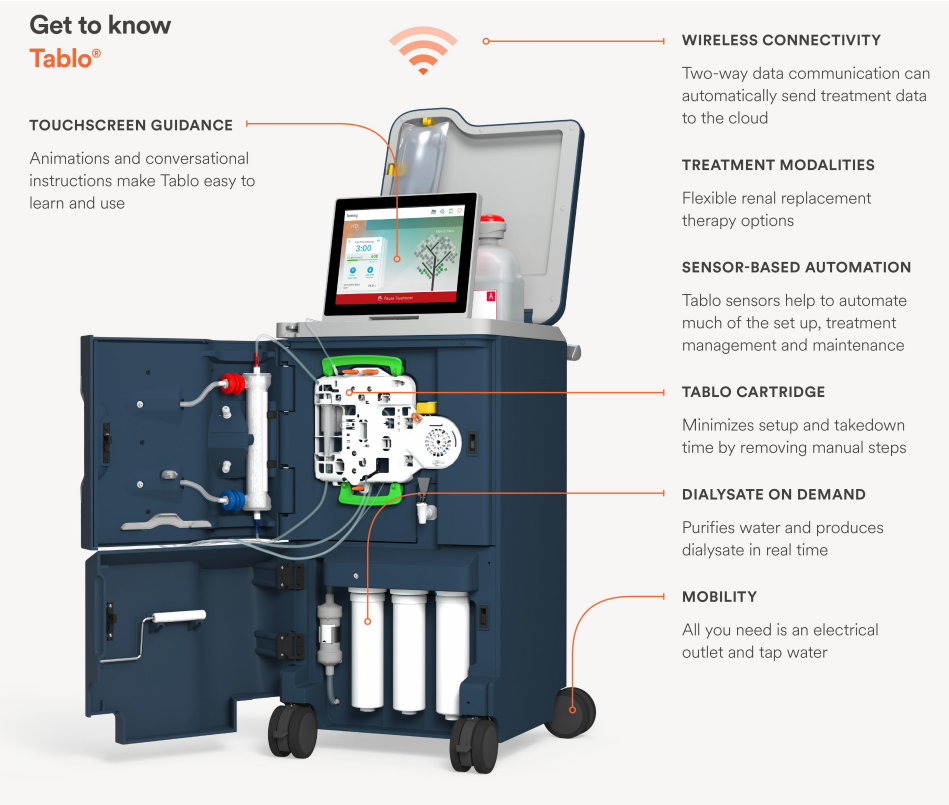
The Tablo Hemodialysis System (Tablo)

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.

The Tablo system 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. The Tablo console can accommodate a wide range of treatment modalities, durations and flow rates, allowing for broad clinical applications. The Tablo console requires only a standard electrical outlet and tap water to operate. This eliminates the need for industrial water treatment rooms, separate water purification machines and pre-filled bags of dialysate associated with traditional dialysis machines. We recently introduced TabloCart, a non-medical accessory for the Tablo Hemodialysis System that provides added maneuverability and optional prefiltration 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. The Tablo cartridge was designed to simplify and streamline treatment setup to minimize the potential for user error. The 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. The Tablo cartridge consists of a user-friendly pre-configured blood, saline, and infusion tubing. The 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 the 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 and treatments remotely, perform patient and population analytics, and automate clinical recordkeeping. Due to Tablo's wireless connectivity, we can release new features and enhancements through over-the-air (OTA) updates, without requiring hardware changes or interventions from field service engineers (FSEs). We also release user trainings this way, which means that customers can train and upgrade their device on their own schedule. We have used these OTA updates to add important new features designed to extend Tablo's clinical applicability in addition to updates designed to enhance device uptime by enabling remote diagnostics and support. We believe these OTA updates help Tablo get smarter over time.

Tablo's connectedness also allows it to continually stream to the cloud over 500,000 device performance data points after every treatment. We use this data, in conjunction with our diagnostic and predictive algorithms, to determine failure types and, in some instances, predict failures before they occur. Equipped with this information, our FSEs can visit sites knowing they have the correct parts and consumables to address the issues reported, and 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 trainings. It is accessible from virtually anywhere, using a smart phone, tablet, or a web browser.

Through the Tablo application programming interface (API), providers can integrate Tablo with their Electronic Medical Records (EMR) to receive treatment data and flowsheets automatically to reduce manual record keeping, which in turn, helps reduce record-entry errors and auditing risks. Tablo's two-way wireless transmission delivers data intended to be compliant with the federal Health Insurance Portability and Accountability Act (HIPAA) to the provider without any need for additional equipment. It connects to the cloud using a standard Ethernet or Wi-Fi connection. 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. Through the MyTablo portal, patients have the ability to access training materials and download their own 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 also 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 the Tablo Hemodialysis System 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, compliance 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 competitors. We believe these factors will reduce patient 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 due 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 the Tablo console, including those related to pressure sensors, blood leakage and pump control loops.

Patents

As of December 31, 2022, we had 21 issued U.S. patents, as well as 10 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 19 pending patent applications in Australia, Brazil, Canada, China, the European Patent Office, Hong Kong, Japan, 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 the Tablo console, the Tablo cartridge and other consumables (electrolyte concentrates and plastic tubing that transports the concentrates into Tablo to enable on-demand dialysate production). We partner with several different contract manufacturers in the assembly and testing of our products and operate under a Quality Management System that has been certified to ISO 13485 Medical Device Quality Management System standard.

Tablo Console

We established a manufacturing facility in Tijuana, Mexico, which enabled us to fully insource Tablo console manufacturing during 2021. 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.

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. We are currently undertaking a second source qualification process for the majority of these critical components. Where second sourcing is unavailable or infeasible and likely to remain so, we have sought to mitigate supply interruption risks with increased levels of safety stock.

Tablo Cartridge

Until recently, the Tablo cartridge was manufactured exclusively by our two contract manufacturing partners. During 2022, we moved production of a majority of Tablo cartridges to a manufacturing site in Tijuana, Mexico in partnership with Providien Medical (Providien), in order to help us achieve cost reductions through lower freight costs and mitigate against global supply chain interruption. Providien, part of Carlisle Companies Incorporated, offers expertise in high volume disposable assembly services. Tablo cartridges produced at this facility undergo sterilization using electronic beam (e-beam) technology, which is an environmentally friendly sterilization method for which we received 510(k) clearance from the FDA in November 2021.

During 2022, we also continued to produce a portion of Tablo cartridges through Infus Medical Co. Ltd. (Infus), a contract manufacturer with two facilities in Thailand. As part of this arrangement, we direct the oversight of the raw materials sourcing, selection and planning while Infus takes receipt of the Tablo cartridge components, and performs assembly, testing and Ethylene

Oxide sterilization before shipment. Tablo cartridges produced through Infus have shipped primarily via ocean freight, though in times of peak demand or other supply chain constraints, we have shipped by air freight. Our team inspects the product before releasing it for shipment.

More recently, we also initiated production of Tablo cartridges in-house at our manufacturing facility in Tijuana, Mexico that we operate in collaboration with TACNA. We intend to increase the quantity of Tablo cartridges produced at this facility as we ramp our cartridge manufacturing capabilities during the remainder of the year, while continuing to rely on one or more of our contract manufacturers as additional sources for cartridge production. We expect that insourcing Tablo cartridges will ultimately further our long-term gross margin expansion and supply continuity strategies and improve the flexibility of our operations. Tablo cartridges produced at our facility are sterilized using e-beam technology.

The various components for the Tablo cartridge are manufactured by approximately 30 different single-source suppliers located in various countries including the United States, Mexico, Europe and Asia.

In addition to the Tablo cartridge, each treatment requires a concentrated container of bicarbonate and a concentrated container of acid, and two small plastic straws that draw the appropriate amount of the concentrates into the Tablo console in order to produce dialysate on demand.

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, we are 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 the Tablo Hemodialysis System 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. The Tablo Hemodialysis System is also indicated for use in the home and observed by a trained individual. The Tablo Hemodialysis System is not cleared by the FDA for Continuous Renal Replacement Therapy (CRRT), a subtype of hemodialysis intended to be performed without interruption at lower flow and ultrafiltration rates for hemodynamically unstable patients who may not tolerate higher flow or ultrafiltration rates typically associated with conventional dialysis. 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 the 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.

The FDA previously issued to us a post-market surveillance order under Section 522 of the FDCA which required that we conduct a human factors study, as well as conduct a detailed analysis of adverse events and complaints from home users. While the FDA recently placed this 522 study requirement on hold because the original order specifically pertained to a prior version of Tablo, the FDA may decide to issue a new 522 order applicable to the current version of Tablo or extend the requirements of the prior 522 study order to apply to the version of Tablo that is the subject of the recently cleared 510(k) application. If the FDA does require us to run a 522 study with the version of Tablo that is the subject of the July 2022 clearance, we would need to submit and obtain the FDA's approval of an updated 522 study protocol for the current version of Tablo before we could commence, conduct and complete the study. Should the FDA decide that the use of the Tablo System in the home environment identifies new concerns related to the safety and effectiveness of the product, or if the FDA determines that the requirements of the 522 order are otherwise unmet, we may be required to make changes to our Tablo System or its labeling for which we may need to submit new marketing authorization applications and obtain clearance, we may need to temporarily suspend shipment of Tablo, withdraw or recall the Tablo System from the market, and we may be subject to other enforcement actions, any of which could materially and adversely harm our business.

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. We have received, and are in the process of responding to, a request for additional information regarding some of the modifications included in the 510(k). At this time, this 510(k) application is pending at the FDA. Based on the results of the FDA's review, we may be required to take additional actions, which may include reverting Tablo back to its prior, un-modified configuration.

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 the Tablo Hemodialysis System was not the subject of the FDA's Letter to Healthcare Providers, the FDA reached out to Outset regarding the tubing used in the 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 used in the Tablo Hemodialysis System. The FDA is requesting data on three specific compounds of PCB / PCBA as well as screening for other toxins and PCB/PCBAs. We are cooperating fully with the agency and are in the process of finalizing testing and screening protocols for submission to the FDA, and plan to perform the analysis in the first half of 2023. Based on the results of this testing, Outset may be required to take additional actions including submission of a 510(k) application for modified silicone tubing, if necessary.

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.

In the first quarter of 2023, the FDA conducted their first quality system inspection of our San Jose, California facility. At completion, the FDA issued a Form FDA-483 identifying four inspectional observations, relating to: (i) a single medical device report (MDR) that was not submitted within the required time period, (ii) completeness of software validation documentation, (iii) procedures defining escalation of nonconforming product to Corrective and Preventive Action (CAPA), and (iv) procedures connecting actions in customer complaints and the CAPA system. We intend to provide a complete response to the FDA and to implement a corrective action plan to address these observations within the requisite timeframe. Although we believe we are in material compliance with the QSR and will be able to address the observations identified in the Form-483 in a timely manner, 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 observations do not affect our ability to serve patients in both the home and acute end markets, and we intend to expeditiously and effectively address them in a way that strengthens our quality system.

Healthcare Fraud and Abuse Laws

Certain U.S. federal healthcare fraud and abuse laws apply by virtue of the fact that our customers will submit claims for our products and services that are reimbursed, in whole or in part, by Medicare, Medicaid, or other federal healthcare programs (as that term is defined at 42 U.S.C. § 1320a-7b(f)). 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, or reimbursed by, in whole or in part, a federal healthcare program, such as Medicare or Medicaid. This includes products, like Tablo, that are not directly reimbursed but are purchased and used in a service 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 Affordable Care Act (ACA) healthcare reform legislation 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 federal Anti-Kickback Statute and the sales and marketing activities of medical device manufacturers and other healthcare companies, and routinely bring cases 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. Conviction under the federal Anti-Kickback Statue results in mandatory exclusion from participation in the federal healthcare programs, meaning that federal healthcare programs will not reimburse (directly or indirectly) for products or services furnished by the excluded entity or individuals. Violators are subject to, among other things, imprisonment and significant criminal fines for each violation under the Anti-Kickback Statute, plus up to three times the remuneration involved and other civil penalties under the False Claims Act, as discussed in more detail below.

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 educational grants or reimbursement support programs. 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.

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

Another key federal healthcare law is the federal 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 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 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 (CCPA) became effective on January 1, 2020. The CCPA gives California residents new rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined) and provide such consumers new ways to opt-out of certain sales of personal information. 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. Additionally, a California ballot initiative, the California Privacy Rights Act (CPRA), passed in November 2020, and the majority of the provisions took effect on January 1, 2023. The CPRA amendments to the CCPA impose additional data protection obligations on companies doing business in California, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. The amendments also created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may be required. Laws similar to the California laws have passed in Virginia, Colorado, Connecticut, and Utah and have been proposed in other states and 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. 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.

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.

Our business relies on secure and continuous processing of information and the availability of our Information technology (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 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. We may face increased cybersecurity risks 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. OCR, in partnership with the Healthcare and Public Health Sector Coordinating Council, issued cybersecurity guidelines for healthcare organizations that reflect consensus-based, voluntary practices to cost-effectively reduce cybersecurity risks for organizations of varying sizes. Although these Department of Health and Human Services (HHS)-backed guidelines, entitled "Health Industry Cybersecurity Practices: Managing Threats and Protecting Patients," are voluntary, they are likely to serve as an important reference point for the healthcare industry, and may cause us to invest additional resources in technology, personnel and programmatic cybersecurity controls as the cybersecurity risks we face continue to evolve.

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, and data, as well as those of our third-party service providers, may be vulnerable to privacy and information security incidents such as data breaches, viruses or other malicious code, exploitation of known or unknown vulnerabilities, coordinated attacks, data loss, phishing attacks, ransomware, denial of service attacks, or other security or IT incidents caused by threat actors, technological vulnerabilities or human error. If we, or any of our IT support vendors, 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.

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.

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 the 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 October 31, 2022, CMS published the final rule for Calendar Year (CY) 2023, which increased the base reimbursement rate per dialysis treatment to $265.57, an increase of $7.67 over the CY 2022 base rate of $257.90. 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. The Tablo system 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 the Tablo system 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 the Tablo system 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 Tablo Hemodialysis System use by one patient per one machine in the home, pursuant to which Medicare will pay 65% of the Medicare Administrative Contractor-determined pre-adjusted per treatment amount for two calendar years beginning in CY 2022.

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 vary by sponsor and plan.

Reimbursement in the Critical Care Setting

For Medicare patients, both acute kidney failure 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 application 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 2031 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 until 2031. To offset the temporary suspension during the COVID-19 pandemic, in 2030, the sequestration will be 2.25% for the first half of the year, and 3% in the second half of the year. 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 will adjust 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. 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. Most recently, on November 7, 2022, CMS issued a final rule regarding the ETC Model that, among other changes, revised the scoring methodology of the Performance Payment Adjustment and provided additional protections for furnishing and billing kidney disease patient education services. 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 issuance of the executive order and the ETC Model final rule, 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, 2022, we had 518 full-time employees, with 47% in our field sales and service teams and 53% 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, 2022, our manufacturing facility in Tijuana, Mexico had 210 full-time team members on-site across quality, engineering, manufacturing, supply chain, and 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.

In 2021, we published our inaugural Environmental, Social, and Governance (ESG) Report, which we supplemented in September 2022 (as supplemented, our ESG Report). Our ESG Report is available on our website at https://investors.outsetmedical.com/environmental-social-and-governance and includes more detailed information on our human capital programs and initiatives. 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 welcome diverse candidates. We have a principle that “everyone is a recruiter” and often hold crowd recruiting sessions to identify candidates collectively, and welcome employee referrals.

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 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 learnings 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 four key areas of focus: (1) raising awareness of disparities in kidney care across demographic groups, (2) broadening the diversity of our talent pools, (3) educating local students about career opportunities in the medical technology industry, and (4) elevating community volunteering opportunities. Our diversity, equity and inclusion strategy and related initiatives are overseen by our Chief People Officer, with active participation from our executive team, as well as support from our Better Together committee, an engaged group of employees responsible for ongoing evaluation and implementation. Our Board receives 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 benefits program is designed to help employees balance their work lives and personal lives. We maintain a whole person wellbeing approach, providing resources to support physical, 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	52	President, Chief Executive Officer and Chair of the Board
Nabeel Ahmed	47	Chief Financial Officer
John L. Brottem	49	General Counsel and Secretary
Stacey Porter	48	Chief People Officer
Jean-Olivier Racine	41	Chief Technology Officer
Martín Vazquez	53	Chief Operating Officer
Steve Williamson	50	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 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.

Stacey Porter

Stacey Porter has served as our Chief People Officer since October 2021. Ms. Porter joined the Company in November 2018 as Vice President, People Operations. Prior to joining the Company, Ms. Porter served as Head of Global Talent Development at Intuitive Surgical, Inc., a manufacturer of robotic surgical systems, from October 2012 to November 2018. Prior to that, Ms. Porter held various leadership positions in talent development, including as Director, Global Talent Development at VMware, Inc. from 2011 to 2012, and as Head of Learning and Development at Roche Pharmaceuticals from 2005 to 2009. Ms. Porter holds a B.A. from University of Kentucky and a MSW from University of Louisville.

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.

Martín Vazquez

Martín Vazquez has served as our Chief Operating Officer since November 2017. Prior to joining the Company, Mr. Vazquez was Vice President of North America Operations and Global Sales and Operations Planning at Abbott Rapid Dx (formerly Alere), a rapid point-of-care diagnostics company, from July 2015 to November 2017. Prior to that, Mr. Vazquez served as Vice President, Manufacturing Management/WW Operations at Becton Dickinson, a medical technology company, from March 2012 to June 2015, and Director Operations Mexico at Smiths Medical, a manufacturer of specialty medical devices, from May 2009 to March 2012. He also previously held positions with Integer Holdings (formerly Greatbatch Medical), a medical device manufacturing company, Alcon Laboratories, a subsidiary of Novartis AG focused on eye care products, Venusa, a medical device manufacturing company, and Ethicon (J&J), a medical device company. Mr. Vazquez holds a B.S. from University of Texas at El Paso and an M.B.A. from The Marshall School of Business, University of Southern California.

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 reduce manufacturing 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 our largest customer
- Risks associated with our international manufacturing operations
- Our ability to expand into the home hemodialysis market and the expansion of the home hemodialysis market itself
- Our reliance on third-party suppliers, including single source suppliers and contract manufacturers, and our ability to overcome manufacturing disruptions, including any supply chain disruptions resulting from the recent COVID-19 pandemic
- Financial pressures faced by our customers including staffing shortages and increased costs and the resulting cost-containment efforts of our current and potential customers
- The impact of the recent pandemic, natural or man-made disasters and similar events on our business
- 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
- 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 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: comply with the post-market surveillance order recently issued by the FDA for Tablo; 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 $163.0 million, $131.9 million and $121.5 million for the years ended December 31, 2022, 2021, and 2020, respectively. As of December 31, 2022, we had $290.8 million in cash, cash equivalents, restricted cash and short-term investments, and an accumulated deficit of $789.0 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 and currently available 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.

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 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 initiatives designed to reduce the costs of manufacturing and producing our products, mitigate against supply chain challenges, and drive down service costs per console.

We have undertaken a number of initiatives designed to reduce the cost of producing our products and otherwise mitigate against supply chain challenges. We established a manufacturing facility for the production of Tablo consoles in Mexico which we operate in collaboration with our outsourced business administration service provider, TACNA. During 2021, we fully insourced Tablo console manufacturing at this facility, which has lowered our costs of manufacturing and producing consoles. We continue to partner with contract manufacturers in the production of the Tablo cartridge. During 2022, we moved production of a majority of Tablo cartridges to a contract manufacturer in Mexico, while continuing to produce a portion through our contract manufacturer in Southeast Asia. We believe this transition has helped us achieve cost reductions through lower freight costs and mitigate against global supply chain challenges. Recently, in an effort to further our long-term gross margin expansion and supply continuity strategies and improve the flexibility of our operations, we initiated production of Tablo cartridges in-house at our manufacturing facility in Mexico which we operate in collaboration with TACNA, and we intend to increase the quantity of Tablo cartridges produced at this facility as we ramp our cartridge manufacturing capabilities during the remainder of the year.

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 consoles 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. 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. See the risk factor below entitled “We depend upon third-party suppliers, including contract manufacturers and single source suppliers, making us vulnerable to supply problems and price fluctuations.” 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 reduce our costs, if cost reductions or other anticipated benefits are less significant or less timely than projected or if we are unable to maintain our product pricing, 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.

Our ability to recognize our goal of expanding 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 timeframes 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 limited commercialization experience makes it difficult to evaluate our current business and predict our future prospects. We cannot 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
.

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 staffing shortages, increased costs and other financial pressures that have had, and may continue to have, a negative impact on our revenue.

Healthcare providers (including our existing and prospective customers) are facing a nationwide shortage of qualified nurses and other clinical personnel due to long-term trends that have been exacerbated by the recent COVID-19 pandemic. As competition for these healthcare professionals has intensified, providers are facing increased difficulties attracting and retaining skilled clinical personnel, resulting in increased costs, staffing shortages, and other disruptions. These challenging labor market conditions in the healthcare industry have been heightened by the increased demand for, and demand upon, nurses and other staff resulting from the pandemic. There is a risk that the increased costs and other disruptions caused by the shortage of dialysis nurses, technicians and other staff could cause existing or prospective customers to delay continued investment in or adoption of new technologies and postpone purchasing decisions. For example, during 2022, our existing and potential customers faced increasing staffing shortages and 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 volatility, uncertainty, staffing shortages, rising costs and financial pressures, whether due to the ongoing effects of the pandemic, general macroeconomic conditions or otherwise, it could ultimately adversely impact our ability to expand existing customer relationships or attract new customers of Tablo, and have a material adverse effect on our bookings, revenues, results of operations, and, ultimately, our future growth and profitability.

We recently launched a new 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. This pilot program is in its early stages and may not

be successful in achieving the objectives we intend and anticipate and ultimately, it may fail to meet our customers' expectations, any of which could harm our reputation and customer relationships. In addition, the program may not generate sufficient returns to justify our investment, or may result in unanticipated costs, which could 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 adoption 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, our ability to continue regaining momentum in our home commercialization and marketing and rebuilding our home patient pipeline following the release of our prior home shipment hold in 2022, 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 the 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.

We continue to rely primarily on contract manufacturing partners in Mexico and, to a lesser extent, in Southeast Asia, for the production of the Tablo cartridge. If any 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 or otherwise, it could cause substantial delays in our operations and result in our having insufficient Tablo cartridge in inventory to fulfill orders. Further, to the extent we seek to renew or renegotiate our arrangements with any of our contract manufacturing partners, and cannot agree to the terms and conditions of future contract manufacturing arrangements, or if any of our contract manufacturing partners terminate existing agreements with us, our ability to produce and sell Tablo cartridges could be delayed until an alternative manufacturing partner or arrangement is identified, a new contract manufacturing agreement is negotiated and new production lines are established.

In addition, we have insourced the production of Tablo consoles at our manufacturing facility in Tijuana, Mexico which we operate in collaboration with our outsourced business administration service provider, TACNA. Recently, we also initiated production of Tablo cartridges in-house at this Mexico facility, and we intend to increase the quantity of Tablo cartridges produced at this facility as we ramp our cartridge manufacturing capabilities during the remainder of the year. 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 increased international manufacturing operations generally, and many of these risks may heighten to the extent we 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. 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.

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, at present, we rely primarily on contract manufacturers for the production of the Tablo cartridge. 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 our Tablo system, 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 our Tablo system 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 our Tablo system, the supply of our products to customers and the development of any future products will be delayed, limited or prevented, which could have material adverse effect on our business, financial condition and results of operations.

For example, the COVID-19 pandemic disrupted the operations of certain of our third-party suppliers, resulting in increased lead-times, higher component costs and lower allocations for our purchases of some components (including certain critical components) and, in certain cases, requiring us to procure materials from alternative sources or incur higher logistical expenses. We 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, there is no assurance that we will not experience more significant disruptions in our supply chain in the future, particularly if the operations of our contract manufacturing partners, any of our critical single source component providers, or the facility we operate in Tijuana, Mexico in collaboration with our outsourced business administration service provider, TACNA, are more severely impacted by the pandemic and associated containment measures. If these contract manufacturers or suppliers experience disruptions as a result of the pandemic that impede their ability to meet our demand in a timely manner, we may be unable to find alternative sources of supply, be required to pay higher prices, or fail to meet customer demand, any of which would harm our business.

Additionally, surges and shifts in consumer demand as the economy reopens, further exacerbated by COVID-19 outbreaks and protocols, have strained the global freight network and placed significant stress on air, ocean and ground freight carriers. This resulted in labor shortages, container and chassis shortages, reduced carrier capacity, carrier delays and longer lead times, shipment receiving and unloading backlogs at many U.S. ports, and escalating freight costs. During late 2021, these supply chain disruptions escalated, and, as a result, we faced increased supply chain constraints, notably with the transportation of Tablo cartridges from our contract manufacturing partner in Southeast Asia. As a result, we have faced, and may continue to face, increased transportation and related costs, and/or delays, associated with delivering adequate supply of Tablo treatments to our customers. We believe that

transitioning production of a majority of Tablo cartridges during 2022 to a contract manufacturer in Mexico helped us achieve cost reductions through lower freight costs, and that our recent efforts to initiate production of Tablo cartridges in-house at our manufacturing facility in Mexico which we operate in collaboration with TACNA will help further our long-term gross margin expansion and supply continuity strategies as well as improve the flexibility of our operations. However, there is no assurance that we will not continue to face supply chain constraints. Continued escalation of these supply chain disruptions and a sustained rise in freight costs 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 operation.

A pandemic, epidemic or outbreak of an infectious disease in the United States or worldwide, including 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, have impacted, and may in the future impact, many of the regions in which we, our customers and our suppliers operate. Moreover, new or more restrictive measures have and may continue to be adopted or reimposed if the pandemic worsens or evolves, including due to new variants of the COVID-19 virus. Disruptions or potential disruptions to our business from COVID-19 or 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.

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. We have since moved toward more normal operations, including resuming business travel and on-site activity. Nevertheless, we may experience future disruptions as a result of the recent COVID-19 pandemic that could adversely impact the health and availability our workforce, particularly in light of the possibility of a resurgence of it and the emergence of new variants. If significant or critical portions of our workforce are unable to work effectively, or at all, as a result of the COVID-19 pandemic, including because of illness, quarantines, facility closures, ineffective remote work arrangements or technology failures or limitations, our operations would be materially adversely impacted.

The extent, duration, and impact of the pandemic remain uncertain and depends on ongoing developments, including but not limited to any resurgences of the virus including emerging variant strains, actions taken to contain or mitigate its impact, as well as the direct and indirect economic effects of the pandemic and related containment measures. As a result, we cannot predict what effect COVID-19, the associated containment measures, and the related supply chain disruptions will ultimately have on our business and result of operations.

The recent COVID-19 pandemic resulted in, and may in the future 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 of an infectious disease, including COVID-19 or the resurgence of it, 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. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this "Risk Factors" section.

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 transition to manufacturing Tablo consoles at our facility in Tijuana, Mexico operated in collaboration with TACNA, and our plans to ramp production of Tablo cartridges in-house at this facility, we are

more exposed to risks relating to product quality and reliability until the manufacturing processes mature. 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; and
- demonstrate Tablo's economic, clinical, compliance and operational benefits relative to outsourcing dialysis services.

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 May 2022, Medtronic and DaVita announced a joint venture to form 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, which could ultimately result in another competitor for us.

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 September 2021, and other advances in kidney transplantation.

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. 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. We may need to expend significant resources and make significant capital investment 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, 2022, we had 518 full-time employees. Over the next several years, we expect to increase the scope of our operations, particularly in the areas of manufacturing and commercial functions, including sales and marketing and field service, as well as in research and development and general and administrative functions to support our growth. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational quality and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources, we may not be able to manage the expansion of our operations or recruit and train additional qualified personnel in an effective manner. In addition, the physical expansion of our operations, including the establishment of our manufacturing facility in Tijuana, Mexico, may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our 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 that has been exacerbated by the COVID-19 pandemic 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, with our largest customer accounting for a large portion of our revenues.

For the year ended December 31, 2022, our largest customer accounted for 14% 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.

Natural or man-made disasters and other similar events, including the COVID-19 pandemic, 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, including 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.

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 the Tablo console and the Tablo cartridge 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 including 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.

Inadequate training of, and improper use of Tablo by, nurses, dialysis technicians, care partners and patients may lead to negative patient outcomes, affect adoption 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 or 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 rate at which we grow our sales force and the speed at which newly hired salespeople become effective, and the cost and level of investment therein;
- 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 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;
- the timing and cost of obtaining and maintaining regulatory approvals or clearances for the current version of Tablo, as well as planned or future improvements or enhancements to Tablo;
- 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 critical 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 have entered into two senior secured credit facilities in November 2022 that provide for up to a $250.0 million term loan and up to a $50.0 million asset-based revolving credit facility, we only have access to $200.0 million of such borrowings since an additional $100.0 million of such borrowings is subject to us achieving certain 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, 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 stockholders' rights. If we raise additional capital through debt financing (including through refinancing our existing debt), we may be subject to 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.

We entered into two senior secured credit facilities (the SLR Credit Facilities) on November 3, 2022 (the Closing Date) which provide for up to a $250.0 million term loan (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 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). While the SLR Credit Facilities provide for borrowings of up to $300.0 million, we only have access to $200.0 million of such borrowings as of the Closing Date and the additional $100.0 million of such borrowings 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 $250.0 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 borrow up to $300.0 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 full $300.0 million borrowing amounts under the SLR Credit Facilities. The SLR Credit Facilities are secured by substantially all of our assets, including all of the capital stock held by us, if any, (subject to a 65% limitation on pledges of voting capital stock of foreign subsidiaries), and 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 50% of the sum of (a) 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 (or maintain gross profit margins) in excess of specified amounts (or percentages) 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 our Tablo system 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 our Tablo system 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 continue to 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 our Tablo system on a timely basis.

We bear the risk of warranty claims on our Tablo system.

We bear the risk of warranty claims on our Tablo system. 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 sales and marketing personnel and, as we grow, 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 and grow 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 and grow, or adequately train, our team of FSEs could negatively impact our services revenue.

In order to generate future growth, we plan to continue to expand and leverage 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 the Tablo Hemodialysis System 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. For further information, see the section entitled "Litigation" in Note 6, Commitments and Contingencies, to our audited financial statements included in this Annual Report. Litigation is inherently unpredictable and can result in excessive or unanticipated verdicts and/or injunctive relief that affect how we operate our

business. We could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. There may be an increase in the scope of these matters or there may be additional lawsuits, claims, proceedings or investigations in the future, which could have a material adverse effect on our business, financial condition and results of operations. Adverse publicity about regulatory or legal action against us could damage our reputation and brand image, undermine our customers' confidence and reduce long-term demand for Tablo, even if the regulatory or legal action is unfounded or not material to our operations.

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

We may form or seek strategic alliances, make minority investments, create joint ventures or collaborations or enter into licensing or partnership arrangements with third parties that we believe will compliment or augment our sales and marketing and/or product development efforts with respect to Tablo. We may not be successful in our efforts to establish such collaborations for Tablo. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic alliance or other alternative arrangements for Tablo. We cannot be certain that, following a strategic alliance or similar arrangement, we will achieve the revenue, cash flows or specific net income that justifies such transaction. In addition, any potential future collaborations may be terminable by our collaborators, and we may not be able to adequately protect our rights under these agreements. Any termination of collaborations we enter into in the future, or delays in entering into new strategic partnership agreements could delay our sales and marketing efforts, which would harm our business prospects, financial condition and results of operations.

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

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

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

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

As of December 31, 2022, we had U.S. federal and state net operating loss (NOL) carryforwards of $526.8 million and $298.1 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 will begin to expire in 2023. 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, 2022, we also had U.S. federal and state research and development credits of $7.8 million and $6.4 million, respectively. Our U.S. federal research and development credits 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

While we resumed marketing and shipping the Tablo System for home use following the FDA's clearance of the related 510(k) submission, our business and operations may continue to experience disruptions as a result of the prior shipment hold.

Since Tablo's original clearance by the FDA for home use in March 2020, we have made certain changes to the device over time. 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.

The shipment hold on Tablo for home use had a significant negative impact on our bookings and revenue for the last three quarters of 2022, as well as on our pipeline of potential new deals. Following the most recent 510(k) clearance, we have resumed marketing and shipping Tablo for home use. However, we may continue to experience disruptions to our home and acute business and operations that could materially and adversely impact our results of operations, financial condition and growth prospects as we continue recovering from the interruption to, and loss of momentum in, our home commercialization and marketing, related disruptions to our acute business, and any negative effects to our reputation as a result of the hold.

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 the Tablo System, 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.

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 October 2022, we submitted a 510(k) application 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 We have received, and are in the process of responding to, a request for additional information regarding some of the modifications included in the 510(k). At

this time, this 510(k) application is pending at the FDA, and we cannot predict with certainty when the FDA will complete its review or whether the FDA will ultimately grant clearance of the pending application. Based on the results of the FDA's review, we may be required to take additional actions, which may include actions from reverting Tablo back to its prior, un-modified configuration, , up to not clearing the 510(k) and conducting a recall, any of which would materially and adversely disrupt and harm our business and future growth.

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 October 31, 2022, CMS issued a final rule updating the PPS to, among other things, increase the base rate from $257.90 to $265.57, an increase that CMS projects will increase the total payments to all ESRD facilities by 3.1% in CY 2023. 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 Tablo Hemodialysis System use by one patient per one machine in the home, pursuant to which Medicare will pay 65% of the Medicare Administrative Contractor-determined pre-adjusted per treatment amount for two calendar years beginning with CY 2022. In a final rule issued on November 7, 2022, CMS confirmed that it will continue Tablo's eligibility for TPNIES through CY 2023. Though our TPNIES approval may increase provider reimbursement over the short term and positively affect our revenues as a result, such increased reimbursement is temporary and, thus, may not be sufficient to cause healthcare providers to adopt Tablo at rates we expect. Accordingly, we cannot fully assess the impact of the 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 the Tablo System 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.

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 ETC Model final rule, 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. However, Tablo is not cleared by the FDA for CRRT.

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

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

- adverse publicity, warning letters, untitled letters, it has come to our attention letters, fines, injunctions, consent decrees and civil penalties;

- repair, replacement, refunds, recall or seizure of Tablo;
- operating restrictions, partial suspension or total shutdown of production;
- denial of our requests for regulatory clearance or PMA approval of new products or services, new intended uses or modifications to existing products or services;
- withdrawal of regulatory clearance or PMA approvals that have already been granted; or
- criminal prosecution.

If any of these events were to occur, it would negatively affect our business, financial condition and results of operations.

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, in the first quarter of 2023, the FDA conducted their first quality system inspection of our San Jose, California facility. At completion, the FDA issued a Form FDA-483 identifying four inspectional observations. We intend to provide a complete response to the FDA and to implement a corrective action plan to address these observations within the requisite timeframe. Although we believe we are in material compliance with the QSR and will be able to address the observations identified in the Form-483 in a timely manner, 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. For example, the FDA previously issued to us a post-market surveillance order under Section 522 of the FDCA which required that we conduct a human factors study, as well as conduct a detailed analysis of adverse events and complaints from home users. While the FDA recently placed this 522 study requirement on hold because the original order specifically pertained to a prior version of Tablo, the FDA may decide to issue a new 522 order applicable to the current version of Tablo or extend the requirements of the prior 522 study order to apply to the version of Tablo that is the subject of the recently cleared 510(k).

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 the Tablo Hemodialysis System was not the subject of the FDA's Letter to Healthcare Providers, the FDA reached out to Outset regarding the tubing used in the 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 used in the Tablo Hemodialysis System. The FDA is requesting data on three specific compounds of PCB / PCBA as well as screening for other toxins and PCB/PCBAs. We are cooperating fully with the agency and are in the process of finalizing testing and screening protocols for submission to the FDA, and plan to perform the analysis in the first half of 2023. Based on the results of this testing, Outset may be required to take additional actions including submission of a 510(k) application for modified silicone tubing, if necessary, or even conduct a recall of previously marketed products.

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.

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 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. 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. 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 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 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.

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 including 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 we execute business associate agreements with our clients.

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 suit 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. For example, the CCPA, became effective on January 1, 2020. The CCPA gives California residents new rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined) and provide such consumers new ways to opt-out of certain sales of personal information. 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 the law includes limited exceptions, including for PHI maintained by a covered entity or business associate, it may regulate or impact our processing of personal information depending on the context, and the CCPA may 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.

Other states, including Nevada, Virginia, Colorado, and Utah have passed data protection laws, or are considering passing legislation, similar to CCPA. To the extent these laws apply to our operations, they may impose organizational requirements and grant individual rights that are comparable to those established in the CCPA. Additionally, a ballot initiative, the CPRA, passed in November 2020 in California. The CPRA amendments to the CCPA impose additional data protection obligations on companies doing business in California, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. The amendments also created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions went into effect on January 1, 2023, and additional compliance investment and potential business process changes will be required.

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.

We regularly monitor, defend against and respond to attacks to our networks and other information security incidents. Despite our information security efforts, our facilities, systems, and data, as well as those of our third-party service providers, may be vulnerable to privacy and information security incidents such as data breaches, viruses or other malicious code, coordinated attacks, data loss, phishing attacks, ransomware, denial of service attacks, or other security or IT incidents caused by threat actors, technological vulnerabilities or human error. If we, or any of our vendors that support our IT or have access to our data, fail to comply with laws requiring the protection of personal information, or fail to safeguard and defend personal information or other critical data assets or IT systems, we may 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.

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;
- announcements by us or our competitors of significant products or features, technical innovations, acquisitions, strategic partnerships, joint ventures or capital commitments;
- changes in operating performance and stock market valuations of companies in our industry, including our competitors;
- price and volume fluctuations in the overall stock market, including as a result of trends in the economy as a whole;
- lawsuits threatened or filed against us;
- developments in new legislation and pending lawsuits or regulatory actions, including interim or final rulings by judicial or regulatory bodies; and
- other events or factors, including those resulting from political conditions, election cycles, war or incidents of terrorism, or responses to these events.

In addition, extreme price and volume fluctuations in the stock markets have affected and continue to affect many life sciences and technology companies' stock prices. Stock prices often fluctuate in ways unrelated or disproportionate to the companies' operating performance. In the past, stockholders have filed securities class action litigation following periods of market volatility. 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, 2022, our executive officers, directors and 5% stockholders beneficially owned approximately 52% of the outstanding shares of capital stock. In addition, as of December 31, 2022, our executive officers and directors held options to purchase an aggregate of 1,892,625 shares of our common stock at a

weighted-average exercise price of $10.95 per share, and 622,145 restricted stock units, which would give our officers and directors ownership of approximately 5% of our outstanding common stock as of December 31, 2022 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), 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. In particular, the ultimate impact of the conflict in Ukraine 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. 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.

Based on the market value of our common stock held by non-affiliates as of the last business day of our fiscal second quarter ended June 30, 2021, we ceased to be an "emerging growth company" as defined in the Jumpstart our Business Startups Act of 2012 as of December 31, 2021. As a result, we have experienced and expect to continue to experience, additional costs associated with being a public company, including costs associated with the auditor attestation requirement of Section 404 of the Sarbanes-Oxley Act, the adoption of certain Accounting Standard Updates upon losing such status, and additional disclosure requirements. As part of these requirements, we have made changes to our corporate governance practices and will need to maintain effective disclosure and financial controls that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our principal executive and financial officers. Any failure to maintain effective controls could adversely affect the results of periodic management evaluations.

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. We expect to continue to hire aggressively as we expand, and we believe our corporate culture has been crucial in 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. Our anticipated headcount growth and our public company status may result in a change to our corporate culture, which could harm our business.

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 doubtful accounts, 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 October 2021, we published our inaugural ESG Report, including updates on our ESG programs, priorities, initiatives, goals and performance, which we updated with a supplemental ESG report in September 2022. 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 2. Properties.

In May 2020, we entered into an operating lease agreement for our manufacturing facility in Tijuana, Mexico. This facility includes a main building with 48,437 square feet and a secondary space with 38,750 square feet. The initial term of this lease expires in 2026.

In addition, we lease 40,413 square feet 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, as well as distribution for consoles and service parts.

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 January 31, 2023, there were 117 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.

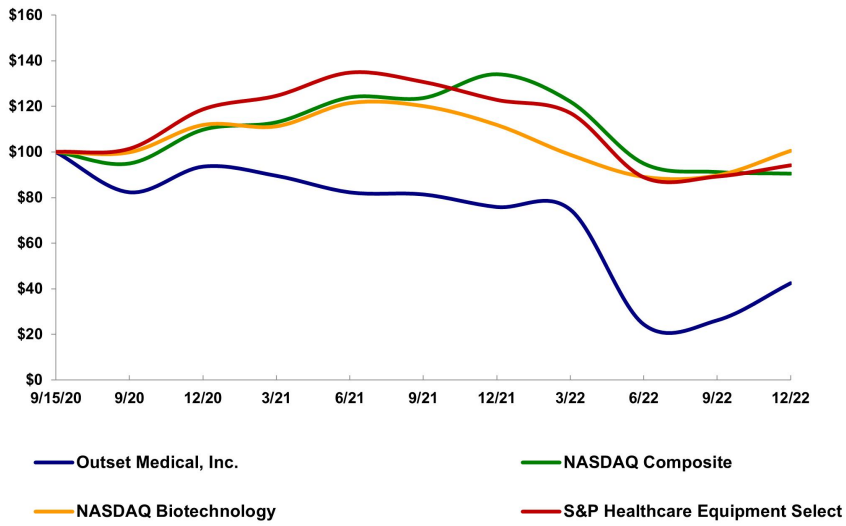
Stock Performance Graph

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, the S&P Healthcare Equipment Select Industry Index (SPSIHE) and the NASDAQ Biotechnology Index for the period from September 15, 2020 (the first day of trading of our common stock) through December 31, 2022. In our prior Form 10-Ks we utilized the NASDAQ Biotechnology Index as the industry index for comparison. In our performance graph below for the year ended December 31, 2022, we added SPSIHE, which will replace our comparison to the NASDAQ Biotechnology Index in future periods. We believe that the new index provides for greater comparability as it is better aligned with our industry and business. Total return comparisons for both the prior index and new index are included in the performance graph below. The graph assumes an investment of $100 on September 15, 2020 and its relative performance is tracked through December 31, 2022. 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.

COMPARISON OF 28 MONTH CUMULATIVE TOTAL RETURN

Among Outset Medical, Inc., the NASDAQ Composite Index,
the NASDAQ Biotechnology Index, and the S&P Healthcare Equipment Select Index



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, 2021 for reference to discussion of the year ended December 31, 2020, 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, the Tablo® Hemodialysis System 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 and treatments remotely, perform patient and population analytics, and automate clinical recordkeeping, while also enabling us to release features and enhancements through over-the-air updates. Tablo's connectedness also allows it to continually stream more than 500,000 device performance data points after every treatment. We use this data, in conjunction with our diagnostic and predictive algorithms, to determine failure types and, in some instances, predict failures before they occur. 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 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.

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. During the hold, we continued to market and ship Tablo for use by healthcare professionals in chronic and acute care settings. In addition, devices that were already distributed to home users at the time the hold was implemented were not removed and current users were able to continue working with their healthcare providers on appropriate treatment. 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.

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 sell our solution 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 consoles at existing customer sites. In addition, our field service team provides maintenance services and product support to Tablo customers. Our field sales and service teams represent 47% of our total full-time employees as of December 31, 2022. 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.

We generate revenue primarily from the initial sale of Tablo consoles, and recurring sales of consumables, including the Tablo cartridge, which generates significant total revenue over the life of the console. We generate additional recurring revenue via annual service contracts and shipping and handling charged to customers. For the years ended December 31, 2022, 2021 and 2020, sales of our consoles accounted for 56%, 63% and 66% of our revenue, respectively, sales of our consumables accounted for 25%, 19% and 13% of our revenue, respectively, and sales of services and other accounted for 19%, 18% and 21% of our revenue, respectively.

Historically, we have financed our operations and capital expenditures primarily through sales of redeemable convertible preferred stock and common stock, revenue from sales, and debt financing. Since our inception, we have incurred net losses in each year. For the years ended December 31, 2022, 2021 and 2020, we incurred net losses of $163.0 million, $131.9 million and $121.5 million, respectively. As of December 31, 2022, we had an accumulated deficit of $789.0 million. We expect to continue to incur significant expenses for the foreseeable future and to incur operating losses in the near term.

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 in part on 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 and health systems 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 continue regaining momentum in our home commercialization and marketing and rebuilding our home patient pipeline following the release of our prior home shipment hold, as well as our ability to further evolve our commercial infrastructure and sales processes as we scale our business in the home market.

Gross Margin

We are continuing to execute a well-defined strategy designed to expand gross margins. First, during 2021, we fully insourced console manufacturing at our own manufacturing facility in Tijuana, Mexico which we operate in collaboration with our outsourced business administration service provider, TACNA. Second, during 2022, we moved production of a majority of Tablo cartridges from our contract manufacturer in Southeast Asia to a contract manufacturer in Mexico, which helped us achieve cost reductions through lower freight costs and mitigate against global supply chain challenges. Recently, we initiated production of Tablo cartridges in-house at our manufacturing facility in Mexico which we operate in collaboration with TACNA in an effort to help further our long-term gross margin expansion and supply continuity strategies and improve the flexibility of our operations. Third, we will continue to use our design, engineering and manufacturing capabilities to help further advance and improve the efficiency of our manufacturing processes and lower our costs of production. Fourth, we will continue to utilize our cloud-based data system, as well as enhanced product performance, to help drive down the cost of service. Our ability to grow our business will depend in part on these and other measures to control the costs of our products being successful. Likewise, it will be important that we effectively manage the costs of generating our service revenue.

Impacts of the COVID-19 Pandemic and Other Macroeconomic Factors

Our business may be impacted by a resurgence of the recent COVID-19 pandemic or emergence of new variants of COVID-19. While the operations at our contract manufacturing partners' facilities and our outsourced business administration service provider, TACNA, for our facility in Tijuana, Mexico, have not yet experienced significant disruption as a result of the recent pandemic, the possibility that such disruption may occur remains. Additionally, the recent COVID-19 pandemic has at various times since its onset disrupted the operations of certain of our third-party suppliers, resulting in increased lead-times, higher component costs, and lower allocations for our purchase of some components (including certain critical components) and, in certain cases, requiring us to procure materials from alternative sources, procure higher quantities of materials when they become available, or incur higher logistical expenses. 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.

Additionally, surges and shifts in consumer demand as the economy reopens, further exacerbated by COVID-19 outbreaks and protocols, have strained the global freight network and placed significant stress on air, ocean, and ground freight carriers. This has resulted in labor shortages, container and chassis shortages, reduced carrier capacity, carrier delays and longer lead times, shipment receiving and unloading backlogs at many U.S. ports, and escalating freight costs. During late 2021, these supply chain disruptions escalated, and, as a result, we faced increased supply chain constraints, notably with the transportation of Tablo cartridges from our contract manufacturing partner in Southeast Asia. As a result, we have faced, and may continue to face, increased transportation and related costs, and potentially delays, associated with delivering adequate supply of Tablo treatments to our customers. We believe that transitioning production of a majority of Tablo cartridges during 2022 to a contract manufacturer in Mexico helped us achieve cost reductions through lower freight costs, and that our recent efforts to initiate production of cartridges in-house at our manufacturing facility in Mexico which we operate in collaboration with TACNA will help further our long-term gross margin expansion and supply continuity strategies and improve the flexibility of our operations. However, there is no assurance that we will not continue to face supply chain constraints. Continued escalation of these supply chain disruptions 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. Further, a sustained rise in material and freight costs could also unfavorably impact our operating margins and results of operations.

The extent, duration, and impact of the pandemic remain uncertain and depend on ongoing developments, including but not limited to any resurgences of the virus including emerging variant strains, actions taken to contain or mitigate its impact, as well as the direct and indirect economic effects of the pandemic and related containment measures. Additionally, the duration and severity of disruptions in the global supply chain, largely driven by high demand as the economy reopens and the ongoing impact of the pandemic, also remain uncertain and depend on various factors, including the effectiveness of government actions intended to mitigate these disruptions. As a result, we cannot predict what effect COVID-19, the associated containment measures, and the related supply chain disruptions will ultimately have on our business and result of operations, on our customers, or on our suppliers and vendors. There is no assurance that we will not experience more significant disruptions in our supply chain in the future, particularly if the operations of our contract manufacturing partners, our critical single-source component providers, or the facility we operate in Tijuana, Mexico in collaboration with TACNA, are more severely impacted by the pandemic and associated containment measures.

Moreover, healthcare providers (including our existing and prospective customers) are facing a nationwide shortage of qualified nurses and other clinical personnel due to long-term trends that were exacerbated by the recent COVID-19 pandemic. As competition for these healthcare professionals has intensified, providers are facing increased difficulties attracting and retaining skilled clinical personnel, resulting in increased costs, staffing shortages and other disruptions. These challenging labor market conditions in the healthcare industry have been heightened by the increased demand for, and demand upon, nurses and other staff. 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, there is a risk that the increased costs and other disruptions caused by the shortage of dialysis nurses, technicians, other staff, and implementation resources could cause existing or prospective customers to delay continued investment in or adoption of new technologies and postpone purchasing decisions. For example, during 2022, our existing and potential customers faced increasing staffing shortages and 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 staffing shortages, volatility, uncertainty, rising costs and financial pressures, whether due to the ongoing effects of the pandemic, general macroeconomic conditions or otherwise, it could ultimately adversely impact our ability to expand existing customer relationships or attract new customers of Tablo, and have a material adverse effect on our bookings, revenues, results of operations, and, ultimately, our future growth and profitability.

We recently launched a new 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. This pilot program is in its early stages and may not be successful in achieving the objectives we intend and anticipate and ultimately, it may fail to meet our customers' expectations, any of which could harm our reputation and customer relationships. In addition, the program may not generate sufficient returns to justify our investment, or may result in unanticipated costs, which could 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, we enter into console operating lease arrangements that contain lease and non-lease components. Revenue related to lease arrangements is allocated to the lease and non-lease elements based on their relative standalone selling price, with the lease component recorded in product revenue and the non-lease component recorded in service and other revenue. Our product and services revenues are generated primarily through direct sales to customers in the United States.

Product Revenue

We generate product revenue from the sale, and to a lesser extent, leasing of our Tablo consoles 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, including Tablo cartridges, 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, including the revenue associated with the first-year service, 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; sales mix changes among consoles, consumables, and services; 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 the costs associated with the production and service of the Tablo console and consumables, that we generate recurring revenues from sales of our consumables, 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 compensation and personnel 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, including hiring additional employees, to enhance existing products and develop new products. As a percentage of revenue, we 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 development initiatives.

Sales and Marketing

Sales and marketing expenses primarily consist of compensation and personnel 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 to continue to invest in our sales and support teams, marketing, and shipping and handling costs. 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 compensation and personnel costs, accounting and legal expenses, general corporate expenses, employee recruiting and training costs, and infrastructure costs including facilities, depreciation, and information technology.

We expect to incur additional general and administrative expenses due to increased costs for accounting, human resources, legal, insurance and investor relations. We expect to continue our hiring in all these areas in line with the continued growth of our business. We also expect infrastructure costs to increase in future periods as a result of higher costs associated with the expansion of our operations. As a result of these and other initiatives, we expect general and administrative expenses to vary from period to period and increase in absolute dollars in future periods. However, 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.

Change in Fair Value of Redeemable Convertible Preferred Stock Warrant Liability

In connection with our prior credit agreements and the Perceptive Term Loan Agreement, we issued warrants to purchase shares of our Series A, Series B and Series C redeemable convertible preferred stock to the respective lenders. We classified these warrants as a liability on our balance sheets that were remeasured to fair value at each reporting date with the corresponding change in fair value recognized in our statements of operations. Upon the completion of our IPO in 2020, the redeemable convertible preferred stock warrant liability was reclassified to additional paid-in capital.

Loss on Extinguishment of Term Loan

Loss on extinguishment of term loan is related to the repayment of the Perceptive Term Loan in July 2020 and 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, 2022 compared to the year ended December 31, 2021.

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

	Years Ended December 31,		
	2022	2021	2020
Revenue:			
Product revenue	$ 93,388	$ 84,312	$ 39,612
Service and other revenue	21,987	18,290	10,323
Total revenue	115,375	102,602	49,935
Cost of revenue:			
Cost of product revenue	82,510	84,639	57,035
Cost of service and other revenue	15,032	10,355	5,937
Total cost of revenue	97,542	94,994	62,972
Gross profit	17,833	7,608	(13,037)
Operating expenses:			
Research and development	48,855	36,741	28,850
Sales and marketing	89,482	65,070	45,068
General and administrative	40,515	36,316	30,512
Total operating expenses	178,852	138,127	104,430
Loss from operations	(161,019)	(130,519)	(117,467)
Interest income and other income, net	3,291	498	526
Interest expense	(3,566)	(1,715)	(2,891)
Loss on extinguishment of term loan	(1,367)	—	(1,567)
Change in fair value of redeemable convertible preferred stock warrant liability	—	—	(93)
Loss before provision for income taxes	(162,661)	(131,736)	(121,492)
Provision for income taxes	295	199	—
Net loss	$ (162,956)	$ (131,935)	$ (121,492)

Revenue

	Years Ended December 31,		Change	
(dollars in thousands)	2022	2021	$	%
Revenue:				
Product revenue	$ 93,388	$ 84,312	$ 9,076	11%
Service and other revenue	21,987	18,290	3,697	20%
Total revenue	$ 115,375	$ 102,602	12,773	12%

Product revenue increased by $9.1 million, or 11%, for the year ended December 31, 2022 as compared to the prior year. The increase was primarily due to a $9.6 million increase in consumables revenue attributable to the growth in our console installed base. This increase was partially offset by a net $0.5 million decrease in console revenue which was primarily comprised of a $2.7 million decrease in console leasing revenue due to the expiration of certain lease agreements, substantially offset by a higher average selling price for consoles.

Service and other revenue increased by $3.7 million, or 20%, for the year ended December 31, 2022 as compared to the prior year. The increase was primarily due to services associated with the growth in our console installed base, which was offset by a decrease in service revenue from leased consoles due to the expiration of certain lease agreements.

Gross Profit and Gross Margin

(dollars in thousands)	Years Ended December 31, 2022	2021	Change $	Change %
Gross profit and gross margin:				
Gross profit	$ 17,833	$ 7,608	$ 10,225	134%
Gross margin	*15.5* %	*7.4* %		

Gross profit increased by $10.2 million, or 134%, for the year ended December 31, 2022 as compared to the prior year. The gross margin percentage improved by 8.1 percentage points for the year ended December 31, 2022 as compared to the prior year. This improvement in gross margin was primarily driven by the impact of our console cost reduction activities and a higher average selling price for consoles. Such improvement was partially offset by the impact from the expiration of certain lease agreements.

Operating Expenses

(dollars in thousands)	Years Ended December 31, 2022	2021	Change $	Change %
Operating expenses:				
Research and development	$ 48,855	$ 36,741	$ 12,114	33%
Sales and marketing	89,482	65,070	24,412	38%
General and administrative	40,515	36,316	4,199	12%
Total operating expenses	$ 178,852	$ 138,127	40,725	29%

Research and development expenses increased by $12.1 million, or 33%, for the year ended December 31, 2022 as compared to the prior year. These increases were primarily due to higher headcount, resulting in increased payroll-related and stock-based compensation expense and increased infrastructure costs to support our growth. In addition, there were higher consulting and travel expenses to support our product research and development activities.

Sales and marketing expenses increased by $24.4 million, or 38% for the year ended December 31, 2022 as compared to the prior year. The increase was primarily driven by higher headcount, resulting in increased payroll-related and stock-based compensation expense and increased infrastructure costs to support our growth. In addition, there were higher freight, travel, consulting, and marketing expenses due to an increase in sales and marketing activities.

General and administrative expenses increased by $4.2 million, or 12%, for the year ended December 31, 2022 as compared to the prior year. The increase was primarily driven by higher headcount, resulting in increased payroll-related and stock-based compensation expense and increased infrastructure costs to support the general expansion of our operation. In addition, there were higher supplies and materials costs and higher travel costs due to an increase in training related activities and in-person events. These increases were partially offset by lower consulting expenses.

Other Income (Expenses), Net

(dollars in thousands)	Years Ended December 31, 2022	2021	Change $	Change %
Other income (expenses), net:				
Interest income and other income, net	$ 3,291	$ 498	$ 2,793	561%
Interest expense	(3,566)	(1,715)	(1,851)	108%
Loss on extinguishment of term loan	(1,367)	—	(1,367)	*
Total other expenses, net	$ (1,642)	$ (1,217)	(425)	35%

** Not meaningful*

The increase in interest income and other income, net, for the year ended December 31, 2022 as compared to the prior year was driven by higher interest rates and higher average short-term investments balance in 2022.

The increase in interest expense for the year ended December 31, 2022 as compared to the prior year was due to higher Prime Rate in 2022, which was the base interest rate used for the SVB Term Loan, and the higher interest expense and outstanding balance under the SLR Term Loan Facility.

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

Liquidity and Capital Resources

Sources of Liquidity

As of December 31, 2022, we had cash, cash equivalents, and short-term investments of $287.5 million, which are available to fund future operations, and restricted cash of $3.3 million, for a total cash, cash equivalents, restricted cash and short-term investments balance of $290.8 million.

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 stock option exercises and employee stock 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. 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 and currently available from the recent 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,		
	2022	2021	2020
Net cash provided by (used in):			
Operating activities	$ (145,729)	$ (130,264)	$ (99,015)
Investing activities	(66,295)	(142,507)	3,947
Financing activities	72,898	160,147	385,682
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (139,126)	$ (112,624)	$ 290,614

Operating Activities

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 payroll 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 of our business and an increase in accrued expenses and other current liabilities.

Net cash used in operating activities of $130.3 million for the year ended December 31, 2021 was due to a net loss of $131.9 million and a net cash outflow from the change in our operating assets and liabilities of $25.6 million, partially offset by the primary non-cash adjustments for stock-based compensation expense of $17.4 million, depreciation and amortization of $5.2 million, accretion of discount on investments of $2.0 million, non-cash lease expense of $1.0 million, provision for inventories of $1.0 million, and non-cash interest expense of $0.6 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 meet anticipated demand and to mitigate supply chain disruptions, an increase in accounts receivable due to timing of collections, a decrease in accounts payable due to timing of vendor payments and a decrease in operating lease liabilities. The net cash outflow from operating assets and liabilities was partially offset by an increase in accrued payroll and related benefits due to an increase in headcount, an increase in accrued expenses and other current liabilities, an increase in deferred revenue due to the growth of our business, a decrease in prepaid expenses and other assets and an increase in accrued warranty liability.

Investing Activities

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 sales and maturities of investment securities of $203.2 million.

Net cash used in investing activities of $142.5 million for the year ended December 31, 2021 was due primarily to purchases of investment securities of $178.4 million and purchases of property and equipment of $3.1 million, partially offset by the sales and maturities of investment securities of $39.0 million.

Financing Activities

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.

Net cash provided by financing activities of $160.1 million for the year ended December 31, 2021 was due primarily to the net proceeds of $149.1 million from the issuance of our common stock in our follow-on offering and the proceeds of $11.1 million from employee exercises of stock options and employee stock purchase plan purchases.

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: (i) a 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) an 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. We are permitted to borrow up to $200.0 million under the SLR Credit Facilities on the Closing Date. 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 $250.0 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), on or before June 30, 2025 and obtain lenders' credit approval, we will be permitted to borrow up to $300.0 million under the SLR Credit Facilities.

Pursuant to the terms and conditions of the SLR Loan Agreement, 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) one or more term loans (in minimum increments of $20.0 million each) in the aggregate of up to $100.0 million (each, a Term B Loan) and (iii) one or more term loans in the aggregate of up to $50.0 million (each, a Term C Loan). 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. The Term A Loan was funded on the Closing Date. The Term B Loan(s) are available for funding until August 22, 2024. The Term C Loan(s) are available subject to the lenders’ credit approval and the achievement of the Second Revenue Milestone on or before June 30, 2025. The Term C Loan 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.

As of December 31, 2022, we had $100.0 million outstanding under the SLR Term Loan Facility.

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). We repaid in full all amounts due under the SVB Term 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 Policies and 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 policies are most important to understanding and evaluating our reported financial results.

Revenue Recognition

We generate our revenue primarily from contracts with customers for the sale of products and services. Each customer contract defines our distinct performance obligations. 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. 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 from service contracts is recognized over time as the service is performed, typically evenly over the contract term. Revenue is recognized net of any taxes collected from customers, which are subsequently remitted to governmental authorities.

Our contracts with customers often include multiple performance obligations. Determining whether the products and services are considered distinct performance obligations that should be accounted for separately may require significant judgment by management. For such contracts, we allocate the contracted transaction price to each distinct performance obligation based upon the relative standalone sale prices (SSP). We determine the 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 customer 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. 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.

Stock-Based Compensation Expense

Our 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 our Employee Stock Purchase Plan (ESPP), restricted stock units (RSUs) and performance stock units (PSUs). Stock-based compensation expense for our stock-based awards is based on their grant date fair value.

We estimate the fair value of stock options with a service condition and stock purchase rights under our ESPP on the grant date 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 our 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, we calculate the expected term using the simplified method for “plain vanilla” stock option awards. We had no publicly available stock price information prior to our IPO and limited available stock price information subsequent to our IPO; therefore, we have 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 of 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. Prior to our IPO in September 2020, we had not recognized any stock-based compensation expense as the satisfaction of the performance condition was not considered probable. Upon the closing of our IPO, we recorded a cumulative stock-based compensation expense using the accelerated attribution method as the performance condition was satisfied. Stock-based compensation expense related to these options is not reversed if the achievement of the market-based vesting 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 service- or performance-based vesting conditions is based on the market price of our common stock on the date of grant. The determination of the stock-based compensation expense related to PSUs with performance-based vesting conditions to be recognized requires the use of certain estimates and assumptions. At each reporting period, we reassess 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 we have recorded in the current period. The fair value of PSUs with market-based vesting conditions 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.

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 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.

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, 2022, we had $100.0 million in variable rate debt outstanding under the SLR Term Loan Facility. 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. An immediate 100 basis point change in the term SOFR rate would not have a material impact on our debt-related obligations, financial position or results of operations.

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, we are exposed to the risk of currency fluctuations between USD and MXN. To date, foreign currency transaction gains and losses have not been material to our financial statements.

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

Item 8. Financial Statements and Supplementary Data.

Outset Medical, Inc.

Index to Financial Statements

Report of Independent Registered Public Accounting Firm

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

Opinions on the Financial Statements and Internal Control Over Financial Reporting

We have audited the accompanying balance sheets of Outset Medical, Inc. (the Company) as of December 31, 2022 and 2021, the related statements of operations, comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2022, and the related notes (collectively, the financial statements). We also have audited the Company's internal control over financial reporting as of December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2022, 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, 2022 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.

Identification of performance obligations in certain revenue contracts

As discussed in Note 3 to the financial statements, the Company recorded $115.4 million of total revenues for the year ended December 31, 2022, of which $93.4 million related to product revenue, and $22.0 million related to service and other revenue. As discussed in Note 2 to the financial statements, the Company's revenue is generated primarily from the sale of its products and services and contracts often include multiple performance obligations. Product revenue consists primarily of sales of the Tablo console and related consumables, including Tablo cartridges, used in treatment delivery. Service and other revenue consists primarily of revenue generated from console service contracts and other revenue from shipping and handling charged to customers. When a contract includes multiple performance obligations, determining whether the products and services are considered distinct performance obligations that should be accounted for separately may require significant judgment by management.

We identified the evaluation of the Company's identification of performance obligations in certain revenue contracts with customers as a critical audit matter. Evaluating whether the Company's promises to transfer products or services are distinct performance obligations that should be accounted for separately required subjective auditor judgment due to the varying nature of the underlying promises and the associated contract terms.

The following are the primary procedures we performed to address the critical audit matter. We evaluated the design and tested the operating effectiveness of certain internal controls related to the Company's revenue recognition process, including a control related to the Company's review of customer contracts for the identification of performance obligations. In addition, for a sample of the Company's recorded revenue, we evaluated the identification of performance obligations by reading the underlying contracts to understand the terms and conditions and considering the nature of the promises within the contract, and whether the promises were distinct from other promised goods and services.

/s/ KPMG LLP

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

San Francisco, California
February 13, 2023

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

	December 31,	
	2022	**2021**
Assets		
Current assets:		
Cash and cash equivalents	$ 73,222	$ 182,348
Short-term investments	214,280	157,140
Accounts receivable, net	28,070	25,600
Inventories	51,476	39,185
Prepaid expenses and other current assets	6,597	5,529
Total current assets	373,645	409,802
Restricted cash	3,311	33,311
Property and equipment, net	15,876	12,964
Operating lease right-of-use assets	6,117	7,231
Other assets	1,166	156
Total assets	$ 400,115	$ 463,464
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 603	$ 1,763
Accrued compensation and related benefits	21,519	24,948
Accrued expenses and other current liabilities	16,227	13,789
Accrued warranty liability	3,620	3,704
Deferred revenue, current	8,662	6,340
Operating lease liabilities, current	1,318	1,151
Total current liabilities	51,949	51,695
Accrued interest	113	721
Deferred revenue	151	312
Operating lease liabilities	5,576	6,893
Term loan	96,336	29,762
Total liabilities	154,125	89,383
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, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value; 300,000 shares authorized as of December 31, 2022 and December 31, 2021; 48,465 and 47,241 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	48	47
Additional paid-in capital	1,035,456	1,000,212
Accumulated other comprehensive loss	(564)	(184)
Accumulated deficit	(788,950)	(625,994)
Total stockholders' equity	245,990	374,081
Total liabilities and stockholders' equity	$ 400,115	$ 463,464

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,		
	2022	**2021**	**2020**
Revenue:			
Product revenue	$ 93,388	$ 84,312	$ 39,612
Service and other revenue	21,987	18,290	10,323
Total revenue	115,375	102,602	49,935
Cost of revenue:			
Cost of product revenue	82,510	84,639	57,035
Cost of service and other revenue	15,032	10,355	5,937
Total cost of revenue	97,542	94,994	62,972
Gross profit	17,833	7,608	(13,037)
Operating expenses:			
Research and development	48,855	36,741	28,850
Sales and marketing	89,482	65,070	45,068
General and administrative	40,515	36,316	30,512
Total operating expenses	178,852	138,127	104,430
Loss from operations	(161,019)	(130,519)	(117,467)
Interest income and other income, net	3,291	498	526
Interest expense	(3,566)	(1,715)	(2,891)
Loss on extinguishment of term loan	(1,367)	—	(1,567)
Change in fair value of redeemable convertible preferred stock warrant liability	—	—	(93)
Loss before provision for income taxes	(162,661)	(131,736)	(121,492)
Provision for income taxes	295	199	—
Net loss	$ (162,956)	$ (131,935)	$ (121,492)
Net loss attributable to common stockholders, basic and diluted	$ (162,956)	$ (131,935)	$ (79,324)
Net loss per share, basic and diluted	$ (3.38)	$ (2.89)	$ (4.85)
Shares used in computing net loss per share, basic and diluted	48,161	45,589	16,358

The accompanying notes are an integral part of these financial statements

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

	Years Ended December 31,		
	2022	**2021**	**2020**
Net loss	$ (162,956)	$ (131,935)	$ (121,492)
Other comprehensive loss:			
Unrealized loss on available-for-sale securities	(380)	(185)	(21)
Comprehensive loss	$ (163,336)	$ (132,120)	$ (121,513)

The accompanying notes are an integral part of these financial statements

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

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders Equity (Deficit)
	Shares	Amount	Shares	Amount	Capital			
Balance as of December 31, 2019	147,214	409,446	922	1	357	22	(372,567)	(372,187)
Issuance of Series E redeemable convertible preferred stock, net of issuance costs	57,782	126,758	—	—	—	—	—	—
Issuance of common stock on settlement of accrued dividend	—	(41,763)	4,850	5	41,758	—	—	41,763
Deemed dividend on settlement of accrued dividend	—	(42,530)	—	—	42,530	—	—	42,530
Adjustment to redemption value on redeemable convertible preferred stock	—	362	—	—	(362)	—	—	(362)
Issuance of common stock upon net exercises of Series B redeemable convertible preferred stock warrants	—	—	65	—	—	—	—	—
Cash exercises of Series C redeemable convertible preferred stock warrants	1,655	4,288	—	—	—	—	—	—
Conversion of Series A redeemable convertible preferred stock warrants to common stock warrants	—	—	—	—	1,252	—	—	1,252
Conversion of redeemable convertible preferred stock to common stock upon initial public offering	(206,651)	(456,561)	26,167	26	456,535	—	—	456,561
Issuance of common stock upon initial public offering, net of issuance costs	—	—	10,294	10	254,795	—	—	254,805
Reclassification of redeemable convertible preferred stock warrant liability to equity	—	—	—	—	3,126	—	—	3,126
Issuance of common stock for settlement of RSUs	—	—	5	—	—	—	—	—
Stock option exercises	—	—	419	1	1,194	—	—	1,195
Stock-based compensation expense	—	—	—	—	21,439	—	—	21,439
Unrealized loss on available-for-sale securities	—	—	—	—	—	(21)	—	(21)
Net loss	—	—	—	—	—	—	(121,492)	(121,492)
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

The accompanying notes are an integral part of these financial statements

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

	Years Ended December 31,		
	2022	2021	2020
Cash flows from operating activities:			
Net loss	$ (162,956)	$ (131,935)	$ (121,492)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	27,203	17,445	21,439
Depreciation and amortization	5,169	5,162	3,159
Non-cash lease expense	1,114	1,022	596
Non-cash interest expense	381	569	641
Accretion of discount on investments, net	449	1,972	50
Provision for inventories	2,610	1,023	534
Other non-cash items	76	81	340
Loss on extinguishment of term loan	1,367	—	1,567
Changes in operating assets and liabilities:			
Accounts receivable	(2,506)	(19,137)	(2,566)
Inventories	(14,730)	(22,042)	(16,287)
Prepaid expenses and other assets	(1,215)	1,860	(6,245)
Accounts payable	(1,281)	(3,066)	737
Accrued payroll and related benefits	(3,428)	8,103	9,889
Accrued expenses and other current liabilities	1,811	5,889	4,798
Accrued warranty liability	(83)	791	1,211
Deferred revenue	2,161	2,881	2,754
Operating lease liabilities	(1,150)	(882)	77
Accrued interest	(721)	—	(217)
Net cash used in operating activities	(145,729)	(130,264)	(99,015)
Cash flows from investing activities:			
Purchases of property and equipment	(8,325)	(3,108)	(9,077)
Purchases of investment securities	(261,154)	(178,432)	(32,884)
Sales and maturities of investment securities	203,184	39,033	45,908
Net cash (used in) provided by investing activities	(66,295)	(142,507)	3,947
Cash flows from financing activities:			
Proceeds from stock option exercises and employee stock purchase plan purchases	8,042	11,062	1,186
Proceeds from issuance of term loan, net of issuance costs	96,059	—	29,630
Repayment of term loan and extinguishment costs	(31,203)	—	(30,985)
Proceeds from issuance of common stock upon initial and follow-on public offerings, net of issuance costs	—	149,085	254,805
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	—	—	126,758
Proceeds from cash exercise of redeemable convertible preferred stock warrants	—	—	4,288
Net cash provided by financing activities	72,898	160,147	385,682
Net (decrease) increase in cash, cash equivalents and restricted cash	(139,126)	(112,624)	290,614
Cash, cash equivalents and restricted cash as of beginning of period	215,659	328,283	37,669
Cash, cash equivalents and restricted cash as of end of period	$ 76,533	$ 215,659	$ 328,283
Supplemental cash flow disclosures:			
Cash paid for income taxes	$ 385	$ 83	$ 19
Cash paid for interest	$ 3,185	$ 1,146	$ 3,270
Cash paid for amounts included in the measurement of operating lease liabilities	$ 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,		
	2022	**2021**	**2020**
Supplemental non-cash investing and financing activities:			
Capital expenditures included in accounts payable and accrued expenses	$ 167	$ 121	$ 323
Deferred financing costs included in accrued expenses	$ 750	$ —	$ —
Transfer of inventories to property and equipment	$ 28	$ 1,410	$ 2,131
Transfer of property and equipment to inventories	$ 199	$ 1,192	$ —
Right-of-use assets obtained in exchange for lease liabilities	$ —	$ —	$ 8,849
Deemed dividend on settlement of accrued dividend	$ —	$ —	$ 42,530
Adjustment to redemption value on redeemable convertible preferred stock	$ —	$ —	$ 362
Conversion of redeemable convertible preferred stock into common stock upon initial public offering	$ —	$ —	$ 456,561
Reclassification of redeemable convertible preferred stock warrant liability for conversion of Series A redeemable preferred stock warrants into common stock warrants	$ —	$ —	$ 1,252
Reclassification of redeemable convertible preferred stock warrant liability to additional paid-in capital	$ —	$ —	$ 3,126
Issuance of common stock on settlement of accrued dividend	$ —	$ —	$ 41,763

The accompanying notes are an integral part of these 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. The 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 $163.0 million, $131.9 million and $121.5 million for the years ended December 31, 2022, 2021, and 2020, respectively. As of December 31, 2022, the Company had an accumulated deficit of $789.0 million.

As of December 31, 2022, the Company had cash, cash equivalents, and short-term investments of $287.5 million, which are available to fund future operations, and restricted cash of $3.3 million, for a total cash, cash equivalents, restricted cash, and short-term investments balance of $290.8 million. 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 and currently available from the recent 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 doubtful accounts, 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. The Company has not experienced any credit losses on its cash and cash equivalents, restricted cash or short-term investments through December 31, 2022.

For the year ended December 31, 2022, the Company's largest customer accounted for 14% of revenues. For the year ended December 31, 2021, two customers accounted for 30% and 15% of revenues, respectively. For the year ended December 31, 2020, three customers accounted for 22%, 19% and 16% of revenues, respectively. Accounts receivable are unsecured; however, the Company does assess the collectability of accounts receivable based on a number of factors, including past transaction history with, and the creditworthiness of, the customer. Accordingly, the Company is exposed to credit risk associated with accounts receivable. One customer accounted for 13% of accounts receivable as of December 31, 2022. One customer accounted for 10% of accounts receivable as of December 31, 2021. 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.

The Company has a 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. The manufacturing operations at the facility may 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 its products. 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.

During the year ended December 31, 2022, financial results of the Company were not significantly affected by the COVID-19 pandemic, which continues to have global impact. The Company has considered all information available as of the date of issuance of these financial statements and the Company is not aware of any specific events or circumstances that would require an update to its estimates or judgments, or a revision to the carrying value of its assets or liabilities. These estimates may change as new events occur and additional information becomes available. The extent to which the pandemic affects the Company’s future financial results and operations will depend on future developments which continue to evolve and are difficult to predict, including but not limited to any resurgences of the virus including emerging variant strains, actions taken to contain or mitigate its impact, as well as the direct and indirect economic effects of the pandemic and related containment measures.

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. Management believes that its term loan bears interest at the prevailing market rates for instruments with similar characteristics; accordingly, the carrying value of this instrument approximates its fair value.

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) 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.

Accounts Receivable, Net

Accounts receivable are recorded at invoice value, net of any allowance for doubtful accounts. Estimates of the allowance for doubtful accounts are determined based on existing contractual payment terms, historical payment patterns of customers and individual customer circumstances. The allowance for doubtful accounts was not significant as of December 31, 2022 and 2021.

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 Company's 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. Certain Tablo consoles under operating leases are depreciated using the accelerated method. 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 Company's 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, 2022 and 2021.

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 multi-year 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 contracts with customers for the sale of its products and services. Product revenue consists primarily of sales of the Tablo console and related consumables, including Tablo cartridges, used in treatment delivery. Service and other revenue consists primarily of revenue generated from console service contracts 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 contracts is recognized over time as the service is performed, typically evenly over the contract term. 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. Determining whether the products and services are considered distinct performance obligations that should be accounted for separately may require significant judgment by management. For such contracts, the Company allocates the contracted transaction price to each distinct performance obligation based upon the relative SSP. 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 customer 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. 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.

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 in 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, RSUs and 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. Prior to the IPO in September 2020, the Company had not recognized any stock-based compensation expense as the satisfaction of the performance condition was not considered probable. Upon the closing of the IPO, the Company recorded a cumulative stock-based compensation expense using the accelerated attribution method as the performance condition was 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 Company's 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, 2022, 2021 and 2020 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 Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders 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, redeemable convertible preferred stock, 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 attributable to common stockholders is the same as diluted net loss per share attributable to common stockholders 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 years ended December 31, 2021 and 2020. 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 $1.4 million for the year ended December 31, 2022.

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, 2022.

Recently Issued Accounting Pronouncements Not Yet Adopted

In June 2016, the 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. In November 2019, the FASB issued ASU 2019-10, *Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815) and Leases (Topic 842): Effective Dates*, which defers the effective date of ASU 2016-13 to fiscal years beginning after December 15, 2022 for all entities except SEC reporting companies that are not smaller reporting companies. ASU 2016-13 became effective for the Company beginning January 1, 2023. The adoption of ASU 2016-13 is not expected to have a material impact on the Company's financial position and results of operations.

3. Revenue from Contracts with Customers

Disaggregation of Revenue

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

	Years Ended December 31,		
	2022	2021	2020
Consoles	$ 64,590	$ 65,133	$ 32,871
Consumables	28,798	19,179	6,741
Total product revenue	93,388	84,312	39,612
Service and other revenue	21,987	18,290	10,323
Total revenue	$ 115,375	$ 102,602	$ 49,935

For the years ended December 31, 2022, 2021 and 2020, $2.0 million, $4.7 million and $3.1 million, respectively, of consoles revenue were from console operating lease arrangements.

Remaining Performance Obligations and Contract Liabilities

As of December 31, 2022, the aggregate amount of the transaction price allocated to the remaining performance obligations related to customer service contracts that are unsatisfied or partially unsatisfied was $8.8 million, which is recorded as deferred revenue on the Company's balance sheet. Of that amount, $8.7 million will be recognized as revenue during the year ended December 31, 2023 and $0.1 million thereafter.

The contract liabilities consist of deferred revenue which represents payments received in advance of revenue recognition. Revenue under these agreements is recognized over the related service period. During the years ended December 31, 2022, 2021 and 2020, the Company recognized $6.3 million, $3.2 million, and $0.9 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, 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

		December 31, 2021			
	Valuation Hierarchy	Amortized Costs	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Assets:					
Cash equivalents:					
Money market funds	Level 1	$ 60,844	$ —	$ —	$ 60,844
Short-term investments:					
U.S. Treasury securities	Level 1	18,064	—	(60)	18,004
Corporate debt	Level 2	124,178	2	(125)	124,055
Commercial paper	Level 2	15,081	—	—	15,081
Total cash equivalents and short-term investments		$ 218,167	$ 2	$ (185)	$ 217,984

As of December 31, 2022, the remaining contractual maturities for short-term investments were as follows (in thousands):

	Aggregate Fair Value
Due within one year	$ 188,368
After one but within five years	25,912
Total	$ 214,280

The Company's Level 2 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.

Impairment assessments are made at the individual security level at each reporting period. When the fair value of an available-for-sale security is less than its cost at the balance sheet date, a determination is made as to whether the impairment is other-than-temporary and, if it is other-than-temporary, an impairment loss is recognized in earnings equal to the difference between the investment's amortized cost and fair value at such date. As of December 31, 2022, there were four securities with a total fair value of $21.1 million in an unrealized loss position for more than 12 months. The unrealized losses totaling $0.1 million as of December 31, 2022 were caused by changes in market interest rates or the widening of market spreads subsequent to the initial purchase of these securities, and not related to the underlying credit of the issuers or the underlying collateral. These securities were issued by public reporting companies with an investment-grade rating by at least one bond credit rating agency. As a result, the Company did not consider these investments to be other-than-temporarily impaired as of December 31, 2022. During the years ended December 31, 2022, 2021 and 2020, the Company did not recognize other-than-temporary impairment losses related to its investment securities.

5. Balance Sheet Components

Cash, Cash Equivalents and Restricted Cash

As of December 31, 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,		
	2022	2021	2020
Cash and cash equivalents	$ 73,222	$ 182,348	$ 294,972
Restricted cash	3,311	33,311	33,311
Total cash, cash equivalents and restricted cash	$ 76,533	$ 215,659	$ 328,283

Inventories

Inventories consist of the following (in thousands):

	December 31,	
	2022	2021
Raw materials	$ 20,623	$ 18,114
Work in process	9,086	6,054
Finished goods	21,767	15,017
Total inventories	$ 51,476	$ 39,185

Property and Equipment, net

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

	December 31,	
	2022	2021
Tablos under operating leases	$ 714	$ 2,412
Computers and software	4,021	3,777
Furniture and fixtures	1,768	1,494
Machinery and equipment	10,367	7,197
Leasehold improvements	5,040	4,864
Construction in progress	4,773	874
Total property and equipment	$ 26,683	$ 20,618
Less: accumulated depreciation and amortization	(10,807)	(7,654)
Property and equipment, net	$ 15,876	$ 12,964

Total depreciation and amortization expense for the years ended December 31, 2022, 2021, and 2020 was $5.2 million, $5.2 million, and $3.2 million, respectively.

Accrued Expenses and Other Current Liabilities

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

	December 31,	
	2022	2021
Inventory	$ 5,585	$ 4,808
Research and development expenses	908	574
Professional services	1,261	1,269
Customer rebates	1,364	3,121
Other	7,109	4,017
Total accrued expenses and other current liabilities	$ 16,227	$ 13,789

Accrued Warranty Liability

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

	December 31,	
	2022	2021
Balance as of December 31, 2021	$ 3,704	$ 2,913
Additions charged to cost of product revenue	5,748	7,310
Consumption	(5,832)	(6,519)
Balance as of December 31, 2022	$ 3,620	$ 3,704

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. The Company took initial possession of the building with 48,437 square feet in May 2020 and subsequently took possession of the second space with 38,750 square feet in June 2021. 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.

Both 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,		
	2022	2021	2020
Operating lease costs	$ 1,759	$ 1,759	$ 1,070
Variable lease costs	329	375	233
Short-term lease costs	170	180	371
Total lease costs	$ 2,258	$ 2,314	$ 1,674

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

	December 31,	
	2022	2021
Weighted-average remaining lease term (in years)	4.3	5.3
Weighted-average discount rate	8.7%	8.7%

The maturity of the Company’s operating lease liabilities as of December 31, 2022 were as follows (in thousands):

Years Ending December 31:	
2023	$ 1,856
2024	1,911
2025	1,969
Thereafter	2,523
Total lease payments	8,259
Less: imputed interest	(1,365)
Present value of operating lease liabilities	$ 6,894
Operating lease liabilities, current	$ 1,318
Operating lease liabilities, noncurrent	$ 5,576

Purchase Commitments

The Company's commitments as of December 31, 2022 were $66.5 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

On July 8, 2022, a purported stockholder class action lawsuit was filed in the U.S. District Court for the Northern District of California, naming the Company, its Chief Executive Officer, Chief Financial Officer, and former Chief Financial Officer as defendants. The complaint alleged that between September 15, 2020 and June 13, 2022, the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended (Exchange Act), by making false or misleading statements regarding the Company’s regulatory studies of the Tablo Hemodialysis System for at home use and the Company’s prospects related to the sale of the system for at home use. The complaint sought relief including damages, attorney fees, and costs in unspecified amounts. On September 7, 2022, the plaintiff filed a notice of voluntary dismissal of this action without prejudice. This action is now concluded.

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

Indemnifications

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

7. Term Loans

Term loans consist of the following (in thousands):

	December 31,	
	2022	**2021**
Principal of term loan	$ 100,000	$ 30,000
Unamortized debt discount	(3,664)	(238)
Term loan, noncurrent	$ 96,336	$ 29,762

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: (i) a 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) an 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. The Company is permitted to borrow up to $200.0 million under the SLR Credit Facilities on the Closing Date. 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 $250.0 million under the SLR Credit Facilities. 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 borrow up to $300.0 million under the SLR Credit Facilities.

SLR Term Loan Facility

Pursuant to the terms and conditions of the SLR Loan Agreement, 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) one or more term loans (in minimum increments of $20.0 million each) in the aggregate of up to $100.0 million (each, a Term B Loan) and (iii) one or more term loans in the aggregate of up to $50.0 million (each, a Term C Loan). 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. The Term A Loan was funded on the Closing Date. The Term B Loan(s) are available for funding until August 22, 2024. The Term C Loan(s) are available subject to the lenders' credit approval and the achievement of the Second Revenue Milestone on or before June 30, 2025. The Term C Loan 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% (9.33% as of December 31, 2022), 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 fee in the amount of $750,000 in respect of the Term B Loan(s), to be due and payable upon the earliest to occur of (a) the funding of the first Term B Loan, (b) December 20, 2023 and (c) the prepayment of the Term 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.

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 continuing 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 Company has also agreed to a financial covenant whereby, 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 (or maintain gross profit margins) in excess of specified amounts (or percentages) 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 certain 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.

In November 2022, the Company borrowed $100.0 million under the Term A Loan on the Closing Date and incurred debt issuance costs of $3.8 million which were recorded as a direct deduction from the Term A Loan on our balance sheets and are being recognized as non-cash interest expense over the term of the loan using the effective interest method, along with the final payment fee. The facility fees of $0.9 million related to the Term B Loan and 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.

Aggregate annual payments due on the Term A Loan as of December 31, 2022 were as follows (in thousands):

Years Ending December 31:	
2023	$ 8,298
2024	9,093
2025	9,068
2026	17,401
2027	100,568
Total future payments	144,428
Less: amount representing interest	(39,678)
Less: final payment	(4,750)
Total term loan	100,000
Less: unamortized debt discount	(3,664)
Total term loan, net of debt discount	$ 96,336

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, 2022, 4,879,000 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

Service-based options 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
Balance as of December 31, 2021	3,533	$ 12.63		
Granted	1	$ 35.14		
Exercised	(790)	$ 4.86		
Forfeited and expired	(142)	$ 31.47		
Balance as of December 31, 2022	2,602	$ 13.97	6.26	$ 42,161
Exercisable as of December 31, 2022	2,114	$ 9.58	5.93	$ 38,984

The weighted average grant date fair value of options granted to employees was $18.56, $24.74, and $7.97 per share during the years ended December 31, 2022, 2021 and 2020, respectively. The total intrinsic value of options exercised during the years ended December 31, 2022, 2021 and 2020 was $22.2 million, $61.0 million, and $8.2 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, 2022, 2021 and 2020 was $6.1 million, $24.5 million and $3.3 million, respectively. As of December 31, 2022, the total unrecognized stock-based compensation expense related to the stock options was $8.0 million, which will be recognized over a weighted-average period of 1.89 years.

As of December 31, 2020, the Company had 1,933,000 shares of outstanding stock options with performance- and market-based vesting conditions. The options were scheduled to vest over the requisite service period if the Company achieved both (i) a performance condition tied to a liquidity event, which included the effectiveness of an IPO, and (ii) certain market conditions, provided the grantee was providing services on the date of the event. For the years ended December 31, 2021 and 2020, the Company recorded stock-based compensation expense of $4.3 million and $18.5 million, respectively, related to these stock options. No such expense was recorded for the year ended December 31, 2022 as all outstanding options with these conditions were fully vested and related stock-based compensation was recognized in full 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	2020
Expected term (in years)	6.08	5.95 – 6.08	5.06 – 10.00
Expected volatility	55.0%	53.9% – 55.3%	52.1% – 62.7%
Risk-free interest rate	1.74%	0.66% – 1.36%	0.35% – 1.54%
Dividend yield	0%	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, 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 2024 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 2023, with 50% of earned units vesting after certification of the achievement level following the end of 2023 and the remaining 50% of earned units vesting at the end of 2024 (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 2024 (market-based vesting conditions, referred to as the Relative TSR PSUs). The number of units earned at the end of the 2023 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 2023 target for the Home PSUs was not determined and approved by the Compensation Committee of the Board until January 2023. Therefore, no expense was recognized for these Home PSUs in 2022.

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, 2021	563	110	$ 47.98	$ 47.65
Granted	1,431	168	$ 32.34	$ 15.32
Vested	(224)	(17)	$ 47.80	$ 48.57
Forfeited	(177)	(22)	$ 40.82	$ 29.80
Outstanding as of December 31, 2022	1,593	239	$ 34.75	$ 26.50

The total grant date fair value of restricted stock vested for the years ended December 31, 2022, 2021 and 2020 were $9.9 million, $1.0 million, and $0.2 million, respectively. As of December 31, 2022, the total unrecognized stock-based compensation expense related to the restricted stock was $45.5 million, which will be recognized over a weighted-average period of 2.18 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, 2022, 1,278,000 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 approximately 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,		
	2022	**2021**	**2020**
Expected term (in years)	0.49 – 2.00	0.50	0.47
Expected volatility	41.1% – 58.0%	41.0% – 43.8%	57.0%
Risk-free interest rate	0.6% – 3.48%	0.06% – 0.07%	0.12%
Dividend yield	0%	0%	0%
Grant Date Fair Value	$4.89–$16.23	$13.25 – $13.95	$8.00

As of December 31, 2022, the total unrecognized stock-based compensation expense related to the ESPP was $6.0 million, which will be recognized over a weighted-average period of 0.95 years.

Stock-based Compensation Expense

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

	Years Ended December 31,		
	2022	**2021**	**2020**
Cost of revenue	$ 701	$ 269	$ 255
Research and development	6,845	3,809	4,615
Sales and marketing	10,269	5,897	4,423
General and administrative	9,388	7,470	12,146
Total stock-based compensation expense	$ 27,203	$ 17,445	$ 21,439

9. Income Taxes

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

	Years Ended December 31,		
	2022	2021	2020
Domestic	$ (153,226)	$ (128,400)	$ (121,492)
Foreign	(9,435)	(3,336)	—
Loss before provision for income taxes	$ (162,661)	$ (131,736)	$ (121,492)

The provision for income taxes were $0.3 million and $0.2 million for the years ended December 31, 2022 and 2021, respectively, which primarily related to foreign income taxes in Mexico. For the year ended December 31, 2020, the provision for income taxes was insignificant. 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,		
	2022	2021	2020
Federal statutory income tax rate	21.0 %	21.0 %	21.0 %
State taxes	4.2	1.3	3.8
Change in valuation allowance	(26.1)	(22.8)	(23.3)
Federal and state tax credits	1.4	1.2	1.0
Stock-based compensation expense	1.2	8.1	1.2
Non-deductible permanent expenses	(0.2)	(0.1)	(0.2)
Effect of deferred tax adjustment	0.2	(0.7)	(1.4)
Non-deductible compensation	(1.9)	(8.2)	(2.1)
Effective income tax rate	(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,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 131,705	$ 102,094
Tax credits	14,172	11,767
Accrual and reserves	4,509	3,573
Tangible and intangible assets	2,143	845
Stock-based compensation expense	4,686	3,566
Capitalized research costs	25,730	19,405
Other deferred tax asset	2,876	2,236
Gross deferred tax assets	185,821	143,486
Valuation allowance	(184,298)	(141,729)
Net deferred tax assets	$ 1,523	$ 1,757

	December 31,	
	2022	2021
Deferred tax liabilities:		
Right-of-use assets	$ (1,523)	$ (1,757)
Gross deferred tax liabilities	$ (1,523)	$ (1,757)

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, 2022 and 2021. The change in the valuation allowance during the years ended December 31, 2022, 2021 and 2020 was an increase of $42.6 million, $30.7 million and $28.4 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 2022 income tax provision, resulting in an increase in deferred tax assets.

Net Operating Loss and Tax Credit Carryforwards

As of December 31, 2022, the Company had a net operating loss carryforward for U.S. federal income tax purposes of $526.8 million. Federal net operating losses of $399.0 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 $298.1 million. State net operating losses of $85.3 million do not expire. The remaining state net operating loss carryforward of $212.7 million will begin to expire in 2023 and continue to expire through 2042.

As of December 31, 2022, the Company had federal research and development credits of $7.8 million, which will begin to expire in 2030 and state research and development credits of $6.4 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 at December 31, 2022 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,	
	2022	**2021**
Balance, beginning of year	$ 2,190	$ 1,582
Increase related to prior years positions	37	—
Decrease related to current year positions	—	—
Increase related to current year positions	800	608
Balance, end of year	$ 3,027	$ 2,190

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 not currently under examination by income tax authorities in federal, state 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 Attributable to Common Stockholders

A reconciliation of the numerator and denominator used in the calculation of basic and diluted net loss per share attributable to common stockholders was as follows (in thousands, except per share amounts):

	Years Ended December 31,		
	2022	**2021**	**2020**
Numerator:			
Net loss	$ (162,956)	$ (131,935)	$ (121,492)
Adjustment to redemption value on redeemable convertible preferred stock	—	—	(362)
Deemed dividend on settlement of accrued dividend	—	—	42,530
Net loss attributable to common stockholders, basic and diluted	$ (162,956)	$ (131,935)	$ (79,324)
Denominator:			
Weighted-average shares of common stock, basic and diluted	48,161	45,589	16,358
Net loss per share attributable to common stockholders, basic and diluted	$ (3.38)	$ (2.89)	$ (4.85)

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,		
	2022	**2021**	**2020**
Stock options to purchase common stock	2,602	3,533	4,763
Restricted stock units	1,593	581	—
Performance stock units	47	17	—
Shares committed under ESPP	90	37	52
Warrant to purchase common stock	63	63	63
Total	4,395	4,231	4,878

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, 2022.

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, 2022.

The effectiveness of our internal control over financial reporting as of December 31, 2022 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, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

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 2023 Annual Meeting of Stockholders within 120 days of our fiscal year ended December 31, 2022 (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	S-1/A	333-248225	10.4	September 9, 2020
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. 2020 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	S-1/A	333-248225	10.7	September 9, 2020
10.12†	Form of Amended and Restated Change in Control and Severance Agreement for non-Chief Executive Officer executive officers	S-1/A	333-248225	10.8	September 9, 2020
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
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				
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 Document				
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101)				

* Filed herewith

† Indicates a management contract or compensatory plan or arrangement.

Portions of the exhibit have been or will be excluded because it is both not material and is the type of information that the registrant treats as private or confidential.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Outset Medical, Inc.

Date: February 13, 2023

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 13, 2023
/s/ Nabeel Ahmed Nabeel Ahmed	Chief Financial Officer (*Principal Financial Officer and Principal Accounting Officer*)	February 13, 2023
/s/ D. Keith Grossman D. Keith Grossman	Lead Independent Director	February 13, 2023
/s/ Karen Drexler Karen Drexler	Director	February 13, 2023
/s/ Patrick T. Hackett Patrick T. Hackett	Director	February 13, 2023
/s/ Jim Hinrichs Jim Hinrichs	Director	February 13, 2023
/s/ Dale Jones Dale Jones	Director	February 13, 2023
/s/ Andrea L. Saia Andrea L. Saia	Director	February 13, 2023
/s/ Catherine Szyman Catherine Szyman	Director	February 13, 2023

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statements (Nos. 333-248903 and 333-262927) on Form S-8 of our report dated February 13, 2023, with respect to the financial statements of Outset Medical, Inc. and the effectiveness of internal control over financial reporting.

/s/ KPMG LLP

San Francisco, California
February 13, 2023

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Leslie Trigg, certify that:

1. I have reviewed this annual report on Form 10-K of Outset Medical, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 13, 2023

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 13, 2023

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, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned certifies, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to her or his knowledge:

1. The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 13, 2023 By: /s/ Leslie Trigg
Leslie Trigg
Chief Executive Officer
(*Principal Executive Officer*)

Date: February 13, 2023 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.