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, 2021

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. ☐

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, 2021 (the last business day of the registrant's most recently completed second quarter) as reported by Nasdaq Global Market on that date was $1.7 billion.

The number of shares of the registrant's common stock, par value $0.001 per share, outstanding as of February 16, 2022 was 47,406,856.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2022 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, 2021, 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 for future operations;
- 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 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 regarding adoption of Tablo by home dialysis patients and patient retention;
- the impact of the ongoing COVID-19 pandemic on our business and results of operations, and on our customers, suppliers and vendors;
- our intent to explore opportunities for international expansion;
- continued execution of our initiatives designed to reduce the cost of producing and shipping Tablo devices and our ability to achieve projected cost reductions at the levels or within the timeframe we estimate;
- our 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; 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, cleared by the U.S. Food and Drug Administration (FDA) for use from the hospital to the home, represents a significant technological advancement that transforms the dialysis experience for patients and operationally simplifies it for providers. 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.

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. 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.

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 (OTA) 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 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 clinical and 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. Tablo is currently cleared by the FDA for use in the hospital, clinic or home setting.

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 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 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. While the ongoing COVID-19 pandemic has presented opportunities to demonstrate the real-world benefits of Tablo over traditional machines, we believe these benefits, in addition to the other advantages of Tablo, are continuing to drive customer purchasing decisions.

Tablo is also well suited for home-based dialysis. Tablo was cleared by the FDA for use in an acute or chronic care facility in September 2014. Subsequently, in March 2020, Tablo was cleared by the FDA for patient use in the home. 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 are focused on refining our home distribution, logistics and support systems to help ensure they are ready for rapid

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.

We completed our initial public offering in September of 2020. Our common stock is listed on the Nasdaq Global Select Market under the symbol “OM.”

Our Market Opportunity

In the United States, dialysis is a large, expensive sector of healthcare that has seen little technology innovation in the last 30 years. We estimate that annual spending on ESRD in the United States is approximately $73 billion, of which an estimated $41 billion is Medicare spending. In 2019, this spending represented 7% of the total Medicare budget despite ESRD patients only representing 1% of the Medicare population. Dialysis is performed in the acute care setting, outpatient dialysis clinics and the patient’s home based on the patient’s condition and preference. As a result of an aging population and the growing incidence of diabetes, hypertension and obesity, based on historical rates of growth, we estimate the ESRD patient population will continue to grow around 3% annually, roughly 30% compounded growth, over the next ten years in the United States, thereby increasing our opportunity in both markets. We believe that any decrease in the size of the ESRD patient population due to COVID-related deaths may be offset by an increase in the population due to COVID-related AKI and delayed diagnosis of advanced stage CKD. As a result, although we cannot predict the full impact of the COVID-19 pandemic on the ESRD patient population with certainty, we do not anticipate that the pandemic will significantly impact the long-term growth rate of the population. We estimate the total annual addressable market opportunity in the United States for Tablo is approximately $2.5 billion in the acute care setting and approximately $8.9 billion in the home setting.

Acute Care

The acute care market includes short-term acute care hospitals, sub-acute long-term acute care hospitals (LTACHs) and skilled nursing facilities (SNFs). As of 2019, there were approximately 4,500 acute care hospitals and approximately 17,000 LTACHs and SNFs facilities in the United States, of which we believe 3,700 hospitals and 1,600 LTACHs and SNFs facilities are included in our acute care addressable market. We expect acute care hospitals to support higher treatment volumes per facility than LTACHs and SNFs and thus represent a greater proportion of the total market opportunity. The cost of managing a dialysis program is high, typically requiring complex equipment, separate infrastructure and specialized staff. We believe the majority of hospitals currently outsource the management of their dialysis programs to a third party, which is costly and may limit their ability to control the quality of patient care. For hospitals that manage their own dialysis programs, we believe that aggressive cost containment measures are motivating administrators to assess technology alternatives in order to lower the overall cost of care.

Home Care

At the end of 2019, there were approximately 570,000 patients in the United States receiving some sort of dialysis in the clinic or home setting. The majority of these patients were treated in dialysis clinics, although a large and growing number of treatments are transitioning to the patient’s home. In 2019, approximately 13% of patients (75,000 individuals), received dialysis treatment at home through peritoneal dialysis or home hemodialysis. From 2009-2019, the home hemodialysis patient population grew 131%, resulting in approximately 12,200 patients on home hemodialysis therapy, and we estimate that there are approximately 13,500 patients on home hemodialysis therapy today. We believe that the dynamics in the non-acute care market will continue to shift towards more home-based treatments as a result of several factors including the recent Executive Order on Advancing American Kidney Health, the expansion of Medicare Advantage to patients with ESRD and increasing commercial payor focus on reducing the total cost of ESRD care. We believe the recent COVID-19 global pandemic will accelerate the need for and adoption of technologies that enable care closer to and within the patient’s home, such as home-based dialysis therapies and telemedicine.

Overview of Kidney Function and Disease

A healthy human kidney removes waste and excess water from the blood on a continuous basis. Without a properly functioning kidney, byproducts and fluids build up in the body, which leads to progressive toxicity, electrolyte imbalance and fluid overload. There are two primary types of kidney disease: CKD and AKI. CKD is the gradual loss of kidney function over many years. CKD is typically irreversible and eventually leads to ESRD, which is the final stage of CKD. AKI is generally shorter in onset and can be reversible or lead to ESRD.

End Stage Renal Disease (ESRD)

ESRD is most often the result of chronic diseases, such as diabetes or high blood pressure, and is diagnosed when a patient’s kidneys no longer have sufficient function to avoid critical buildup of toxins and fluid in the body. If left untreated, ESRD will result

in death. The prevalence of ESRD in the United States has increased significantly over the last 40 years, driven in part by the growing rates of diabetes, hypertension, obesity and the overall aging of the population. At the end of 2019, there were approximately 810,000 patients with ESRD in the United States, of which, approximately 570,000 were treated with dialysis and the remainder of whom were living with a kidney transplant. The total ESRD figure is approximately 40% higher than the number reported ten years prior. We expect multiple pre-existing conditions and demographic factors such as diabetes, hypertension, obesity and an aging population to drive the prevalence of kidney failure to one million individuals by 2030.

Acute Kidney Injury (AKI)

AKI is the temporary loss of kidney function. AKI frequently occurs as a result of other medical conditions or treatment, including loss of other organ functions, severe infection, drug toxicity or post-surgical trauma. Patients experiencing AKI may require some form of dialysis in order to survive. Based on data from Centers for Medicare and Medicaid Services (CMS), the rate of beneficiaries experiencing a hospitalization complicated by AKI doubled from 2006-2016, with an approximate one third probability of these patients being newly diagnosed with CKD within the following 12 months. We estimate that there are over 450,000 admissions for AKI in the United States each year.

Kidney Disease Treatment Alternatives and Care Settings

Treatment of kidney disease typically depends on the type and stage of the disease. Approximately 20-25% of patients admitted to the ICU with a diagnosis of AKI may require dialysis treatment until their kidneys recover. If they fail to recover, AKI patients may need to remain on dialysis or receive a kidney transplant. For CKD, early stages of kidney disease can be managed with education, lifestyle changes and drug-based therapies. As kidney function continues to deteriorate and progress towards ESRD, the patient must either obtain a kidney transplant or receive dialysis for the rest of their life. Although transplantation is usually the most desirable option, a shortage of available organs and patient risk factors limit the use of this option. In 2019, only approximately 25,000 transplant procedures were performed in the United States compared to a total dialysis patient population of approximately 570,000. As a result, the vast majority of patients rely on dialysis to survive. While early CKD education and management can slow the progression of disease and help with a patient's transition to dialysis, the Centers for Disease Control estimates that 90% of patients with CKD do not know they have kidney disease.

Additionally, the United States Renal Data Systems 2021 Annual Report indicates approximately 30% of new ESRD patients receive little or no pre-ESRD care at the time of dialysis initiation and "crash" into dialysis, initiating dialysis in an unplanned fashion.

Hemodialysis, the most common form of dialysis treatment, is a process by which waste products and excess fluid are directly removed from a patient's blood using an external dialysis machine. Blood from the patient is routed to a dialyzer, also known as an artificial kidney, through plastic tubes where toxins are removed by diffusion across the dialyzer's semipermeable membrane into a dialysate solution usually comprised of purified water and electrolytes. Excess fluid within the blood is removed in the dialyzer by the movement of water from higher pressure (blood) to lower pressure (dialysate). Cleansed blood from the dialyzer is then returned to the patient. A physician's dialysis prescription can vary significantly depending on the patient's level of acuity and the care setting. Key elements of a prescription include treatment duration, treatment frequency, blood flow rate, dialysate flow rate, ultrafiltration rate and dialysate electrolyte composition. After treatment, the patient is disconnected from the machine, which is disinfected before the next use.

Dialysis treatments are performed in the acute care setting, outpatient dialysis clinics and the patient's home. The most common treatment option for ESRD patients, representing approximately 88% of ESRD dialysis patients in the United States, is treatments in a dialysis clinic. Most dialysis clinics are outpatient, freestanding facilities designed to treat on average 18 patients at a time. There are approximately 7,500 clinics in the United States that typically are open six days per week, treating patients on two to three shifts per day. In-clinic treatment typically lasts three to four hours and is usually performed three times per week. Outset's commercial efforts are focused on the acute and home care settings where we believe Tablo is most needed and offers the most compelling value proposition based on product-market fit, price tolerance and competitive differentiation
.

Acute Care. The acute care market includes the treatment of AKI and ESRD patients in the hospital setting, or in sub-acute care settings such as LTACHs or SNFs. There are generally three subtypes of hemodialysis treatments that are used in the acute care settings. The decision of which treatment option to use is usually driven by the patient's level of acuity. However, the decision can also be influenced by the availability of the treatment modality and whether the nurses are trained to use the specific type of dialysis machine.

Home. In 2019, approximately 13% of ESRD dialysis patients in the United States were dialyzing at home, with home hemodialysis patients representing 2% and peritoneal dialysis patients representing 11%.The decision on whether the patient stays in

clinic or moves to home-based dialysis is made by the provider and patient based on several factors, including the patient's condition and level of independence. Clinics are mandated by CMS to inform patients of all available treatment alternatives, although surveys show that many patients are unaware of their care setting options. In recent years, there has been a growing trend of delivering dialysis closer to the patient as health systems, dialysis clinic providers and payors are recognizing the opportunity to improve the patient outcomes and lower the total cost of care through home dialysis. In an effort toward moving more patients to home dialysis, some health systems and dialysis providers have established TCUs. TCUs are orientated around educating ESRD patients as they transition into ongoing dialysis care with an emphasis on increasing the percentage of patients who select a home dialysis modality. In addition, there are currently approximately 2,200 clinics with specific home dialysis programs. We expect both TCUs and clinic-based home dialysis programs to grow. Regardless of whether ESRD patients are treated at home or remain in a clinic, they remain under the care of a dialysis provider that purchases their dialysis equipment and treatment supplies. Home dialysis patients receive ongoing clinical support from their nephrologist and the clinic's care team in their home base clinic.

Patients have two modality choices for home therapy—hemodialysis or peritoneal dialysis. The decision between home hemodialysis and peritoneal dialysis is based on several factors, including patient eligibility, the patient's level of independence and the clinic's training capacity.

- *Home Hemodialysis*. A treatment using a hemodialysis machine that stays in the patient's home. Due to the inherent complexity associated with traditional home hemodialysis machines, patients must first undergo several weeks of intensive training from a nurse in their dialysis clinic before beginning to perform treatments in their home. The incumbent home hemodialysis machine requires more frequent dialysis, sometimes up to six times per week, and significant setup and prep time before each treatment. Patients are responsible for manually logging and submitting detailed information about each treatment to their dialysis care team to enable the provider to submit for reimbursement. This manual administrative work adds to patient fatigue and compliance issues.

- *Peritoneal Dialysis (PD)*. A self-administered, at-home treatment option that involves infusing sterile dialysate fluid through a surgically implanted catheter into the patient's abdomen, or peritoneal cavity manually or via a peritoneal dialysis device, known as a cycler. The body's natural internal lining acts as a semipermeable membrane which can eliminate toxins and remove fluid from the blood. After four to six hours, the dialysate fluid is drained from the patient's body through the catheter, disposed of and replaced with fresh dialysate. These exchanges are performed four to five times per day. Peritoneal dialysis is clinically limited due to patients with certain pre-existing conditions such as congestive heart failure and obesity. Additionally, peritoneal dialysis is regarded as a "temporary" modality since approximately 80% of patients are on the therapy for less than three years.

Limitations and Challenges of Current Hemodialysis Machines

Hemodialysis is the most common form of dialysis for both AKI and ESRD patients and is used across multiple care settings. Nevertheless, we believe that limitations of traditional hemodialysis machines create significant operational complexities and challenges to administering dialysis, which ultimately contribute to a higher cost of care. These limitations include:

- Operational challenges. Traditional hemodialysis machines are technically complex and require extensive training for both specialized staff and patients. Additionally, traditional machines require incremental equipment and separate water treatment rooms, which is not always practical depending on the care setting. These machines lack intuitive software, integrated data analytics and two-way wireless connectivity resulting in manual treatment set-up, documentation, reporting and machine management.

- Clinical challenges. Traditional hemodialysis machines are typically used to deliver a single modality of treatment, requiring multiple machines for different types of treatment types across different care settings, therefore reducing clinical versatility.

- Financial challenges. Traditional hemodialysis machines are expensive to operate with high fixed investment in infrastructure, significant recurring supply costs and expensive dialysis-specific labor. In the acute care setting, this very often results in specialized in-house teams or outsourcing to a third-party dialysis provider.

Additionally, we believe there are specific challenges in each individual care setting.

Challenges in the Hospital. In general, the cost of delivering dialysis in the hospital is not reimbursed as a standalone service, so the expense of providing dialysis care, whether managed in-house or outsourced to a third party, has a significant impact on hospital operating margins. In 2018, dialysis was performed across roughly 600 diagnosis-related groups, of which 60% of the inpatient stays with dialysis had negative operating margins, including 30% of inpatient stays that lost more than $10,000 per visit.

Given the complexity of managing dialysis programs with traditional equipment, many hospital administrators choose to outsource their dialysis program, which can be costly and may limit their ability to control patient care quality. The key challenges of delivering dialysis in the hospital include:

- Limited clinical versatility of traditional machines. Hospitals require multiple machines for different treatment modalities to care for patients with varying degrees of acuity. Specifically, patients in the ICU require treatment with machines that deliver lower flow rates for longer durations, while stable patients are typically treated outside of the ICU on devices that deliver higher flow rates for shorter durations. Traditional dialysis machines are typically used to deliver a single modality, requiring different machines for different types of treatment types across care settings. This adds cost, complexity and inefficiency.

- Specialized, dialysis-specific labor. Traditional dialysis machines are complicated to learn and use, and therefore require specially trained clinical staff who are in short supply or may not always be readily available for patient care. Training a dialysis nurse on a traditional dialysis machine typically takes weeks, limiting hospitals' ability to flex their resources on-demand and potentially limiting patient access to prompt care.

- Specialized infrastructure, equipment, and expensive supplies. Traditional dialysis machines require industrial water treatment rooms or separate mobile water filtration systems to generate the purified water necessary for dialysate production, which adds significant cost and space requirements to a hospital-based dialysis program. For machines that rely on sterile-packed dialysate bags in lieu of a separate water treatment and dialysate production area, the cost of purchasing and storing these supplies can be high.

Challenges in the Home. The limited adoption of home hemodialysis is largely a result of suboptimal existing technologies that make it operationally complex and expensive to manage, and consequently an undesirable treatment alternative for providers and patients. We believe the key challenges are:

Challenges for Providers

- Time required to train new patients. The most commonly used home hemodialysis machine requires approximately 100 hours of nurse-led training, which translates into several weeks of commitment, unreimbursed expense and can result in a backlog of patients waiting to be trained due to capacity constraints. This time commitment required of patients and their care partners limits the adoption of home hemodialysis.

- Low retention of patients. The incumbent home hemodialysis machine requires patients to dialyze frequently, sometimes up to six times per week. This involves cumbersome setup procedures requiring up to eight hours of prep work several times per week, to prepare batches of dialysate ahead of treatment. This is impractical and ultimately contributes to patient burnout. The patient drop-out rate for home hemodialysis on the incumbent machine is up to 45% within the first year.

- Manual process of reporting. The incumbent machine requires patients to manually log their treatment regimen for reporting. Additionally, any machine errors impacting a patient's treatment go unnoticed unless reported by the patient. This lack of visibility impacts compliance and reduces quality of care. Since clinics require proof of treatment in order to receive reimbursement, the lag created by manual reporting delays reimbursement timing to the provider.

Challenges for Patients

- Complicated and time-consuming to learn. The incumbent home dialysis machine is technically complex and unintuitive to operate requiring patients to memorize setup procedures and refer to a paper manual for alarm resolution. As noted above, achieving competency requires approximately 100 hours of nurse-led training, which translates into weeks of commitment creating a significant hurdle to adoption.

- Cumbersome setup and burdensome treatment frequency. The incumbent home dialysis machine is limited in its ability to sufficiently remove toxins, which as a result typically requires up to six treatments per week. The requirement of increased treatment frequency intensifies the burden placed on the patient, their care partner and clinical staff. In addition, the need for clean treated water requires significant time to batch and prepare dialysate before treatments. While not required prior to every treatment, this process can range from 16 to 24 hours per week and contributes to lower patient retention on the incumbent machine.

- Manual documentation and reporting. Patients are responsible for reporting the details of each treatment, including vital signs, treatment time and ultrafiltration volumes, to their provider manually given the incumbent machine does not offer integrated wireless connectivity capabilities, or through the purchase of additional hardware, which is not reimbursed. This lack of connectivity limits the ability to remotely assess and troubleshoot any issues with the device, which often results in the machine being sent back to the manufacturer and replaced with a new machine, potentially delaying patient treatment.

Our Solution

We have purposefully designed a dialysis solution to address the limitations and challenges faced by using traditional dialysis systems. In doing so, we sought to completely reinvent the traditional concept of dialysis delivery. We believe Tablo represents meaningful technological advancements in dialysis care, a market which has lacked significant innovation for decades.

Tablo vs. Traditional Hemodialysis Machines.

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 compact, mobile and versatile machine consisting of an integrated water purification, on-demand dialysate production system and simple-to-use touchscreen interface. Using advanced sensors, the console automates much of treatment setup and management and can automatically self-diagnose for potential machine issues.

- 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.

- 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.

Benefits of Tablo

We believe that Tablo's unique features combine to provide a meaningfully differentiated hemodialysis solution, offering the following benefits:

- Simplicity. Tablo's intuitive, simple and appealing touchscreen interface makes it easy to learn and easy to use, guiding users through treatment from start to finish with 3D animations illustrating each step. Embedded sensors simplify the setup and takedown process by providing validation of each step, reducing the chance of user error. During treatment, sensors automatically alert the user of any problems and provide instructions to resolving the issues on the screen. Our proprietary pre-strung cartridge clicks into place and features color-coded, easy-to-follow connections, allowing users to set up the treatment supplies in less than twelve minutes. Tablo's simplicity can also reduce the training time necessary to operate the machine by roughly two thirds compared to training for traditional machines.

- Clinical Flexibility. Tablo can accommodate a wide range of treatment modalities, durations and flow rates, allowing for broad clinical applications. In combination with its compact size and ease-of-use, Tablo's clinical flexibility enables providers to standardize to a single solution across multiple care settings.

- Operational Versatility. Tablo is an all-in-one device with integrated water purification and on-demand dialysate production, eliminating the need for industrial water treatment rooms required to operate traditional hemodialysis machines. Instead, Tablo only needs an electrical outlet and access to tap water. Tablo's independence from this infrastructure enables bedside dialysis in the acute setting, saving the time and expense of transporting patients elsewhere for dialysis. By eliminating the need for separate infrastructure, Tablo can practically and cost-efficiently provide patients with access to treatment in additional care settings that previously has not been feasible with traditional dialysis machines.

- Progressive Intelligence. Tablo's two-way wireless connectivity and data ecosystem connects providers and patients through a cloud-based integrated data platform which enables real-time treatment monitoring, centralizes and automates treatment documentation, thereby simplifying compliance and record-keeping requirements. It streamlines machine management while allowing for feature enhancements through remote software upgrades.

Tablo's clinically differentiated features were specifically designed to address the economic and operational challenges faced by stakeholders across multiple care settings. In addition, patients have reported clinical and quality of life benefits on Tablo compared to other dialysis machines.

In the acute care market, we believe Tablo offers the following benefits:

- Increasing hospital operating margins by lowering the total cost of dialysis-related supplies, infrastructure and labor by up to 80% in the ICU.

- Enabling hospitals to take dialysis back in-house which, including supplies cost reduction, reduces the total cost per treatment by $300 to $500.

- Standardizing to a single, easy-to-learn machine that can deliver multiple dialysis modalities and reduce the cost, complexity and training burden of managing multiple different machines.

- Allowing dialysis to be delivered anywhere across the hospital without the need for additional specialized equipment, infrastructure or specialized dialysis staff, easing operational workflow and enhancing productivity and staffing flexibility.

- Enabling less expensive labor models, for example the insourcing of dialysis service using existing hospital nursing staff and eliminating expensive, fixed dialysis outsourcing contracts.

- Automating data documentation and machine management to increase regulatory compliance.

In the home market, we believe Tablo offers the following benefits for clinics and their patients:

- Improving provider home dialysis economics, including reducing home program staffing costs by reducing total training time and providing a novel learning curriculum that is largely patient managed, resulting in increased patient adoption through a shorter, less burdensome training process.

- Offering flexible treatment frequency that can be aligned with payor reimbursement policies as medically appropriate, overcoming a key limitation to home adoption.

- Reducing the time and nursing resources needed to train new patients and improving remote management and monitoring of home patients, resulting in higher productivity.

- Enabling providers to cost efficiently build TCUs in previously inaccessible locations since specialized infrastructure, such as a water treatment facility, is no longer needed.

- Enabling remote machine maintenance, troubleshooting and software updating.

- Enabling longer retention and higher treatment compliance by giving patients the option of flexible treatment frequency and potentially fewer treatments, as well as less burdensome setup and management.

- Improving treatment experience with fewer headaches, increased energy, less cramping, and a quieter more relaxed experience contributing to improved quality of life.

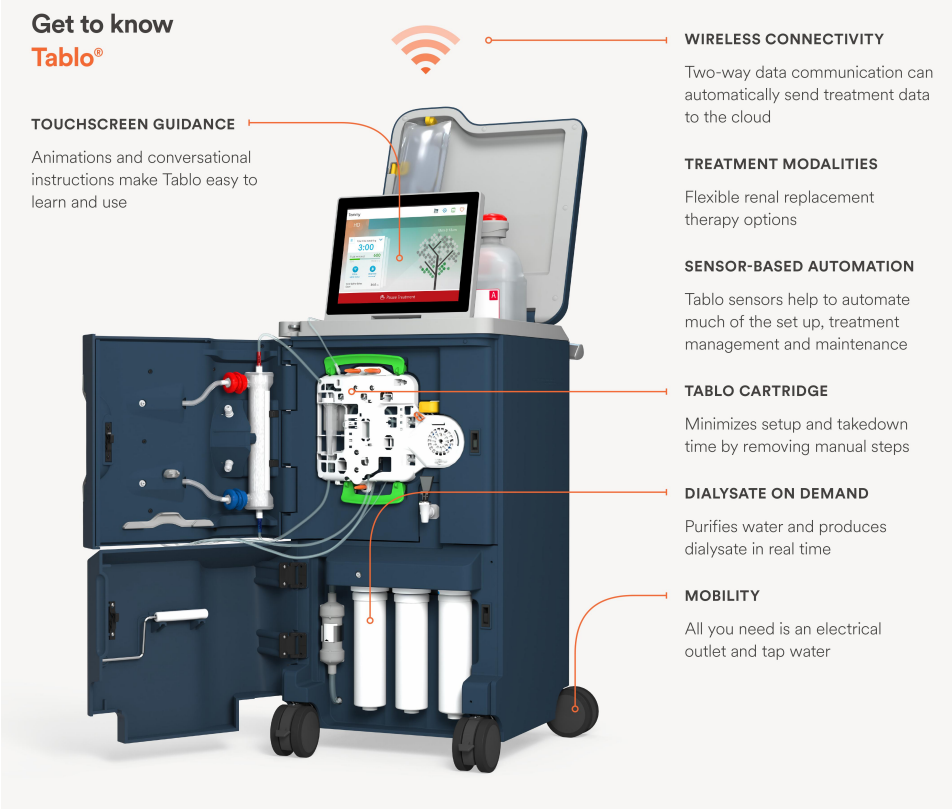
- Improving the accessibility and sustainability of home dialysis for patients. We believe Tablo's compact size, and its ability to operate with a standard electrical outlet, tap water, and less supplies storage, makes it an accessible option for patients regardless of the size of their living space.

Our Product

Tablo

Tablo is a mobile integrated hemodialysis solution for acute and home hemodialysis therapy. We designed Tablo from the inside out to offer a superior experience for patients and providers across multiple care settings. Tablo features an integrated water purification system, the ability to produce dialysate on demand, and an intuitive user interface and two-way wireless connectivity powered by an ecosystem of cloud-connected and intelligent software.

The Tablo Hemodialysis System.



Tablo is the only dialysis technology with a fully integrated water treatment system that allows for dialysate to be produced on demand in real time using bicarbonate and acid concentrates. 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.

The Tablo cartridge is a single use consumable intended to facilitate extracorporeal blood purification for patients. We engineered our unique, one-push cartridge design to reduce set up and take down time and avoid contamination by minimizing manual connections and user touchpoints. 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. Our proprietary cartridge clicks into place and features color-coded, easy-to-follow connections. 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’s simple setup and intuitive touchscreen interface combined with sensor-based automation are designed to enhance the user experience by accelerating the training process, expediting device set up, and streamlining the treatment process. For example, Tablo includes an integrated blood pressure monitor, and 70 embedded sensors, which enable features such as automated air removal, priming, and blood return which minimize user errors and save time. Tablo’s touchscreen panel guides the user through the treatment with 3D animations and conversational instructions, making Tablo easy to learn and use for both professional and non-professional users. The screen can be used to change or manage treatment parameters, add patient information, enter treatment notes as well as set reminders for future actions.

During treatment, should any issues arise, Tablo’s touchscreen panel guides the user through an explanation for the alarm and provides intuitive resolution instructions. Traditional machines provide no video guidance and generally require users to memorize or

reference numerical alarm codes from a separate user manual. Post-treatment, Tablo's touchscreen interface guides the user through treatment takedown.

The Tablo console is compact, self-contained, and mobile. We designed Tablo with the home in mind to look more like a consumer product than a piece of medical equipment in order to increase patient comfort with having it in their living room. The console can be closed completely when not in use, which lowers the intimidation threshold and makes it ideally suited to a home environment. Tablo's design allows the user to transport the unit easily throughout the hospital or home setting for storage. The console's 35-inch height was designed to make it easy for patients, especially those with limited mobility, to engage with the touchscreen during treatment to view progress, resolve alarms and adjust functions as needed. For example, a patient can interact with the touchscreen to adjust the flow rate if they feel the onset of cramping.

Tablo Data Ecosystem

Tablo is the first hemodialysis system on the market with FDA clearance for two-way wireless data transmission. Tablo's connectedness helps reduce maintenance costs and enables 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 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. Over the past two years, we have used these OTA updates to add important new features that extend Tablo's clinical applicability in addition to updates that enhance device uptime by enabling remote diagnostics and support. 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 confidently 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 two key platforms: TabloHub, a customer-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 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.

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.

Tablo Data Ecosystem

Value to Outset

- Reinforces customer loyalty through access to a functionally rich data ecosystem.
- Improves speed and cost efficiency of design and manufacturing.
- Increases efficiency through remote real-time system monitoring, diagnostics, and predictive analytics, lowering servicing costs.
- Accelerates delivery of new features and improvements to customers through continuous in-field data analytics.

Value to Our Providers

- Reduces cost and increases compliance by centralizing and automating documentation and all cloud based medical record reporting from treatment flowsheets to machine management.
- Increases uptime through machine-learning algorithms that feed continuous software improvements and predictive analytics.
- Increases flexibility and efficiency through remote monitoring of patient treatment data.
- Reduces administrative time and cost through EMR integration.

Clinical Outcomes and Studies

We have generated significant evidence to demonstrate that Tablo is safe and effective, clinically versatile and produces robust clinical outcomes, both in acute and non-acute settings. Tablo's evidence base also indicates that its patient centric design, focused on simplicity and ease of use, provides a favorable clinical experience for both patients and providers. We have invested in building a robust Tablo evidence base that captures both patient and provider experience with Tablo.

Research and Development

We invest in research and development efforts that advance our Tablo system with the goal to expand and improve upon our existing product and solutions. Our research and development expenses totaled $36.7 million and $28.9 million for the years ended December 31, 2021 and 2020, respectively.

Our research and development team includes hardware and software engineers with deep expertise in mechanical and electrical engineering, fluidics, embedded software design, and cloud-based data and security architecture. Their collective efforts are applied to three key areas: (1) engineering and cost reduction initiatives that continually enhance device performance and lower our cost of product revenue, (2) expansion of the Tablo data ecosystem to extend economic, operational and clinical benefits to our customers, and (3) advancing our innovation pipeline, which is directed toward broadening Tablo's value in the home, chronic, and acute environments for patients and providers. We intend to continue investing significant resources to maintain and strengthen our technological competitive advantage in order to deliver a steady stream of inventive solutions that provide clinical and operational simplicity, versatility and efficiency.

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 recently 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 and CVS. 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, our competitors are 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.

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 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, 2021, we had 19 issued U.S. patents, as well as nine pending U.S. patent applications, including 12 patents and patent applications previously exclusively licensed to us from Oregon State University (OSU), which OSU assigned to us upon termination of our license agreement with OSU. We had an aggregate of 40 issued patents in Australia, Canada, China, France, Germany, Hong Kong, Japan, Spain and the United Kingdom, as well as 18 pending patent applications in Japan, the European Patent Office and under the Patent Cooperation Treaty, including 22 patents previously exclusively licensed to us from OSU, which OSU assigned to us upon termination of our license agreement with OSU. 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 November 2041. 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

Until early 2021, we exclusively relied on our contract manufacturing partner, Paramit Corporation (Paramit), based in Morgan Hill, California, for the production of the Tablo console. Tablo consoles manufactured by Paramit at their facility in Morgan Hill, California underwent extensive in-process and integrated system testing protocols designed by us. Consoles were then transported to our headquarters in San Jose, California, where our test engineers performed final testing, and then direct-shipped the consoles to our customers. We used a network of short-haul and long-haul freight forwarders optimized for time and cost efficiency.

In order to help ensure a high level of console production capacity through rapid scale, and to help lower our costs, we established a console manufacturing facility in Tijuana, Mexico, enabling us to insource Tablo console manufacturing beginning in early 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 the same 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. We terminated our contract with Paramit.

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 feeding into Tablo console production is in excess of 250 worldwide. We consider approximately 9% of these suppliers, located in the United States, Europe and China, as critical providers of components such as pumps, motors, valves and PCBA boards. We are undertaking a second source qualification process for the majority of these critical components. Where second sourcing is unavailable or infeasible, 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 Infus Medical Co. Ltd. (Infus), a contract manufacturer with two facilities in Thailand. As part of our 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. The various components for the Tablo cartridge are manufactured by approximately 50 different suppliers located in various countries including Singapore, Italy and the United States, some of which are single-source suppliers. The Tablo cartridges 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.

We recently moved production of a majority of Tablo cartridges to a manufacturing site in Tijuana, Mexico in partnership with Providien Medical (Providien). Providien, part of Carlisle Companies Incorporated, offers expertise in high volume disposable assembly services. Through enhanced product design, high capacity tooling and simplified freight and logistics, we expect this site will be able to produce cartridges at a lower cost, increase our supply capacity and help mitigate against global supply chain interruption. Tablo cartridges produced at this new facility undergo sterilization using electronic beam (e-beam) technology, which is an environmentally friendly sterilization method. Following our receipt of 510(k) clearance from the FDA for the new cartridge sterilization method in November 2021, we began manufacturing and commercially distributing Tablo cartridges manufactured at this new facility.

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.

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 also requires, among other things, maintenance of a device master file, device history file, and complaint files. As a manufacturer, we are subject to periodic scheduled or unscheduled 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:

- untitled letters, 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;

- 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 a PMA that has already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

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.

While the Tablo Hemodialysis System is indicated for use in the home, the FDA notified us that the Tablo System is subject to a mandatory post-market surveillance order under Section 522 of FDCA. The FDA has required that we conduct a human factors study, as well as conduct a detailed analysis of adverse events and complaints from home users. In response to the 522 order, we submitted a simulated human factors test protocol to the agency which leveraged testing from our validation study that was initiated in 2019. In late 2020, the FDA requested additional information and notified us that we will need to conduct a new human factors study encompassing both summative and real-world data to meet the requirements of the 522 order. We responded to the FDA's requests for additional information in January 2021 and in March 2021, the FDA approved our 522 study protocol. We have made certain changes over time, including software updates, to the Tablo System, including to accommodate patient use in the home. Although we originally documented these changes in memoranda to file, we have submitted a "catch-up" 510(k) application to the FDA which covers these design changes. Once cleared, this 510(k) will be used as the baseline submission for future 510(k) applications for the Tablo System. Because this also is the version of the Tablo System and software that we plan to use in the human factors study, we intend to initiate the human factors study upon FDA clearance. Once we are able to commence, conduct and complete our study, a final report will be provided to the FDA. Should the FDA decide that 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 for which we may need to submit new marketing authorization applications and obtain clearance.

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.

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 have focused recent federal Anti-Kickback Statute enforcement efforts on, among other things, the sales and marketing activities of medical device manufacturers and other healthcare companies, and recently have brought cases against individuals or entities who allegedly offered 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.

Conduct and business arrangements that do not fully satisfy all elements of an applicable exception or safe harbor may result in increased scrutiny by government enforcement authorities such as the Department of Health and Human Services (HHS) Office of Inspector General (OIG). If scrutinized, arrangements that implicate the federal Anti- Kickback Statute that do not fall within an exception or safe harbor, are analyzed by the OIG and other enforcement authorities on a case-by-case basis with review based on the totality of the facts and circumstances to assess whether a given arrangement is prohibited by the federal Anti-Kickback Statute.

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) was enacted by Congress in 2010 as part of the Affordable Care Act and was amended in 2018 by the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. The Sunshine Act requires us to collect and report annually certain data on payments and other transfers of value we make to U.S.-licensed physicians, teaching hospitals, and, for reporting beginning January 1, 2022, U.S.-licensed physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants, and certified nurse-midwives. Accordingly, we are required to track certain payments and other transfers of value made to these additional covered recipients during the 2021 calendar year. 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 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 and 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 constantly strive to structure our business operations and relationships with our customers to comply with all applicable legal requirements. 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. Moreover, the standards of business conduct expected of healthcare companies under these laws and regulations have become more stringent in recent years, even in instances where there has been no change in statutory or regulatory language. 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 will take effect on January 1, 2023. The CPRA will 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. It 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 and Colorado, and have been proposed in other states and at the federal level that 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 any sensitive 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. As a result of the COVID-19 pandemic, 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 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, private insurers, and other third-party payors.

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, or 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 adoption 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 these 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 drugs. On October 29, 2021, CMS published the final rule for Calendar Year (CY) 2022, which increased the base reimbursement rate per dialysis treatment to $257.90, an increase of $4.77 over the CY 2021 base rate of $253.13. 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 potential customer's decision to use the Tablo and limits the fees for which we can sell or rent the 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, adoption 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. In CY 2021, Medicare Advantage plans overall saw a 31% increase in enrollment of ESRD patients, with the most significant increases coming from lower income patients who are dually eligible for Medicare and Medicaid.

The CY 2021 Medicare ESRD PPS final rule, among other things, encourages the development of new and innovative home dialysis machines that would give Medicare beneficiaries more dialysis treatment options in the home and improve their quality of life. Specifically, the final rule includes 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 to secure TPNIES (CRA). 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, that is, it helps cover Medicare Part B coinsurance and items and services not covered by Medicare Part B, but 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.

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 it varies 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 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 for care of these patients to be cost-effective. Similar to dialysis clinics that are reimbursed by Medicare 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 UF are not directly reimbursed, but rather are paid for out of the in-patient MS-DRG for a patient's 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 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. It is unclear 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 March 31, 2022 due to the COVID-19 pandemic. The law provides for 1% Medicare sequestration in the second quarter of 2022 and allows the full 2% sequestration thereafter until 2030. 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 increased 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 ESRD facilities' treatment base rates under the ESRD Prospective Payment System and managing clinicians' monthly Medicare capitation payments to incentivize greater use of home dialysis and kidney transplants. CMS is also preparing to implement the Kidney Care Choices Model, a voluntary Medicare payment model with four distinct payment options designed to help providers reduce costs and improve quality of care for patients with late-stage chronic kidney disease and ESRD, to delay the need for dialysis and to encourage kidney transplantation. The first performance year of the Kidney Care Choices Model began on January 1, 2022. Finally, the Chronic Kidney Disease Improvement in Research and Treatment Act was introduced in the U.S. Senate (S. 1971) on June 8, 2021 and in the U.S. House of Representatives (H.R. 4065) on June 23, 2021. The Jack Reynolds Memory Medigap Expansion Act (HR 1676) was introduced in the U.S. House of Representatives on March 9, 2021. If enacted, either bill would guarantee access to Medigap insurance policies to all ESRD Medicare beneficiaries regardless of age. The Chronic Kidney Disease Improvement in Research and Treatment Act would also, among other policy changes, allow patients with ESRD to retain private insurance as their primary payer for an additional 12 months, and require CMS to adjust the ESRD PPS bundled rate when the current rate would not cover the cost of adding a new drug, biologic, or other technology into the bundle after the transitional payment period ends. 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 following the November 2020 elections have resulted in and will likely continue to result in further healthcare policy changes. For example, on January 28, 2021, President Biden issued the "Executive Order on Strengthening Medicaid and the Affordable Care Act," which, among other things revoked certain executive orders of the previous administration, stated that it is the current administration's policy "to protect and strengthen Medicaid and the ACA and to make high-quality healthcare accessible and affordable for every American," and directed heads of relevant executive departments and agencies immediately to review agency actions to determine whether any such actions are inconsistent with this policy. Additionally, 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. Other actions by the Biden administration, the Congress, state governments, and third-party payors 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, 2021, we had 444 full-time employees, with 48% in our field sales and service teams and 52% in the rest of the company. Our workforce hails from across industries, including technology, medical devices, life sciences and retail management.

As of December 31, 2021, our manufacturing facility in Tijuana, Mexico had 149 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 October 2021, we published our inaugural Environmental, Social, and Governance (ESG) Report (ESG Report) which 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 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 believe that preparing our employees for growth and development is a key business activity and managers have two key performance conversations a year with their team members. Our year-end conversation, "Yearbook," is focused on evaluating the success and learnings of the past year. Our mid-year conversation, "Passport," is focused on skill development and future growth opportunities.

We have a formalized practice around performance development and have 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, development sessions led by external speakers, and access to on-demand learning resources.

We strongly believe in growing from within and have numerous avenues for in-role stretch assignments, cross-group short assignments, internal mobility, and promotions. In addition, we conduct employee surveys to monitor employee engagement and identify areas of focus for our human capital management. 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.

In mid-2020, we brought together an engaged group of employees to design our diversity, equity and inclusion strategy. We defined three key areas of focus: 1) raising awareness of racial disparities in kidney care, 2) impactful community outreach with students to advocate for careers in the medical device industry, and 3) providing internal education on bias. We continued to actively pursue these three areas of focus in 2021, and intend to do so moving forward.

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.

We determined early in the COVID-19 outbreak that supporting, educating and keeping our workforce safe was paramount. We moved quickly to connect with and help our employees so we could continue our business operations and provide ongoing support for our patient population. Since we qualified as an essential business, we continued to operate our facility in San Jose, California through the shelter-in-place orders, and immediately categorized our workforce based on the essentialness of working onsite. For roles that required employees to be physically onsite, such as our R&D and manufacturing technical staff, we implemented infection control procedures, social distancing protocols, increased sanitization standards, personal protective equipment, and daily temperature checks. When COVID-19 testing became available, we implemented onsite testing in our facilities. We also provided vaccination clinics at each of our facilities to make it convenient for our workforce to receive COVID-19 vaccinations once available. During the third quarter of 2021, we defined a policy requiring our customer-facing and on-site employees to be fully vaccinated by October 2021, subject to religious and medical exemptions. With nearly all our employees now vaccinated, we have begun to move toward more normal operations in accordance with local guidelines, including resuming more on-site activity to increase productive collaboration while continuing to prioritize employee safety. For employees working on-site, we continue to follow masking protocols consistent with evolving health and safety guidelines, facilitate social distancing and practice increased sanitizing standards.

Corporate Information

We were incorporated in the State of Delaware in 2003 under the name Home Dialysis Plus, Ltd. We changed our name to Outset Medical, Inc. in January 2015. Our principal executive offices are located at 3052 Orchard Dr., San Jose, California 95134, and our telephone number is (669) 231-8200.

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	51	President, Chief Executive Officer and Chair of the Board
Nabeel Ahmed	46	Chief Financial Officer
John L. Brottem	48	General Counsel and Secretary
Stacey Porter	47	Chief People Officer
Jean-Olivier Racine	40	Chief Technology Officer
Martín Vazquez	52	Chief Operating Officer
Steve Williamson	49	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 on 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 a limited number of customers
- Our ability to expand into the home hemodialysis market
- 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 ongoing COVID-19 pandemic
- The impact of the ongoing COVID-19 pandemic, natural or man-made disasters and similar events on our business
- Our ability to ensure strong product performance and reliability, offer high quality support, and ensure proper training and use of Tablo
- Our ability to continue innovating and improving Tablo
- Our ability to compete effectively
- 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 ability to manage our growth, including maintaining and growing our sales and marketing organization
- Our estimates of the sizes of the markets for Tablo
- Our ability to accurately forecast customer demand and manage our inventory
- Fluctuations in our operating results
- 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
- Our ability to obtain additional capital when needed
- Cost containment efforts of our customers, purchasing groups and government organizations

Risks Related to Government Regulation

- 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 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
- Impact of future issuances of securities
- 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 operating as a public company, and our ability to maintain effective internal control over financial reporting and disclosure controls and procedures
- 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 critical 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 $131.9 million, $121.5 million and $68.3 million for the years ended December 31, 2021, 2020, and 2019, respectively. As of December 31, 2021, we had $372.8 million in cash, cash equivalents, restricted cash and short-term investments, and an accumulated deficit of $626.0 million. Based on our current planned operations, we expect our existing cash, cash equivalents and short-term investments, and cash generated from revenues from our products and services, 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 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 as well as our status of being 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 cost of manufacturing and producing Tablo devices.

We partner with contract manufacturers in the production of the Tablo cartridge. Until early 2021, we exclusively relied on a contract manufacturer based in California for the production of the Tablo console, which resulted in higher costs associated with labor and component parts. As part of a number of initiatives designed to reduce the cost of producing Tablo devices, we established a new manufacturing facility for the production of Tablo consoles in Tijuana, Mexico which we operate in collaboration with our outsourced business administration service provider, TACNA, enabling us to insource Tablo console manufacturing at this new facility in early 2021. In addition, in the fourth quarter of 2021, we have qualified a second source to increase Tablo cartridge production through a new manufacturing partner in Mexico. Moving Tablo console production to Mexico has lowered our costs of manufacturing and producing consoles, and we anticipate that transitioning cartridge production to our new second source located in Mexico will help mitigate supply chain challenges and reduce the need for costly and capacity-constrained air freight delivery of the cartridges. However, there is no guarantee that we will be able to sustain cost reductions or achieve planned cost reductions from our various cost savings initiatives. For example, we may be unable to sustain the savings associated with our manufacturing facility with TACNA, or the savings we anticipate will result from our second source of Tablo cartridges in Mexico, may not 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 the components of Tablo, changes to labor costs, less favorable terms with third party suppliers or contract manufacturing partners, or disruptions to the operations of our contract manufacturers or third party suppliers including as a result of the ongoing COVID-19 pandemic. For example, during the fourth quarter of 2021, supply chain disruptions exacerbated by COVID-19 outbreaks and protocols escalated, and we have 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 Tablo’s 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 are less significant or less timely than projected or if we are unable to maintain Tablo’s 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.

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 cost of treatment, maintenance and upkeep using Tablo in relation to traditional machines;
- 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 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 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 Inc. (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.

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 feeding into Tablo console production is in excess of 250 worldwide. We consider approximately 9% of these suppliers, located in the United States, Europe and China, 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 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 ongoing 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 has 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 have worked closely with our manufacturing partners and suppliers to enable us to source key components and maintain appropriate inventory levels to meet customer demand, and have not experienced material disruptions in our supply chain to date. However, 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 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 the fourth quarter of 2021, these supply chain disruptions escalated, and we are facing 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 associated with delivering adequate supply of Tablo treatments to our customers. In the fourth quarter of 2021, we have qualified a second source to increase Tablo cartridge production through a new manufacturing partner in Mexico. While we anticipate that this second source will help mitigate supply chain challenges and reduce the need for costly and capacity-constrained air freight delivery of the cartridges, 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.

We may experience manufacturing disruptions, and our transition to manufacturing our Tablo consoles and the majority of Tablo cartridges outside of the United States subjects us to additional risks associated with international manufacturing operations.

We continue to rely on contract manufacturing partners 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 including the ongoing COVID-19 pandemic, riots, terrorism, vandalism, cyber security attacks, natural disaster or otherwise, it could cause substantial delays in our operations and we may not have a sufficient number of Tablo consoles or Tablo cartridges 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 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 established a new manufacturing facility in Tijuana, Mexico which we operate in collaboration with our outsourced business administration service provider, TACNA, for the production of the Tablo console. Under our arrangement with TACNA, we control the operations, engineering, quality and materials supply functions at the new facility, while TACNA provides manufacturing space, the workforce, utilities, cross-border logistics, local permits and licenses. With the establishment of our new manufacturing facility in Tijuana, Mexico and the transfer of the production of a majority of the Tablo cartridge to a new contract manufacturing partner in Tijuana, Mexico, the manufacturing of the Tablo console and a majority of the Tablo cartridge is currently located in Tijuana, Mexico. We are subject to a number of additional risks associated with operating our Mexico-based manufacturing facility and increased international manufacturing operations generally. 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 new facility may also suffer disruptions from global or regional public health crises such as the ongoing COVID-19 pandemic, natural disasters, cyber security attacks, vandalism, terrorism or other

political hostilities. Any such occurrences could negatively impact our ability to produce the Tablo console. 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, changes in export or import regulation and other trade barriers and uncertainties may disrupt our Mexico-based manufacturing operations, and may cause us to be unable to meet customers' demand and adversely impact our results of operations.

A pandemic, epidemic or outbreak of an infectious disease in the United States or worldwide, including the ongoing 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, the COVID-19 pandemic continues to persist and precautionary measures designed to contain the spread and mitigate the impact of COVID-19, such as travel restrictions, "shelter-in-place" orders, quarantines and business shutdowns, have impacted 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 such as the Delta and Omicron variants. 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 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. With nearly all our employees now vaccinated, we have begun to move toward more normal operations in accordance with local guidelines, including resuming more on-site activity to increase productive collaboration while continuing to prioritize employee safety. For employees working on-site, we continue to follow masking protocols consistent with evolving health and safety guidelines, facilitate social distancing and practice increased sanitizing standards. Notwithstanding recent trends that have allowed us to return to more on-site activity, we may experience future disruptions as a result of the ongoing COVID-19 pandemic that could adversely impact the health and availability our workforce, particularly in light of insufficient vaccination of the general population 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. In addition, to the extent dialysis providers, including outpatient dialysis clinics, reduce demand for our products due to COVID-related patient deaths, our business would be adversely impacted.

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 have been exacerbated by the 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 ongoing 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. If our customers continue to face prolonged volatility, uncertainty, and staffing shortages, whether due to the pandemic 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 revenues, results of operations, and future growth.

How long the pandemic, and measures intended to contain the spread of COVID-19, will continue remains uncertain and depends on ongoing developments, including but not limited to any resurgences of the virus including emerging variant strains, federal, state, and local government actions taken in response, and continued availability, effectiveness and public acceptance of

COVID-19 vaccines, as well as the extent and duration of the effect on the economy and how quickly and to what extent normal economic and operating conditions can resume. 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 recent 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.

While the potential economic impact brought by and the duration of any pandemic, epidemic or outbreak of an infectious disease, including COVID-19, may be difficult to assess or predict, the widespread COVID-19 pandemic has resulted in, and may continue to 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. In addition, a recession or market correction resulting from the spread of an infectious disease, including COVID-19, could materially affect our business. Such economic recession could 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.

We need to ensure strong product performance and reliability to maintain and grow our business.

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, 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, Baxter and 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 and CVS. 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.

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; and
- increase adoption of Tablo in the chronic outpatient facility setting via transitional care programs within existing dialysis clinics.

In addition, competitors with greater financial resources than ours could acquire other companies to gain enhanced name recognition and market share, as well as new technologies or products that could effectively compete with our existing products, which may cause our revenue to decline and would harm our business.

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, 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, mailing address, email addresses, mobile telephone number, location information, 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, as a result of the COVID-19 pandemic, we may face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who may continue to 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, 2021, we had 444 full-time employees. Over the next several years, we expect to increase significantly the scope of our operations, particularly in the areas of manufacturing and commercial functions, including sales and marketing, as well as in 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 further increases in the number of patients who adopt home hemodialysis from 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 expanding the home hemodialysis market, but these efforts ultimately may not be successful.

We have significant customer concentration, with a limited number of customers accounting for a substantial portion of our revenues.

For the year ended December 31, 2021, two customers accounted for 30% and 15% of revenues, respectively. 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 ongoing 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.

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 is 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.

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 ongoing

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;
- 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 ongoing 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 the Sarbanes-Oxley Act;
- future accounting pronouncements or changes in our accounting policies; and
- general economic conditions or political instability, including changes in tariff or trade laws and policies.

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.

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. 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.

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, during the fourth quarter of 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 have become 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. 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. 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, 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. 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, 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 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 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.

While we currently do not market or sell Tablo outside of the United States, 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. 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;
- 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, 2021, we had U.S. federal and state net operating loss (NOL) carryforwards of $409.0 million and $213.7 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 2022. 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, 2021, we also had U.S. federal and state research and development credits of $6.6 million and $5.1 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.

The terms of our credit agreement require us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

We entered into a senior secured term loan facility with Silicon Valley Bank (SVB) in July 2020 (the SVB Loan and Security Agreement) which provides for a $30.0 million term loan (the SVB Term Loan). The loan is 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 capital stock of foreign subsidiaries), subject to certain exceptions (including an exception regarding intellectual property). The SVB Loan and Security Agreement contains 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. See the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Debt Obligations.”

The SVB Loan and Security Agreement contains customary representations and warranties and affirmative covenants and also contains 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 SVB Loan and Security Agreement does not include any financial covenants but does require us to maintain cash collateral in a deposit account at SVB in an amount equal to or greater than the outstanding principal balance of the SVB Term Loan. The SVB Loan and Security Agreement also contains customary events of default. If we fail to comply with such covenants, payments or other terms of the SVB Loan and Security Agreement, our lender 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 lender would have the right to proceed against the assets we provided as collateral pursuant to the SVB Loan and Security Agreement. If the debt under SVB Loan and Security 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.

Risks Related to Governmental Regulation

We are subject to a post-market surveillance order issued by the FDA for our Tablo System. If the FDA determines that our Tablo System does not perform as anticipated in the home use setting, or if the FDA identifies new concerns related to the safety and effectiveness of the device, we may need to make changes to or recall or withdraw the Tablo System from the field, which could harm our business.

The FDA has notified us that the Tablo System is subject to a mandatory post-market surveillance order under Section 522 of the FDCA. Section 522 of the FDCA authorizes the FDA to require a manufacturer to conduct post-market surveillance for devices that meet certain criteria. Relevant here, the FDA determined that the Tablo is a device where its failure would be reasonably likely to have serious adverse health consequences, and that it is intended to be a life-sustaining or life-supporting device used outside a device user facility.

The FDA issued this 522 order to address (i) whether there are use-related safety concerns when the Tablo System is used by the new user population in the home environment unsupervised by a trained healthcare professional; (ii) whether the safety profile in this new user population and home environment requires us to provide changes to the device design, labeling, and/or training and, if so, what labeling and training are necessary to support user understanding and adherence to minimize use-related safety concerns, adverse events, or complaints when the Tablo System is used at home; and (iii) what adverse events and complaints are observed when the Tablo System is used at home unsupervised by a trained healthcare professional.

To address these issues, the FDA has required that we conduct a human factors study, as well as conduct a detailed analysis of adverse events and complaints from home users. With respect to the post-market surveillance issues, the FDA has ordered collection of prospective data on use in the home environment to assess adverse events and human factors.

In March 2021, the FDA approved our 522 study protocol. We subsequently submitted a "catch-up" 510(k) application to the FDA which covers certain design changes, including software updates, we have made over time to the Tablo System, including to accommodate patient use in the home, that we originally documented in memoranda to file. Because this also is the version of the Tablo System and software that we plan to use in the human factors study, we intend to initiate the human factors study upon FDA clearance. Once we are able to commence, conduct and complete our study, a final report will be provided to the FDA. Should the FDA decide that use of the Tablo System in the home environment identifies new concerns related to the safety and effectiveness of the product, does not clear our pending 510(k), or if the FDA determines that the requirements of the 522 order are otherwise unmet, we may be required to make additional changes to our Tablo System for which we may need to submit new marketing authorization applications and obtain clearance, we may be required to conduct additional studies or collect additional information, we may need to withdraw or recall the Tablo System from the market, and may be subject to other enforcement action, which could harm our business.

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 commercial 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 coverage, virtually all payments for renal dialysis services are currently made under a single bundled payment rate which provides a fixed payment rate to encompass virtually all goods and services provided during the dialysis treatment. The bundled payment rate is also adjusted for certain patient characteristics, a geographic wage index, and other factors. The ESRD PPS is subject to rebasing, which can have a positive financial effect, or a negative one if the government fails to rebase in a manner that adequately addresses the costs borne by dialysis facilities.

Additionally, 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. 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. In CY 2021, Medicare Advantage plans overall saw a 31% increase in enrollment of ESRD patients, with the most significant increases coming from lower income patients who are dually eligible for Medicare and Medicaid.

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.

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 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.

Any reduction in reimbursement rates for dialysis treatments may adversely affect our customers' businesses and cause them to enact cost reduction measures that may include 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. 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 significantly impacts 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 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 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.

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. Additionally, as discussed in the section titled "Government Regulation – United States Health Reform" above, changes to federal and state legislatures and executive offices following the November 2020 elections have resulted, and could continue to result, in further healthcare policy changes. 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.

The FDA classifies medical devices into one of three classes on the basis of the intended use of the device, the risk associated with the use of the device for that indication, as determined by the FDA, and on the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness.

Before a new medical device, or a new intended use of, claim for, or significant modification to an existing device, can be marketed in the United States, a company must first submit an application for and receive either 510(k) clearance pursuant to a premarket notification submitted under Section 510(k) of the FDCA, de-novo classification, or PMA approval from the FDA, unless an exemption applies. The 510(k), de-novo or PMA processes can be expensive, lengthy and unpredictable. The FDA’s 510(k) clearance process usually takes from three to 12 months but can last longer. The process of obtaining a PMA approval is much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is filed with the FDA. In addition, a PMA approval generally requires the performance of one or more clinical trials. Despite the time, effort and cost, a device may not be approved or cleared by the FDA. Any delay or failure to obtain necessary regulatory clearances or approvals could harm our business. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the device, which may limit the market for the device.

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.

Modifications to our marketed products may require new 510(k) clearances or approval of PMA supplements, or may require us to cease marketing or recall the modified products until clearances or approvals are obtained.

Modifications to Tablo and associated consumables may require new regulatory approvals or clearances, including 510(k) clearances or approval of PMA supplements, or require us to recall or cease marketing the modified systems until these clearances or approvals are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine that a modification could not significantly affect safety or efficacy and does not represent a major change in its intended use, so that no new 510(k) clearance is necessary. However, the FDA can review a manufacturer's decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval is required. We have made modifications to Tablo in the past and may make additional modifications in the future that, except for the changes for which we have previously submitted 510(k) clearances, we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing Tablo as modified, which could require us to redesign Tablo and/or seek new marketing authorizations and harm our operating results. In these circumstances, we may also be subject to significant enforcement actions.

If a manufacturer determines that a modification to an FDA-cleared device could significantly affect its safety or effectiveness or would constitute a major change in its intended use, then the manufacturer must file for a new 510(k) clearance or possibly a new PMA or approval of a PMA supplement. Where we determine that modifications to Tablo require a new 510(k) clearance or PMA approval, we may not be able to obtain those additional clearances or approvals for the modifications or additional indications in a timely manner, or at all. Obtaining clearances and approvals can be a time-consuming process, and delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. For example, we have made certain changes over time, including software updates, to Tablo that we originally documented in memoranda to file, and recently submitted a "catch-up" 510(k) application to the FDA which covers these design changes for patient use in the home. However, if the FDA fails to clear this pending 510(k) application, we may be required to stop marketing and selling Tablo as modified in the home market, which could have a material adverse effect on our reputation, business, financial condition and results of operations.

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. Regulatory bodies, such as the FDA, enforce the QSR and other regulations through periodic 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:

- untitled letters, 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;
- operating restrictions;
- withdrawal of 510(k) clearances on PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

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 has issued to us a post-market surveillance order under Section 522 of the FDCA which requires that we conduct a human factors study, as well as conduct a detailed analysis of adverse events and complaints from home users. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

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

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

The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. 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.

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.

Our products must be manufactured in accordance with federal and state regulations, and we could be forced to recall our devices or terminate production if we fail to comply with these regulations.

The methods used in, and the facilities used for, the manufacture of our products must comply with the FDA's QSR, which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing and shipping of medical devices. Furthermore, we are required to verify that our suppliers maintain facilities, procedures and operations that comply with our quality standards and applicable regulatory requirements. The FDA enforces the QSR through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors. Our products are also subject to similar state regulations and various laws and regulations of foreign countries governing manufacturing.

Our third-party manufacturers may not take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our products. In addition, failure to comply with applicable FDA requirements or later discovery of previously unknown problems with our products or manufacturing processes could result in, among other things: warning letters or untitled letters; fines, injunctions or civil penalties; suspension or withdrawal of approvals; seizures or recalls of our products; total or partial suspension of production or distribution; administrative or judicially imposed sanctions; the FDA's refusal to grant pending or future clearances or approvals for our products; clinical holds; refusal to permit the import or export of our products; and criminal prosecution of us, our suppliers, or our employees.

Any of these actions could significantly and negatively affect supply of our products. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers and experience reduced sales and increased costs.

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. We may initiate voluntary recalls involving Tablo in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. Product recalls may divert management attention and financial resources, expose us to product liability or other claims, harm our reputation with customers and adversely impact our business, financial condition and results of operations.

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 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. For example, the change in administration may impact our business and industry. Namely, the Trump administration took several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict whether or how these executive actions will be implemented, or whether they will be rescinded or replaced under the current Biden administration. The policies and priorities of a new administration are unknown and could materially impact the regulation governing our products.

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, or 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 ongoing 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, in recent years, including for 35 days beginning on December 22, 2018, the U.S. government shut down several times and certain regulatory agencies, including the FDA, had to furlough critical employees and stop critical activities. Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities. On March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials. In May 2020, the FDA announced that it will continue to postpone domestic and foreign routine surveillance inspections due to COVID-19. Beginning in July 2020, the agency has resumed some prioritized domestic inspections deemed to be "mission-critical." The FDA has published guidance, most recently updated in May 2021, outlining how it determines which inspections are "mission-critical." While the FDA indicated that it will consider alternative methods for inspections and could exercise discretion on a case-by-case basis to approve products based on a desk review, if a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. In addition, 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 and Colorado, have passed data protection laws, or are considering passing legislation, similar to CCPA. These laws would 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 will 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. It 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 will go 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 commission, 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 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 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 SVB Loan and Security Agreement restrict our ability to pay dividends to limited circumstances. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments.

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

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

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

As of December 31, 2021, our executive officers, directors and 5% stockholders beneficially owned approximately 52% of the outstanding shares of capital stock. In addition, as of December 31, 2021, our executive officers and directors held options to purchase an aggregate of 2,303,391 shares of our common stock at a weighted-average exercise price of $9.81 per share, and 257,820 restricted stock units, which would give our officers and directors ownership of approximately 5% of our outstanding common stock as of December 31, 2021 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, resulting in reductions in available credit and government spending, economic downturn or stagnation, foreign currency fluctuations and volatility in the valuations of securities generally. 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.

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, 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 may limit our ability to hire and retain highly qualified personnel on acceptable terms, or at all. 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.

Operating as a public company requires us to incur substantial costs and requires substantial management attention.

We have incurred and will continue to incur substantial legal, accounting and other expenses as a result of operating as a public company. For example, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the Exchange Act), the applicable requirements of the Sarbanes-Oxley Act and the Dodd-Frank Wall Street Reform and Consumer Protection Act and the rules and regulations of the SEC. Our management and other personnel have needed to divert attention from other business matters to devote substantial time to the reporting and other requirements of being a public company. Until December 31, 2021, we were eligible for reduced reporting and disclosure requirements as an "emerging growth company." We are no longer an "emerging growth company" and, accordingly, we are required to comply with several supplemental requirements that will necessitate additional resources and management time and expense. The rules and regulations of the Nasdaq Global Select Market also apply to us. 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. Compliance with these requirements has and will continue to increase our legal and financial compliance costs and will continue to make some activities more time-consuming.

Additionally, being a public company and complying with applicable rules and regulations also makes 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 recently became 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 anticipate hiring additional accounting and financial staff with appropriate public company experience and technical accounting knowledge 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 July 2020, we entered into the SVB Loan and Security Agreement which

also restricts our ability to pursue certain mergers, acquisitions, amalgamations 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 critical 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 concerning corporate responsibility, specifically related to ESG factors. 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.

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. 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 complimentary manufacturing and 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, 2022, there were 131 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

Dividend Policy

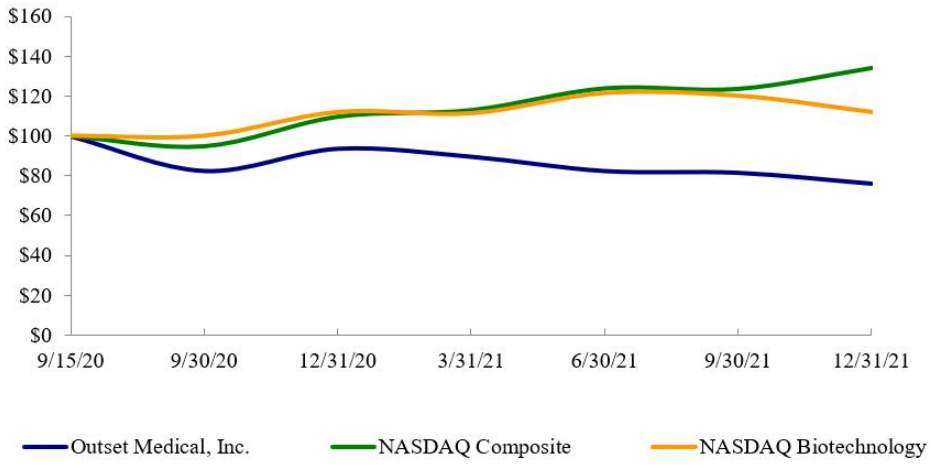
We have never declared or paid, and do not anticipate declaring or paying in the foreseeable future, any cash dividends on our capital stock. Any future determination as to the declaration and payment of dividends, if any, will be at the discretion of our board of directors, subject to applicable laws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

Stock Performance Graph

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

The following graph compares the cumulative total return on our common stock relative to the cumulative total returns of the NASDAQ Composite Index and the NASDAQ Biotechnology Index for the period from September 15, 2020 (the first day of trading of our common stock) through December 31, 2021. An investment of $100 is assumed to have been made in our common stock and each index at market close on September 15, 2020 and its relative performance is tracked through December 31, 2021. 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 16 MONTH CUMULATIVE TOTAL RETURN
Among Outset Medical, Inc., the NASDAQ Composite Index
and the NASDAQ Biotechnology 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, 2020, filed with the SEC on March 22, 2021, for reference to discussion of the year ended December 31, 2019, 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 new 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 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 OTA 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 intensive care unit. In addition, Tablo has been shown to deliver robust clinical care. In studies we have conducted, patients have reported experiencing fewer symptoms and better quality sleep while on Tablo. We believe Tablo empowers patients, who have traditionally been passive recipients of care, to regain agency and ownership of their treatment. Tablo is cleared by the FDA for use in the hospital, clinic, or home setting.

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 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. While the ongoing COVID-19 pandemic has presented opportunities to demonstrate the real-world benefits of Tablo over traditional machines, we believe these benefits, in addition to the other advantages of Tablo, are continuing to drive customer purchasing decisions.

Tablo is also well suited for home-based dialysis. 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 are focused on refining our home distribution, logistics and support systems to help ensure they are ready for rapid 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. As of December 31, 2021, our sales organization is comprised of 36 capital sales team members, responsible for generating new customer demand for Tablo, and 82 clinical sales team members, responsible for driving utilization and fleet expansion of Tablo consoles at existing customer sites. In addition, our field service team, comprised of 93 members, provides maintenance services and

product support to Tablo customers. 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 per-treatment consumables, including the Tablo cartridge, which generates significant total revenue over the life of the console. We generate additional revenue via annual service contracts and shipping and handling charged to customers. For the years ended December 31, 2021, 2020 and 2019, sales of our consoles accounted for 63%, 66% and 81% of our revenue, respectively, sales of our consumables accounted for 19%, 13% and 10% of our revenue, respectively, and sales of services and other accounted for 18%, 21% and 9% 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. On September 17, 2020, we completed our IPO, in which we sold 10,293,777 shares of common stock (which included 1,342,666 shares that were offered and sold pursuant to the full exercise of the IPO underwriters' option to purchase additional shares in connection with the IPO) at a price to the public of $27.00 per share. Including the full exercise of the underwriters' option to purchase additional shares, we received aggregate net proceeds of approximately $254.8 million after deducting offering costs, underwriting discounts and commissions of approximately $23.1 million. Upon the closing of the IPO, all of our outstanding redeemable convertible preferred stock automatically converted into shares of common stock.

On April 13, 2021, we completed a follow-on public offering and sold 2,945,864 shares of our common stock (which included 445,864 shares that were offered and sold pursuant to the full exercise of the underwriters' option to purchase additional shares) at a price to the public of $53.50 per share. We received aggregate net proceeds of approximately $149.1 million after deducting offering costs, underwriting discounts and commissions of $8.5 million.

Since our inception, we have incurred net losses in each year. For the years ended December 31, 2021, 2020 and 2019, we incurred net losses of $131.9 million, $121.5 million and $68.3 million, respectively. As of December 31, 2021, we had an accumulated deficit of $626.0 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, and sub-acute LTACH and SNF providers. In addition, we focus on driving utilization and fleet expansion with existing customers by providing an exceptional user experience delivered through our commercial team and a steady release of software enhancements that amplify Tablo's operational reliability and clinical versatility. Our ability to successfully execute on this strategy, and thereby increase our revenue, will in part drive our results of operations and the growth of our business.

Expansion of Tablo within the Home Setting

We believe 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.

Gross Margin

We are continuing to execute a well-defined strategy designed to expand gross margins. First, in the first quarter of 2021, we successfully began production at our own console manufacturing facility in Tijuana, Mexico which we operate in collaboration with our outsourced business administration service provider, TACNA. Second, following our receipt of 510(k) clearance from the FDA

for the new cartridge sterilization method in the fourth quarter of 2021, we have qualified a second source to increase Tablo cartridge production through a new manufacturing partner in Mexico, which we anticipate will result in cost reductions, including lower freight costs. Third, we will continue to drive scale across our console platform to leverage our supply base and help improve our manufacturing efficiency. 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

We believe that the ongoing COVID-19 pandemic has highlighted the limitations of traditional machines and the benefits of Tablo, which drove an increase in demand for Tablo during 2020. We also believe the advantages of Tablo highlighted by the pandemic are now embedded as one of the many factors driving our customers' purchasing decisions. We did not experience significant demand driven by COVID-19 during 2021 and do not expect to in future periods.

In response to the COVID-19 pandemic, we made modifications to our normal operations, employing precautionary measures designed to help protect our employees while providing ongoing support for our customers and their patients. Among other measures, we restricted non-essential travel of our employees and asked the majority of our employees to work from home. When COVID-19 testing became available, we implemented onsite testing in our facilities. We also provided vaccination clinics at each of our facilities to make it convenient for our workforce to receive COVID-19 vaccinations once available. During the third quarter of 2021, we defined a policy requiring our customer-facing and on-site employees to be fully vaccinated by October 2021, subject to medical and religious exemptions. With nearly all our employees now vaccinated, we have begun to move toward more normal business operations in accordance with local guidelines, including resuming more on-site activity to increase productive collaboration while continuing to prioritize employee safety. For employees working on-site, we continue to follow masking protocols consistent with evolving health and safety guidelines, facilitate social distancing, and practice increased sanitizing standards. Lastly, we have created a business continuity plan and incident management team to respond quickly and effectively to changes in order to offer customers uninterrupted products, services and support while safeguarding the best interest of employees, suppliers and stockholders.

Our business may be impacted by an escalation or a continuation of the COVID-19 pandemic. 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 pandemic, the possibility that such disruption may occur remains. Additionally, the COVID-19 pandemic has 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 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 the fourth quarter of 2021, these supply chain disruptions escalated, and we are facing 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 associated with delivering adequate supply of Tablo treatments to our customers. In the fourth quarter of 2021, we have qualified a second source to increase Tablo cartridge production through a new manufacturing partner in Mexico. While we anticipate that this second source will help mitigate supply chain challenges and reduce the need for costly and capacity-constrained air freight delivery of the cartridges, 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 operations.

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 have been exacerbated by the COVID-19 pandemic. As competition for these healthcare professionals has intensified, and 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 ongoing pandemic. 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 also 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 delay continued investment in or adoption of new technologies and postpone purchasing decisions. If our customers continue to face prolonged volatility, uncertainty, and staffing shortages, whether due to the pandemic 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 revenues, results of operations, and future growth.

How long the pandemic, and measures intended to contain the spread of COVID-19, will continue remains uncertain and depends on ongoing developments, including but not limited to any resurgences of the virus including emerging variant strains such as the Delta and Omicron variants, federal, state, and local government actions taken in response, and continued availability, effectiveness and public acceptance of COVID-19 vaccines. 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 recent 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 results of operations, on our customers, or on our suppliers and vendors, in particular for any of our suppliers and vendors that may not qualify as essential businesses and suffer more significant or lengthier disruptions to their business operations. 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.

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

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 allocated costs including facilities and information technology. We plan to grow our manufacturing workforce as well as expand our manufacturing capabilities to support our growth. In addition, cost of product revenue includes warranty costs and provisions for excess and obsolete inventory. Cost of product revenue in absolute dollars will increase as our sales volume increases.

Cost of Service and Other Revenue

Cost of service and other revenue primarily consists of personnel and related costs and component costs incurred in connection with our obligations under our service agreements. We plan to invest in personnel to support the expansion of our Tablo fleet while also utilizing our cloud-based data system, as well as enhanced product performance, to lower the cost of service as a percentage of revenue. Cost of service and other revenue in absolute dollars will increase as our sales volume increases.

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 Tablo 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 margin to increase over the long term to the extent we are successful in our ability to lower the costs associated with the production of the Tablo console and consumables. 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, consulting services, laboratory supplies and materials expenses, and allocated costs including facilities 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, marketing and promotional activities, government affairs, costs of outside consultants, travel and customer services costs, and allocated costs including facilities 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, regulatory fees, general corporate expenses and allocated costs including facilities 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 allocated facilities 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 due primarily to potential increases in the value of our common stock and 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, which included early prepayment and exit fees.

Provision for Income Taxes

Provision for income taxes primarily consists of foreign taxes in Mexico and state taxes in the United States. 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, 2021 compared to the year ended December 31, 2020.

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

	Years Ended December 31,		
	2021	2020	2019
Revenue:			
Product revenue	$ 84,312	$ 39,612	$ 13,750
Service and other revenue	18,290	10,323	1,328
Total revenue	102,602	49,935	15,078
Cost of revenue:			
Cost of product revenue	84,639	57,035	27,164
Cost of service and other revenue	10,355	5,937	5,716
Total cost of revenue	94,994	62,972	32,880
Gross profit	7,608	(13,037)	(17,802)
Operating expenses:			
Research and development	36,741	28,850	23,327
Sales and marketing	65,070	45,068	20,259
General and administrative	36,316	30,512	8,919
Total operating expenses	138,127	104,430	52,505
Loss from operations	(130,519)	(117,467)	(70,307)
Interest income and other income, net	498	526	2,485
Interest expense	(1,715)	(2,891)	(4,257)
Change in fair value of redeemable convertible preferred stock warrant liability	—	(93)	3,800
Loss on extinguishment of term loan	—	(1,567)	—
Loss before provision for income taxes	(131,736)	(121,492)	(68,279)
Provision for income taxes	199	—	20
Net loss	$ (131,935)	$ (121,492)	$ (68,299)

Revenue

	Years Ended December 31,		Change	
(dollars in thousands)	2021	2020	$	%
Revenue:				
Product revenue	$ 84,312	$ 39,612	$ 44,700	113%
Service and other revenue	18,290	10,323	7,967	77%
Total revenue	$ 102,602	$ 49,935	52,667	105%

Product revenue increased by $44.7 million, or 113%, for the year ended December 31, 2021 as compared to the prior year. The increase was primarily due to a $32.3 million increase in console revenue and a $12.4 million increase in consumables revenue. The increase in consoles revenue was driven by new customer adoption, fleet expansion across existing customer sites, a higher average selling price, and an increase in console leasing revenue. The increase in consumables revenue was driven by the growth in our Tablo installed base.

Service and other revenue increased by $8.0 million, or 77%, for the year ended December 31, 2021 as compared to the prior year. The increase was primarily due to services associated with our larger Tablo installed base, including leased consoles.

Cost of Revenue, Gross Profit and Gross Margin

(dollars in thousands)	Years Ended December 31, 2021	2020	Change $	Change %
Cost of revenue:				
Cost of product revenue	$ 84,639	$ 57,035	$ 27,604	48%
Cost of service and other revenue	10,355	5,937	4,418	74%
Total cost of revenue	$ 94,994	$ 62,972	32,022	51%
Gross profit	7,608	(13,037)	20,645	158%
Gross margin	*7.4* %	*(26.1)* %		

The total cost of revenue increased by $32.0 million, or 51%, for the year ended December 31, 2021 as compared to the prior year. This increase was primarily due to growth in sales volume. Gross profit increased by $20.6 million, or 158%, for the year ended December 31, 2021 as compared to the prior year. The gross margin percentage improved by 33.5 percentage points for the year ended December 31, 2021 as compared to the prior year. This improvement in gross profit and gross margin was primarily driven by the impact of our cost reduction activities and higher average selling prices.

During the fourth quarter of 2021, supply chain disruptions driven primarily by the ongoing COVID-19 pandemic escalated, and we are facing increased supply chain constraints, most notably with the transportation of the 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 associated with delivering adequate supply of Tablo treatments to our customers. In the fourth quarter of 2021, we have qualified a second source to increase Tablo cartridge production through a new manufacturing partner in Mexico. While we anticipate that this second source will help mitigate supply chain challenges and reduce the need for costly and capacity-constrained air freight delivery of the cartridges, 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 gross margin in future periods.

Operating Expenses

(dollars in thousands)	Years Ended December 31, 2021	2020	Change $	Change %
Operating expenses:				
Research and development	$ 36,741	$ 28,850	$ 7,891	27%
Sales and marketing	65,070	45,068	20,002	44%
General and administrative	36,316	30,512	5,804	19%
Total operating expenses	$ 138,127	$ 104,430	33,697	32%

Research and development expenses increased by $7.9 million, or 27%, for the year ended December 31, 2021 as compared to the prior year. The increase was primarily due to a $4.5 million increase in consulting services, a $3.4 million net increase in compensation and personnel costs as a result of increased headcount, which includes a $4.2 million increase in compensation offset by a $0.8 million decrease in stock-based compensation expense due to the one-time cumulative expense related to stock options with performance and market-based vesting conditions in 2020, and a $0.4 million increase in travel expenses. The increases were partially offset by a $0.4 million decrease in supplies and materials.

Sales and marketing expenses increased by $20.0 million, or 44% for the year ended December 31, 2021 as compared to the prior year. The increase was primarily due to a $13.3 million increase in compensation and personnel costs as a result of increased headcount, which includes a $1.5 million increase in stock-based compensation expense, a $2.2 million increase in clinical sales consultant and professional services, a $2.1 million increase in allocated costs for facilities and information technology to support the general expansion of our operations, a $1.7 million increase in travel expenses, and a $0.7 million increase in distribution expenses related to increased sales volume and freight costs.

General and administrative expenses increased by $5.8 million, or 19%, for the year ended December 31, 2021 as compared to the prior year. The increase was primarily due to a $2.5 million increase in insurance costs, a $1.7 million net increase in compensation and personnel costs as a result of increased headcount, which includes a $6.4 million increase in compensation offset by a $4.7 million decrease in stock-based compensation expense due to the one-time cumulative expense related to stock options with performance and market-based vesting conditions in 2020, a $0.7 million increase in professional and consulting services and a $0.8 million increase in allocated costs for facilities and information technology to support the general expansion of our operations.

Other Income (Expenses), Net

(dollars in thousands)	Years Ended December 31, 2021	2020	Change $	Change %
Other Income (Expenses), Net:				
Interest income and other income, net	$ 498	$ 526	$ (28)	(5)%
Interest expense	(1,715)	(2,891)	1,176	(41)%
Change in fair value of redeemable convertible preferred stock warrant liability	—	(93)	93	*
Loss on extinguishment of term loan	—	(1,567)	1,567	*
Total other expenses, net	$ (1,217)	$ (4,025)	2,808	(70)%

** Not meaningful*

Interest income and other income, net, for the year ended December 31, 2021 was relatively consistent with the prior year amount.

Interest expense decreased by $1.2 million, or 41%, for the year ended December 31, 2021 as compared to the prior year. The decrease was driven primarily by a lower interest rate under the SVB Term Loan as compared to the rate under the Perceptive Term Loan, which we voluntarily repaid in the prior year.

The change in the fair value of redeemable convertible preferred stock warrant liability was driven by the changes in assumptions used to value the warrant liability. Upon the closing of our IPO in the third quarter of 2020, all shares of our outstanding redeemable convertible preferred stock warrants were either exercised into common stock or automatically converted into warrants to purchase common stock. Accordingly, we have ceased to incur the change in fair value of redeemable convertible preferred stock warrant liability as the entire redeemable convertible preferred stock warrant liability was reclassified to additional paid-in capital.

The loss on extinguishment of term loan of $1.6 million was recognized for the repayment of the Perceptive Term Loan in the prior year, which included early prepayment and exit fees.

Liquidity and Capital Resources

Sources of Liquidity

As of December 31, 2021, the Company had cash, cash equivalents, and short-term investments of $339.5 million, which are available to fund future operations, and restricted cash of $33.3 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. In September 2020, we completed our IPO for aggregate net proceeds of approximately $254.8 million (inclusive of the full exercise of the underwriters' option to purchase additional shares), net of offering costs, underwriter discounts and commissions of approximately $23.1 million. In April 2021, we completed a follow-on public offering for aggregate net proceeds of approximately $149.1 million, after deducting offering costs, underwriting discounts and commissions of $8.5 million.

We expect to continue to incur significant expenses for the foreseeable future and to incur operating losses in the near term while we make investments to support our anticipated growth. We may raise additional capital through the issuance of additional equity financing, debt financings, including through refinancing our existing debt, or other sources. If this financing is not available to us at adequate levels or on acceptable terms, we may need to reevaluate our operating plans. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights. If we raise additional capital through debt financing, 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. We believe that our existing cash, cash equivalents and short-term investments, and cash generated from sales of our products and services, will be sufficient to meet our anticipated needs for at least the next 12 months from the 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,		
	2021	2020	2019
Net cash (used in) provided by:			
Operating activities	$ (130,264)	$ (99,015)	$ (70,292)
Investing activities	(142,507)	3,947	74,297
Financing activities	160,147	385,682	249
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (112,624)	$ 290,614	$ 4,254

Operating Activities

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.

The net cash used in operating activities of $99.0 million for the year ended December 30, 2020 was due to a net loss of $121.5 million and a net cash outflow from the change in our operating assets and liabilities of $5.8 million, which were partially offset by the primary non-cash adjustments for stock-based compensation expense of $21.4 million, depreciation and amortization of $3.2 million, loss on extinguishment of term loan of $1.6 million, non-cash interest expense of $0.6 million, and non-cash lease expense of $0.6 million, provision for inventories of $0.5 million, and loss on disposal of property and equipment of $0.2 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, an increase in prepaid expenses and other assets, an increase in accounts receivable due to timing of collections and a decrease in accrued interest. 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 due to the growth of our business, an increase in deferred revenue, an increase in accrued warranty liability, and an increase in accounts payable due to timing of vendor payments.

Investing Activities

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.

Net cash provided by investing activities of $3.9 million for the year ended December 31, 2020 was due primarily to the sales and maturities of short-term investments of $45.9 million, partially offset by the purchases of investment securities of $32.9 million and purchases of property and equipment of $9.1 million.

Financing Activities

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.

Net cash provided by financing activities of $385.7 million for the year ended December 31, 2020 was due primarily to the net proceeds of $254.8 million from the issuance of our common stock in our IPO, net of issuance costs, the net proceeds of $126.8 million from the issuance of our Series E redeemable convertible preferred stock, the net proceeds of $29.6 million from borrowings on the SVB Loan and Security Agreement, proceeds of $4.3 million from the exercise of the Series C redeemable convertible

preferred stock warrants, and proceeds of $1.2 million from the issuance of common stock from exercises of stock options, partially offset by the cash outflow of $31.0 million in repayment of the Perceptive Term Loan which included early prepayment and exit fees.

Debt Obligations

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 used the SVB Term Loan proceeds to repay in full all amounts due under the Perceptive Term Loan and cash on hand to pay $1.2 million in early prepayment, accrued interest and exit fees.

The SVB Term Loan matures on November 1, 2025. Payments under the SVB Term Loan are for interest only through May 2023, and then 30 monthly principal and interest payments from June 2023 until maturity. The SVB Term Loan bears interest at a rate per annum equal to the greater of (A) 0.50% above the Prime Rate as reported in the Wall Street Journal then in effect (which shall not be less than zero) and (B) 3.75%.

There is also a final payment equal to 6.75% of the original principal amount of the SVB Term Loan, or approximately $2.0 million, due at maturity (or any earlier date of optional pre-payment or acceleration of principal due to an event of default). We may, at our option, prepay the SVB Term Loan in full, subject to an additional prepayment fee ranging between 1% and 3% of the outstanding principal amount of the SVB Term Loan. The prepayment fee would also be due and payable in the event of an acceleration of the principal amount of the supplemental term loan due to an event of default. The SVB Term Loan is 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 capital stock of foreign subsidiaries), subject to certain exceptions.

In the event of default or change in control, all unpaid principal and all accrued and unpaid interest amounts (if any) become immediately due and payable including the prepayment fee. Events of default include, but are not limited to, a payment default, a material adverse change, and insolvency. The SVB Loan and Security Agreement contains customary representations, warranties, affirmative covenants and also contains 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. We are also obligated to maintain a restricted cash balance greater or equal to the outstanding principal balance of $30.0 million of the SVB Term Loan.

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. For such contracts, we allocate the contracted transaction price to each 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 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 accumulative 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 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.

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, 2021, we had $30.0 million in variable rate debt outstanding. The SVB Term Loan matures on November 1, 2025. Payments under the SVB Term Loan are for interest only through May 2023, and then 30 monthly principal and interest payments from June 2023 until maturity. The SVB Term Loan bears interest at a rate per annum equal to the greater of (A) 0.50% above the Prime Rate as reported in the Wall Street Journal then in effect (which shall not be less than zero) and (B) 3.75%. An immediate 100 basis point change in the prime 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, 2021 and 2020, 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, 2021, and the related notes (collectively, the financial statements). We also have audited the Company's internal control over financial reporting as of December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2021, 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, 2021 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 $102,602 thousand of total revenues for the year ended December 31, 2021, of which $84,312 thousand related to product revenue, and $18,290 thousand 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 contract to understand its 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 23, 2022

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

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

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,		
	2021	**2020**	**2019**
Revenue:			
Product revenue	$ 84,312	$ 39,612	$ 13,750
Service and other revenue	18,290	10,323	1,328
Total revenue	102,602	49,935	15,078
Cost of revenue:			
Cost of product revenue	84,639	57,035	27,164
Cost of service and other revenue	10,355	5,937	5,716
Total cost of revenue	94,994	62,972	32,880
Gross profit	7,608	(13,037)	(17,802)
Operating expenses:			
Research and development	36,741	28,850	23,327
Sales and marketing	65,070	45,068	20,259
General and administrative	36,316	30,512	8,919
Total operating expenses	138,127	104,430	52,505
Loss from operations	(130,519)	(117,467)	(70,307)
Interest income and other income, net	498	526	2,485
Interest expense	(1,715)	(2,891)	(4,257)
Change in fair value of redeemable convertible preferred stock warrant liability	—	(93)	3,800
Loss on extinguishment of term loan	—	(1,567)	—
Loss before provision for income taxes	(131,736)	(121,492)	(68,279)
Provision for income taxes	199	—	20
Net loss	$ (131,935)	$ (121,492)	$ (68,299)
Net loss attributable to common stockholders, basic and diluted	$ (131,935)	$ (79,324)	$ (85,461)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.89)	$ (4.85)	$ (99.58)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	45,589	16,358	858

The accompanying notes are an integral part of these financial statements

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

	Years Ended December 31,		
	2021	**2020**	**2019**
Net loss	$ (131,935)	$ (121,492)	$ (68,299)
Other comprehensive income (loss):			
Unrealized gain (loss) on available-for-sale securities	(185)	(21)	82
Comprehensive loss	$ (132,120)	$ (121,513)	$ (68,217)

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	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital		Deficit	(Deficit)
Balance as of December 31, 2018	147,214	392,284	789	1	—	(60)	(287,891)	(287,950)
Common stock warrant exercises	—	—	9	—	76	—	—	76
Adjustment to redemption value on redeemable convertible preferred stock	—	134,760	—	—	(966)	—	(133,794)	(134,760)
Gain on extinguishment of redeemable convertible preferred stock	—	(117,417)	—	—	—	—	117,417	117,417
Costs to adjust the redemption value on redeemable convertible preferred stock	—	(181)	—	—	—	—	—	—
Stock option exercises	—	—	124	—	364	—	—	364
Stock-based compensation expense	—	—	—	—	883	—	—	883
Unrealized gain on available-for-sale securities	—	—	—	—	—	82	—	82
Net loss	—	—	—	—	—	—	(68,299)	(68,299)
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

The accompanying notes are an integral part of these financial statements

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

	Years Ended December 31,		
	2021	**2020**	**2019**
Cash flows from operating activities:			
Net loss	$ (131,935)	$ (121,492)	$ (68,299)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	5,162	3,159	1,484
Non-cash lease expense	1,022	596	451
Non-cash interest expense	569	641	893
Accretion (amortization) of discount (premium) on investments, net	1,972	50	(983)
Provision for accounts receivable	5	12	59
Provision for inventories	1,023	534	326
Loss on disposal of property and equipment	76	235	293
Stock-based compensation expense	17,445	21,439	883
Change in fair value of redeemable convertible preferred stock warrant liability	—	93	(3,800)
Loss on extinguishment of term loan	—	1,567	—
Changes in operating assets and liabilities:			
Accounts receivable	(19,137)	(2,566)	(2,886)
Inventories	(22,042)	(16,287)	(5,020)
Prepaid expenses and other assets	1,860	(6,245)	(228)
Accounts payable	(3,066)	737	802
Accrued payroll and related benefits	8,103	9,889	3,119
Accrued expenses and other current liabilities	5,889	4,798	974
Accrued warranty liability	791	1,211	1,410
Deferred revenue	2,881	2,754	735
Accrued interest	—	(217)	—
Operating lease liabilities	(882)	77	(505)
Net cash used in operating activities	(130,264)	(99,015)	(70,292)
Cash flows from investing activities:			
Purchases of property and equipment	(3,108)	(9,108)	(3,293)
Purchases of investment securities	(178,432)	(32,884)	(91,878)
Sales and maturities of investment securities	39,033	45,908	169,468
Net cash provided by (used in) investing activities	(142,507)	3,947	74,297
Cash flows from financing activities:			
Proceeds from issuance of common stock upon initial and follow-on public offerings, net of issuance costs	149,085	254,805	—
Proceeds from cash exercise of redeemable convertible preferred stock warrants	—	4,288	—
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	—	126,758	—
Proceeds from stock option exercises and employee stock purchase plan purchases	11,062	1,195	363
Proceeds from issuance of term loan, net of issuance costs	—	29,630	—
Repayment of term loan and extinguishment costs	—	(30,985)	—
Repayment of finance lease	—	(9)	(9)
Proceeds from exercise of common stock warrant	—	—	76
Payment of redeemable convertible preferred stock issuance costs	—	—	(181)
Net cash provided by financing activities	160,147	385,682	249
Net (decrease) increase in cash, cash equivalents and restricted cash	(112,624)	290,614	4,254
Cash, cash equivalents and restricted cash as of beginning of period	328,283	37,669	33,415
Cash, cash equivalents and restricted cash as of end of period	$ 215,659	$ 328,283	$ 37,669
Supplemental cash flow disclosures:			
Cash paid for income taxes	$ 83	$ 19	$ 35
Cash paid for interest	$ 1,146	$ 3,270	$ 3,352
Cash paid for amounts included in the measurement of operating lease liabilities	$ 882	$ —	$ 505

The accompanying notes are an integral part of these financial statements

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

	Years Ended December 31,		
	2021	**2020**	**2019**
Supplemental non-cash investing and financing activities:			
Capital expenditures included in accounts payable and accrued expenses	$ 121	$ 323	$ 867
Transfer of inventories to property and equipment	$ 1,410	$ 2,131	$ 3,119
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	$ 134,760
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	$ —
Gain on extinguishment of redeemable convertible preferred stock	$ —	$ —	$ 117,598
Transfer of property and equipment to inventories	$ 1,192	$ —	$ —

The accompanying notes are an integral part of these financial statements

1. Description of Business

Outset Medical, Inc. is a medical technology company pioneering a first-of-its-kind technology to reduce the cost and complexity of dialysis. The Tablo® Hemodialysis System, FDA cleared for use from the hospital to the home, represents a significant technological advancement 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.

The Company's registration statement on Form S-1 related to its IPO was declared effective by the SEC on September 14, 2020, and the Company's common stock began trading on the Nasdaq Global Select Market on September 15, 2020. Upon the completion of the IPO, the Company sold 10,294,000 shares of common stock (which included 1,343,000 shares that were sold pursuant to the full exercise of the underwriters' option to purchase additional shares in connection with the IPO) at a price to the public of $27.00 per share. Including the full exercise of the underwriters' option to purchase additional shares, the Company received aggregate net proceeds of approximately $254.8 million after deducting offering costs, underwriting discounts and commissions of approximately $23.1 million.

On April 13, 2021, the Company completed a follow-on public offering and sold 2,946,000 shares of common stock (which included 446,000 shares that were offered and sold pursuant to the full exercise of the underwriters' option to purchase additional shares) at a price to the public of $53.50 per share. The Company received aggregate net proceeds of approximately $149.1 million after deducting offering costs, underwriting discounts and commissions of $8.5 million.

Reverse Stock Split

In September 2020, the Company's board of directors and shareholders approved a certificate of amendment to the amended and restated certificate of incorporation to effect a reverse split of shares of the Company's common stock on a 7.9-for-one basis (the Reverse Stock Split) effective as of September 8, 2020. The number of authorized shares and the par values of the common stock and redeemable convertible preferred stock were not adjusted as a result of the Reverse Stock Split. In connection with the Reverse Stock Split, the conversion ratio for the Company's outstanding redeemable convertible preferred stock was proportionately adjusted such that the common stock issuable upon conversion of such preferred stock was decreased in proportion to the Reverse Stock Split. All references to common stock and options to purchase common stock, share data, per share data and related information contained in these financial statements and related notes have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented.

Liquidity

Since inception, the Company has incurred net losses and negative cash flows from operations. The Company incurred net losses of $131.9 million, $121.5 million and $68.3 million for the years ended December 31, 2021, 2020, and 2019, respectively. As of December 31, 2021, the Company had an accumulated deficit of $626.0 million.

As of December 31, 2021, the Company had cash, cash equivalents and short-term investments of $339.5 million, which are available to fund future operations, and restricted cash of $33.3 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 and short-term investments, which include the proceeds from the IPO and the follow-on public offering, and cash generated from revenues from its products and services, will be sufficient to meet its anticipated needs for at least the next 12 months from the issuance date of the 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, 2021.

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. One customer accounted for 11% of revenues for the year ended December 31, 2019. Accounts receivable are unsecured and the Company does not require collateral; 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 10% of accounts receivable as of December 31, 2021. Two customers accounted for 22% and 16% of accounts receivable, respectively, as of December 31, 2020. 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, for the production of the Tablo console. 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 ongoing 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 the Tablo console. 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.

The Company is subject to additional risks and uncertainties due to the COVID-19 pandemic. How long the pandemic, and measures intended to contain the spread of COVID-19, will continue remains uncertain and depends on ongoing developments, including but not limited to any resurgences of the virus including emerging variant strains, federal, state and local government actions taken in response, and continued availability, effectiveness and public acceptance of COVID-19 vaccines, as well as the extent and duration of the effect on the economy and how quickly and to what extent normal economic and operating conditions can resume. 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 recent government actions intended to mitigate these disruptions. As a result, the Company cannot predict what effect COVID-19, the associated containment measures and the related supply chain disruptions will ultimately have on its business and result of operations.

While the potential economic impact and duration of the COVID-19 pandemic may be difficult to assess or predict, the widespread COVID-19 pandemic has resulted in, and may continue to result in, significant disruption of global financial markets,

which could result in a reduction in the Company's ability to access capital and delays in payments of outstanding receivables that could adversely affect our liquidity. In addition, a recession or market correction resulting from the spread COVID-19 could materially affect the Company's business and financial results. As of the date of issuance of the financial statements, the extent to which the COVID-19 pandemic may materially adversely affect the Company's financial condition, liquidity, or results of operations is uncertain.

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 consist primarily of amounts invested in money market funds and are stated at fair value.

The Company primarily holds 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, 2021 and 2020.

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, 2021 and 2020.

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 consoles 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. For such contracts, the Company allocates the contracted transaction price to each 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 three months 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 our 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.

Service-based options granted to an optionee 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. 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.

RSUs with a service-based vesting condition granted to an optionee 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. 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 accumulative 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, consulting services, supplies and materials expenses, and allocated costs including facilities and information technology.

Advertising Costs

Advertising costs are expensed as incurred. The advertising costs for years ended December 31, 2021, 2020 and 2019 were not significant.

Income Taxes

The Company accounts for income taxes under the asset and 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 has not made such contributions for the years ended December 31, 2021, 2020 and 2019. 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.

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 has operated a manufacturing facility in Mexico since 2020. The Company's long-lived tangible assets, net, as well as the Company's operating lease right-of-use assets recognized on the balance sheets, located in Mexico were $6.2 million as of December 31, 2021.

Recently Adopted Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board (FASB) issued ASU No. 2019-12, *Income Taxes (Topic 740)*, which simplifies the accounting for income taxes, primarily by eliminating certain exceptions to ASC 740. The Company early adopted ASU 2019-12 on a modified retrospective basis as of January 1, 2021, which did not have a material impact on its financial statements.

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 will be effective for the Company beginning January 1, 2023. The Company is currently evaluating the impact of the adoption of ASU 2016-13 on its financial statements.

3. Revenue from Contracts with Customers

Disaggregation of Revenue

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

	Years Ended December 31,		
	2021	**2020**	**2019**
Consoles	$ 65,133	$ 32,871	$ 12,187
Consumables	19,179	6,742	1,563
Total product revenue	84,312	39,612	13,750
Service and other revenue	18,290	10,323	1,328
Total revenue	$ 102,602	$ 49,935	$ 15,078

For the years ended December 31, 2021, 2020 and 2019, $4.7 million, $3.1 million and $0.5 million, respectively, of consoles revenue were from console operating lease arrangements. The remaining operating lease payments of $1.7 million as of December 31, 2021 will be recognized during the year ending December 31, 2022.

Remaining Performance Obligations and Contract Liabilities

As of December 31, 2021, 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 $6.7 million, which is recorded as deferred revenue on the Company's balance sheet. Of that amount, $6.3 million will be recognized as revenue during the year ended December 31, 2022, and $0.3 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, 2021, 2020 and 2019, the Company recognized $3.2 million, $0.9 million, and $0.3 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, 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

		December 31, 2020			
	Valuation Hierarchy	Amortized Costs	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Assets:					
Cash equivalents:					
Money market funds	Level 1	$ 56,056	$ —	$ —	$ 56,056
Short-term investments:					
U.S. Treasury securities	Level 1	14,999	1	—	15,000
Corporate debt	Level 2	4,898	—	—	4,898
Total cash equivalents and short-term investments		$ 75,953	$ 1	$ —	$ 75,954

As of December 31, 2021, the remaining contractual maturities for short-term investments were as follows (in thousands):

	Aggregate Fair Value
Due within one year	$ 135,766
After one but within five years	21,374
Total	$ 157,140

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. There were no unrealized losses for securities in an unrealized loss position for more than 12 months as of December 31, 2021. During the years ended December 31, 2021, 2020 and 2019, 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, 2021 and 2020, the restricted cash balance of $33.3 million primarily relates to contractual obligations under the SVB Loan and Security Agreement (see Note 7) and collateral for the building leases in San Jose, CA and Tijuana, Mexico (see Note 6). The restricted cash balance of $0.7 million as of December 31, 2019 relates to collateral for 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,		
	2021	2020	2019
Cash and cash equivalents	$ 182,348	$ 294,972	$ 36,926
Restricted cash	33,311	33,311	743
Total cash, cash equivalents and restricted cash	$ 215,659	$ 328,283	$ 37,669

Inventories

Inventories consist of the following (in thousands):

	December 31,	
	2021	2020
Raw materials	$ 18,114	$ 7,989
Work in process	6,054	6,200
Finished goods	15,017	4,195
Total inventories	$ 39,185	$ 18,384

Property and Equipment, net

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

	December 31,	
	2021	2020
Tablos under operating leases	2,412	5,158
Computers and software	3,777	3,131
Furniture and fixtures	1,494	1,399
Machinery and equipment	7,197	4,496
Leasehold improvements	4,864	4,459
Construction in progress	874	1,343
Total property and equipment	20,618	19,986
Less: accumulated depreciation and amortization	(7,654)	(4,988)
Property and equipment, net	12,964	14,998

Total depreciation and amortization expense for the years ended December 31, 2021, 2020, and 2019 was $5.2 million, $3.2 million, and $1.5 million, respectively.

Accrued Expenses and Other Current Liabilities

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

	December 31,	
	2021	2020
Accrued inventory	$ 4,808	$ 3,576
Accrued research and development expenses	574	175
Accrued professional services	1,269	2,187
Accrued rebate	3,121	566
Other	4,017	1,399
Total accrued expenses and other current liabilities	$ 13,789	$ 7,903

Accrued Warranty Liability

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

	December 31,	
	2021	2020
Balance at the beginning of the period	$ 2,913	$ 1,702
Additions charged to cost of product revenue	7,310	4,858
Consumption	(6,519)	(3,647)
Balance at the end of the period	$ 3,704	$ 2,913

6. Commitments and Contingencies

Leases

In September 2019, the Company entered into an operating lease agreement for its new 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,		
	2021	2020	2019
Operating lease costs	1,759	1,070	—
Variable lease costs	375	233	100
Short-term lease costs	180	371	520
Total lease costs	$ 2,314	$ 1,674	$ 620

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

	December 31,	
	2021	2020
Weighted-average remaining lease term (in years)	5.3	6.3
Weighted-average discount rate	8.7%	8.7%

The maturity of the Company's operating lease liabilities as of December 31, 2021 were as follows (in thousands):

Years Ending December 31:		
2022	$	1,796
2023		1,856
2024		1,911
2025		1,969
Thereafter		2,523
Total lease payments	$	10,055
Less: imputed interest		(2,011)
Present value of operating lease liabilities	$	8,044
Operating lease liabilities, current	$	1,151
Operating lease liabilities, noncurrent	$	6,893

Purchase Commitments

The Company's commitments as of December 31, 2021 include an estimated amount of $68.6 million relating to the Company's open purchase orders and contractual obligations that occur in the ordinary course of business, including commitments with contract manufacturers and suppliers for which the Company has not received the goods or services, commitments for capital expenditures, consulting activities for which the Company has not received the services, and subscription of software services. Although open purchase orders are considered enforceable and legally binding, the terms generally allow the Company the option to cancel within a reasonable period, reschedule, and adjust its requirements based on its business needs prior to the delivery of goods or performance of services.

Litigation

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

Indemnifications

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

7. Term Loans

Term loans consist of the following (in thousands):

	December 31, 2021	December 31, 2020
Principal of term loan	$ 30,000	$ 30,000
Unamortized debt discount	(238)	(326)
Total term loan, noncurrent	$ 29,762	$ 29,674

Perceptive Term Loans

In 2017, the Company entered into a senior, secured, delayed-draw term loan facility (the Perceptive Term Loan Agreement) with Perceptive Credit Holdings, LP, as the administrative agent and the collateral agent, for various related Perceptive group companies to borrow up to $40.0 million (the Perceptive Term Loans). The Perceptive Term Loans bore interest at a rate of 8.55%, plus the greater of the three-month London Inter-bank Offered Rate (LIBOR) and 2.00%.

In July 2020, the Company used the SVB Term Loan (see below) to repay in full all amounts due under the Perceptive Term Loan and cash on hand to pay $1.2 million in early prepayment, accrued interest and exit fees. The repayment of the Perceptive Term Loan was accounted for as a debt extinguishment, which resulted in a loss on extinguishment of $1.6 million recorded in the statements of operations for the year ended December 31, 2020.

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 provides for a $30.0 million term loan (the SVB Term Loan).

The SVB Term Loan matures on November 1, 2025. Payments under the SVB Term Loan are for interest only through May 2023, and then 30 monthly principal and interest payments from June 2023 until maturity. The SVB Term Loan bears interest at a rate per annum equal to the greater of (A) 0.50% above the Prime Rate as reported in the Wall Street Journal then in effect (which shall not be less than zero) and (B) 3.75% (3.75% as of December 31, 2021). The Company is obligated to maintain a restricted cash balance greater or equal to the outstanding principal balance of $30.0 million of the SVB Term Loan.

There is also a final payment fee equal to 6.75% of the original principal amount of the SVB Term Loan, or approximately $2.0 million, due at maturity (or any earlier date of optional pre-payment or acceleration of principal due to an event of default). Such fee is being accreted to interest expense using the effective interest method with the offset recorded in noncurrent accrued interest. The Company may, at its option, prepay the SVB Term Loan in full, subject to an additional prepayment fee ranging between 1% and 3% of the outstanding principal amount of the SVB Term Loan.

In the event of default or change in control, all unpaid principal and all accrued and unpaid interest amounts (if any) become immediately due and payable including the prepayment fee. Events of default include, but are not limited to, a payment default, a material adverse change, and insolvency. The SVB Term Loan is secured by substantially all of the Company’s assets, including all of the capital stock held by the Company, if any (subject to a 65% limitation on pledges of capital stock of foreign subsidiaries), subject to certain exceptions. The SVB Loan and Security Agreement contains customary representations, warranties, affirmative covenants and also contains certain restrictive covenants.

Debt issuance costs paid directly to SVB and other debt issuance costs amounting to $0.4 million were accounted for as discounts on the SVB Term Loan. These debt discounts, along with the final payment fee, are being amortized over the term of the SVB Term Loan using the effective interest rate method. As of December 31, 2021, the unamortized debt discount was $0.2 million, which is recorded as a direct deduction from the SVB Term Loan on the balance sheets.

Aggregate annual payments due on the SVB Term Loan as of December 31, 2021 were as follows (in thousands):

Years Ending December 31:	
2022	$ 1,141
2023	8,073
2024	12,667
2025	13,233
Total future payments	35,114
Less: amount representing interest	(3,089)
Less: final payment	(2,025)
Total term loan	30,000
Less: unamortized debt discount	(238)
Total term loan, net of debt discount	$ 29,762

8. Stockholders' Equity

The Company has reserved shares of common stock for issuance as of December 31, 2021 as follows (in thousands):

	Shares
Warrants to purchase common stock	63
Stock options outstanding	3,533
Restricted stock units outstanding	563
Performance stock units outstanding	110
Shares available for future purchase under ESPP	999
Shares available for future grant under 2020 Plan	4,415
Total reserved shares	9,683

9. 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 the third quarter of 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 has 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. On January 1, 2021, the number of shares of common stock reserved for the issuance of awards under the 2020 Plan was increased by 1,709,000 shares as a result of the automatic increase pursuant to 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

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, 2020	4,763	$ 6.35		
Granted	634	$ 47.91		
Exercised	(1,437)	$ 5.31		
Forfeited and expired	(427)	$ 19.58		
Balance as of December 31, 2021	3,533	$ 12.63	6.82	$ 119,959
Exercisable as of December 31, 2021	2,453	$ 5.42	6.07	$ 99,853

The weighted average grant date fair value of options granted to employees was $24.74, $7.97, and $2.77 per share during the years ended December 31, 2021, 2020 and 2019, respectively. The total intrinsic value of options exercised during the years ended December 31, 2021, 2020 and 2019 was $61.0 million, $8.2 million, and $0.2 million, respectively. The intrinsic value is the difference between the estimated 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, 2021, 2020 and 2019 was $24.5 million, $3.3 million, and $0.7 million, respectively. As of December 31, 2021, the total unrecognized stock-based compensation expense related to the stock options was $14.0 million, which will be recognized over a weighted-average period of 2.63 years.

Stock Options with Performance and Market Conditions

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 achieves both (i) a performance condition tied to a liquidity event, which includes the effectiveness of an IPO, and (ii) certain market conditions, provided the optionee is providing services on the date of the event. As of December 31, 2021, all outstanding options with these conditions were fully vested and related stock-based compensation was recognized in full. 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, 2019 as the performance-based vesting condition was not satisfied until the closing of the IPO in September 2020.

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,		
	2021	2020	2019
Expected term (in years)	5.95 – 6.08	5.06 – 10.00	4.97 – 5.05
Expected volatility	53.9% – 55.3%	52.1% – 62.7%	49.3% – 50.9%
Risk-free interest rate	0.66% – 1.36%	0.35% – 1.54%	1.57% – 2.48%
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. The PSUs may 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, 2020	44	25	$ 52.32	$ 52.55
Granted	639	85	$ 47.78	$ 46.22
Vested	(19)	—	$ 51.03	$ —
Forfeited	(101)	—	$ 48.04	$ —
Outstanding as of December 31, 2021	563	110	$ 47.98	$ 47.65

The total grant date fair value of RSUs vested for the years ended December 31, 2021 and 2020 were $1.0 million and $0.2 million, respectively. There were no RSUs granted prior to 2020. As of December 31, 2021, the total unrecognized stock-based compensation expense related to the RSUs was $22.6 million, which will be recognized over a weighted-average period of 3.12 years.

As of December 31, 2021, the total unrecognized stock-based compensation expense related to the PSUs with market-based vesting conditions was $1.3 million, which will be recognized over a weighted-average period of 1.25 years.

Employees Stock Purchase Plan (ESPP)

In the third quarter of 2020, the Company adopted the ESPP. The Company has 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. On January 1, 2021, the number of shares of common stock reserved for purchase under the ESPP was increased by 427,000 shares as a result of the automatic increase pursuant to 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 will be 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 fair value of the stock purchase rights under the ESPP is estimated using the Black-Scholes option pricing model. The weighted average 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,	
	2021	2020
Expected term (in years)	0.50	0.47
Expected volatility	41.0% – 43.8%	57.0%
Risk-free interest rate	0.06% – 0.07%	0.12%
Dividend yield	0%	0%
Grant Date Fair Value	$13.25 – $13.95	$8.00

During the years ended December 31, 2021 and 2020, 116,000 and zero shares of common stock were purchased pursuant to the ESPP, respectively. As of December 31, 2021, the total unrecognized stock-based compensation expense related to the ESPP was $0.2 million, which will be recognized over a weighted-average period of 0.17 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,		
	2021	2020	2019
Cost of revenue	$ 269	$ 255	$ 5
Research and development	3,809	4,615	328
Sales and marketing	5,897	4,423	172
General and administrative	7,470	12,146	378
Total stock-based compensation expense	$ 17,445	$ 21,439	$ 883

10. Income Taxes

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

	Years Ended December 31,		
	2021	2020	2019
Domestic	$ (128,400)	$ (121,492)	$ (68,299)
Foreign	(3,336)	—	—
Loss before provision for income taxes	$ (131,736)	$ (121,492)	$ (68,299)

The provision for income taxes was $0.2 million for the years ended December 31, 2021, which related to foreign income taxes. For years ended December 31, 2020 and 2019, the provision for income taxes were 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 of the provision for income taxes differs from the federal statutory rate as follows:

	Years Ended December 31,		
	2021	2020	2019
Federal statutory income tax rate	21.0 %	21.0 %	21.0 %
State taxes	1.3	3.8	7.8
Change in valuation allowance	(22.8)	(23.3)	(28.5)
Federal and state tax credits	1.2	1.0	0.9
Stock-based compensation expense	8.1	1.2	—
Non-deductible permanent expenses	(0.1)	(0.2)	(1.2)
Effect of deferred tax adjustment	(0.7)	(1.4)	—
Non-deductible compensation	(8.2)	(2.1)	—
Effective income tax rate	(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,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	$ 102,094	$ 76,838
Tax credits	11,767	10,039
Accrual and reserves	3,573	2,392
Tangible and intangible assets	20,249	19,090
Stock-based compensation expense	3,566	2,843
Lease liabilities	1,955	1,733
Other deferred tax asset	282	—
Gross deferred tax assets	143,486	112,935
Valuation allowance	(141,729)	(111,061)
Net deferred tax assets	$ 1,757	$ 1,874

	December 31,	
	2021	2020
Deferred tax liabilities:		
Right-of-use assets	$ (1,757)	$ (1,874)
Gross deferred tax liabilities	$ (1,757)	$ (1,874)

Realization of the deferred tax assets is dependent upon future taxable income, if any, the amount and timing of which are uncertain. The Company has established a valuation allowance to offset deferred tax assets as of December 31, 2021 and 2020 due to the uncertainty of realizing future tax benefits from its net operating loss carryforwards and other deferred tax assets. The valuation allowance increased by $30.7 million, $28.4 million and $23.7 million during the years ended December 31, 2021, 2020 and 2019, respectively.

Net Operating Loss and Tax Credit Carryforwards

As of December 31, 2021, the Company had a net operating loss carryforward for federal income tax purposes of $409.0 million. Federal net operating losses of $281.2 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 state net operating loss carryforward of $213.7 million. State net operating losses of $53.2 million do not expire. The remaining state net operating loss carryforward of $160.5 million will begin to expire in 2022 and continue to expire through 2041.

The Company had federal research and development credits of $6.6 million, which will begin to expire in 2030 and state research and development credits of $5.1 million which have no expiration date. These tax credits are subject to the same limitations discussed above.

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, 2021 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,	
	2021	2020
Balance, beginning of year	$ 1,582	$ 1,020
Decrease related to current year positions	—	
Increase related to current year positions	608	562
Balance, end of year	$ 2,190	$ 1,582

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 and various 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.

11. 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,		
	2021	2020	2019
Numerator:			
Net loss	$ (131,935)	$ (121,492)	$ (68,299)
Adjustment to redemption value on redeemable convertible preferred stock	—	(362)	(134,760)
Deemed dividend on settlement of accrued dividend	—	42,530	—
Gain on extinguishment of redeemable convertible preferred stock	—	—	117,598
Net loss attributable to common stockholders, basic and diluted	$ (131,935)	$ (79,324)	$ (85,461)
Denominator:			
Weighted-average shares of common stock, basic and diluted	45,589	16,358	858
Net loss per share attributable to common stockholders, basic and diluted	$ (2.89)	$ (4.85)	$ (99.58)

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,		
	2021	2020	2019
Stock options to purchase common stock	3,533	4,763	3,757
Warrant to purchase common stock	63	63	—
Restricted stock units	581	—	—
Shares committed under ESPP	37	52	—
Performance stock units	17	—	—
Redeemable convertible preferred stock, on an as-if converted basis	—	—	18,634
Warrants to purchase redeemable convertible preferred stock	—	—	599
Total	4,231	4,878	22,990

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, 2021.

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, 2021.

The effectiveness of our internal control over financial reporting as of December 31, 2021 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, 2021 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 2022 Annual Meeting of Stockholders within 120 days of our fiscal year ended December 31, 2021 (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				
10.10†	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#	Loan and Security Agreement by and between Silicon Valley Bank and Outset Medical, Inc. dated as of July 2, 2020	S-1	333-248225	10.14	August 21, 2020

10.18#	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
10.19#	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
10.20#	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
10.21#	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
10.22#	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
10.23#	Award/Contract from the Biomedical Advanced Research and Development Authority to Outset Medical, Inc., effective September 30, 2019	S-1	333-248225	10.22	August 21, 2020
10.24#	Amendment of Solicitation/Modification of Contract from the Biomedical Advanced Research and Development Authority to Outset Medical, Inc., effective May 9, 2020	S-1	333-248225	10.23	August 21, 2020
10.25#	Solicitation/Contract/Order for Commercial Items from ASPR/SNS to Outset Medical, Inc., effective August 17, 2020	S-1/A	333-248225	10.24	September 9, 2020
10.26#	Amendment to Solicitation/Modification of Contract from ASPR-BARDA to Outset Medical, Inc., dated November 25, 2020	10-K	001-39513	10.29	March 22, 2021
10.27#	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
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 23, 2022

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 23, 2022
/s/ Nabeel Ahmed Nabeel Ahmed	Chief Financial Officer (*Principal Financial Officer and Principal Accounting Officer*)	February 23, 2022
/s/ D. Keith Grossman D. Keith Grossman	Lead Independent Director	February 23, 2022
/s/ Karen Drexler Karen Drexler	Director	February 23, 2022
/s/ Patrick T. Hackett Patrick T. Hackett	Director	February 23, 2022
/s/ Jim Hinrichs Jim Hinrichs	Director	February 23, 2022
/s/ Andrea L. Saia Andrea L. Saia	Director	February 23, 2022
/s/ Catherine Szyman Catherine Szyman	Director	February 23, 2022

Exhibit 10.9

OUTSET MEDICAL, INC.

EMPLOYEE STOCK PURCHASE PLAN

ADOPTED BY THE BOARD OF DIRECTORS: SEPTEMBER 2, 2020
APPROVED BY THE STOCKHOLDERS: SEPTEMBER 7, 2020
TERMINATION DATE: SEPTEMBER 2, 2030
(AMENDED AND RESTATED, EFFECTIVE MARCH 1, 2022)

1. PURPOSE. The purpose of the Outset Medical, Inc. Employee Stock Purchase Plan (this "Plan") is to provide eligible Employees of the Company and Participating Subsidiaries with a convenient means of acquiring an equity interest in the Company through payroll deductions and other contributions in order to enhance such employees' sense of participation in the affairs of the Company. This Plan is amended and restated as set forth herein and such amendment and restatement shall apply to Offering Periods beginning on or after March 1, 2022.

This Plan includes two components: (a) a component intended to qualify as an "employee stock purchase plan" under Section 423 of the Code (the "423 Component"), the provisions of which shall be construed so as to extend and limit participation in a uniform and nondiscriminatory manner consistent with the requirements of Section 423 of the Code; and (b) a component that does not qualify as an "employee stock purchase plan" under Section 423 of the Code (the "Non-423 Component"), under which options shall be granted pursuant to rules, procedures or sub-plans adopted by the Committee designed to achieve tax, securities laws or other objectives for eligible Employees, the Company and its Participating Subsidiaries. Except as otherwise provided in this Plan, the Non-423 Component will operate and be administered in the same manner as the 423 Component.

2.DEFINITIONS. As used herein, the terms set forth below have the meanings assigned to them in this Section 2 and shall include the plural as well as the singular.

"1933 Act" means the Securities Act of 1933, as amended.

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

"Board" means the Board of Directors of Outset Medical, Inc.

"Business Day" shall mean a day on which NASDAQ is open for trading.

"Brokerage Account" means the account in which the Purchased Shares are held.

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

"Committee" means the Compensation Committee of the Board, or the designee of the Compensation Committee.

"Company" means Outset Medical, Inc., a Delaware corporation.

"Compensation" means base pay, commissions, overtime, and vacation, holiday and sick pay. Compensation does not include: (1) income related to stock option awards, stock grants and other equity incentive awards, (2) expense reimbursements, (3) relocation-related payments, (4) benefit plan payments (including but not limited to short-term disability pay, long-term disability pay, maternity pay, military pay, tuition reimbursement and adoption assistance), (5) accrued but unpaid compensation for a deceased Participant, (6) income from non-cash and fringe benefits, (7) severance payments, (8) annual, quarterly, monthly and other cash bonuses, and (9) other forms of compensation not specifically listed herein.

"Employee" means any individual who is a common law employee of the Company or any other Participating Subsidiary. For purposes of the Plan, the employment relationship shall be treated as continuing intact while the individual is on sick leave or other leave of absence approved by the Company or the Participating Subsidiary, as appropriate, and only to the extent permitted under Section 423 of the Code with respect to the 423 Component. For purposes of the Plan, an individual who performs services for the Company or a Participating Subsidiary pursuant to an agreement (written or oral) that classifies such individual's relationship with the Company or a Participating Subsidiary as other than a common law employee shall not be considered an "employee" with respect to any period preceding the date on which a court or administrative agency issues a final determination that such individual is an "employee."

"Enrollment Date" means the first Business Day of each Offering Period.

"Exercise Date" means the last Business Day of each Offering Period (or, if determined by the Committee, the Purchase Period if different from the Offering Period).

"Fair Market Value" on or as of any date means the official closing price for a Share as reported on NASDAQ on the relevant valuation date or, if no official closing price is reported on such date, on the preceding day on which an official closing price is reported on NASDAQ was reported; or, if the Shares are no longer listed on NASDAQ, the closing price for Shares as reported on the official website for such other exchange on which the Shares are listed. Notwithstanding the foregoing, if the first Offering Period commences on the first Business Day on or after the date on which the Securities and Exchange Commission declares the Company's Registration Statement to be effective, the Fair Market Value for purposes of the Enrollment Date for such first Offering Period shall be the initial price to the public as set forth in the final prospectus included in the Registration Statement.

"Offering Period" means each six-month period or, effective March 1, 2022, each 24-month period, beginning the first Business Day of March and the first Business Day of September or such other period designated by the Committee; provided that in no event shall an Offering Period exceed 27 months, with the commencement of the first Offering Period to be determined by the Committee. Notwithstanding anything herein to the contrary, the Committee may establish an Offering Period with multiple Purchase Periods within such Offering Period.

"Option" means an option granted under this Plan that entitles a Participant to purchase Shares.

"Participant" means an Employee who satisfies the requirements of Sections 3 and 5 of the Plan.

"Participating Subsidiary" means each Subsidiary other than those that the Committee or the Board has excluded from participation in the Plan.

"Plan" means this Outset Medical, Inc. Employee Stock Purchase Plan, as amended from time to time.

"Purchase Account" means the account used to purchase Shares through the exercise of Options under the Plan.

"Purchase Period" means the period designated by Committee during which payroll deductions and other contributions of the Participants are accumulated under the Plan. A Purchase Period may coincide with an entire Offering Period or there may be multiple Purchase Periods within an Offering Period, as determined by the Committee prior to the commencement of the applicable Offering Period.

"Purchase Price" shall be the lesser of: (i) 85% percent of the Fair Market Value of a Share on the applicable Enrollment Date for an Offering Period and (ii) 85% percent of the Fair Market Value of a Share on the applicable Exercise Date; provided, however, that the Committee may determine a different per share Purchase Price provided that such per share Purchase Price is communicated to Participants prior to the beginning of the Offering Period and provided that in no event shall such per share Purchase Price be less than the lesser of (i) 85% of the Fair Market Value of a Share on the applicable Enrollment Date or (ii) 85% of the Fair Market Value of a Share on the Exercise Date.

"Purchased Shares" means the full Shares issued or delivered pursuant to the exercise of Options under the Plan.

"Registration Statement" means the registration statement on Form S-1 filed with the Securities and Exchange Commission for the initial public offering of the Common Stock.

"Shares" means shares of the common stock of the Company.

"Subsidiary" means an entity, domestic or foreign, of which not less than 50% of the voting equity is held by the Company or a Subsidiary, whether or not such entity now exists or is hereafter organized or acquired by the Company or a Subsidiary; provided such entity is also a "subsidiary" within the meaning of Section 424 of the Code.

"Termination Date" means (i) the date on which a Participant terminates employment or on which the Participant ceases to provide services to the Company or a Subsidiary as an employee or as otherwise required under Section 423 with respect to the 423 Component or (ii) subject to Section 423 of the Code with respect to the 423 Component, the date on which the Participant's employment is determined to have been terminated for purposes of the Plan by the Committee. The Termination Date specifically does not include any period following that date which the Participant may be eligible for or in receipt of other payments from the Company including in lieu of notice or termination or severance pay or as wrongful dismissal damages.

3.ELIGIBILITY.

(a) Only Employees of the Company or a Participating Subsidiary (i) whose customary employment is 20 hours or more per week and (ii) whose customary employment is for five months or more in any calendar year shall be eligible to be granted Options under the Plan and, in no event may a Participant be granted an Option under the Plan following his or her Termination Date.

(b) Any provisions of the Plan to the contrary notwithstanding, no Employee shall be granted an Option under the 423 Component of the Plan if (i) immediately after the grant, such Employee (or any other person whose stock would be attributed to such Employee pursuant to Section 424(d) of the Code) would own capital stock of the Company and/or hold outstanding Options or options to purchase stock possessing 5% or more of the total combined voting power or value of all classes of stock of the Company or of any of its Subsidiaries or (ii) such Option would permit his or her rights to purchase stock under all employee stock purchase plans (described in Section 423 of the Code) of the Company and its Subsidiaries to accrue at a rate that exceeds $25,000 of the Fair Market Value of such stock (determined at the time each such Option is granted) for each calendar year in which such Option is outstanding at any time. Except as otherwise determined by the Committee prior to the commencement of an Offering Period, no Participant may purchase more than 1,265 Shares during any Offering Period.

4.EXERCISE OF AN OPTION. Options shall be exercised on behalf of Participants in the Plan every Exercise Date, using (i) payroll deductions that have accumulated in the Participants' Purchase Accounts during the immediately preceding Purchase Period or that have been retained from a prior Purchase Period pursuant to Section 8 hereof and (ii) additional contributions to the Company made pursuant to the Cashless Participation Program approved by the Committee.

5.PARTICIPATION.

(a) Unless otherwise determined by the Committee prior to the commencement of an Offering Period and in accordance with Section 423 of the Code with respect to the 423 Component, an Employee shall be eligible to participate on the first Enrollment Date that occurs after such Employee's first date of employment with the Company or a Participating Subsidiary; provided, that such Employee properly completes and submits an election form by the deadline prescribed by the Company.

(b) An Employee who does not become a Participant on the first Enrollment Date on which he or she is eligible may thereafter become a Participant on any subsequent Enrollment Date by properly completing and submitting an election form by the deadline prescribed by the Company.

(c) Payroll deductions for a Participant shall commence on the first payroll date following the Enrollment Date and shall end on the last payroll date in the Purchase Period to which such authorization is applicable, unless sooner terminated by the Participant as provided in Section 12 hereof.

6.PAYROLL DEDUCTIONS AND OTHER CONTRIBUTIONS.

(a) A Participant shall elect to have payroll deductions made during a Purchase Period equal to no less than 1% of the Participant's Compensation up to a maximum of 15% (or such greater amount as the Committee establishes from time to time). The amount of such payroll deductions shall be in whole percentages. All payroll deductions made by a Participant shall be credited to his or her Purchase Account. In addition to such payroll deductions credited to a Participant's Purchase Account during the Purchase Period, Participants other than executive officers of the Company, within the meaning of the 1934 Act, may elect to purchase Shares pursuant to a cashless participation program approved by the Committee (the "Cashless Participation Program") by designating an additional amount to be contributed to such Participant's Purchase Account at the end of such Purchase Period. In addition, notwithstanding any provisions to the contrary in the Plan, the Committee may allow participants to make other contributions under the Plan via cash, check, or other means instead of payroll deductions if payroll deductions are not permitted under applicable local law, and for any Offering Period under the 423 Component, the Committee determines that such other contributions are permissible under Section 423 of the Code.

(b) Except as otherwise determined by the Committee prior to the commencement of an Offering Period, a Participant may not increase the rate of payroll deductions or other contributions to be made to the Plan during a Purchase Period. A Participant may decrease the rate of payroll deductions during a Purchase Period by properly completing and submitting an election change form in accordance with the procedures prescribed by the Committee and/or any other forms required by the Committee and by following any other procedures as may be established by the Committee, in which case the new rate shall become effective as soon as administratively practicable after the Participant elects such change and shall continue for the remainder of the Offering Period unless changed as described below. Such change in the rate of payroll deductions may be made at any time during a Purchase Period, but not more than one (1) change may be made effective during any Purchase Period, except that a Participant may elect at any time during a Purchase Period, regardless of whether the Participant previously decreased his or her payroll deduction percentage, to reduce his or her contribution percentage to 0% and such change shall become effective as soon as administratively practicable after the Participant elects such change and shall continue for the remainder of the Offering Period unless changed as described below. If a Participant reduces his or her payroll deduction percentage to 0%, then any election to purchase Shares pursuant to the Cashless Participation Program shall automatically terminate. A Participant may change his or her payroll deduction percentage or additional contribution amount under subsection (a) above for any subsequent Purchase Period by properly completing and submitting an election change form in accordance with the procedures prescribed by the Committee. The change in amount shall be effective as of the first Enrollment Date following the date of filing of the election change form. Unless otherwise determined by the Committee prior to the commencement of an Offering Period, a payroll deduction election and additional contribution election will automatically apply to the next Offering Period, unless otherwise cancelled or changed by the Participant prior to the commencement of such Offering Period.

(c) Notwithstanding the foregoing, to the extent necessary to comply with Section 423(b)(8) of the Code and Section 3(b) hereof, a Participant's payroll deduction and additional contribution elections may be decreased to 0% at any time during an Offering Period. Payroll deductions and additional contributions shall recommence at the rate provided in such Participant's election form at the beginning of the first Offering Period which is scheduled to end in the following calendar year, unless terminated by the Participant as provided in Section 12 hereof.

7. Grant of Option. On the applicable Enrollment Date, each Participant in an Offering Period shall be granted an Option to purchase on the applicable Exercise Date a number of full Shares determined by dividing such Participant's payroll deductions and additional contributions accumulated on or before such Exercise Date and retained in the Participant's Purchase Account as of the applicable Exercise Date by the applicable Purchase Price.

8. Exercise of Option. A Participant's Option for the purchase of Shares shall be exercised automatically on the Exercise Date, and the maximum number of Shares subject to the Option shall be purchased for such Participant at the applicable Purchase Price with the accumulated payroll deductions and additional contributions in his or her Purchase Account. If the Fair Market Value of a Share on the first day of the current Offering Period in which a participant is enrolled is higher than the Fair Market Value of a Share on the first day of any subsequent Offering Period, the Company may establish procedures to automatically enroll such participant in the subsequent Offering Period and any funds accumulated in a participant's account prior to the first day of such subsequent Offering Period will be applied to the purchase of shares on the Exercise Date immediately prior to the first day of such subsequent Offering Period. A participant does not need to file any forms with the Company to be automatically enrolled in the subsequent Offering Period.

No fractional Shares shall be purchased; any payroll deductions and other contributions accumulated in a Participant's Purchase Account which are not sufficient to purchase a full Share shall be retained in the Purchase Account for the next subsequent Purchase Period, subject to earlier withdrawal by the Participant as provided in Section 12 hereof. All other payroll deductions and other contributions accumulated in a Participant's Purchase Account and not used to purchase Shares on an Exercise Date shall be distributed to the Participant. During a Participant's lifetime, a Participant's Option is exercisable only by him or her. The Company shall satisfy the exercise of all Participants' Options for the purchase of Shares through (a) the issuance of authorized but unissued Shares, (b) the transfer of treasury Shares, (c) the purchase of Shares on behalf of the applicable Participants on the open market through an independent broker and/or (d) a combination of the foregoing.

9.Issuance of Stock. The Shares purchased by each Participant shall be issued in book entry form and shall be considered to be issued and outstanding to such Participant's credit as of the end of the last day of each Purchase Period. The Committee may permit or require that shares be deposited directly in a Brokerage Account with one or more brokers designated by the Committee or to one or more designated agents of the Company, and the Committee may use electronic or automated methods of share transfer. The Committee may require that Shares be retained with such brokers or agents for a designated period of time and/or may establish other procedures to permit tracking of disqualifying dispositions of such shares, and may also impose a transaction fee with respect to a sale of Shares issued to a Participant's credit and held by such a broker or agent. The Committee may permit Shares purchased under the Plan to participate in a dividend reinvestment plan or program maintained by the Company, and establish a default method for the payment of dividends.

10.Approval by Stockholders. Notwithstanding the above, the Plan is expressly made subject to the approval of the stockholders of the Company within 12 months before or after the date the Plan is adopted by the Board. Such stockholder approval shall be obtained in the manner and to the degree required under applicable federal and state law. If the Plan is not so approved by the stockholders within 12 months before or after the date the Plan is adopted by the Board, this Plan shall not come into effect.

11.Administration.

(a) Powers and Duties of the Committee. The Plan shall be administered by the Committee. Subject to the provisions of the Plan, Section 423 of the Code and the regulations thereunder with respect to the 423 Component, the Committee shall have the discretionary authority to determine the time and frequency of granting Options, the duration of Offering Periods and Purchase Periods, the terms and conditions of the Options and the number of Shares subject to each Option. The Committee shall also have the discretionary authority to do everything necessary and appropriate to administer the Plan, including, without limitation, interpreting the provisions of the Plan (but any such interpretation shall not be inconsistent with the provisions of Section 423 of the Code with respect to the 423 Component). All actions, decisions and determinations of, and interpretations by the Committee with respect to the Plan shall be final and binding upon all Participants and upon their executors, administrators, personal representatives, heirs and legatees. No member of the Board or the Committee shall be liable for any action, decision, determination or interpretation made in good faith with respect to the Plan or any Option granted hereunder. With respect to the 423 Component, an Offering Period shall be administered so as to ensure that all Participants have the same rights and privileges as provided by Section 423(b)(5) of the Code.

(b) Administrator. The Company, Board or the Committee may engage the services of one or more brokerage firms or other companies to perform certain ministerial and procedural duties under the Plan including, but not limited to, mailing and receiving notices contemplated under the Plan, determining the number of Purchased Shares for each Participant, maintaining or causing to be maintained the Purchase Account and the Brokerage Account, disbursing funds maintained in the Purchase Account or proceeds from the sale of Shares through the Brokerage Account, and filing with the appropriate tax authorities proper tax returns and forms (including information returns) and providing to each Participant statements as required by law or regulation.

(c) Indemnification. Each person who is or shall have been (a) a member of the Board, (b) a member of the Committee, or (c) an officer or employee of the Company to whom authority was delegated in relation to this Plan, shall be indemnified and held harmless by the Company against and from any loss, cost, liability or expense that may be imposed upon or reasonably incurred by him or her in connection with or resulting from any claim, action, suit or proceeding to which he or she may be a party or in which he or she may be involved by reason of any action taken or failure to act under the Plan and against and from any and all amounts paid by him or her in settlement thereof, with the Company's approval, or paid by him or her in satisfaction of any judgment in any such claim, action, suit or proceeding against him or her; provided, however, that he or she shall give the Company an opportunity, at its own expense, to handle and defend the same before he or she undertakes to handle and defend it on his or her own behalf, unless such loss, cost, liability or expense is a result of his or her own willful misconduct or except as expressly provided by statute.

The foregoing right of indemnification shall not be exclusive of any other rights of indemnification to which such persons may be entitled under the Company's certificate of incorporation or bylaws, any contract with the Company, as a matter of law, or otherwise, or of any power that the Company may have to indemnify them or hold them harmless.

12. Withdrawal. A Participant may withdraw from the Plan by properly completing and submitting to the Company a withdrawal form in accordance with the procedures prescribed by the Committee, which must be submitted prior to the date specified by the Committee before the last day of the applicable Offering Period. Upon withdrawal, any payroll deductions credited to the Participant's Purchase Account prior to the effective date of the Participant's withdrawal from the Plan will be returned to the Participant. No further payroll deductions or additional contributions for the purchase of Shares will be made during subsequent Offering Periods, unless the Participant properly completes and submits an election form, by the deadline prescribed by the Company. A Participant's withdrawal from an offering will not have any effect upon his or her eligibility to participate in the Plan or in any similar plan that may hereafter be adopted by the Company.

13. Termination of Employment. On the Termination Date of a Participant for any reason prior to the applicable Exercise Date, whether voluntary or involuntary, and including termination of employment due to retirement, death or as a result of liquidation, dissolution, sale, merger or a similar event affecting the Company or a Participating Subsidiary, the corresponding payroll deductions credited to his or her Purchase Account will be returned to him or her or, in the case of the Participant's death, to the person or persons entitled thereto under Section 16, and his or her Option will be automatically terminated.

14. Interest. No interest shall accrue on the payroll deductions or other contributions of a Participant in the Plan.

15. Stock.

(a) The stock subject to Options shall be common stock of the Company as traded on NASDAQ or on such other exchange as the Shares may be listed.

(b) Subject to adjustment upon changes in capitalization of the Company as provided in Section 18 hereof, the maximum number of Shares which shall be made available for sale under the Plan shall be 687,218 Shares. In addition, subject to adjustments upon changes in capitalization of the Company as provided in Section 18 hereof, the maximum number of Shares which shall be made available for sale under the Plan shall automatically increase on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2021, and continuing until (and including) the fiscal year ending December 31, 2030, with such annual increase equal to the lesser of (i) 687,218 Shares, (ii) 1% of the number of Shares issued and outstanding on December 31 of the immediately preceding fiscal year, and (iii) an amount determined by the Board. If, on a given Exercise Date, the number of Shares with respect to which Options are to be exercised exceeds the number of Shares then available under the Plan, the Committee shall make a pro rata allocation of the Shares remaining available for purchase in as uniform a manner as shall be practicable and as it shall determine to be equitable.

(c) A Participant shall have no interest or voting right in Shares covered by his or her Option until such Option has been exercised and the Participant has become a holder of record of Shares acquired pursuant to such exercise.

16. Designation of Beneficiary. The Committee may permit Participants to designate beneficiaries to receive any Purchased Shares or payroll deductions, if any, in the Participant's accounts under the Plan in the event of such Participant's death. Beneficiary designations shall be made in accordance with procedures prescribed by the Committee. If no properly designated beneficiary survives the Participant, the Purchased Shares and payroll deductions, if any, will be distributed to the Participant's estate.

17. Assignability of Options. Neither payroll deductions or other contributions credited to a Participant's Purchase Account nor any rights with regard to the exercise of an Option or to receive Shares under the Plan may be assigned, transferred, pledged or otherwise disposed of in any way (other than by will, the laws of descent and distribution or as provided in Section 16 hereof) by the Participant; provided that the Shares acquired pursuant to the terms of the Cashless Participation Program may be pledged and sold pursuant to the terms of the Cashless Participation Program. Any such attempt at assignment, transfer, pledge or other disposition shall be without effect, except that the Company may treat such act as an election to withdraw from an Offering Period in accordance with Section 12 hereof.

18. Adjustment of Number of Shares Subject to Options.

(a) Adjustment. Subject to any required action by the stockholders of the Company, the maximum number of securities available for purchase under the Plan, as well as the price per security and the number of securities covered by each Option under the Plan which has not yet been exercised shall be appropriately adjusted in the event of any a stock split, reverse stock split, stock dividend, combination or reclassification of the common stock of the Company, or any other increase or decrease in the number of Shares effected without receipt of consideration by the Company; provided, however, that conversion of any convertible securities of the Company shall not be deemed to have been "effected without receipt of consideration." Such adjustment shall be made by the Board or the Committee, whose determination in that respect shall be final, binding and conclusive. If any such adjustment would result in a fractional security being available under the Plan, such fractional security shall be disregarded. Except as expressly provided herein, no issuance by the Company of shares of stock of any class, or securities convertible into shares of stock of any class, shall affect, and no adjustment by reason thereof shall be made with respect to, the number or price of Shares subject to an Option. With respect to the 423 Component, the Options granted pursuant to the Plan shall not be adjusted in a manner that causes the Options to fail to qualify as options issued pursuant to an "employee stock purchase plan" within the meaning of Section 423 of the Code.

(b) Dissolution or Liquidation. In the event of the proposed dissolution or liquidation of the Company, any Offering Period then in progress will terminate immediately prior to the consummation of such proposed action, unless otherwise provided by the Board, and the Board may either provide for the purchase of Shares as of the date on which such Offering Period terminates or return to each Participant the payroll deductions credited to such Participant's Purchase Account.

(c) Merger or Asset Sale. In the event of a proposed sale of all or substantially all of the assets of the Company, or the merger of the Company with or into another corporation, each outstanding Option shall be assumed or an equivalent option substituted by the successor corporation or a parent or subsidiary of the successor corporation, unless the Board determines, in the exercise of its sole discretion, that in lieu of such assumption or substitution to either terminate all outstanding Options and return to each Participant the payroll deductions credited to such Participant's Purchase Account or to provide for the Offering Period in progress to end on a date prior to the consummation of such sale or merger.

19. Amendments or Termination of the Plan.

(a) The Board or the Committee may at any time and for any reason amend, modify, suspend, discontinue or terminate the Plan without notice; provided that no Participant's existing rights in respect of existing Options are adversely affected thereby. To the extent necessary to comply with Section 423 of the Code (or any other applicable law, regulation or stock exchange rule), the Company shall obtain stockholder approval in such a manner and to such a degree as required.

(b) Without stockholder consent and without regard to whether any Participant rights may be considered to have been "adversely affected," the Board or the Committee shall be entitled to change the Purchase Price, Offering Periods, Purchase Periods, eligibility requirements, limit or increase the frequency and/or number of changes in the amount withheld during a Purchase Period, establish the exchange ratio applicable to amounts withheld in a currency other than U.S. dollars, permit payroll withholding or other contributions in an amount less than or greater than the amount designated by a Participant in order to adjust for delays or mistakes in the Company's processing of properly completed withholding elections, establish reasonable waiting and adjustment periods and/or accounting and crediting procedures to ensure that amounts applied toward the purchase of Shares for each Participant properly correspond with amounts withheld from the Participant's Compensation, and establish such other limitations or procedures as the Board or the Committee determines in its sole discretion advisable which are consistent with the Plan; provided, however, that changes to (i) the Purchase Price, (ii) the Offering Period, (iii) the Purchase Period, (iv) the maximum percentage of Compensation that may be deducted pursuant to Section 6(a) or (v) the maximum number of Shares that may be purchased in a Purchase Period, shall not be effective until communicated to Participants in a reasonable manner, with the determination of such reasonable manner in the sole discretion of the Board or the Committee.

20.No Other Obligations. The receipt of an Option pursuant to the Plan shall impose no obligation upon the Participant to purchase any Shares covered by such Option. Nor shall the granting of an Option pursuant to the Plan constitute an agreement or an understanding, express or implied, on the part of the Company to employ the Participant for any specified period.

21.Notices and Communication. Any notice or other form of communication which the Company or a Participant may be required or permitted to give to the other shall be provided through such means as designated by the Committee, including but not limited to any paper or electronic method.

22.Condition upon Issuance of Shares.

(a) Shares shall not be issued with respect to an Option unless the exercise of such Option and the issuance and delivery of such Shares pursuant thereto shall comply with all applicable provisions of law, domestic or foreign, including, without limitation, the 1933 Act and the 1934 Act and the rules and regulations promulgated thereunder, and the requirements of any stock exchange upon which the Shares may then be listed, and shall be further subject to the approval of counsel for the Company with respect to such compliance.

(b) As a condition to the exercise of an Option, the Company may require the person exercising such Option to represent and warrant at the time of any such exercise that the Shares are being purchased only for investment and without any present intention to sell or distribute such Shares if, in the opinion of counsel for the Company, such a representation is required by any of the aforementioned applicable provisions of law.

23.General Compliance. The Plan will be administered and Options will be exercised in compliance with the 1933 Act, 1934 Act and all other applicable securities laws and Company policies, including without limitation, any insider trading policy of the Company.

24.Term of the Plan. The Plan shall become effective upon the earlier to occur of (i) its adoption by the Board and (ii) its approval by the stockholders of the Company (the earlier of such events, the "Effective Date"), and shall continue in effect until the earlier of (A) the termination of the Plan pursuant to Section 19 hereof and (B) the ten-year anniversary of the Effective Date, with no new Offering Periods commencing on or after such ten-year anniversary.

25.Governing Law. The Plan and all Options granted hereunder shall be construed in accordance with and governed by the laws of the State of Delaware without reference to choice of law principles and subject in all cases to the Code and the regulations thereunder.

26.Non-U.S. Participants. To the extent permitted under Section 423 of the Code, without the amendment of the Plan, the Company may provide for the participation in the Plan by Employees who are subject to the laws of foreign countries or jurisdictions on such terms and conditions different from those specified in the Plan as may in the judgment of the Company be necessary or desirable to foster and promote achievement of the purposes of the Plan and, in furtherance of such purposes the Company may make such modifications, amendments, procedures, subplans and the like as may be necessary or advisable to comply with provisions of laws of other countries or jurisdictions in which the Company or the Participating Subsidiaries operate or have employees. Each subplan shall constitute a separate "offering" under this Plan in accordance with Treas. Reg. §1.423-2(a) and, to the extent inconsistent with the requirements of Section 423, any such subplan shall be considered part of the Non-423 Component, and rights granted thereunder shall not be required by the terms of the Plan to comply with Section 423 of the Code.

27.Section 409A. The 423 Component is exempt from the application of Section 409A of the Code, and any ambiguities herein shall be interpreted to so be exempt from Section 409A of the Code. The Non-423 Component is intended to be exempt from the application of Section 409A of the Code under the short-term deferral exception and any ambiguities shall be construed and interpreted in accordance with such intent. In furtherance of the foregoing and notwithstanding any provision in the Plan to the contrary, if the Committee determines that an option granted under the Plan may be subject to Section 409A of the Code or that any provision in the Plan would cause an option under the Plan to be subject to Section 409A, the Committee may amend the terms of the Plan and/or of an outstanding option granted under the Plan, or take such other action the Committee determines is necessary or appropriate, in each case, without the participant's consent, to exempt any outstanding option or future option that may be granted under the Plan from or to allow any such options to comply with Section 409A of the Code, but only to the extent any such amendments or action by the Committee would not violate Section 409A of the Code. Notwithstanding the foregoing, the Company shall have no liability to a participant or any other party if the option under the Plan that is intended to be exempt from or compliant with Section 409A of the Code is not so exempt or compliant or for any action taken by the Committee with respect thereto.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statement (No. 333-248903) on Form S-8 of our report dated February 23, 2022, 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 23, 2022

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 23, 2022

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 23, 2022

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, 2021, 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 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 the Company.

Date: February 23, 2022 By: /s/ Leslie Trigg
Leslie Trigg
Chief Executive Officer
(*Principal Executive Officer*)

Date: February 23, 2022 By: /s/ Nabeel Ahmed
Nabeel Ahmed
Chief Financial Officer
(*Principal Financial Officer*)