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, 2020

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 ☒

The registrant was not a public company as of June 30, 2020, the last business day of its most recently completed second fiscal quarter and therefore, cannot calculate the aggregate market value of its voting and non-voting common equity held by non-affiliates as of such date. The registrant's common stock began trading on The Nasdaq Global Select Market on September 15, 2020.

The number of shares of the registrant's common stock, par value $0.001 per share, outstanding as of March 15, 2021 was 42,805,772.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2021 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, 2020, 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 regarding our revenues, cost of revenues, operating expenses (including as a percentage of revenue), gross margin and our ability to achieve and maintain future profitability;
- our business strategy;
- plans and objectives of management for future operations;
- our growth strategies, including our ability to implement such strategies, and our beliefs about the anticipated impacts of such strategies 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 COVID-19 pandemic on our business and results of operations;
- our intent to explore opportunities for international expansion;
- planned initiatives designed to reduce the cost of producing Tablo devices and our ability to achieve projected cost reductions at the levels or within the timeframe we estimate;
- 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 rapidly growing medical technology company pioneering a first-of-its-kind technology to reduce the cost and complexity of dialysis. We believe Tablo represents a significant technological advancement enabling novel, transformational dialysis care in acute and home settings. 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 anyone.

Our technology is designed to elevate the dialysis experience for patients, and help providers overcome traditional care delivery challenges. Our relentless 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 enables Tablo to serve as a dialysis clinic on wheels and allows providers to standardize to a single platform from the hospital to the home. Tablo is also intelligent and connected, with automated documentation and the ability to integrate with electronic medical record reporting, along with streamlined remote machine management to maximize 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 United States Food and Drug Administration (FDA) for use in the hospital, clinic or home setting.

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 annual spending on dialysis in the United States is approximately $74 billion of which an estimated $44 billion is Medicare spending. Kidney failure affects a large and growing number of individuals; we estimate kidney failure affected approximately 810,000 people in the United States alone in 2020. 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. 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). Approximately 40% of ESRD patients begin their dialysis journey in a chronic setting, either in a dialysis clinic or at home, and approximately 60% of dialysis patients “crash” into dialysis, meaning they have little to no clinical care in advance.

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.

In 2017, Medicare spending on dialysis accounted for 7% of the total Medicare budget despite ESRD patients only representing 1% of the Medicare population. Dialysis is performed in the acute care setting, which includes hospitals and sub-acute facilities, outpatient dialysis clinics or the patient’s home based on the patient’s condition and preference.

To date, we have focused primarily on the acute care setting, which we estimate represents a total addressable market opportunity for Tablo of approximately $2.2 billion. We are expanding our focus to the home setting, which we estimate represents a total addressable market opportunity of approximately $8.9 billion. 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 grow 30% over the next ten years, thereby increasing our opportunity across both settings. 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. 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. The majority of ESRD patients are treated in outpatient facilities. However, recently, several factors including the COVID-19 pandemic, changing patient preferences, government initiatives, and reimbursement changes are supporting a long-anticipated shift toward home dialysis. We believe the benefits of our Tablo system are well positioned to address the shortcomings in the acute market and to help accelerate this shift to home-based hemodialysis therapy.

Traditional hemodialysis machines are burdensome to use and require connection to an industrial water treatment room to operate. In settings where large water treatment rooms are unavailable, as is often the case in hospitals, traditional machines must be connected to an additional piece of equipment that purifies water for dialysis and feeds it into the hemodialysis machine. Because the design of traditional dialysis machines has changed little in the last 30 years, the set-up and management process is mostly manual, and is burdensome for users to master.

Dialysis machines available in the home also have seen minimal innovation. Most patients using the incumbent home machine are required to spend 16 to 24 hours per week manually making dialysate in advance of their treatments using a separate machine. In addition, patients are required to dialyze more frequently than they do in dialysis clinics due to limitations with the incumbent device. Lastly, set-up and take-down are manual, requiring users to memorize dozens of steps, making training difficult and lengthy.

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 anyone. Tablo is comprised of a compact console with integrated water purification, on-demand dialysate production and a simple-to-use touchscreen interface. With Tablo, we are bringing data to dialysis. Tablo is built to live in a connected setting with cloud-based system monitoring, patient analytics, remote treatment monitoring and clinical recordkeeping and the ability to activate new capabilities and enhancements through wireless software updates. Tablo's data analytics and connectivity also enable predictive preventative maintenance to maximize machine uptime. Unlike existing hemodialysis machines, which have limited clinical versatility across care settings and are generally burdened by specialized and expensive infrastructure, Tablo is a single enterprise solution that can be seamlessly utilized across different care settings and for multiple clinical needs.

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

- Simplicity. Tablo's intuitive touchscreen interface makes it easy to learn and easy to use, guiding users through treatment from start to finish using step-by-step instructions with simple words and animation. 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 resolve 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 five minutes. Tablo's simplicity can also reduce the training time required to operate the machine by roughly two thirds compared to traditional machines.

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

- Operational Versatility. Tablo is an all-in-one device with integrated water purification and on-demand dialysate production, eliminating the need for the industrial water treatment rooms required to operate traditional dialysis 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 have 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 and simplifies compliance and record-keeping requirements. Tablo's connectivity also streamlines machine management and maintenance and allows for feature enhancements through remote software updates.

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 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 patients with acute and/or chronic renal failure in September 2014. Subsequently, on March 31, 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. Patients in the trial 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 will also be collecting additional patient clinical experience and outcomes data.

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

What Sets Us Apart

At Outset, we are reimagining the future of dialysis. Our culture of innovation and design permeates all aspects of our organization and informs our approach to transforming the experience of dialysis. We are focused on changing a historically stagnant space, driving widespread adoption of our new technology, and delivering on the promise of improved experience for patients while also creating cost-reducing value for healthcare providers. We believe the following strengths set us apart:

First-of-its kind enterprise dialysis solution, offering significant advantages over traditional machines. Tablo is the first and only fully integrated hemodialysis system that can be used to deliver treatment across all care settings from the ICU to home. Tablo provides real time water purification and dialysate production, eliminating the need for industrial water treatment rooms. Tablo simplifies training and operation using advanced software, sensor technology and a consumer-friendly touchscreen design, enabling ease of use. Tablo is clinically versatile, allowing clinicians to prescribe treatments for everything from high acuity ICU patients to routine at home care. Tablo is compact and mobile, enabling use in confined environments such as ICUs and living rooms.

Tablo’s unique features offer a compelling value proposition across both acute and home care settings.

We believe Tablo offers the following advantages in the acute care setting:

- Increases hospital operating margins by lowering the overall cost of dialysis-related supplies, infrastructure and labor by up to 80% in the ICU.
- Reduces the average supplies cost associated with ICU dialysis treatments from approximately $300 per treatment to below $100.
- Reduces reliance on specialized dialysis staff.
- Increases productivity by shortening turnaround times and multi-system remote monitoring.
- Enables hospitals to take dialysis back in-house, which including supplies cost reduction, reduces the total cost per treatment by $300 to $500.
- Reduces operational complexity by eliminating the need for multiple dialysis machines and streamlining documentation and compliance.
- Standardizing reduces the need to maintain clinical staff competency on multiple machines.
- Eliminates the need for specialized infrastructure, easing operational workflow and enhancing productivity and staffing flexibility.
- Automated treatment documentation and fleet management and maintenance.

We believe Tablo offers the following advantages in the home setting:

- Improves provider home dialysis economics.
- Offers flexible treatment frequency that can be aligned with payor reimbursement policies as medically appropriate.
- Reduces home program staffing costs by reducing total training time and providing a novel learning curriculum that is largely patient-managed.
- Enables providers to cost efficiently build TCUs in previously inaccessible locations since specialized infrastructure, such as water treatment facilities, are no longer needed.
- Improves the accessibility and sustainability of home dialysis for patients.
- Increases patient adoption through a shorter, less burdensome training process.
- Enables longer retention and higher treatment compliance by giving patients the option of flexible treatment frequency and less burdensome setup and management.
- Reduces patients' symptoms during treatment and offers quality of life improvements.

Our early investment in software, data science and machine learning. We have constructed a powerful two-way wireless data ecosystem around Tablo that delivers significant value to our healthcare customers while enabling us to efficiently scale the company itself. We have highly experienced software, data science and machine learning engineers who deliver cutting-edge solutions.

Tablo Data Ecosystem 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 emergency medical record (EMR) integration.

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.

Dialysis is a large recession-proof market, supporting our recurring therapy revenue model. Dialysis is a highly predictable life-sustaining therapy with established reimbursement. Dialysis patients must receive dialysis at least three times per week, 52 weeks per year. We have high visibility into the utilization and maintenance of each Tablo unit. Additionally, customers purchase an annual service agreement, which also provides an associated recurring revenue stream.

Our sales organization advantages us in executing our strategy. Our commercial leadership team has experience scaling high growth medical technology companies. We believe the profile and strong track record of our capital and clinical sales teams set

us apart from other dialysis equipment manufacturers, with specific skills and competencies to drive Tablo adoption top-down through C-suite buy-in and bottom-up through clinical staff support, respectively.

An invention mindset that permeates our design and execution. Within Outset, we take a crowd-sourcing approach to problem-solving in order to leverage our diversity of thinking and collective creativity. This invention mindset informs one of our core competencies—hardware and software design. We believe in the power of a single hardware platform with software used to fuel continuous upgrades and improvements. We believe in the power of an integrated data lake that allows us to translate clinical and machine learning data points into insights and efficiencies. We believe in "surprise and delight" design that elevates a medical therapy into a consumer experience. Our research and development (R&D) team's differentiated power is rooted in empathy and urgency, which we will continue to harness for rapid, meaningful device improvements that over-deliver on our brand promise.

Growth Strategies

We intend to continue building a high growth business that is sustainable, predictable and profitable over time. In order to achieve this goal, we plan to employ the following strategies:

Further penetrate the acute care market through new customer acquisition and current customer fleet expansion. There are two important elements to our acute care commercial strategy:

1) *Broaden our installed base*. We plan to continue targeting Integrated Delivery Networks (IDNs) and health systems, the Veteran Affairs (VA) and sub-acute long-term acute care hospital (LTACH) and skilled nursing facility (SNF) providers. Our sales team drives adoption network wide, which we believe accelerates sales cycle times and expansion speed. We have grown our regional accounts team as well as the size of our national capital sales team.

2) *Drive utilization with existing customers*. We believe increased device utilization leads to Tablo fleet expansion with existing customers. We deploy two approaches to increasing device utilization: a) ensuring an exceptional user experience delivered through our commercial team, and b) steadily releasing software product enhancements that amplify Tablo's operational simplicity and clinical versatility.

Expand within the home dialysis market with a two-pronged approach to long-term scalable growth. We are partnering with health systems and innovative dialysis clinic providers who are motivated to grow their home hemodialysis population, and who share our vision for offering patients a materially easier and more convenient path home. We believe our early growth will be driven by patients already receiving home hemodialysis who will switch to Tablo and by patients who have desired a home solution but were previously deterred by the complicated process. We will also invest in market development over the longer term to expand the home hemodialysis market itself. These strategies will include ongoing economic and patient experience evidence development, governmental policy activities, and, over time, direct to patient communication.

Leverage the emergence of transitional care units to expand the market for home and the demand for Tablo. Located within existing healthcare facilities, such as hospitals or clinics, or built as stand-alone centers, TCUs are specifically designed to transition patients to home dialysis. Tablo is uniquely suited for use in small-footprint TCUs because it does not require industrial water treatment rooms to operate. Tablo's flexibility enables patients to transition home on the same device as used in the TCU.

In a TCU program, patients learn Tablo by setting up and managing their own treatments with staff available to assist as needed. Once home, patients can return back to the TCU periodically for "respite" dialysis on Tablo. By offering this service, the TCU functions as a bi-directional bridge aimed at increasing home dialysis adoption and retention. Providers have reported a 50% home adoption rate among patients in a TCU setting compared to a 15% home adoption rate in a traditional dialysis clinic environment. We believe the use of TCUs will grow amongst health systems that want to manage ESRD patients from the inpatient setting all the way to home, and amongst dialysis clinic providers looking to expand their home dialysis population. We believe the use of TCUs will grow, serving both to increase Tablo's market share and enlarge the size of the home dialysis market itself.

Maintain and widen our technology lead over competitors. We intend to capitalize on two of our key strengths—an invention mindset, and rapid product development cycles—in order to continuously deliver new product enhancements to patients, providers and clinicians. Our product enhancements will focus on (1) simplicity and ease of use, (2) operational cost reduction, and (3) clinical versatility. We will continue to leverage our unique ability to create many of our device improvements through software, instead of hardware, and push wireless upgrades to minimize costs and maximize customer uptime.

Drive to expand gross margins. We are executing a well-defined, three-pronged strategy designed to deliver improved profitability. First, we have moved our console manufacturing operations to Tijuana, Mexico, which we expect to lower console cost as a result of labor, overhead and supply chain efficiencies. Second, with a second-source treatment contract manufacturer onboard, also in Tijuana, Mexico, we expect to gain higher efficiency and lower materials cost. Third, 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 Market Opportunity

We estimate that annual spending on dialysis in the United States is approximately $74 billion of which an estimated $44 billion is Medicare spending. This represents 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. We estimate the total annual addressable market opportunity in the United States for Tablo is approximately $2.2 billion in the acute care setting and approximately $8.9 billion in the home setting. 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 grow 30% over the next ten years in the United States, thereby increasing our opportunity in both markets.

Acute Care

The acute care market includes short-term acute care hospitals, sub-acute LTACHs and 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 2,300 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. We estimate the acute care market to grow at an annual rate of approximately 7% over the next five years.

Home Care

At the end of 2018, there were approximately 550,000 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 2018, approximately 12.5% of patients (69,000 individuals), received dialysis treatment at home through peritoneal dialysis or home hemodialysis. From 2008-2018, the home hemodialysis patient population grew 133%, resulting in approximately 10,350 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 kidney disease 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. We estimate that the number of patients with ESRD in

the United States in 2020 was approximately 810,000, of which, approximately 560,000 were treated with dialysis and the remainder of whom received a transplant by the end of 2020. The total ESRD figure is approximately 40% higher than the number reported ten years prior.

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 300,000 cases of acute kidney failure 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 will 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 2017, only 21,000 transplant procedures were performed in the United States compared to a total ESRD patient population of over 520,000. 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 2019 Annual Report indicates 33.4% 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. 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 2,300 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. 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 2017, approximately 12% of ESRD dialysis patients in the United States were dialyzing at home, with home hemodialysis patients representing 2% and peritoneal dialysis patients representing 10%. 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 all 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.

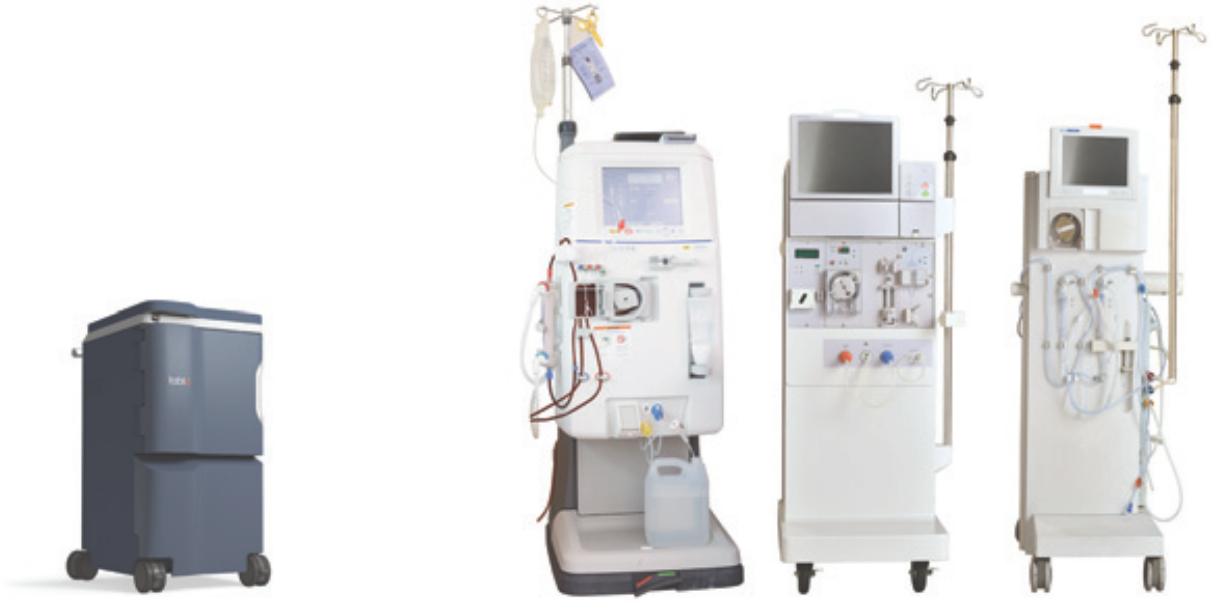
- Cumbersome setup and burdensome treatment frequency. The incumbent home dialysis machine is limited in its ability to sufficiently remove toxins, which as a result typically requires up to six treatments per week. The requirement of increased treatment frequency intensifies the burden placed on the 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 Machine.



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 anyone. Unlike traditional hemodialysis machines, Tablo offers a single, enterprise solution that 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:

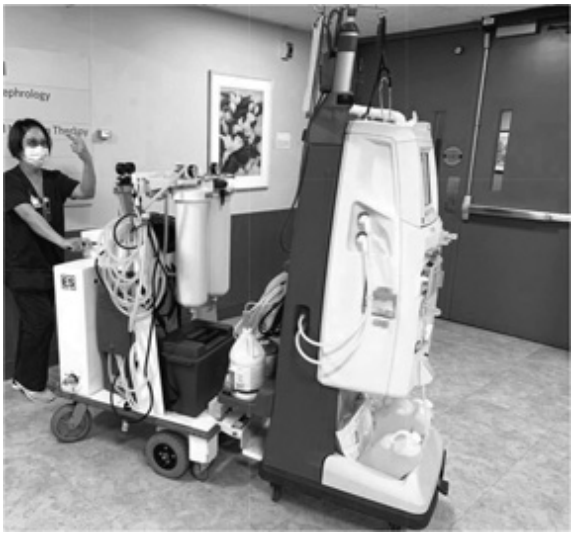
- Tablo Console. A compact, mobile and versatile machine consisting of an integrated water purification, on-demand dialysate production system and simple-to-use touchscreen interface. Using advanced sensors, the console automates much of treatment setup and management and can automatically self-diagnose 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 for streamlined set up times to as little as 20 minutes. The Tablo cartridge was designed to simplify and streamline treatment setup to minimize the potential for user error.

- Tablo Connectivity and 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.

Traditional Hemodialysis Machine with Water Filtration Equipment vs Tablo Console.

Traditional Hemodialysis Machine with Water Filtration Equipment



Tablo Console

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 touchscreen interface makes it easy to learn and easy to use, guiding users through treatment from start to finish using step-by-step instructions with simple words and animation. 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 five 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 all 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 all care settings. In addition, patients have reported clinical and quality of life benefits on Tablo compared to other dialysis machines.

Tablo integrates seamlessly in both the ICU setting and home environment.

Tablo in the hospital

Tablo in the home

In the acute care market, Tablo simplifies dialysis management and improves operating margins for health providers by lowering the overall cost of dialysis-related supplies, infrastructure and labor. Tablo has shown the ability to reduce ongoing supply costs by up to 80% in the ICU as well as delivering on the following operational improvements:

- 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.
- Enabling less expensive labor models, for example the insourcing of dialysis service using existing hospital nursing staff and eliminating expensive, fixed dialysis outsourcing contracts.
- Eliminating the need for pre-filled bagged dialysate, thereby lowering supplies cost in the ICU.
- 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:

Improved provider home dialysis economics

- 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.
- Helping increase patient compliance and reducing patient burnout.
- Enabling remote machine maintenance, troubleshooting and software updating.
- Providing differentiated marketing for the clinic to drive increased patient volumes.

Improved accessibility and sustainability of home dialysis for patients

- Giving patients back their time by:
    - Reducing training time through ease-of-use and intuitive design, requiring significantly less time than traditional home hemodialysis machines.
    - Reducing preparation and set up time by eliminating the need to batch and prepare dialysate, which typically takes 16 to 24 hours per week.
    - Reducing the required number of weekly treatments from up to six to as few as three.
    - Connecting the patient to his or her clinic care team through automated flow of treatment documentation.
    - Improved treatment experience with fewer headaches, increased energy, less cramping, and a quieter more relaxed *experience contributing to* improved *quality of life.*

"I want my loved ones to know that I'm going to be OK. I have trust in Tablo, it's convenient. And Tablo will allow me to spend more time with my family."
-Patient training to go home with Tablo

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.

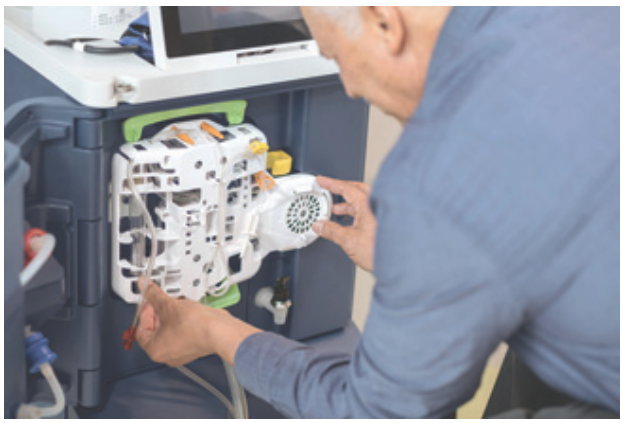
The Tablo Hemodialysis System.

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, a drain, 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.

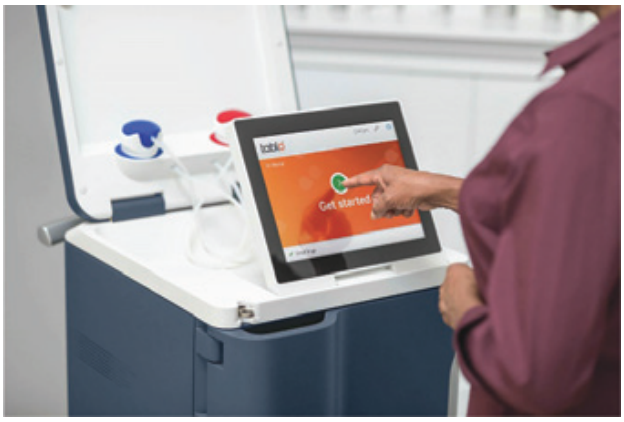
The Tablo cartridge consists of a user-friendly pre-configured blood, saline, and infusion tubing. The Tablo cartridge requires only two connections to operate as compared to other machines that require stringing, hanging, snapping and tapping multiple lines. Our proprietary cartridge clicks into place and features color-coded, easy-to-follow connections, allowing users to setup the treatment supplies in less than five minutes. In our home investigational device exemption (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.

The Tablo cartridge snaps onto the Tablo console before dialysis treatment.



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 touch screen panel guides the user through the treatment with animations and non-technical language, tailored to 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.

Tablo's intuitive touchscreen makes the entire treatment process simple to navigate.



During treatment, should any issues arise, Tablo's touch screen 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. From a home use standpoint, Tablo was intentionally designed 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 36-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 touch screen to adjust the flow rate if they feel the onset of cramping.

Tablo is Connected and Intelligent

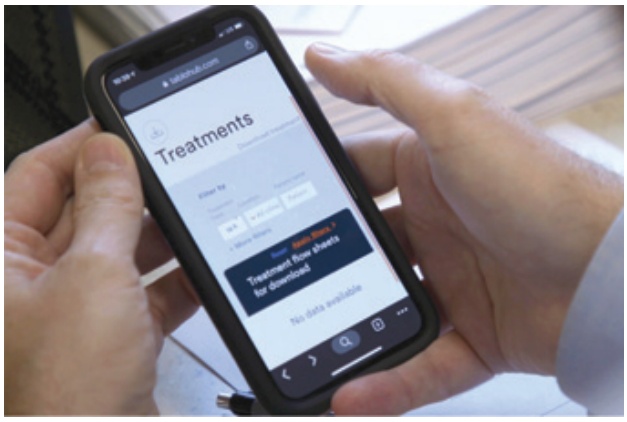
Tablo's cloud connectivity and intelligent software enable an ecosystem of machine diagnostics and analytics, treatment instruction, monitoring and reporting, improved documentation and remote machine management. With two-way data transmission capabilities, treatment and machine data is continuously uploaded to the cloud and analyzed, informing software improvements to optimize performance, reliability and ease of use. Our ability to push software updates ensures that patients and providers have access to the latest optimizations without the need to replace existing hardware. Over the last two years, we have enabled new features on Tablo, such as the ability to do isolated ultrafiltration treatments and extend treatment duration up to 24 hours, all through software upgrades. In addition, we have designed a cloud-based data platform, Tablo Cloud, that allows us to assess and manage Tablo units remotely while also providing our customers with automated documentation of records related to treatments, machine disinfect and service logs, and online machine training.

Tablo Cloud powers two key platforms that we use for machine management and which our providers and patients use for critical treatment and reporting information.

Tablo Hub

Tablo Hub is a customer-facing platform that provides immediate, cloud-based access to critical treatment and machine information, strengthening patient care and simplifying billing and compliance related reporting. Through Tablo Hub, providers are able to access and download treatment records, see system disinfection and service records, as well as access documentation and training materials on Tablo, all from a phone, tablet or web-browser. We also have the ability to integrate these records with provider EMRs, either through discrete data integration or downloadable PDFs. Our automated medical record reporting process is designed to improve provider operating efficiency associated with documentation and reduce the compliance risk associated with poor record-keeping during quality audits. We believe Tablo is the only hemodialysis system with two-way wireless transmission delivering data in a manner intended to be compliant with the federal Health Insurance Portability and Accountability Act (HIPAA) to the provider without any need for additional equipment. This frees patients from the need to manually document treatment data by hand or on a separate tablet and ensures higher data accuracy.

Tablo Hub provides immediate access to treatment and machine information.



Tablo Dash

Tablo Dash is used internally by Outset to improve efficiency of our service model and maximize machine uptime by enabling cloud-based machine management, real-time performance analytics and diagnostics. During each treatment, Tablo's sensors capture over 500,000 data points on the inner workings of the system. If there is an issue with Tablo, our technical support team is able to remotely diagnose the alarm in real-time, and if it is necessary to dispatch a service engineer, we ensure they arrive with the right part to complete the repair. This capability increases the efficiency of our service model by reducing unnecessary field service visits and reducing the time spent on site conducting the repair. In addition, our machine learning capabilities and analytics enable us to predict and identify potential Tablo component failures before they occur, allowing failures to be fixed before they happen and focusing internal R&D efforts on reliability improvements, further improving system uptime.

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.

Patient Experience with Tablo

Tablo is Safe and Effective for Home Hemodialysis

We conducted an IDE trial to evaluate the safety and efficacy of Tablo when used in-center, managed by trained health professionals, and in-home, by trained patients or a care partner. The IDE trial was a prospective, multicenter, open-label crossover trial comparing in-center and home hemodialysis performance using the Tablo System. This trial consisted of 30 patients ranging from 26 to 71 years of age, of which 43% were African American and 27% were Hispanic or Latino. Many of the patients had a history of a number of co-morbidities representative of the typical ESRD patient with 96% having hypertension, 60% having diabetes and 40% having coronary artery disease. Participants remained in the trial for approximately 21 weeks, during which time they were prescribed hemodialysis with Tablo four times per week. The primary efficacy endpoint was achievement of a weekly standard Kt/Vurea greater than or equal to 2.1 for participants during the treatment period. The primary safety endpoint was the number of adverse events observed during a dialysis interval. The secondary efficacy endpoints were the achieved ultrafiltration (UF) volume and rate relative to the prescribed UF volume and rate.

Successful delivery of UF was defined as having achieved an UF rate within 10% of the prescribed value during each treatment period.

The IDE study achieved the primary endpoint and all secondary efficacy and safety endpoints for patients treated in-center and in-home using the Tablo System. The primary efficacy endpoint for the intention-to-treat cohort was achieved in 199/200 (99.5%) of measurements during the in-center period and in 168/171 (98.3%) of measurements during the in-home period. The average weekly standard Kt/Vurea was 2.8 in both periods, the compliance to the protocol treatment schedule was over 95%, achieved UF was within

10% of target in 94% of treatments, and the median time to resolution of alarms was eight seconds in-center and five seconds in-home. Two pre-specified adverse events occurred during the in-center period and six occurred in the in-home period. None of the adverse events were deemed by investigators to be related to Tablo.

The study demonstrates that Tablo can successfully be learned and used in the home in a diverse cohort of patients, including by older patients and patients with considerable comorbidities. In the IDE study, patients demonstrated the ability to achieve proficiency on Tablo (i.e., an ability to perform all set-up steps) within four training sessions. The modest duration of the transition period also confirms and extends previously published human factors studies wherein nurses and patients could learn how to use Tablo, and independently, accurately, and rapidly set up the system. We considered the rapid resolution of alarms in the clinic by staff and in the home by patients or their care partners to be a good indicator of the ease of use of the system. These data confirm and substantially extend previously published results, highlighting Tablo as a novel hemodialysis system with the potential to expand the usage of in-center self-care and home-based hemodialysis.

Tablo achieved all primary and secondary efficacy and safety endpoints both in-center and in-home.

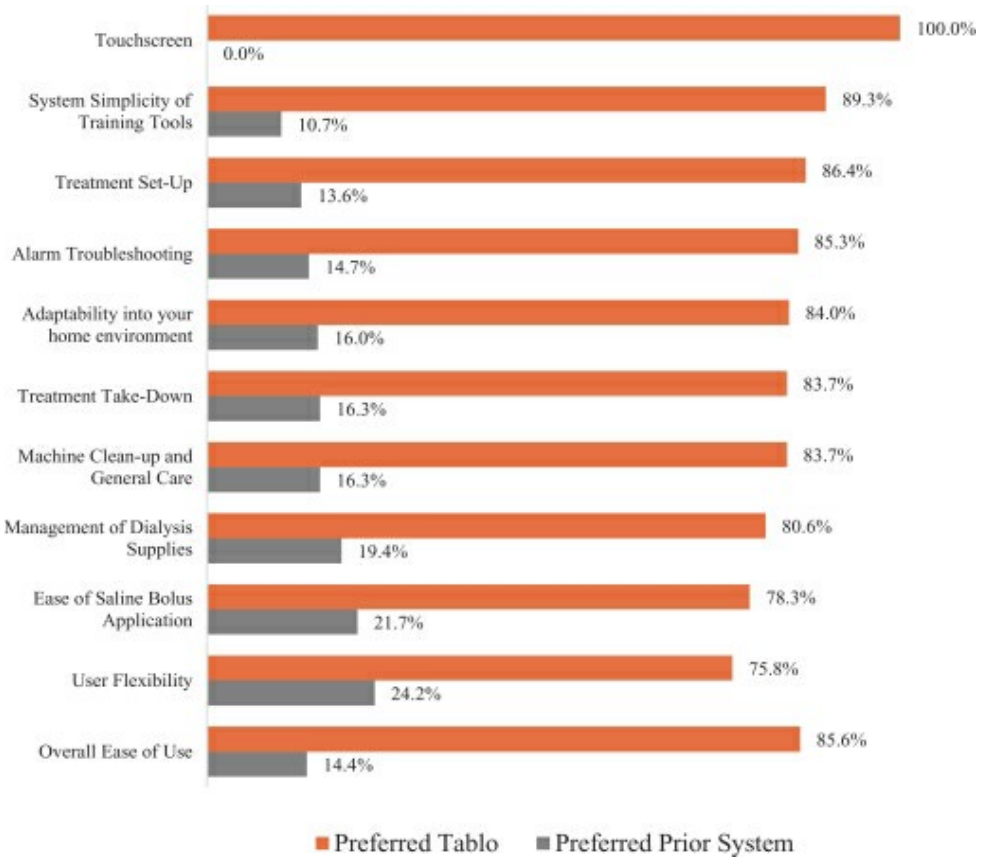
Parameter	**In-Center**	**In-Home**
Primary Efficacy Endpoint	99.5%	98.3%
Average Weekly Standard Kt/Vurea	2.8	2.8
Compliance to Protocol Treatment Schedule	>95%	>95%
Achieved UF	Within 10% of target in 94% of treatments	Within 10% of target in 94% of treatments
Median Time to Resolution of Alarms	8 seconds	5 seconds

Tablo Preferred by Previous Home Patients in the IDE

We conducted a study to assess actual patient experiences with our solution and demonstrated that patients could quickly set up Tablo for in-center self-care hemodialysis. The study was designed to measure the time required for patients to set up the disposable components of the system that are required to initiate treatment. We also recorded the type, frequency, and time required for the user to clear any alarms. The study included 50 participants using Tablo who were treated across four dialysis units, with a total of 733 dialysis treatments monitored for the type and frequency of potential alarms. The study resulted in 18/20 (90%) of patients able to set up the disposables needed to initiate therapy in less than 5 minutes.

We believe that Tablo's patient centric design and intuitive user interface make it a preferred solution for home hemodialysis relative to traditional machines. In order to assess patient device preferences for home hemodialysis, we surveyed 13 patients participating in our home IDE trial who had previously undertaken home hemodialysis using non-Tablo dialysis machines. The patients were surveyed every week during the 8-week home period about their device preferences based on 10 distinct aspects of treatment and overall ease of use. Per the survey results, 100% of the patients preferred Tablo's touchscreen interface compared to their previous home device and 86% of patients found Tablo easier to use. As shown in the figure below, the majority of participants preferred Tablo across each dimension measured.

Patient preference results – Tablo vs prior home system (n=13).



Home Hemodialysis with Tablo Improves Sleep Related Symptoms of ESRD

Poor sleep quality is a common symptom among patients with ESRD. We evaluated a subset of patients enrolled in our IDE trial to evaluate the sleep quality of patients using Tablo for dialysis treatment four times per week. Sleep quality was measured via a weekly questionnaire during the trial to determine how many days per week participants experienced difficulty falling asleep, staying asleep, or trouble feeling rested. Thirteen patients who previously received in-home hemodialysis (PIH) and 15 patients who previously received in-center dialysis treatment (PIC) completed all phases of the trial, and 98.7% (221/224) of all weekly surveys were completed. As outlined in the figure below, a lower percentage of study participants receiving dialysis treatment on Tablo, four times per week for approximately 21 weeks, reported incidence of sleep-related problems compared to the percentage of participants at baseline.

A lower percentage of study participants on Tablo reported incidence of sleep-related problems as compared to baseline

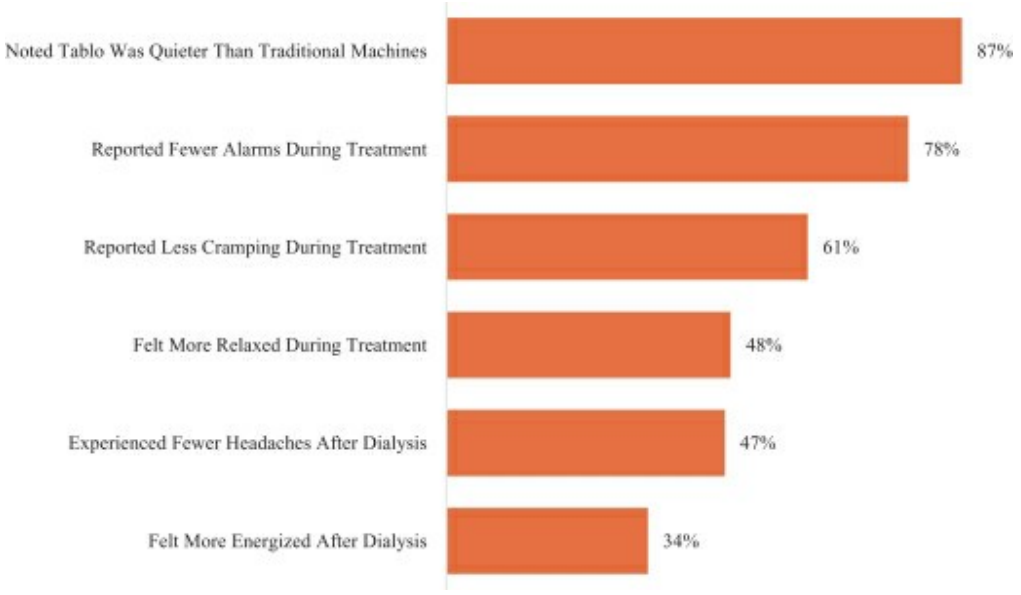
Sleep Question	**Baseline (%)**		**In-Home (%)**	
	PIH (N=13)	PIC (N=15)	PIH (N=13)	PIC (N=15)
Have trouble falling asleep	23.1	33.3	14.0	20.7
Wake up several times during the night	38.5	33.3	24.0	21.5
Have trouble staying asleep	38.5	33.3	17.0	27.3
Wake up feeling tired and worn out	30.8	26.7	17.0	23.1

Patients Experience Fewer Symptoms Dialyzing on Tablo In-Center

We conducted a multi-center study to evaluate early patient experiences using Tablo compared to traditional hemodialysis devices. Patients on traditional in-center hemodialysis often experience a range of symptoms and disturbances during, immediately following, and between dialysis sessions. We surveyed 33 patients at three different dialysis units for a total of 152 dialysis treatments.

The surveyed patient population ranged in age from 28-80 years and had been on dialysis for eight months to over 20 years. 47% of the patients experienced fewer headaches and 61% reported less cramping during dialysis using Tablo. During treatment with Tablo and compared to other dialysis machines, 78% of patients reported fewer alarms and 48% of patients felt more relaxed. 87% of surveyed participants also noted that Tablo was quieter than traditional machines.

Patient survey rendered favorable clinical experience with Tablo (n=33)



We believe when patients don't feel well during treatment, they are less likely to complete all their treatments. In a retrospective observational study, hemodialysis patients missed approximately 10% of their treatments. A single missed treatment was associated with a two-fold greater risk of death in the subsequent 30 days.

Provider Experience with Tablo

Tablo Demonstrated Comparable Performance to Traditional Dialysis Systems in the Acute Setting

In a retrospective study of dialysis patients conducted at St Francis Medical Center in Lynwood, California, we demonstrated that Tablo yielded similar clinical results for patients when compared to a traditional dialysis system in an acute care setting. Over 13 months, 105 of 289 patients dialyzed on Tablo were also treated on a Fresenius 2008T (FMC-T) machine during their hospitalization. In those 105 patients, the average treatment time on both devices was 3.3 hours per treatment, for 363 total treatments (172 treatments on Tablo and 191 treatments on FMC-T). As shown in the figure below, with equivalent treatment times and dialyzers, results were similar one day after treatment for both potassium (K) and blood urea nitrogen (BUN) on Tablo at dialysate flow rates (Qd) of 300mL/min compared to a traditional device at Qd of 500mL/min or greater.

In the acute care setting, Tablo yielded similar results to traditional systems.

Parameter	Treatments on Tablo (n=172)	Treatments on FMC-T (n=191)
Treatment Time (hrs)	3.3	3.3
K(mEq/L)		
Day of Avg	5.1	5.1
Next Day Avg	4.4	4.2
Pre-K = 5.5	39.0%	33.5%
BUN (mg/dL)		
Day of Avg	75	75
Next Day Avg	52	50

Tablo is Easy for Providers to Learn and Use

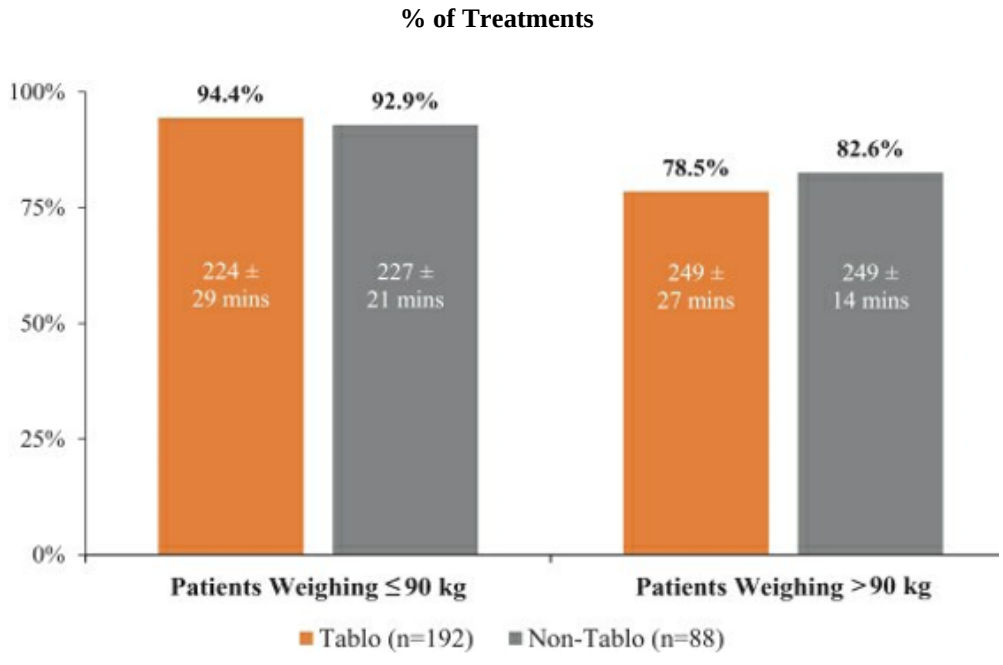
We have demonstrated that users have found Tablo easier to use than a traditional dialysis machine and that Tablo's design allows users to be quickly trained, reaching competency after only a few training sessions. We believe that Tablo's simplicity enables users to quickly and easily master preparation and treatment management, leading to high satisfaction and device preference.

In a study conducted at Baylor, the majority of nurses and medical technicians found Tablo easy to use and most nurses felt comfortable providing treatment with the system after a short training session. Nurses were also satisfied with Tablo as a treatment option and several participants reported that the Tablo console was easy to transport and took up less space in an ICU room as compared with conventional systems. Nursing satisfaction was assessed by a Likert scale questionnaire. Most nurses felt comfortable providing treatment with Tablo after a short training session (average score 4.9/5) and nurses were also satisfied with Tablo as a treatment option (average score 4.9/5).

Tablo Achieves Urea Clearance Levels Comparable to Traditional Machines

We conducted a study at two dialysis clinics and demonstrated that patients on Tablo achieved a urea clearance rate comparable to therapy using alternative dialysis machines. In the study, Kt/Vurea was measured in 29 patients dialyzed three times weekly using Tablo. 280 Kt/Vurea assessments were recorded, including 192 on Tablo and 88 on non-Tablo machines. As shown in the figure below, patients on Tablo achieved Kt/Vurea targets at a comparable rate as non-Tablo machines.

Percentages of treatments reaching the target Kt/Vurea (>=1.2) on Tablo and non-Tablo systems. Average treatment times are also shown.



Reimbursement

Acute Care

In the in-patient setting under Medicare, dialysis and UF are not directly reimbursed, but rather are paid for out of the in-patient Medicare Severity Diagnosis Related Group (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.

Outpatient Dialysis Clinic and Home

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. We sell Tablo to the dialysis providers, who in turn provide equipment and services to the patient and bill Medicare.

Medicare. While Medicare generally only provides coverage for people over 65, in the case of ESRD eligibility is not limited by age, and all ESRD patients without alternative coverage become eligible for Medicare after a three-month waiting period (unless they are training for self-care, in which case they become eligible for Medicare Day 1).

Medicare reimburses providers for dialysis services through a bundled rate per treatment that is intended to cover the cost of the machines and treatment supplies, labs, drugs, and labor. This base payment rate is adjusted up or down for each patient based on factors such as age, co- morbidities and clinic locations. The current base payment rate for calendar year 2021 is $253.13. Medicare rules limit the number of hemodialysis treatments paid for by Medicare to three a week, unless there is medical justification for the additional treatments. The determination of medical justification must be made at the local Medicare contractor level on a case-by-case basis. Providers are able to obtain incremental reimbursement for training patients for self-care, whether that be in the clinic or in a patient's home. Finally, in addition to the bundled rate, 2% of a provider's total reimbursement is at risk as part of the Quality Incentive Program. This program evaluates providers across the range of clinical, safety and patient reported outcomes.

Medicaid. Medicaid is a state level program designed to support individuals falling under a certain income and asset level and who are also uninsured. In most cases, Medicaid serves as the secondary payor for services not covered by Medicare. The specific level of this coverage, including patient co-pay amounts, varies state by state.

Private Insurance. Patients with employer group health insurance will typically remain with their commercial insurance coverage as the primary payor for a period of 30 months and with Medicare as the secondary payor. After 30 months, patients will typically move to Medicare as the primary payor and their private insurance as the secondary payor. Private insurance typically reimburses providers at a rate significantly higher than Medicare.

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 $28.9 million and $23.3 million for the years ended December 31, 2020 and 2019, 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) sustaining engineering and cost reduction initiatives that continually improve device performance and lower our cost of revenues, (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 environment for patients and providers and leveraging core elements of the Tablo platform more broadly within dialysis. We intend to continue investing significant resources to maintain and strengthen our technological competitive advantage to deliver a steady stream of inventive solutions that provide clinical and operational simplicity, versatility and insights.

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 will be 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 will be 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 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. We have also licensed patents from Oregon State University (OSU) for exclusive use in our field, as detailed further below. 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, 2020, we had seven issued U.S. patents, as well as six pending U.S. patent applications. We had an aggregate of 16 issued patents in Australia, Canada, China, France, Germany, Hong Kong, Japan, Spain and the United Kingdom, as well as six pending patent applications in Japan, the European Patent Office and under the Patent Cooperation Treaty. We have exclusive licenses from OSU to 12 U.S. patents, nine of which we co-own with OSU, and 22 foreign patents, all of which we co-own 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 July 2038. 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 connecting straws that help transport 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 recently, 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 undergo extensive in-process and integrated system testing protocols designed by us. Consoles are then transported to our headquarters in San Jose, California, where our test engineers perform final testing, and then direct-ship the consoles to our customers. We use 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 recently established a console manufacturing facility in Tijuana, Mexico and have begun manufacturing at this facility in the first quarter of 2021. We are operating in Mexico in collaboration with 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 with an expectation that Paramit may serve as a second-source contract manufacturer for our consoles in the future.

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

Currently, the Tablo cartridge is manufactured by Infus Medical Co. Ltd. (Infus), a contract manufacturer with two facilities in Thailand that produces dialysis supplies for a number of leading global companies. 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 are shipped primarily via ocean freight, though in times of peak demand, we may ship by air freight. Our team inspects the product before releasing it for shipment.

We are also establishing a second source 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 mitigate against global supply chain interruption. We submitted a 510(k) clearance application to the FDA for Tablo cartridges manufactured at this new facility in March 2021.

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. Our currently marketed product is a Class II device subject to 510(k) clearance.

510(k) Clearance Marketing Pathway

Our current products are subject to premarket notification and clearance under section 510(k) of the FDCA. 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.

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.

Over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. For example, in November 2018, FDA officials announced forthcoming steps that the FDA intends to take to modernize the premarket notification pathway under Section 510(k) of the FDCA. Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. The FDA also announced that it intends to finalize guidance to establish a premarket review pathway for "manufacturers of certain well-understood device types" as an alternative to the 510(k) clearance pathway and that such premarket review pathway would allow manufacturers to rely on objective safety and performance criteria recognized by the FDA to demonstrate substantial equivalence, obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process.

In May 2019, the FDA solicited public feedback on its plans to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates, including whether the FDA should publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. The FDA requested public feedback on whether it should consider certain actions that might require new authority, such as whether to sunset certain older devices that were used as predicates under the 510(k) clearance pathway. These proposals have not yet been finalized or adopted, and the FDA may work with Congress to implement such proposals through legislation.

In September 2019, the FDA finalized guidance to establish an optional "safety and performance based" premarket review pathway for manufacturers of "certain, well-understood device types" to demonstrate substantial equivalence under the 510(k) clearance pathway, by demonstrating that such device meets objective safety and performance criteria established by the FDA, obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA intends to maintain a list of device types appropriate for the "safety and performance based pathway" and develop product-specific guidance documents that identify the performance criteria for each such device type, as well as the testing methods recommended in the guidance documents, where feasible.

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.

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, 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 over a 24-hour period at lower flow and ultrafiltration rates designed for hemodynamically unstable patients who require significant fluid removal. 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 will conduct the study in accordance with the FDA approved protocol. Once we are able to 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, among other things, prohibits 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. Further, the term "remuneration" has been broadly interpreted to include anything of value. The Affordable Care Act 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 an entity cannot receive reimbursement from federal healthcare programs or contract with anyone who receives reimbursement from federal healthcare programs. 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 be otherwise prohibited by 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. 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. However, these exceptions and safe harbors are narrowly drawn. Congress granted statutory authority to the Department of Health and Human Services (HHS) Office of Inspector General (OIG), the agency tasked with enforcing the federal Anti-Kickback Statute, to establish new safe harbors and modify existing safe harbors based on changing business practices in the healthcare industry. Most recently, on December 2, 2020, the OIG published a final rule creating several new safe harbors and modifying certain existing safe harbors to promote certain value-based and coordinated care arrangements and to reduce regulatory burden, which became effective on January 19, 2021, although many of the new safe harbors for value-based arrangements do not extend to device manufacturers.

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 OIG). If scrutinized, arrangements that implicate the federal Anti- Kickback Statute, and 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 involves the intent and conduct 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 to the government that are false or fraudulent, or knowingly making, using or causing to be made or used a false record or statement material to such a false or fraudulent claim, 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, broadly stated, prohibits defrauding or attempting to defraud “any healthcare benefit program,” including both private third-party payors and government healthcare programs.

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, 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 similar state anti-kickback and false claims laws that typically apply to arrangements involving reimbursement by a state-funded Medicaid or other healthcare program. Often, these laws closely follow the language of their federal law counterparts, although they do not always have the same exceptions or safe harbors. In some states, these anti-kickback laws apply with respect to all payors, including commercial health insurance companies.

A number of states have enacted laws that require pharmaceutical and medical device companies to monitor and report payments, gifts and other remuneration made to physicians and other healthcare providers, and, in some states, marketing expenditures. In addition, some state statutes impose outright bans on certain manufacturer gifts to physicians or other healthcare professionals. Some of these laws, referred to as “aggregate spend” or “gift” laws, carry substantial fines if they are violated.

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

Numerous federal and state laws and regulations, including HIPAA and the Health Information Technology for Economic and Clinical Health Act (HITECH Act), govern the collection, dissemination, security, use and confidentiality of patient-identifiable health information or personal information. In the course of performing our business we obtain personally identifiable information (PII), including health-related 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 certain services for, or on behalf of, a covered entity that involve creating, receiving, maintaining or transmitting PHI. Penalties for failure to comply with a requirement of HIPAA and HITECH 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 expanded 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 new California ballot initiative, the California Privacy Rights Act (CPRA), recently passed 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 will also create 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 may be required. Similar laws have been proposed in other states and at the federal level, and if passed, such laws may have potentially conflicting requirements that would make compliance challenging. Further, new health information standards, whether implemented pursuant to HIPAA, the HITECH Act, 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 acts or practices in or affecting commerce in violation of Section 5 of the FTC Act.

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 number of our employees who are 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 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 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, 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.

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.

Reimbursement in the Clinic and Home Settings

We sell our Tablo to dialysis clinics. These clinics, in turn, are reimbursed by Medicare, Medicaid, private insurers, and other third-party payors. 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 November 9, 2020, CMS published the final rule for CY 2021, which increased the base reimbursement rate per dialysis treatment to $253.13, an increase of $13.80 over the CY 2020 base rate of $239.33. 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 are expected to have coverage under a Medicare Advantage plan when changes from the 21st Century Cures Act go 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 will depend on each Medicare Advantage plan's contracts and network agreements with each dialysis facility. This reimbursement, and patient's coverage for dialysis, could potentially be more favorable than Medicare Part B coverage and payment for dialysis services, but such details will vary by plan.

On November 9, 2020, CMS published a final rule to update payment policies and rates under the Medicare ESRD PPS for calendar year 2021. The 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 to 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). Only capital-related assets that are new home dialysis machines cleared by FDA after January 2020 are eligible for application. Consistent with other dialysis equipment and supplies that are potentially eligible for the TPNIES, CMS will evaluate applications to determine whether the home dialysis machine represents an advance that substantially improves the diagnosis or treatment of Medicare beneficiaries compared to existing technology and meets other regulatory requirements. Under the final rule, CMS will pay 65% of the Medicare Administrative Contractor-determined pre-adjusted per treatment amount, reduced by an average per treatment offset, for two calendar years for those home dialysis machines that receive TPNIES.

We submitted a TPNIES application in January 2020 for the Tablo cartridge for use with the Tablo Hemodialysis System. In evaluating our application, CMS found the cartridge does not meet the newness eligibility criteria and that the cartridge does not show evidence of substantial clinical improvement. The updated TPNIES policy published by CMS in November 2020 as part of the calendar year 2021 ESRD PPS final rule, which provides that certain capital-related assets that are home dialysis machines may be eligible for TPNIES, afforded us a pathway to submit an application that includes the Tablo console. We submitted a TPNIES application in February 2021 for the Tablo Hemodialysis System. If we receive a favorable decision, we estimate that this would increase the per-treatment payment that dialysis providers who use Tablo for home dialysis would receive in 2022 and 2023. CMS noted in the November 2020 ESRD PPS final rule that manufacturers are eligible to apply within three years of FDA marketing authorization. This policy would afford us a final opportunity to reapply in 2022 if CMS denies our application and determines we need to collect additional data.

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.

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. 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.

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 legislative modifications and judicial challenges with respect to certain aspects of the Affordable Care Act. For example, the Tax Cuts and Jobs Act of 2017, among other things, included a provision eliminating, effective January 1, 2019, the tax-based shared responsibility payment, or penalty, imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." 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. Currently, the U.S. Supreme Court is considering whether the Affordable Care Act's individual mandate, post-repeal of its associated tax penalty, is unconstitutional, and, if so, whether the remaining provisions of the Affordable Care Act are inseverable from the mandate; a ruling could produce any of a number of results, including invalidation of the Affordable Care Act in its entirety based on a finding of inseverability, and is expected by mid-2021.

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 through 2030 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, 2021 due to the COVID-19 pandemic. 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, in July 2019, President Trump signed an executive order directing the Secretary of Health and Human Services to develop, among other things, 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, 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 PPS 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. Finally, the BETTER Kidney Care Act was introduced in the U.S. House of Representatives (H.R. 8254) and the U.S. Senate (S. 4574) on September 15, 2020. Similar legislation has not been introduced in the new Congress to date. However, if enacted, the BETTER Kidney Care Act would require HHS to establish a voluntary integrated care demonstration program for Medicare beneficiaries with ESRD.

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 could result in further healthcare policy changes. The Biden administration has taken several executive actions that signal changes in policy from the prior administration. On January 20, 2021, the Biden administration directed all federal departments and agencies to consider taking steps to withdraw or delay certain regulations and guidance issued by the Trump administration that had not become effective as of January 20, 2021 to permit the Biden administration to review such actions for questions of fact, law, and policy. And, on January 28, 2021, President Biden issued the "Executive Order on Strengthening Medicaid and the Affordable Care Act," among other things revoking certain executive orders of the previous administration, stating 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 directing heads of relevant executive departments and agencies immediately to review agency actions to determine whether any such actions are inconsistent with this policy. 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, 2020, we had 313 full-time employees, with 44% in our field sales and service teams and 56% in the rest of the company. Our workforce hails from across industries, including technology, medical devices, life sciences and retail management.

We recently established a manufacturing facility in Tijuana, Mexico that we operate in collaboration with our outsourced business administration service provider, Tacna, and have collaborators in subassembly, integration, quality, testing, and supply chain. Tacna facilitates the hiring of new collaborators and is responsible for human resource functions and payroll processing.

Talent Philosophy and Principles

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. 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 yearbook conversation is typically held in February and is focused on evaluating the success and learnings of the past year. Our passport conversation is typically held in August and is focused on skill development and future growth opportunities. 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 gauge employee engagement and identify areas of focus.

Inclusion, Diversity, and Equity Strategy

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

Employee Safety

In response to the COVID-19 pandemic, we defined two values that guided our decisions: 1) employee safety, and 2) business continuity to enable us to meet the needs of our patients and clinical customers. 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 safety precautions including increased sanitization standards, infection reduction and control, distribution of protective equipment to employees, as well as enforcement of mask-wearing and social distancing protocols. When testing became available, we implemented onsite testing in our facilities.

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 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	50	President, Chief Executive Officer and Director
John L. Brottem	47	General Counsel and Secretary
Rebecca Chambers	43	Chief Financial Officer
Martín Vazquez	51	Chief Operating Officer
Steve Williamson	48	Chief Commercial Officer

Leslie Trigg

Leslie Trigg has served as our President and Chief Executive Officer since November 2014. 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.

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.

Rebecca Chambers

Rebecca Chambers has served as our Chief Financial Officer since June 2019. Ms. Chambers joined the Company from Illumina, a genetic tools company, where she served in a number of roles: as the Vice President, Financial Planning and Analysis from July 2017 to May 2019, as Vice President, Investor Relations and Treasury from April 2015 to June 2017, and as Senior Director, Investor Relations from October 2012 to April 2015. Previously, Ms. Chambers served as Head of Investor Relations and Corporate Communications at Myriad Genetics, a molecular diagnostic company, from January 2011 to October 2012, and Senior Manager, Investor Relations at Life Technologies, a biotechnology company, from May 2009 to December 2010. She also previously held positions with Bank of America, a financial services company, and Millennium Pharmaceuticals, a biopharmaceutical company. Ms. Chambers holds a B.S. from John Carroll University and an M.B.A. from The S.C. Johnson Graduate School of Management, Cornell University.

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 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
- 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:
  - anti-kickback, fraud and abuse, false claims, transparency and other healthcare laws and regulations;
  - complex and evolving data privacy and security regulations that govern our use, disclosure and other processing of personally identifiable information, including health information; and
  - environmental and occupational safety laws

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
- Potential claims that we or our employees have misappropriated third party intellectual property rights

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
- Impact of future sales by existing stockholders or future issuances of securities
- Influence of principal stockholders and management over matters subject to stockholder approval
- Substantial resources associated with operating as a public company
- 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
- Our ability to attract and retain key personnel and maintain our corporate culture
- 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
- Risks associated with potential future acquisitions or investments

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 Securities and Exchange Commission (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 $121.5 million, $68.3 million and $49.8 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020, we had $348.2 million in cash, cash equivalents, restricted cash and short-term investments, and an accumulated deficit of $494.1 million. Based on our current planned operations, we expect our existing cash, cash equivalents and short-term investments, and cash generated from sales of our products, 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 new 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.

We may not be able to sufficiently reduce costs in the manufacturing and production of the Tablo system to achieve sustainable gross margins.

We partner with contract manufacturers in the production of the Tablo cartridge, and may continue to use a contract manufacturing partner as a second source for the production of Tablo consoles. Until recently, we exclusively relied on our contract manufacturer based in Morgan Hill, 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 recently 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 Services (Tacna), and began manufacturing consoles at the new facility, and we are in the process of moving production of a majority of the Tablo cartridges from our existing contract manufacturing partner to a new contract manufacturer in Tijuana, Mexico. There is no guarantee that we will be able to achieve planned cost reductions from our various cost savings initiatives. For example, the savings associated with our recently established manufacturing facility with Tacna 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. 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 implementation is subject to certain risks, including our ability to attract, retain and manage patients. Our business strategy, including our pricing of Tablo, is based 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 is a 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 PCBA boards. While we are undertaking a second source qualification process for the majority of these critical components, we may not 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. Additionally, at present, we rely on contract manufacturers for the production of the Tablo cartridge, and may continue to use a contract manufacturing partner as a second source for the production of Tablo consoles. 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 the ongoing COVID-19 pandemic, 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. In addition, 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 manufacture our Tablo system, establishing additional or replacement suppliers for any of these materials, components or services, if required, 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 for our purchases of some components and, in certain cases, requiring us to procure materials from alternative sources or incur higher logistics 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 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.

We may experience manufacturing disruptions, and our transition to manufacturing the majority of our Tablo consoles and 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, and may continue to use a contract manufacturing partner as a second source for the production of Tablo consoles. 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, 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 recently 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 planned transfer of the production of a majority of the Tablo cartridge to a new contract manufacturing partner in Tijuana, Mexico, the manufacturing of a majority of the Tablo console and cartridge will be 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 employee 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, vandalism, terrorism or other political hostilities. Any such occurrences could negatively impact our ability to produce the Tablo console. We will also be 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. dollar 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. For example, recently, the United States-Mexico-Canada Agreement (USMCA), a new trade deal among the United States, Mexico and Canada to replace the North American Free Trade Agreement, was approved by the U.S. Congress and signed into law. Although the USMCA went into effect on July 1, 2020, its full impact on manufacturing operations in Mexico, as well as economic conditions and markets generally, is still unknown. Further, during the negotiations leading up to the USMCA, the political and trade relationship between the United States and Mexico was strained, and such relationship may deteriorate. If our ability, the ability of our partners or our contract manufacturer's ability, to manufacture Tablo consoles and cartridges is interrupted as a result, or if our ability to import Tablo consoles and cartridges into the United States is impacted, we may not have a sufficient

number of Tablo consoles or cartridges in inventory to fulfill all orders requested, which could adversely affect our business, financial condition or results of operations.

A pandemic, epidemic or outbreak of an infectious disease in the United States or worldwide, including the outbreak of the novel strain of coronavirus disease, COVID-19, 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, in response to the ongoing COVID-19 pandemic, efforts to contain the spread and mitigate the impact of COVID-19 continue in the United States and across the globe, with the implementation of "shelter-in-place" orders, quarantines, executive orders and similar government orders and restrictions. Such orders or restrictions have resulted in work stoppages, slowdowns and delays, travel restrictions and cancellation of events. 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 order to operate in a safe manner, we have restricted non-essential travel of our employees and the majority of our employees at our headquarters have been asked to work from home. For roles that require employees to be physically on-site, such as our R&D and manufacturing technical staff, we have and continue to provide protective equipment, practice social distancing, enforce mask wearing, increase sanitization standards and implement onsite COVID-19 testing at our facilities once testing became available. 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.

While we believe the COVID-19 pandemic has highlighted the limitations of traditional machines and the benefits of Tablo, it is possible that the increased demands we experienced during the second and third quarters of 2020 may decrease as the pandemic dissipates, whether due to the availability of vaccines, or otherwise, which would have an adverse effect on our business and results of operations. Any increase in revenue due to a corresponding increase in demand for Tablo during periods when COVID-19 persists may not be indicative of our revenue in future periods. 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.

The extent to which the COVID-19 pandemic impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity, spread, resurgences, and duration of the COVID-19 pandemic, the nature, extent and effectiveness of actions to contain or treat the disease including the availability and distribution of an effective vaccine, the extent and duration of the effect on the economy and how quickly and to what extent normal economic and operating conditions can resume. 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 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, as we continue to transition the manufacturing of the Tablo console to our

new 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 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 recently 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 or partners. Despite the implementation of security measures, our internal computer systems and those of our third-party service providers and 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 are working 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, as amended by the HITECH Act, and all regulations promulgated thereunder. 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, 2020, we had 313 full-time employees. Over the next several years, we expect to increase significantly the scope of our operations, particularly in the areas of manufacturing, sales and support, product development, regulatory affairs, marketing and other functional areas, including finance, accounting, quality and legal. 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 recent 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. We will need to continue to devote significant resources to expanding the home hemodialysis market, but these efforts ultimately may not be successful.

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.

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, 2020, a government distributor customer, a federal health department customer, and one other customer accounted for 22%, 19% and 16% of our revenue, 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.

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 revenue and operating results 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, and our ability to accurately forecast and meet customer demand;
- 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 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 COVID-19 may have on 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 its agreement 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 agreement 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 expect to require substantial additional capital beyond the proceeds from our recent initial public offering 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.

Notwithstanding our recent initial public offering (IPO), 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, 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.

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.

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. 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.

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 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 clients and clinics 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.

Our future growth may depend, in part, on our ability to penetrate foreign markets, where 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, our future profitability may depend, in part, on our ability to sell Tablo in foreign markets. 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.

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

As of December 31, 2020, we had U.S. federal and state net operating loss (NOL) carryforwards of approximately $301.3 million and $174.0 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 in conforming states generated in taxable years beginning before 2018 have begun to expire in 2020. Deductibility of U.S. federal NOLs generated in taxable years beginning after 2017 and used in taxable years beginning after 2020 are limited to 80% of our taxable income before the deduction of such NOLs. As of December 31, 2020, we also had U.S. federal and state research and development credits of approximately $5.8 million and $4.3 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 Federal Food Drug and Cosmetic Act (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 response to the 522 order, we submitted a simulated human factors test protocol to the agency that was largely based on simulated use human factors validation testing. 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 will conduct the study in accordance with the FDA approved protocol. Once we are able to 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 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, 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.

Current Centers for Medicare and Medicaid Services (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 will depend on each Medicare Advantage plan's contracts and network agreements with each dialysis facility. There is uncertainty as to how many or which newly eligible ESRD patients will seek to enroll in Medicare Advantage plans and how quickly enrollment would occur, and whether coverage and reimbursement is more favorable than Medicare Part B will vary by plan.

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. Federal and state lawmakers regularly propose and, at times, enact legislation 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 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 will impact existing government healthcare programs and have resulted in the development of new programs.

There have been legislative modifications and judicial challenges with respect to certain aspects of the Affordable Care Act. For example, Congress eliminated the tax penalty, starting January 1, 2019, 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. Currently, the U.S. Supreme Court is considering whether the Affordable Care Act's individual mandate, post-repeal of its associated tax penalty, is unconstitutional, and, if so, whether the remaining provisions of the Affordable Care Act are inseverable from the mandate; a ruling could produce any of a number of results, including invalidation of the Affordable Care Act in its entirety based on a finding of inseverability, and is expected by mid-2021. It is unclear how this decision, and other efforts to challenge, repeal, replace, or otherwise 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, included reductions to Medicare payments to 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 through 2030 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, 2021 due to the COVID-19 pandemic. 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 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. Finally, the BETTER Kidney Care Act was introduced in the U.S. House of Representatives (H.R. 8254) and the U.S. Senate (S. 4574) on September 15, 2020. Similar legislation has not been introduced in the new Congress to date. However, if enacted, the BETTER Kidney Care Act would require HHS to establish a voluntary integrated care demonstration program for Medicare beneficiaries with ESRD. 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. Changes to federal and state legislatures and executive offices following the November 2020 elections could result in further healthcare policy changes. The Biden administration has taken several executive actions that signal changes in policy from the prior administration. On January 20, 2021, the Biden administration directed all federal departments and agencies to consider taking steps to withdraw or delay certain regulations and guidance issued by the Trump administration that had not become effective as of January 20, 2021 to permit the Biden administration to review such actions for questions of fact, law, and policy. And, on January 28, 2021, President Biden issued the "Executive Order on Strengthening Medicaid and the Affordable Care Act," among other things revoking certain executive orders of the previous administration, stating 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 directing heads of relevant executive departments and agencies immediately to review agency actions to determine whether any such actions are inconsistent with this policy. 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 U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order, or arranging for or recommending the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. 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;

- the U.S. federal false claims laws, including the FCA, which can be enforced by the U.S. Department of Justice or through "qui tam," whistleblower actions, which are filed by private citizens on behalf of the federal government. The FCA prohibits any person from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment of government funds; 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 and improperly avoiding, decreasing or concealing an obligation to pay money to the U.S. federal government. In addition, 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 FCA;

- federal criminal healthcare statutes that were added by HIPAA, which 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) and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the CMS information related to certain payments made in the preceding calendar year and other transfers of value to physicians and teaching hospitals as well as ownership and investment interests held by physicians and their immediate family members. For reporting beginning January 1, 2022, manufacturers will also need to report payments and other transfers of value made to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives. Accordingly, we are required to track certain payments and other transfers of value to these additional covered recipients during the 2021 calendar year. The maximum penalty for failure to timely report information under the Sunshine Act is $11,766 per payment or other transfer of value or ownership or investment interest, with a calendar year cap of $176,495, and the maximum individual penalty and calendar year cap for knowing violations are $117,664 and $1,176,638, respectively;

- the Federal Food, Drug, and Cosmetic Act, which governs, among other things, the misbranding and adulteration of medical devices; and

- 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.

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, additional 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.

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 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 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 application. Some pre-amendment devices are unclassified but are subject to FDA's premarket notification and clearance process in order to be commercially distributed. Our currently marketed product is a Class II device subject to 510(k) clearance.

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 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 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 are establishing a second source manufacturing site in Tijuana, Mexico for the production of Tablo cartridges in partnership with our contract manufacturer, Providien. We were required to submit a new 510(k) clearance application for Tablo cartridges manufactured at this new facility, which we submitted in March 2021. If we do not receive this 510(k) clearance from the FDA in a timely manner, or at all, we will be unable to begin shipping Tablo cartridges produced at the new facility on our planned timeline, or at all. As a result, we would be required to continue relying exclusively on our existing contract manufacturer or execute other contingency plans to meet our supply needs, which could limit our supply capacity and ability to meet customer demand, increase production costs, and adversely impact our business, result of operations and future growth.

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, 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, it 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. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled 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, additional reporting requirements and 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 recent 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 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 the laws and regulations of the FDA and other applicable regulatory authorities' 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. 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.

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 for services. 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 certain notification 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 expanded 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, 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 new ballot initiative, the CPRA, recently passed 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 will also create 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 may be required.

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, additional reporting requirements and 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.

Future sales of shares by existing stockholders could cause our stock price to decline.

In connection with our IPO, each of our directors, executive officers and other holders of substantially all our outstanding equity securities entered into lock-up agreements that restricted their ability to sell or transfer their shares for a period of 180 days after the date of the prospectus of our IPO. Such lock-up agreements expired on March 13, 2021 and as a result, all 42,722,492 shares outstanding as of December 31, 2020 are now eligible for sale in the public market, of which 7,828,000 shares are held by directors, executive officers and other affiliates that are subject to volume limitations under Rule 144 of the Securities Act of 1933, as amended (the Securities Act), and various vesting agreements. Sales of a substantial number of such shares or the perception that such sales may occur, could cause our market price to fall or make it more difficult for you to sell your common stock at a time and price that you deem appropriate.

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, 2020, our executive officers, directors and 5% stockholders beneficially owned approximately 68% of the outstanding shares of capital stock. In addition, as of December 31, 2020, our executive officers and directors held options to purchase an aggregate of 3,156,768 shares of our common stock at a weighted-average exercise price of $6.33 per share, and 80,000 restricted stock units, which would give our officers and directors ownership of approximately 8% of our outstanding common stock as of December 31, 2020 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.

We are an "emerging growth company," and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and, for as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to "emerging growth companies," including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this Annual Report;

- not being required to have our independent registered public accounting firm audit our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act;

- reduced disclosure obligations regarding executive compensation in this Annual Report on our 10-K, our periodic reports and proxy statements; and

- exemptions from the requirements of holding non-binding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

As a result, our stockholders may not have access to certain information that they may deem important. We could be an emerging growth company for up to five years following our IPO, although circumstances could cause us to lose that status earlier, including if our total annual gross revenues exceed $1.07 billion, if we issue more than $1.0 billion in non-convertible debt securities during any three-year period, or if we are a large accelerated filer and the market value of our common stock held by non-affiliates exceeds $700 million as of the end of any second quarter before that time. We cannot predict if investors will find our common stock less attractive if we choose to rely on any of the exemptions afforded emerging growth companies. If some investors find our common stock less attractive because we rely on any of these exemptions, there may be a less active trading market for our common stock and the market price of our common stock may be more volatile.

Under the JOBS Act, "emerging growth companies" can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We elected to use the extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (1) are no longer an emerging growth company or (2) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

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.

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

As a new public company, we have incurred substantial legal, accounting and other expenses that we did not incur as a private 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. 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 make some activities more time-consuming.

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. In particular, we expect to incur significant expense and devote substantial management effort to complying with the requirements of Section 404 of the Sarbanes-Oxley Act once we lose our status as an emerging growth company or voluntarily choose to forego the exemption from compliance with Section 404 of the Sarbanes-Oxley Act. We will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge.

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.

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 the U.S. dollar 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.

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. Moreover, liquidity available to our employee securityholders following our recent IPO could lead to disparities of wealth among our employees, which could adversely impact relations among employees and our culture in general. Our anticipated headcount growth and our status as a newly public company may result in a change to our corporate culture, which could harm our business.

We must comply with anti-corruption, anti-bribery, anti-money laundering and similar laws.

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.

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.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

In May 2020, we entered into an operating lease agreement for our new manufacturing facility in Tijuana, Mexico. We took initial possession of the building with approximately 48,437 square feet in May 2020 and are scheduled to take possession of the second space with approximately 38,750 square feet in June 2021.

In addition, we lease approximately 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 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 March 15, 2021, there were 369 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.

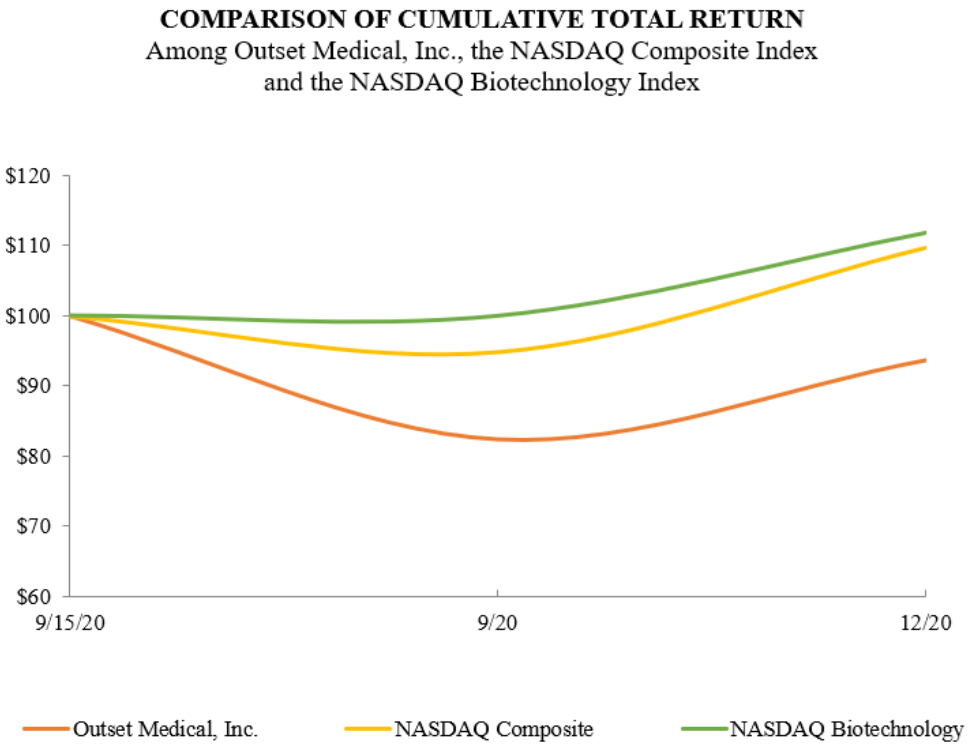
Dividend Policy

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, 2020. 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, 2020. Pursuant to applicable Securities and Exchange Commission 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 IPO, which had a closing stock price of $60.68 on September 15, 2020, was $27.00 per share. Note that historic stock price performance is not necessarily indicative of future stock price performance.



Recent Sales of Unregistered Securities

Capital Stock Issuances

In January and March 2020, excluding shares issued pursuant to stock purchase rights as described below, we sold an aggregate of 56,818,179 shares of our Series E redeemable convertible preferred stock to accredited investors at a purchase price of $2.20 per share, for an aggregate purchase price of $124,999,994.

In January 2020, we issued an aggregate of 4,849,933 shares of our common stock as a stock dividend to the holders of our redeemable convertible preferred stock.

In September 2020, we issued an aggregate of 25,957,884 shares of our common stock upon the automatic conversion of all shares of our redeemable convertible preferred stock in connection with our initial public offering.

In September 2020, we issued an aggregate of 274,590 shares of our common stock upon the exercise of outstanding warrants.

The capital stock issuances described above were exempt from registration under the Securities Act (or Regulation D promulgated thereunder) by virtue of Section 4(a)(2) of the Securities Act as transactions by an issuer not involving a public offering. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed upon the stock certificates issued in these transactions. All recipients had adequate access, through their relationships with us, to information about us. The sales of these securities were made without any general solicitation or advertising.

Option Issuances

From January 1, 2020 through September 9, 2020, we granted to our directors, officers, employees, consultants and other service providers options to purchase an aggregate of 1,480,135 shares of our common stock under our 2019 Equity Incentive Plan and 2020 Equity Incentive Plan at exercise prices ranging from approximately $8.62 to $27.00 per share and have issued 322,602 shares of our common stock upon exercise of such options from January 1, 2020 to September 18, 2020.

In March 2020, we granted to our directors, officers, employees, consultants and other service providers rights to purchase an aggregate of 963,696 shares of our Series E redeemable convertible preferred stock under our 2020 Preferred Stock Purchase Plan at an exercise price of $2.20 per share and have issued 963,696 shares of our Series E redeemable convertible preferred stock upon exercise of such rights.

The option issuances described above were exempt from registration under the Securities Act under Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of such securities were the registrant's employees, consultants or directors and received the securities under the registrant's equity compensation plans. The recipients of securities in each of these transactions represented their intention to acquire the securities for investment only and not with view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions.

Use of Proceeds

On September 14, 2020, our registration on Form S-1 (File No. 333-248225) was declared effective for our IPO and on September 17, 2020, we completed our IPO, in which we sold 10,293,777 shares of common stock at a price to the public of $27.00 per share. As a result of the IPO, we received aggregate net proceeds of approximately $254.8 million after deducting offering costs, underwriting discounts and commissions of approximately $23.1 million. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates, or to our affiliates.

BofA Securities, Inc., Morgan Stanley & Co. LLC and Goldman Sachs & Co. LLC acted as representatives of the underwriters for the IPO. There has been no material change in the expected use of the net proceeds from our IPO, as described in our final prospectus filed with the SEC on September 16, 2020 pursuant to Rule 424(b) under the Securities Act.

Issuer Purchases or Equity Securities

None.

Item 6. Selected Financial Data.

	Years Ended December 31,		
	2020	2019	2018
	(in thousands, except per share amount)		
Statement of Operations Data:			
Revenue:			
Product revenue	$ 39,612	$ 13,750	$ 1,749
Service and other revenue	10,323	1,328	258
Total revenue	49,935	15,078	2,007
Cost of revenue:			
Cost of product revenue	57,035	27,164	7,806
Cost of service and other revenue	5,937	5,716	316
Total cost of revenue	62,972	32,880	8,122
Gross profit	(13,037)	(17,802)	(6,115)
Operating expenses:			
Research and development	28,850	23,327	22,916
Sales and marketing	45,068	20,259	11,279
General and administrative	30,512	8,919	6,253
Total operating expenses	104,430	52,505	40,448
Loss from operations	(117,467)	(70,307)	(46,563)
Other income (expense):			
Interest income and other income, net	526	2,485	1,709
Interest expense	(2,891)	(4,257)	(4,639)
Change in fair value of redeemable convertible preferred stock warrant liability	(93)	3,800	(262)
Loss on extinguishment of term loan	(1,567)	—	—
Loss before provision for income taxes	(121,492)	(68,279)	(49,755)
Provision for income taxes	—	20	25
Net loss	$ (121,492)	$ (68,299)	$ (49,780)
Net loss attributable to common stockholders, basic and diluted[(1)]	$ (79,324)	$ (85,461)	$ (73,080)
Net loss per share attributable to common stockholders, basic and diluted[(1)]	$ (4.85)	$ (99.58)	$ (100.75)
Weighted average shares used in computing net loss per share attributable to common stockholders, basic and diluted[(1)]	16,358	858	725

(1) See Note 2 and Note 11 to the Notes to Financial Statements included in Part II, Item 8 of this Annual Report for further details on the calculation of net loss per share attributable to common stockholders, basic and diluted, the weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted.

	As of December 31,	
	2020	2019
	(in thousands)	
Balance Sheet Data		
Cash, cash equivalents, restricted cash and short-term investments	$ 348,181	$ 70,821
Working capital[(1)]	309,219	54,736
Total assets	403,829	88,366
Term note, current and noncurrent	29,674	29,061
Redeemable convertible preferred stock warrant liability	—	4,285
Redeemable convertible preferred stock	—	409,446
Accumulated deficit	(494,059)	(372,567)
Total stockholders' equity (deficit)	328,609	(372,187)

(1) We define working capital as current assets less current liabilities. See our financial statements and the related notes included elsewhere in this Annual Report for further details regarding our current assets and current liabilities.

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 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.

Overview

Our technology is designed to elevate the dialysis experience for patients, and help providers overcome traditional care delivery challenges. Requiring only an electrical outlet and tap water to operate, Tablo frees patients and providers from the burdensome infrastructure required to operate traditional dialysis machines. The integration of water purification and on-demand dialysate production enables Tablo to serve as a dialysis clinic on wheels and allows providers to standardize to a single technology platform from the hospital to the home. Tablo is also intelligent and connected, with automated documentation and the ability to integrate with electronic medical record reporting, along with streamlined remote machine management to maximize 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 U.S. Food and Drug Administration (FDA) for use in the hospital, clinic or home setting.

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 anyone. Tablo is comprised of a compact console with integrated water purification, on-demand dialysate production and a simple-to-use touchscreen interface. With Tablo, we are bringing data to dialysis. Tablo is built to live in a connected setting with cloud-based system monitoring, patient analytics, remote treatment monitoring and clinical recordkeeping and the ability to activate new capabilities and enhancements through wireless software updates. Tablo's data analytics and connectivity also enable predictive preventative maintenance to maximize machine uptime. Unlike existing hemodialysis machines, which have limited clinical versatility across care settings and are generally burdened by specialized and expensive infrastructure, Tablo is a single enterprise solution that can be seamlessly utilized across different care settings and for multiple clinical needs.

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.

We sell our solution through our direct sales organization, which covers most major metropolitan markets in the United States. As of December 31, 2020, our sales organization is comprised of 32 capital sales team members, responsible for generating new customer demand for Tablo, and 47 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 69 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 are executing a well-defined, three-pronged strategy designed to expand gross margins. First, we have insourced our console manufacturing to help lower console cost. Second, we are adding a second-source contract manufacturer for our cartridges to gain higher efficiency and lower material cost. Third, we will continue to utilize our cloud-based data system, as well as enhanced product performance, to help drive down the cost of service.

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 customer. Our total revenue was $49.9 million, $15.1 million and $2.0 million for the years ended December 31, 2020, 2019 and 2018, respectively. For the years ended December 31, 2020, 2019 and 2018, we incurred net losses of $121.5 million, $68.3 million and $49.8 million, respectively. As of December 31, 2020, we had an accumulated deficit of $494.1 million.

Initial Public Offering

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.

Factors Affecting Our Business

- ***Market Acceptance of Tablo in Acute Setting.*** We plan to broaden our installed base by continuing to target IDNs and health systems, the VA and sub-acute LTACH and SNF providers. In addition, we plan to 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. Our ability to successfully execute on this strategy, and thereby increase our revenue, will in part drive our results of operations and impact on 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 health systems and innovative dialysis clinic providers who are motivated to grow their home hemodialysis population, and who share our vision of creating a seamless and supported transition to the home. We will also invest 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.

- ***Cost of Revenue.*** The results of our business will depend in part on our ability to increase our gross margins by more effectively managing our costs to produce Tablo consoles and consumables, as well as subsequently servicing Tablo for our customers. The Tablo cartridge is currently produced by our contract manufacturer based in Thailand, and, until recently, we exclusively relied on our contract manufacturer based in Morgan Hill, California for production of the Tablo console. Utilizing these contract manufacturers has resulted in higher direct console and cartridge costs. As a result, cost of product revenue was $57.0 million, $27.2 million and $7.8 million for the years ended December 31, 2020, 2019 and 2018, respectively. We are currently undertaking a number of initiatives in order to help reduce these costs. We recently 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, and have begun manufacturing in the first quarter of 2021. In addition, we are moving production of a majority of Tablo cartridges from our existing contract manufacturing partner to a new contract manufacturer, also located in Tijuana, Mexico. Our ability to grow our business will depend in part on these and other measures to control the costs of producing Tablo being successful. Likewise, it will be important that we effectively manage the costs of generating our service revenue. Our cost of service and other revenue was $5.9 million, $5.7 million and $0.3 million for the years ended December 31, 2020, 2019 and 2018.

- ***Impacts of the COVID-19 pandemic.*** In March 2020, the World Health Organization declared the global outbreak of COVID-19 to be a pandemic. Since then, COVID-19 has continued to spread throughout much of the United States and the world causing uncertainty and disruption to business activities. We continue to closely monitor the recent developments surrounding the continued spread and potential resurgence of COVID-19. The results of our business may be impacted by developments related to the COVID-19 pandemic.

  We believe that the COVID-19 pandemic has highlighted the limitations of traditional machines and the benefits of Tablo, driving an increase in demand for Tablo during the second and third quarters of 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 and do not expect to experience significant revenue driven solely by COVID-19 in future periods. However, the duration and extent of the COVID-19 pandemic are uncertain, and we cannot predict with certainty the full impact of the COVID-19 pandemic and related containment measures on our business.

In order to operate in a safe manner, we are following the health and safety guidelines of the U.S. Centers for Disease Control and Prevention, Occupational Safety and Health Administration, and local and state public health departments where we operate. We have restricted non-essential travel by our employees, and the majority of our employees at our headquarters have been asked to work from home, with only limited access given to employees to work in the office. For roles that require employees to be physically on-site, such as our R&D and manufacturing technical staff, we have and continue to provide protective equipment, practice social distancing, enforce mask wearing, increase sanitizing standards and implement COVID-19 testing at our facilities. In addition, 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 also be impacted by an escalation or a continuation of the COVID-19 pandemic. Operations at our contract manufacturing partners' facilities and our outsourced business administration service provider, Tacna, for our new facility in Tijuana, Mexico, may be disrupted. Additionally, the COVID-19 pandemic has disrupted the operations of certain of our third-party suppliers, resulting in increased lead-times for our purchase of some components and, in certain cases, requiring us to procure materials from alternative sources or incur higher logistics 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 disruptions in our supply chain to date. However, we cannot predict how long the pandemic and measures intended to contain the spread of COVID-19 will continue and what effect COVID-19 and the associated containment measures will have 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 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.

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 cartridge. Revenue is recognized when control of our Tablo consoles is transferred, generally upon shipment, and excludes the value of the first-year service agreement, which is recognized as service and other revenue. Leases of Tablo consoles are considered operating leases and recognized as revenue over their lease term. Consumables, including the Tablo cartridge, are recognized primarily upon shipment. Our product revenue has been generated by direct sales to customers in the United States.

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 Tablo Hub, as well as software updates, 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, reserves for excess and obsolete inventories, manufacturing overhead and warranty costs. Manufacturing overhead costs include the cost of quality assurance, material procurement, depreciation expense for equipment, facilities and information technology. We currently partner with contract manufacturers to produce Tablo cartridges and some Tablo consoles. As described above, we have also invested in insourcing Tablo console manufacturing at a

facility we recently established in Tijuana, Mexico, where we direct the manufacturing of Tablo consoles, as well as the associated warehousing and product distribution. 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 material expenses related to our employees performing maintenance and support services, including salaries, benefits, stock-based compensation expense and related expenses such as employer taxes, materials and supplies and allocated costs including facilities and information technology. We anticipate that we will continue 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 revenue. Our gross profit has been and will continue to be, affected by a variety of factors, including sales volume of Tablo consoles and related consumables, the success of our cost-reduction strategies, the cost of direct materials, labor and manufacturing overhead, the contribution of console leases and associated services, discounting practices, product yields and headcount. 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, which depends on our ability to drive lower costs with our suppliers, increase our sales volume, and maintain or increase our average selling price, which will enable us to leverage our fixed costs. In addition, sales of our Tablo consumables carry a higher margin than sales of our Tablo consoles. We intend 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 costs of developing hardware and software enhancements to improve Tablo performance and lower cost of product revenue, software update releases, yield improvement activities and platform extensions, as well as clinical affairs and related clinical studies. Other research and development costs include personnel and related costs, supplies, testing, contract and other outside service fees, depreciation expense and allocated costs including facilities and information technology. In 2020, we experienced a significant increase in our stock-based compensation expense as a result of the cumulative stock-based compensation expense we recorded for outstanding options with performance and market-based vesting conditions when the performance vesting condition was satisfied upon the closing of our IPO. We expect our stock-based compensation expense to decrease in 2021 as compared to 2020 and then continue to increase in future periods, 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. We plan to continue to invest in our research and development efforts. As a percentage of revenue, we expect research and development expenses to vary over time, depending on the level and timing of new product development initiatives.

Sales and Marketing

Sales and marketing expenses primarily consist of personnel expenses including salaries, benefits, sales commissions, travel and stock-based compensation expense. Other sales and marketing expenses include marketing and promotional activities, including trade shows and market research, government affairs and costs of outside consultants. In 2020, we experienced a significant increase in our stock-based compensation expense as a result of the cumulative stock-based compensation expense we recorded for outstanding options with performance and market-based vesting conditions when the performance vesting condition was satisfied upon the closing of our IPO. We expect our stock-based compensation expense to decrease in 2021 as compared to 2020 and then continue to increase in future periods, 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. 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 personnel expenses, including salaries, benefits, bonuses, travel and stock-based compensation expense. Other general and administrative expenses include professional services fees, such as legal, audit and tax fees, insurance costs, costs of outside consultants, employee recruiting and training costs. Moreover, we expect to incur additional expenses associated with operating as a public company, including legal, accounting, insurance, exchange listing, SEC compliance and investor relations, and as we expand our headcount to support our growth. In 2020, we experienced a significant increase in our stock-based compensation expense as a result of the cumulative stock-based compensation expense we recorded for outstanding options with performance and market-based vesting conditions when the performance vesting condition was satisfied upon the closing of our IPO. We expect our stock-based compensation expense to decrease in 2021 as compared to 2020 and then continue to increase in future periods, 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. As a result, we expect general and administrative expenses to increase in absolute dollars in future periods. 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.

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. In June 2017, we entered into a senior, secured, delayed draw term facility (the Perceptive Term Loan Agreement) with Perceptive Credit Holdings, LP to borrow up to $40.0 million (the Perceptive Term Loan) as described in Note 7 to our audited financial statements included elsewhere in this Annual Report. We borrowed $30.0 million of the term loan on the closing date of the Perceptive Term Loan Agreement. In July 2020, we used $30.0 million of the proceeds from the SVB Term Loan to repay in full all amounts due under the Perceptive Term Loan Agreement and cash on hand to pay $1.2 million in early prepayment, accrued interest and exit fees.

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, 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 income taxes in certain states in which we conduct business. 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

Comparison of the Years Ended December 31, 2020 and 2019:

The following table summarizes our results of operations for the years ended December 31, 2020 and 2019 (in thousands, except percentages):

	Years Ended December 31,		Change	
	2020	2019	$	%
Revenue:				
Product revenue	$ 39,612	$ 13,750	$ 25,862	188 %
Service and other revenue	10,323	1,328	8,995	677 %
Total revenue	49,935	15,078	34,857	231 %
Cost of revenue:				
Cost of product revenue	57,035	27,164	29,871	110 %
Cost of service and other revenue	5,937	5,716	221	4 %
Total cost of revenue	62,972	32,880	30,092	92 %
Gross profit	(13,037)	(17,802)	4,765	27 %
Gross margin	*(26)*%	*(118)*%		
Operating expenses:				
Research and development	28,850	23,327	5,523	24 %
Sales and marketing	45,068	20,259	24,809	122 %
General and administrative	30,512	8,919	21,593	242 %
Total operating expenses	104,430	52,505	51,925	99 %
Loss from operations	(117,467)	(70,307)	(47,160)	67 %
Interest income and other income, net	526	2,485	(1,959)	(79)%
Interest expense	(2,891)	(4,257)	1,366	(32)%
Change in fair value of redeemable convertible preferred stock warrant liability	(93)	3,800	(3,893)	(102)%
Loss on extinguishment of term loan	(1,567)	—	(1,567)	*
Loss before provision for income taxes	(121,492)	(68,279)	(53,213)	78 %
Provision for income taxes	—	20	(20)	*
Net loss	$ (121,492)	$ (68,299)	$ (53,193)	78 %

* *Not meaningful*

Revenue

Product Revenue

Product revenue increased by $25.9 million, or 188%, for the year ended December 31, 2020 as compared to the year ended December 31, 2019. The increase was primarily due to a $21.2 million increase in console revenue driven by new customer adoption, fleet expansion across existing customers, sales that we believe were attributable to COVID-19 driven demand, and increased console leasing revenue ($2.6 million). In addition, sales of Tablo consumables, including cartridges, for the year ended December 31, 2020 increased by $4.7 million given our larger console installed base as compared to the prior year period.

Service and Other Revenue

Service and other revenue increased by $9.0 million, or 677%, for the year ended December 31, 2020 as compared to the year ended December 31, 2019. The increase was primarily due to services associated with our larger Tablo installed base, including leased consoles, as well as COVID-19 driven demand for services associated with leased consoles.

Cost of Revenue

Cost of Product Revenue

Cost of product revenue increased by $29.9 million, or 110%, for the year ended December 31, 2020 as compared to the year ended December 31, 2019. This increase was primarily due to higher console and consumable volume of $35.4 million, higher manufacturing overhead of $5.5 million, resulting primarily from our investments in our manufacturing facility in Tijuana, Mexico, and a $0.3 million increase in stock-based compensation expense. This was offset by an $11.3 million reduction in product costs.

Cost of Service and Other Revenue

Cost of service and other revenue increased by $0.2 million, or 4%, for the year ended December 31, 2020 as compared to the year ended December 31, 2019. This increase was primarily due to additional headcount costs in our service department, which were offset by higher absorption of these costs across our larger installed base.

Gross Profit and Gross Margin

Gross profit increased by $4.8 million, or 27%, for the year ended December 31, 2020 as compared to the year ended December 31, 2019. The gross margin percentage improved by 92 percentage points for the year ended December 31, 2020 as compared to the year ended December 31, 2019, driven primarily by $18.3 million related to higher margin sales of our products and $7.6 million in higher service revenue as a result of our larger installed base, including leased consoles. This was offset by $15.9 million in increased costs as a result of selling more product and a $5.5 million increase in in higher manufacturing overhead, which was, in turn, driven by a $2.2 million investment in our new manufacturing facility in Tijuana, Mexico, a $1.0 million increase in allocated costs and a $0.8 million increase in compensation and personnel costs.

Research and Development

Research and development expenses increased by $5.5 million, or 24%, for the year ended December 31, 2020 as compared to the year ended December 31, 2019. The increase was primarily due to a $6.1 million increase in compensation and personnel costs, which includes a $4.3 million increase in stock-based compensation expense, and a $0.3 million increase in materials and supplies. These increases were partially offset by a $0.9 million decrease in professional service and consultant service expenses.

Sales and Marketing

Sales and marketing expenses increased by $24.8 million, or 122% for the year ended December 31, 2020 as compared to the year ended December 31, 2019. The increase was primarily due to a $22.4 million increase in compensation and personnel costs as a result of increased headcount, which includes a $4.3 million increase in stock-based compensation expense, and a $10.1 million increase in commission expense as a result of higher orders, a $0.9 million increase in supplies, materials and freight expenses related to increased activities in support of driving penetration of Tablo, a $0.9 million increase in facilities and other allocated costs and a $0.6 million increase in professional service and consultant service expenses.

General and Administrative

General and administrative expenses increased by $21.6 million, or 242%, for the year ended December 31, 2020 as compared to the year ended December 31, 2019. The increase was primarily due to a $17.2 million increase in compensation and personnel costs, which includes a $11.8 million increase in stock-based compensation expense, a $4.5 million increase in professional and consultant services associated with being a public company including legal, accounting, and secondary offering costs, and a $0.3 million increase in depreciation expense. The increases were partially offset by a $0.4 million decrease in facilities and other allocated costs.

Interest Income and Other Income, Net

Interest income and other income, net decreased by $2.0 million, or 79%, for the year ended December 31, 2020 as compared to the year ended December 31, 2019. This decrease was driven by lower interest rates and a lower average balance in money market funds and short-term investment securities during 2020.

Interest Expense

Interest expense decreased by $1.4 million, or 32%, for the year ended December 31, 2020 as compared to the year ended December 31, 2019. This decrease was primarily due to a lower debt discount amortization expense in the year ended December 31, 2020, the repayment of our Perceptive Term Loan in July 2020 and a lower interest rate under the SVB Term Loan.

Change in Fair Value of Redeemable Convertible Preferred Stock Warrant Liability

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 September 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.

Loss on Extinguishment of Term Loan

The loss on extinguishment of term loan of $1.6 million was recognized for the repayment of the Perceptive Term Loan in July 2020, which included early prepayment and exit fees.

Comparison of Years Ended December 31, 2019 and 2018

The following table summarizes our results of operations for the years ended December 31, 2019 and 2018 (in thousands, except percentages):

	Years Ended December 31,		Change	
	2019	2018	$	%
Revenue:				
Product revenue	$ 13,750	$ 1,749	$ 12,001	686%
Service and other revenue	1,328	258	1,070	415%
Total revenue	15,078	2,007	13,071	651%
Cost of revenue:				
Cost of product revenue	27,164	7,806	19,358	248%
Cost of service and other revenue	5,716	316	5,400	*
Total cost of revenue	32,880	8,122	24,758	305%
Gross profit	(17,802)	(6,115)	(11,687)	191%
Gross margin	*(118)%*	*(305)%*		
Operating expenses:				
Research and development	23,327	22,916	411	2%
Sales and marketing	20,259	11,279	8,980	80%
General and administrative	8,919	6,253	2,666	43%
Total operating expenses	52,505	40,448	12,057	30%
Loss from operations	(70,307)	(46,563)	(23,744)	51%
Interest income and other income, net	2,485	1,709	776	45%
Interest expense	(4,257)	(4,639)	382	(8)%
Change in fair value of redeemable convertible preferred stock warrant liability	3,800	(262)	4,062	*
Loss before provision for income taxes	(68,279)	(49,755)	(18,524)	37%
Provision for income taxes	20	25	(5)	(20)
Net loss	$ (68,299)	$ (49,780)	$ (18,519)	37%

* *Not meaningful*

Revenue

Product Revenue

Product revenue increased by $12.0 million, or 686%, for the year ended December 31, 2019, compared to the year ended December 31, 2018. The increase was primarily due to $10.0 million in higher Tablo console revenue, which was driven by new customer adoption and fleet expansion with existing customers, as well as $0.5 million in increased console leasing revenue and $1.0 million in increased sales of Tablo consumables, including cartridges, given our higher Tablo installed base.

Service and Other Revenue

Service and other revenue increased by $1.1 million, or 415%, for the year ended December 31, 2019, compared to the year ended December 31, 2018. The increase was primarily due to growth in service contracts as a result of a higher Tablo installed base, as well as services associated with leased consoles.

Cost of Revenue

Cost of Product Revenue

Cost of product revenue increased by $19.4 million, or 248%, for the year ended December 31, 2019, compared to the year ended December 31, 2018. This increase was primarily due to higher console and consumable volume of $30.1 million, which was offset by a $10.6 million reduction in product costs and expense associated with upgrading certain prior generation consoles.

Cost of Service and Other Revenue

Cost of service and other revenue increased by $5.4 million for the year ended December 31, 2019, compared to the year ended December 31, 2018. This increase was primarily due to field service-related expenses resulting from the full rollout of Tablo into the commercial market.

Gross Profit and Gross Margin

Gross profit decreased by $11.7 million, or 191%, for the year ended December 31, 2019, compared to the year ended December 31, 2018. Gross margin increased for the year ended December 31, 2019, compared to the year ended December 31, 2018 by 187 percentage points. The decline in gross profit was primarily attributable to selling more Tablo consoles and cartridges for less than cost, partially offset by the lower materials cost as a result of our cost reduction efforts.

Research and Development

Research and development expenses increased by $0.4 million, or 2%, for the year ended December 31, 2019, compared to the year ended December 31, 2018. This increase was primarily due to a $1.3 million increase in compensation and personnel costs as a result of increased research and development headcount, a $1.2 million increase in outside service fees to support research and development and a $0.6 million increase in facilities and other allocated costs. Partially offsetting this increase was a decline of $2.2 million in materials and supplies and a $0.6 million decrease in clinical-related and other costs resulting from the completion of development of Tablo in late 2018.

Sales and Marketing

Sales and marketing expenses increased by $9.0 million, or 80%, for the year ended December 31, 2019, compared to the year ended December 31, 2018. This increase was primarily due to a $5.0 million increase in compensation and personnel costs, including a $1.4 million increase in commission expense as a result of higher product revenue, a $1.6 million increase in promotional and travel expenses related to an increase in activities in support of driving penetration in the acute care market, a $1.2 million increase in facilities and other allocated costs and a $1.1 million increase in outside service fees related to the clinical adoption of our products.

General and Administrative

General and administrative expenses increased by $2.7 million, or 43%, for the year ended December 31, 2019, compared to the year ended December 31, 2018. This increase was primarily due to a $1.9 million increase in compensation and personnel costs as a result of increased headcount and a $0.7 million increase in outside consultant expenses and professional service expenses.

Interest Income and Other Income, Net

Interest income and other income, net increased by $0.8 million, or 45%, for the year ended December 31, 2019, compared to for the year ended December 31, 2018. This increase was primarily due to a higher average balance in money market funds and short-term investment securities during the year ended December 31, 2019.

Interest Expense

Interest expense decreased by $0.4 million, or 8%, for the year ended December 31, 2019, compared to the year ended December 31, 2018, primarily due to lower debt discount amortization expense for the year ended December 31, 2019.

Change in Fair Value of Redeemable Convertible Preferred Stock Warrant Liability

The change in fair value of the redeemable convertible preferred stock warrant liability increased by $4.1 million for the year ended December 31, 2019, compared to the year ended December 31, 2018, reflecting a decrease in the redeemable convertible preferred stock warrant liability that resulted from the amendment and restatement of our certificate of incorporation in September 2019.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred net losses and negative cash flows from operations. To date, we have financed our operations and capital expenditures primarily through sales of redeemable convertible preferred stock and common stock, revenue from sales and issuances of debt. 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.

As of December 31, 2020, the Company had cash, cash equivalents and short-term investments of $314.9 million, which are available to fund future operations, and restricted cash of $33.3 million, for a total cash, cash equivalents, restricted cash and short-term investments balance of $348.2 million and an accumulated deficit of $494.1 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 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, 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,		
	2020	2019	2018
Net cash (used in) provided by:			
Operating activities	$ (99,015)	$ (70,292)	$ (46,442)
Investing activities	3,947	74,297	(68,776)
Financing activities	385,682	249	134,872
Net increase in cash, cash equivalents and restricted cash	$ 290,614	$ 4,254	$ 19,654

Net Cash Flows from Operating Activities

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, partially offset by 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, non-cash lease expense of $0.6 million, provision for inventories of $0.5 million, loss on disposal of property and equipment of $0.2 million, and change in fair value of redeemable convertible preferred stock warrant liability of $0.1 million. The net cash outflow from operating assets and liabilities was primarily due to an increase in inventories of $16.3 million due to the timing of inventory purchases including advance purchases of inventory due to anticipated demand, an increase in prepaid expenses and other assets of $6.2 million, an increase in accounts receivable of $2.6 million due to timing of collections, and an increase in accrued interest of $0.2 million for the SVB Term Loan. The net cash outflow from operating assets and liabilities was partially offset by an increase in accrued payroll and related benefits of $9.9 million due to an increase in headcount, an increase in accrued expenses and other current liabilities of $4.8 million consistent with the growth of our business, an increase in deferred revenue of $2.8 million, an increase in accrued warranty liability of $1.2 million, an increase in accounts payable of $0.7 million due to timing of vendor payments, and an increase in operating lease liability of $0.1 million.

Net cash used in operating activities for the year ended December 31, 2019 was $70.3 million, attributable to a net loss of $68.3 million and a net cash outflow from the change in our operating assets and liabilities of $1.6 million and net non-cash adjustment of $0.4 million. Non-cash adjustments primarily consisted of $3.8 million in change in fair value of the redeemable convertible preferred stock warrant liability and $1.0 million in amortization of premium on investments, partially offset by $1.5 million in depreciation and amortization, $0.9 million in non-cash interest expense, $0.9 million in stock-based compensation expense, $0.5 million in non-cash lease expense, $0.3 million in loss on disposal of property and equipment and $0.3 million in provision for inventory. The net cash outflow from the change in our operating assets and liabilities was primarily due to a $5.0 million increase in inventory to support the growth in our business, a $2.9 million increase in accounts receivable due to higher revenue, a $0.2 million increase in prepaid expenses and other assets and a $0.5 million decrease in operating lease liability. These changes were partially offset by a $3.1 million increase in accrued payroll and related benefits due to higher headcount, a $1.8 million increase in accounts payable and accrued expenses and other current liabilities attributable to expansion in our operating activities and timing of payment, a $1.4 million increase in accrued warranty liability and a $0.7 million increase in deferred revenue mainly due to the growth of our business.

Net cash used in operating activities for the year ended December 31, 2018 was $46.4 million, attributable to a net loss of $49.8 million and a net cash outflow from the change in our operating assets and liabilities of $0.2 million, partially offset by non-cash adjustments of $3.6 million. Non-cash charges primarily consisted of $1.3 million amortization of deferred financing costs and fees, $1.1 million in depreciation, $0.4 million in provision for inventory and $0.4 million in non-cash lease expense, partially offset by $0.8 million in amortization of premium on investments. The change in our net operating assets and liabilities was primarily due to a $3.1 million increase in accounts payable and accrued expenses resulting primarily from expansion in our operating activities and timing of payment and a $0.6 million increase in accrued payroll and related benefits due to increased headcount. These changes were partially offset by a $2.2 million increase in inventories, a $0.6 million increase in accounts receivable due to higher revenue, a $0.5 million increase in prepaid expenses and other current assets, a $0.5 million decrease in operating lease liability, a $0.4 million decrease in accrued warranty liability and a $0.3 million increase in prepaid expenses and other assets.

Net Cash Flows from Investing Activities

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

Net cash provided by investing activities for the year ended December 31, 2019 was $74.3 million and related to the sales and maturities of short-term investments of $169.5 million, partially offset by purchases of short-term investments of $91.9 million and purchases of property and equipment of $3.3 million.

Net cash used in investing activities for the year ended December 31, 2018 was $68.8 million and related to the purchases of short-term investments of $132.3 million and the purchases of property and equipment of $1.8 million, partially offset by sales and maturities of short-term investments of $65.3 million.

Net Cash Flows from Financing Activities

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 approximately $254.8 million from the issuance of our common stock in our IPO, net of issuance costs paid to date, 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.

Net cash provided by financing activities for the year ended December 31, 2019 was $0.2 million and related to proceeds of $0.3 million from the exercise of stock options and $0.1 million from the exercise of a common stock warrant, partially offset by $0.2 million in paid issuance costs on our Series D redeemable convertible preferred stock issued in November 2018.

Net cash provided by financing activities for the year ended December 31, 2018 was $134.9 million and related primarily to net proceeds of $134.6 million from the issuance of our Series D redeemable convertible preferred stock and $0.3 million from the exercise of stock options.

Debt Obligations

SVB Loan and Security Agreement

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). 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 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.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations and other commitments as of December 31, 2020:

	Payments Due by Period				
	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years	Total
	(in thousands)				
Operating lease obligation, including interest[1]	$ 1,619	$ 3,652	$ 3,880	$ 2,523	$ 11,674
Debt obligations, including interest[2]	1,141	9,214	25,900	—	36,255
Purchase commitments[3]	46,472	—	—	—	46,472
Total contractual obligations	49,232	12,866	29,780	2,523	94,401

(1) We have entered into leases for office and laboratory space in San Jose, California with contractual lease periods expiring in 2027 and our new manufacturing facility in Tijuana, Mexico with contractual lease periods expiring in 2026.

(2) Principal payments associated with the SVB Term Loan are included in the above table. Interest expense incurred on the term loan is included in the above table based on the obligations outstanding and the interest rate effective as of December 31, 2020, including a final one-time payment of $0.2 million in 2025.

(3) We have obligations under non-cancellable purchase commitments primarily related to our contract manufacturers.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Critical Accounting Policies and Estimates

Management's discussion and analysis of the financial condition and results of operations is based on the financial statements, which 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 consider each product and each service contract to be a distinct performance obligation. Revenue is recognized when a performance obligation is satisfied, which occurs when control of the promised products or services is transferred to the customer in an amount that reflects the consideration we expect to receive in exchange for those products or services. 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 support and maintenance contracts is recognized as the output of the service is transferred to the customer over time, typically evenly over the contract term. Revenue is recognized net of allowances for returns and any taxes collected from customers, which are subsequently remitted to governmental authorities.

Our contracts with customers often include promises to transfer multiple products and services to a customer. Determining whether products and services are considered distinct performance obligations that should be accounted for separately versus together may require significant judgment. Judgment is also required to determine the stand-alone selling price (SSP) for each distinct performance obligation. We use an observable price to estimate SSP for items that are sold separately, including customer support

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. This is considered a material right and an additional performance obligation of the contract. SSP is assigned based on the estimated value of the material right.

Costs associated with product sales include commissions. We apply 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.

Stock-Based Compensation Expense

Our stock-based compensation expense relates to stock options with a service 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.

Service-based options initially 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. Any subsequent follow-on options granted to the optionee generally vest monthly over four years. 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 is recognized 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 condition does not occur. The fair value of these stock options is estimated using the Monte Carlo approach.

RSUs initially 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 is based on the market price of our common stock on the date of grant. The determination of fair value of performance stock units requires the use of certain estimates and assumptions that affect the amount of stock-based compensation expense recognized in our statements of operations. At each reported 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.

Inventories

Inventories are stated at the lower of cost or net realizable value. Cost is determined using the standard cost method, which approximates actual costs as determined on a first-in, first-out basis. The carrying value of inventories is reduced for any difference between cost and net realizable value of inventories that is determined to be obsolete or unmarketable, based upon assumptions about future demand and market conditions. We also review our inventory value to determine if it reflects the lower of cost or net realizable value based on factors such as inventory items sold at negative gross margins and non-cancellable purchase commitments. Adjustments to the value of inventory establish a new cost basis and are considered permanent even if circumstances later suggest that increased carrying amounts are recoverable. If demand is higher than expected, we may sell inventory that had previously been written down.

Common Stock Valuations

Prior to our IPO, there was no public market for our common stock. As such, the estimated fair value of our common stock and underlying stock options has been determined at each grant date by our board of directors, with input from management, based on the information known to us on the recent events and their potential impact on the estimated per share fair value of our common stock. As part of these fair value determinations, our board of directors obtained and considered valuation reports prepared by a third-party valuation firm in accordance with the guidance outlined in the American Institute of Certified Public Accountants Technical Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*.

For valuations after the completion of our IPO, the fair value of each share of underlying common stock is based on the closing price of our common stock as reported on the date of grant.

Redeemable Convertible Preferred Stock Warrant Liability

We accounted for our freestanding warrants to purchase shares of our redeemable convertible preferred stock prior to our IPO as liabilities at fair value upon issuance primarily because the shares underlying the warrants contained contingent redemption features outside of our control. The warrants were subject to re-measurement at each balance sheet date and any change in fair value was recognized in the statements of operations as the change in fair value of redeemable convertible preferred stock warrant liability. Upon the completion of our IPO, the liability on the redeemable convertible preferred stock warrants was reclassified to additional paid-in capital.

We estimated the fair value of these liabilities using the Black-Scholes option pricing model and assumptions that were based on the individual characteristics of the warrants on the valuation date, as well as assumptions for future financings, expected volatility, expected life, yield, and risk-free interest rate.

Emerging Growth Company Status

We are an emerging growth company, as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

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 as of December 31, 2020 consist of $348.2 million 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, 2020, we had $30.0 million in variable rate debt outstanding. The SVB Term Loan matures on November 1, 2025, with interest-only monthly payments until June 2023. The term loan accrues interest at a rate per annum equal to the greater of (A) one-half of one percent (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) three and three-quarters of one percent (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 U.S. dollars. However, we have entered into a limited number of supply contracts with vendors with payments denominated in foreign currencies. We are subject to foreign currency transaction gains or losses on our contracts denominated in foreign currencies. To date, foreign currency transaction gains and losses have not been material to our financial statements.

Unfavorable changes in foreign exchange rates versus the U.S. dollar 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 the U.S. dollar 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.:

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Outset Medical, Inc. (the Company) as of December 31, 2020 and 2019, 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, 2020, and the related notes (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements 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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits 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. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

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

San Francisco, California

March 22, 2021

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

	December 31,	
	2020	**2019**
Assets		
Current assets:		
Cash and cash equivalents	$ 294,972	$ 36,926
Short-term investments	19,898	33,152
Accounts receivable, net	6,468	3,914
Inventories	18,384	4,596
Prepaid expenses and other current assets	6,189	1,058
Total current assets	345,911	79,646
Restricted cash	33,311	743
Property and equipment, net	14,998	7,895
Operating lease right-of-use assets	8,253	—
Other assets	1,356	82
Total assets	$ 403,829	$ 88,366
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 4,948	$ 4,960
Accrued compensation and related benefits	16,845	6,956
Accrued expenses and other current liabilities	7,903	2,909
Accrued warranty liability	2,913	1,702
Deferred revenue, current	3,201	883
Operating lease liabilities, current	882	—
Term loan, current	—	7,500
Total current liabilities	36,692	24,910
Accrued interest, noncurrent	240	217
Deferred revenue, noncurrent	570	134
Operating lease liabilities, noncurrent	8,044	—
Redeemable convertible preferred stock warrant liability	—	4,285
Term loan, noncurrent	29,674	21,561
Total liabilities	75,220	51,107
Commitments and contingencies (Note 6)		
Redeemable convertible preferred stock, $0.001 par value; no shares authorized and no shares issued and outstanding as of December 31, 2020; 154,592 shares authorized and 147,214 shares issued and outstanding as of December 31, 2019	—	409,446
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value; 5,000 shares authorized, and no shares issued and outstanding as of December 31, 2020 and 2019	—	—
Common stock, $0.001 par value; 300,000 and 240,000 shares authorized as of December 31, 2020 and 2019, respectively; 42,722 and 922 shares issued and outstanding as of December 31, 2020 and 2019, respectively	43	1
Additional paid-in capital	822,624	357
Accumulated other comprehensive income	1	22
Accumulated deficit	(494,059)	(372,567)
Total stockholders' equity (deficit)	328,609	(372,187)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 403,829	$ 88,366

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,		
	2020	**2019**	**2018**
Revenue:			
Product revenue	$ 39,612	$ 13,750	$ 1,749
Service and other revenue	10,323	1,328	258
Total revenue	49,935	15,078	2,007
Cost of revenue:			
Cost of product revenue	57,035	27,164	7,806
Cost of service and other revenue	5,937	5,716	316
Total cost of revenue	62,972	32,880	8,122
Gross profit	(13,037)	(17,802)	(6,115)
Operating expenses:			
Research and development	28,850	23,327	22,916
Sales and marketing	45,068	20,259	11,279
General and administrative	30,512	8,919	6,253
Total operating expenses	104,430	52,505	40,448
Loss from operations	(117,467)	(70,307)	(46,563)
Interest income and other income, net	526	2,485	1,709
Interest expense	(2,891)	(4,257)	(4,639)
Change in fair value of redeemable convertible preferred stock warrant liability	(93)	3,800	(262)
Loss on extinguishment of term loan	(1,567)	—	—
Loss before provision for income taxes	(121,492)	(68,279)	(49,755)
Provision for income taxes	—	20	25
Net loss	$ (121,492)	$ (68,299)	$ (49,780)
Adjustment to redemption value on redeemable convertible preferred stock	(362)	(134,760)	(23,300)
Gain on extinguishment of redeemable convertible preferred stock	—	117,598	—
Deemed dividend on settlement of accrued dividend	42,530	—	—
Net loss attributable to common stockholders, basic and diluted	$ (79,324)	$ (85,461)	$ (73,080)
Net loss per share attributable to common stockholders, basic and diluted	$ (4.85)	$ (99.58)	$ (100.75)
Weighted average shares used in computing net loss per share attributable to common stockholders, basic and diluted	16,358	858	725

The accompanying notes are an integral part of these financial statements

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

	Years Ended December 31,		
	2020	**2019**	**2018**
Net loss	$ (121,492)	$ (68,299)	$ (49,780)
Other comprehensive income (loss):			
Unrealized gain (loss) on available-for-sale securities	(21)	82	(37)
Comprehensive loss	$ (121,513)	$ (68,217)	$ (49,817)

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 Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2017	103,862	$ 234,418	678	$ 1	$ —	$ (23)	$ (215,915)	$ (215,937)
Issuance of Series D redeemable convertible preferred stock, net of issuance costs	43,352	134,567	—	—	—	—	—	—
Adjustment to redemption value on redeemable convertible preferred stock	—	23,299	—	—	(1,103)	—	(22,196)	(23,299)
Stock option exercises	—	—	111	—	315	—	—	315
Stock-based compensation expense	—	—	—	—	788	—	—	788
Unrealized loss on available-for-sale securities	—	—	—	—	—	(37)	—	(37)
Net loss	—	—	—	—	—	—	(49,780)	(49,780)
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

The accompanying notes are an integral part of these financial statements

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

	Years Ended December 31,		
	2020	**2019**	**2018**
Cash flows from operating activities:			
Net loss	$ (121,492)	$ (68,299)	$ (49,780)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,159	1,484	1,069
Non-cash lease expense	596	451	425
Non-cash interest expense	641	893	1,348
Amortization (accretion) of premium (discount) on investments, net	50	(983)	(779)
Provision for accounts receivable	12	59	—
Provision for inventories	534	326	442
Loss on disposal of property and equipment	235	293	—
Stock-based compensation expense	21,439	883	788
Change in fair value of redeemable convertible preferred stock warrant liability	93	(3,800)	262
Loss on extinguishment of term loan	1,567	—	—
Changes in operating assets and liabilities:			
Accounts receivable	(2,566)	(2,886)	(552)
Inventories	(16,287)	(5,020)	(2,212)
Prepaid expenses and other assets	(6,245)	(228)	(270)
Accounts payable	737	802	2,675
Accrued payroll and related benefits	9,889	3,119	647
Accrued expenses and other current liabilities	4,798	974	457
Accrued warranty liability	1,211	1,410	(443)
Deferred revenue	2,754	735	(55)
Accrued interest	(217)	—	—
Operating lease liabilities	77	(505)	(464)
Net cash used in operating activities	(99,015)	(70,292)	(46,442)
Cash flows from investing activities:			
Purchases of property and equipment	(9,108)	(3,293)	(1,766)
Purchases of short-term investments	(32,884)	(91,878)	(132,310)
Sales and maturities of short-term investments	45,908	169,468	65,300
Proceed from sales of property and equipment	31	—	—
Net cash provided by (used in) investing activities	3,947	74,297	(68,776)
Cash flows from financing activities:			
Proceeds from issuance of common stock upon initial public offering, net of issuance costs paid	254,805	—	134,567
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	1,195	363	314
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)	(9)
Proceeds from exercise of common stock warrant	—	76	—
Payment of redeemable convertible preferred stock issuance costs	—	(181)	—
Net cash provided by financing activities	385,682	249	134,872
Net increase in cash, cash equivalents and restricted cash	290,614	4,254	19,654
Cash, cash equivalents and restricted cash as of beginning of period	37,669	33,415	13,761
Cash, cash equivalents and restricted cash as of end of period	$ 328,283	$ 37,669	$ 33,415
Supplemental cash flow disclosures:			
Cash paid for income taxes	$ 19	$ 35	$ 9
Cash paid for interest	$ 3,270	$ 3,352	$ 3,292
Cash paid for amounts included in the measurement of operating lease liabilities	$ —	$ 505	$ 464

The accompanying notes are an integral part of these financial statements

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

	Years Ended December 31,		
	2020	**2019**	**2018**
Supplemental non-cash investing and financing activities:			
Capital expenditures included in accounts payable and accrued expenses	$ 323	$ 867	$ 83
Transfer of inventories to property and equipment	$ 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	$ 23,299
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	$ —

The accompanying notes are an integral part of these financial statements

Notes to Financial Statements

1. Description of Business

Outset Medical, Inc. (the Company) was originally incorporated on May 5, 2003 in the state of Delaware under the name Home Dialysis Plus, Ltd. The name of the Company was changed to Outset Medical, Inc. on January 5, 2015. 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 that designed to be utilized across the continuum of care, allowing dialysis to be delivered anytime, anywhere and by anyone. The integration of water purification and on-demand dialysate production enables Tablo to serve as a dialysis clinic on wheels, with 2-way wireless data transmission and a proprietary data analytics platform powering a new holistic approach to dialysis care. The Company's headquarters are located in San Jose, CA.

The Company's registration statement on Form S-1 related to its initial public offering (IPO) was declared effective by the Securities and Exchange Commission (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.

During the year ended December 31, 2020, the Company recognized $18.5 million of cumulative stock-based compensation expense associated with stock options that vest upon the achievement of market and performance conditions satisfied on the effectiveness of the IPO (see Note 9 for further discussion).

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. During the years ended December 31, 2020, 2019 and 2018, the Company incurred net losses of $121.5 million, $68.3 million and $49.8 million, respectively. As of December 31, 2020, the Company had an accumulated deficit of $494.1 million.

As of December 31, 2020, the Company had cash, cash equivalents and short-term investments of $314.9 million, which are available to fund future operations, and restricted cash of $33.3 million, for a total cash, cash equivalents, restricted cash and short-term investments balance of $348.2 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 cash generated from revenues from its products, as well as services and other sales, will be sufficient to meet its anticipated needs for at least the next 12 months from the issuance date of the financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The financial statements have been prepared in accordance with U.S. generally accepted accounting principles (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.

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 common stock and redeemable convertible preferred stock, the fair value of stock options, the fair value of the redeemable convertible preferred stock warrant liability, valuation of investments, recoverability of the Company's net deferred tax assets and the related valuation allowance, 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.

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's primary operation is in the United States and it has derived its revenue from sales to customers in the United States. The Company has operated a manufacturing facility in Mexico since 2020. The Company's long-lived tangible assets, as well as the Company's operating lease right-of-use assets recognized on the balance sheets, located in Mexico were $6.0 million as of December 31, 2020.

Cash, Cash Equivalents and Restricted Cash

As of December 31, 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. The restricted cash balance of $0.7 million as of December 31, 2019 relates to collateral for the building leases.

The Company considers all highly liquid investments purchased with an original maturity of three months or less at the date of purchase to be cash equivalents. As of December 31, 2020 and 2019, the Company's cash equivalents were held in institutions in the United States and include deposits in a money market fund which were unrestricted as to withdrawal or use.

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,	
	2020	2019
Cash and cash equivalents	$ 294,972	$ 36,926
Restricted cash	33,311	743
Total cash, cash equivalents and restricted cash	$ 328,283	$ 37,669

Short-Term Investments

Short-term investments have been classified as available-for-sale and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. The Company determines the appropriate classification of its investments in debt securities at the time of purchase. Available-for-sale securities with original maturities beyond three months at the date of purchase are classified as current based on their availability for use in current operations.

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. Commercial paper, corporate debt and asset-backed securities are 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.

Concentration of Credit Risk

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 deposits 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, 2020.

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. Two customers accounted for 22% and 16% of accounts receivable, respectively, as of December 31, 2020. Four customers accounted for 22%, 13%, 11% and 10% of accounts receivable, respectively, as of December 31, 2019. 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.

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.

A fair value hierarchy has been established which gives precedence to fair value measurements calculated using observable inputs over those using unobservable inputs. This hierarchy prioritized the inputs into three broad levels as follows:

Level 1: Quoted prices in active markets for identical instruments;

Level 2: Other significant observable inputs (including quoted prices in active markets for similar instruments); and

Level 3: Significant unobservable inputs (including assumptions in determining the fair value of certain investments).

The Company's cash and cash equivalents, restricted cash, short-term investments, 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. Money market funds are highly liquid investments and are actively traded. The pricing information on the Company's money market funds are readily available and can be independently validated as of the measurement date. This approach results in the classification of these securities as Level 1 of the fair value hierarchy.

The Company has issued redeemable convertible preferred stock warrants and estimated the fair value of these warrants using the Black-Scholes option pricing model, which is considered to be a Level 3 fair value measurement. The assumptions were based on the individual characteristics of the warrants on the valuation date, as well as assumptions for future financings, expected volatility, expected life, yield, and risk-free interest rate. Effective on the date of the IPO, the redeemable convertible preferred stock warrants

were considered to be indexed to the Company's stock, and accordingly, the fair value of redeemable convertible preferred stock warrant liability was remeasured immediately prior to the IPO (See Note 4).

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, 2020 and 2019, respectively.

Inventories

Inventories are stated at the lower of cost or net realizable value. Cost is determined using the standard cost method, which approximates actual costs as determined on a first-in, first-out basis. The carrying value of inventories is reduced for any difference between cost and net realizable value of inventories that is determined to be obsolete or unmarketable, based upon assumptions about future demand and market conditions. The Company also reviews its inventory value to determine if it reflects the lower of cost or net realizable value based on factors such as inventory items sold at negative gross margins and purchase commitments. Adjustments to the value of inventory establish a new cost basis and are considered permanent even if circumstances later suggest that increased carrying amounts are recoverable. If demand is higher than expected, the Company may sell inventory that had previously been written down. 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.

Impairment for Long-Lived Assets

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, 2020 and 2019.

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 and 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.

Redeemable Convertible Preferred Stock Warrant Liability

The Company has accounted for its freestanding warrants to purchase shares of the Company's redeemable convertible preferred stock as liabilities at fair value upon issuance primarily because the shares underlying the warrants contained contingent redemption features outside of the Company's control. The warrants were subject to re-measurement at each balance sheet date and any change in fair value was recognized in the statements of operations as the change in fair value of redeemable convertible preferred stock warrant liability. The carrying value of the warrants would continue to be adjusted until these instruments are exercised, expire or convert into warrants to purchase shares of the Company's common stock upon the completion of a liquidation event, including the completion of the IPO, which occurred on September 15, 2020. Upon the closing of the IPO, the liabilities were reclassified to additional paid-in capital, a component of Stockholders' equity (deficit).

The Company estimated the fair value of these liabilities using the Black-Scholes option pricing model and assumptions that were based on the individual characteristics of the warrants on the valuation date, as well as assumptions for future financings, expected volatility, expected life, yield, and risk-free interest rate.

Defined Contribution 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 annual compensation on a pre-tax basis. The Company is authorized to make matching contributions but has not made such contributions for the years ended December 31, 2020, 2019 and 2018.

Revenue

The Company's revenue is generated primarily from 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.

The Company considers each product and each service contract to be a distinct performance obligation. Revenue is recognized when a performance obligation is satisfied, which occurs when control of the promised products or services is transferred to the customer in an amount that reflects the consideration the Company expects to receive in exchange for those products or services. 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 as the output of the service is transferred to the customer over time, typically evenly over the contract term. Revenue is recognized net of allowances for returns and any taxes collected from customers, which are subsequently remitted to governmental authorities.

The Company's contracts with customers often include promises to transfer multiple products and services to a customer. Determining whether products and services are considered distinct performance obligations that should be accounted for separately versus together may require significant judgment. Judgment is also required to determine the stand-alone selling price (SSP) for each distinct performance obligation. The Company uses an observable price to estimate SSP for items that are sold separately, including customer support 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. This is considered a material right and an additional performance obligation of the contract. 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 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 the Company's stock-based awards is based on their grant date fair value.

Service-based options initially 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. Any subsequent follow-on options granted to the optionee generally vest monthly over four 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 of the equity-settled award.

For stock options with performance and market-based vesting conditions, stock-based compensation expense is recognized when it is considered probably 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 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 approach.

RSUs initially 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 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.

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 include personnel and related costs, supplies, testing, contract and other outside service fees, depreciation expense and allocated costs including facilities and information technology.

Advertising Costs

Advertising costs are expensed as incurred. The advertising costs for years ended December 31, 2020, 2019 and 2018 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.

Recently Adopted Accounting Pronouncements

In August 2018, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement* (ASU 2018-13). The amendments on changes in unrealized gains and losses recognized in other comprehensive income

categorized within Level 3, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should be applied prospectively in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. The Company adopted ASU 2018-13 as of January 1, 2020, 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.

In December 2019, the 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. This standard is effective for fiscal periods beginning after December 15, 2021. The Company is currently evaluating this standard and the impact it may have 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,		
	2020	**2019**	**2018**
Consoles	$ 32,871	$ 12,187	$ 1,226
Consumables	6,742	1,563	523
Total product revenue	39,612	13,750	1,749
Service and other revenue	10,323	1,328	258
Total revenue	$ 49,935	$ 15,078	$ 2,007

For the years ended December 31, 2020 and 2019, $3.1 million and $0.5 million of consoles revenue were from console operating lease arrangements. There was no such lease revenue for the year ended December 31, 2018.

The maturity of the Company's operating leases as of December 31, 2020 was as follows (in thousands):

Years Ending December 31:	
2021	$ 4,431
2022	1,699
Total minimum lease payments	6,130

Performance Obligations

As of December 31, 2020, 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 $3.8 million, which is recorded as deferred revenue on the Company's balance sheet. Of that amount, $3.2 million will be recognized as revenue during the year ended December 31, 2021 and approximately $0.6 million thereafter.

Contract Liabilities

The contract liabilities consist of deferred revenue which represents payments received in advance of revenue recognition related to console service agreements and for prepayments for products or services yet to be delivered. Revenue under these agreements is recognized over the related service period. The following table summarizes the Company's contract liabilities (in thousands):

	December 31,	
	2020	2019
Deferred revenue, current	$ 3,201	$ 883
Deferred revenue, noncurrent	570	134
Total deferred revenue	$ 3,771	$ 1,017

During the year ended December 31, 2020, 2019 and 2018, the Company recognized $0.9 million, $0.3 million, and $0.3 million of revenue, respectively, that was included in the deferred revenue balance at the beginning of the period.

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, 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 assets		$ 75,953	$ 1	$ —	$ 75,954

		December 31, 2019			
	Valuation Hierarchy	Amortized Costs	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Assets:					
Cash equivalents:					
Money market funds	Level 1	$ 29,761	$ —	$ —	$ 29,761
Commercial paper	Level 2	2,299	—	—	2,299
Short-term investments:					
Commercial paper	Level 2	10,972	—	—	10,972
Corporate debt	Level 2	17,357	19	—	17,376
Asset-backed securities	Level 2	4,801	3	—	4,804
Total assets		$ 65,190	$ 22	$ —	$ 65,212
Liabilities:					
Redeemable convertible preferred stock warrant liability	Level 3	$ 4,285	$ —	$ —	$ 4,285
Total liabilities		$ 4,285	$ —	$ —	$ 4,285

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.

As of December 31, 2020, the remaining contractual maturities for available-for-sale securities were less than one year.

Impairment assessments are made at the individual security level each reporting period. When the fair value of an available-for-sale security is less than its cost at the balance sheet date, a determination is made as to whether the impairment is other-than-temporary and, if it is other-than-temporary, an impairment loss is recognized in earnings equal to the difference between the investment's amortized cost and fair value at such date. As of December 31, 2020 and December 31, 2019, none of the Company's available-for-sale securities were in an unrealized loss position.

Redeemable Convertible Preferred Stock Warrant Liability

The valuation of the Company's redeemable convertible preferred stock warrant liability contained unobservable inputs that reflected the Company's own assumptions for which there was little, if any, market activity at the measurement date. Accordingly, the Company's redeemable convertible preferred stock warrant liability was measured at fair value on a recurring basis using unobservable inputs and were classified as Level 3 inputs, and any change in fair value of the redeemable convertible preferred stock warrant liability was recognized in the statements of operations.

Effective on the date of the IPO, the redeemable convertible preferred stock warrants were considered to be indexed to the Company's stock and now meet the criteria to be classified in equity. The Company remeasured the warrants immediately prior to the IPO. The fair value of the Series A redeemable convertible preferred stock warrants which were converted into common stock warrants was determined using the Black-Scholes option-pricing model and deemed a Level 3 fair value measurement. The fair value of Series B and C redeemable convertible preferred stock warrants which were exercised was determined using the intrinsic method based on the IPO price of $27.00 per share and deemed a Level 2 fair value measurement. Subsequently, the entire redeemable convertible preferred stock warrants liability was reclassified to additional paid-in capital.

The fair value of the warrants, prior to the IPO, was determined using the Black-Scholes option pricing model and the following assumptions:

	Years Ended December 31,		
	2020	2019	2018
Fair value of shares of redeemable convertible preferred stock	$1.39 – $27.00	$1.36 – $2.40	$2.05 – $3.25
Expected term (in years)	3.24 – 7.25	3.74 – 7.50	4.74 – 8.50
Expected volatility	53.7% – 57.2%	48.1% – 50.0%	48.8% – 50.1%
Risk-free interest rate	0.18% – 1.83%	1.76% – 1.83%	2.51% – 2.59%
Dividend yield	0%	0%	0%

The change in fair value of the redeemable convertible preferred stock warrant liability was as follows (in thousands):

	Years Ended December 31,		
	2020	2019	2018
Beginning balance	$ 4,285	$ 8,085	$ 7,823
Change in fair value	93	(3,800)	262
Conversion of Series A redeemable convertible preferred stock warrants to common stock warrants upon the closing of the IPO	(1,252)	—	—
Reclassified to additional paid-in capital	(3,126)	—	—
Ending balance	$ —	$ 4,285	$ 8,085

5. Balance Sheet Components

Inventories

Inventories consist of the following (in thousands):

	December 31,	
	2020	2019
Raw materials	$ 7,989	$ 1,143
Work in process	6,200	842
Finished goods	4,195	2,611
Total inventories	$ 18,384	$ 4,596

Property and Equipment, net

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

	December 31,	
	2020	2019
Tablos under operating leases	5,158	3,120
Computers and software	3,131	1,768
Furniture and fixtures	1,399	648
Machinery and equipment	4,496	2,395
Leasehold improvements	4,459	174
Construction in progress	1,343	2,460
Total property and equipment	19,986	10,565
Less: accumulated depreciation and amortization	(4,988)	(2,670)
Property and equipment, net	14,998	7,895

Total depreciation and amortization expense for the years ended December 31, 2020, 2019 and 2018 was $3.2 million, $1.5 million and $1.1 million, respectively.

Accrued Expenses and Other Current Liabilities

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

	December 31,	
	2020	2019
Accrued inventory	$ 3,576	$ 798
Accrued research and development expenses	175	421
Accrued professional services	2,187	553
Others	1,965	1,137
Total accrued expenses and other current liabilities	$ 7,903	$ 2,909

Accrued Warranty Liability

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

	December 31,	
	2020	2019
Balance at the beginning of the period	$ 1,702	$ 293
Additions charge to cost of product revenue	4,858	2,578
Consumption	(3,647)	(1,169)
Balance at the end of the period	$ 2,913	$ 1,702

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 new 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 will take 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 Company also had a finance lease for office equipment that expired in 2020.

The following table presents the Company's ROU assets and lease liabilities (in thousands):

		December 31,	
Lease Classification	**Balance Sheet Classification**	**2020**	**2019**
Assets:			
Operating	Operating lease right-of-use assets	$ 8,253	$ —
Finance	Property and equipment	—	6
Total ROU assets		$ 8,253	$ 6
Liabilities:			
Current:			
Operating	Operating lease liabilities, current	$ 882	$ —
Finance	Accrued expense and other current liabilities	—	9
Noncurrent:			
Operating	Operating lease liabilities, noncurrent	8,044	—
Total lease liabilities		$ 8,926	$ 9

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

	Years ended December 31,		
	2020	2019	2018
Finance lease costs:			
Amortization of right-of-use assets	$ 6	$ 13	$ 10
Interest on lease liabilities	—	1	1
Operating lease costs	1,070	—	505
Variable lease costs	233	100	97
Short-term lease costs	371	520	—
Total lease costs	$ 1,680	$ 634	$ 613

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

	December 31,	
	2020	2019
Operating leases:		
Weighted-average remaining lease term	6.3 years	—
Weighted-average discount rate	8.7 %	—
Finance lease:		
Weighted-average remaining lease term	—	0.5 years
Weighted-average discount rate	—	10.6 %

The maturity of the Company's operating lease liabilities as of December 31, 2020 were as follows (in thousands):

Years Ending December 31:	
2021	$ 1,619
2022	1,796
2023	1,856
2024	1,911
2025	1,969
Thereafter	2,523
Total lease payments	$ 11,674
Less: imputed interest	(2,748)
Present value of operating lease liabilities	$ 8,926
Operating lease liabilities, current	$ 882
Operating lease liabilities, noncurrent	$ 8,044

Purchase Commitments

As of December 31, 2020, the Company had obligations under non-cancellable purchase commitments totaling $46.5 million, all of which will require payment within the next 12 months.

Litigation

From time to time, the Company may be involved in legal proceedings or investigations our reputation, business and financial condition and divert the attention of our management from the operation of our business. The Company is 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.

Indemnifications

In the ordinary course of business, the Company often includes standard indemnification provisions its arrangements with its partners, customer 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,	
	2020	**2019**
Principal of term loan	$ 30,000	$ 30,000
Unamortized debt discount	(326)	(939)
Total term loan	29,674	29,061
Less: term loan, current	—	(7,500)
Term loan, noncurrent	$ 29,674	$ 21,561

Perceptive Term Loans

On June 30, 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 the greater of (A) 0.5% above the Prime Rate as reported in the Wall Street Journal and (B) 3.75% (3.75% as of December 31, 2020). 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, 2020, the unamortized debt discount was $0.3 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, 2020 were as follows (in thousands):

Years Ending December 31:	
2021	$ 1,141
2022	1,141
2023	8,073
2024	12,667
2025	13,233
Total future payments	36,255
Less: amount representing interest	(4,230)
Less: final payment	(2,025)
Total term loan	30,000
Less: unamortized debt discount	(326)
Total term loan, net of debt discount	29,674

8. Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)

Redeemable Convertible Preferred Stock

Immediately prior to the closing of the Company's IPO, all of the outstanding shares of redeemable convertible preferred stock converted into 25,958,000 shares of common stock, excluding the 274,000 shares of common stock that were issued on the exercise of outstanding redeemable convertible preferred stock warrants.

Preferred Stock

Upon the closing of the IPO, the Company's amended and restated certificate of incorporation authorized 5,000,000 shares of undesignated preferred stock, $0.001 par value per share, the rights, preferences and privileges of which may be designated from time to time by the Company's board of directors. As of December 31, 2020, no shares of the preferred stock were issued and outstanding.

Redeemable Convertible Preferred Stock Warrants and Common Stock Warrants

On the closing of the IPO, the aggregate outstanding Series A redeemable convertible preferred stock warrants of 500,000 shares converted into 63,000 common stock warrants with an exercise price of $7.96 per share, which resulted in the reclassification of the convertible preferred stock warrant liability of $1.2 million to additional paid-in capital. The common stock warrants expire in September 2025.

On the closing of the IPO, the aggregate outstanding Series B redeemable convertible preferred stock warrants of 2,176,000 shares were net exercised with an exercise price of $2.2674 per share, which resulted in the issuance of 65,000 shares of the Company's common stock based on the IPO price of $27.00 per share. In addition, the aggregate outstanding Series C redeemable convertible preferred stock warrants of 1,655,000 shares were cash exercised at an exercise price of $2.5915 per share, which resulted in the issuance of 209,000 shares of the Company's common stock with total aggregate cash proceeds of $4.3 million.

In 2009, the Company issued a warrant to purchase 8,860 shares of common stock with an exercise price of $8.61 per share and a fair value of $30,000 in connection with a product development agreement. The warrant was fully vested and exercised during the first quarter of 2019.

Common Stock

The Company has reserved shares of common stock, on an as-if converted basis, for issuance as of December 31, 2020 as follows (in thousands):

	Shares
Warrants to purchase common stock	63
Stock options outstanding	4,763
Restricted stock units outstanding	44
Performance stock units outstanding	25
Shares available for future purchase under ESPP	687
Shares available for future grant under 2020 Plan	3,537
	9,118

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 September 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 will automatically increase on the first day of each fiscal year, commencing January 2021, and continuing until (and including) the fiscal year ending December 31, 2030, with such annual increase equal to an amount equal to the lesser of (i) 4% of the number of shares of common stock issued and outstanding on December 31 of the immediately preceding calendar year, and (ii) an amount determined by the Company's board of directors.

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, 2019	3,757	$ 3.95	7.81	$ 8,618
Granted	1,542	$ 11.31		
Exercised	(419)	$ 2.86		
Forfeited and expired	(117)	$ 7.28		
Balance as of December 31, 2020	4,763	$ 6.35	7.71	$ 240,504
Exercisable as of December 31, 2020	1,591	$ 3.89	6.40	$ 84,226

The weighted average grant date fair value of options granted to employees was $7.97, $2.77 and $1.90 per share during the years ended December 31, 2020, 2019 and 2018, respectively. The total intrinsic value of options exercised during the years ended December 31, 2020, 2019 and 2018 was $8.2 million, $0.2 million and $0.1 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, 2020, 2019 and 2018 was $3.3 million, $0.7 million and $0.7 million, respectively. As of December 31, 2020, the total unrecognized stock-based compensation expense related to the stock options, excluding stock options with market and performance conditions, was $6.2 million, which will be recognized over a weighted-average period of approximately 1.32 years.

Stock Options with Performance and Market Conditions

During the years ended December 31, 2020, 2019 and 2018, the Company granted 504,000, 632,000 and 321,000 shares of stock options with performance and market-based conditions to employees and executive officers. The options 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. In February 2020, the Company modified the market conditions, which resulted in a new grant date fair value for 1,457,000 stock options with performance and market-based conditions as of the modification date. As of December 31, 2020, 1,933,000 shares of these stock options were outstanding.

For the year ended December 31, 2020, the Company recorded cumulative stock-based compensation expense of $18.5 million related to all outstanding stock options with performance and market-based vesting conditions as the performance vesting condition was satisfied upon the closing of the IPO. As of December 31, 2020, 152,000 shares of these options were fully vested. Unamortized stock-based compensation expense amounted to $4.8 million as of December 31, 2020, which the Company expects to recognize over an estimated weighted-average period of 0.29 years.

Stock Option Valuation Assumptions

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,		
	2020	**2019**	**2018**
Expected term (in years)	5.06 – 10.00	4.97 – 5.05	4.78 – 4.98
Expected volatility	52.1% – 62.7%	49.3% – 50.9%	48.4% – 48.8%
Risk-free interest rate	0.35% – 1.54%	1.57% – 2.48%	2.65% – 3.02%
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 vest over the requisite service period if the Company achieves specified revenue targets. The PSUs 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, 2019	—	—	—	—
Granted	49	25	$ 50.69	$ 52.55
Vested	(5)	—	$ (43.26)	—
Outstanding as of December 31, 2020	44	25		

The total grant date fair value of RSUs vested for the year ended December 31, 2020 was $0.2 million. There were no RSUs granted prior to 2020. As of December 31, 2020, the total unrecognized stock-based compensation expense related to the RSUs was $2.2 million, which will be recognized over a weighted-average period of approximately 3.12 years.

As of December 31, 2020, the achievement of the performance goal for PSUs was not considered probable. As a result, no associated expense was recognized during the year ended December 31, 2020. There were no PSUs granted prior to 2020. The total unrecognized stock-based compensation expense related to the PSUs was $1.3 million as of December 31, 2020.

Employees Stock Purchase Plan (ESPP)

In September 2020, the Company adopted the Employee Stock Purchase Plan (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 will automatically increase on the first day of each fiscal year, commencing January 2021 and continuing 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.

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. The initial offering period began on September 15, 2020 and ran through February 26, 2021.

The fair value of the stock purchase rights under the ESPP is estimated using the Black-Scholes option pricing model. For the year ended December 31, 2020, the grant date fair value was $8.00 and estimated using the following assumptions:

Expected term (in years)	0.42
Expected volatility	57.0%
Risk-free interest rate	0.12%
Dividend yield	0%

The ESPP commenced in September 2020. No shares of common stock were purchased pursuant to the ESPP in 2020. As of December 31, 2020, 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 approximately 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,		
	2020	**2019**	**2018**
Cost of revenue	$ 255	$ 5	$ 14
Research and development	4,615	328	234
Sales and marketing	4,423	172	176
General and administrative	12,146	378	364
Total stock-based compensation expense	21,439	883	788

10. Income Taxes

The provision for income taxes was zero, $20,000 and $25,000 for the years ended December 31, 2020, 2019 and 2018, respectively. 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,		
	2020	2019	2018
Federal statutory income tax rate	21.0 %	21.0 %	21.0 %
State taxes	4.3	7.8	4.9
Change in valuation allowance	(23.4)	(28.5)	(27.2)
Federal and state tax credits	0.5	0.9	2.0
Stock based compensation	(0.6)	—	—
Non-deductible permanent expenses	(0.4)	—	—
Effect of deferred tax adjustment	(1.4)	—	—
Other	—	(1.2)	(0.7)
	— %	— %	— %

Deferred Tax Assets

The major components of deferred tax assets were as follows as of the dates indicated (in thousands):

	December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 76,838	$ 56,127
Tax credits	10,039	8,777
Accrual and reserves	2,392	1,675
Tangible and intangible assets	19,090	15,553
Stock-based compensation	2,843	733
Gross deferred tax assets	111,202	82,865
Valuation allowance	(111,202)	(82,865)
Net deferred tax assets	$ —	$ —

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, 2020 and 2019 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 $28.3 million, $24.0 million and $13.6 million during the years ended December 31, 2020, 2019 and 2018, respectively.

Net Operating Loss and Tax Credit Carryforwards

As of December 31, 2020, the Company had a net operating loss carryforward for federal income tax purposes of $301.3 million. Federal net operating losses of $173.5 million incurred after 2017 do not expire. 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 $174.0 million. State net operating losses of $30.9 million do not expire. The remaining state net operating loss carryforward of $143.1 million will begin to expire in 2021 and continue to expire through 2040.

The Company had federal research and development credits of $5.8 million, which will begin to expire in 2030 and state research and development credits of $4.3 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, 2020 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 year ended December 31, 2020 was as follows (in thousands):

Balance, beginning of year	$ 1,020
Decrease related to current year positions	—
Increase related to current year positions	562
Balance, end of year	$ 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. 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 and state authorities for three and four 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,		
	2020	**2019**	**2018**
Numerator:			
Net loss	$ (121,492)	$ (68,299)	$ (49,780)
Adjustment to redemption value on redeemable convertible preferred stock	(362)	(134,760)	(23,300)
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	$ (79,324)	$ (85,461)	$ (73,080)
Denominator:			
Weighted-average shares of common stock, basic and diluted	16,358	858	725
Net loss per share attributable to common stockholders, basic and diluted	$ (4.85)	$ (99.58)	$ (100.75)

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,		
	2020	**2019**	**2018**
Stock options to purchase common stock	4,763	3,757	3,311
Warrant to purchase common stock	63	—	9
Restricted stock units	44	—	—
Shares committed under ESPP	52	—	—
Redeemable convertible preferred stock, on an as-if converted basis	—	18,644	18,634
Warrants to purchase redeemable convertible preferred stock	—	505	599
Total	4,922	3,757	3,320

12. Selected Quarterly Information

The following tables present certain unaudited quarterly financial information for each of the eight quarters in the two-year period ended December 31, 2020. This quarterly information has been prepared on the same basis as the audited financial statements and includes all adjustments necessary to state fairly the information for the periods presented.

	Fiscal 2020 Quarter Ended (Unaudited)			
	March 31	June 30	September 30	December 31
	(in thousands, except per share amounts)			
Revenue	$ 7,190	$ 11,742	$ 13,756	$ 17,247
Gross profit	$ (3,564)	$ (4,764)	$ (5,126)	$ 417
Net loss	$ (20,650)	$ (26,505)	$ (42,294)	$ (32,043)
Net income (loss) attributable to common stockholders, basic	$ 3,387	$ (26,505)	$ (42,294)	$ (32,043)
Net income (loss) attributable to common stockholders, diluted	$ 4,161	$ (26,505)	$ (42,294)	$ (32,043)
Net income (loss) per share attributable to common stockholders, basic	$ 0.77	$ (4.58)	$ (3.44)	$ (0.75)
Net income (loss) per share attributable to common stockholders, diluted	$ 0.74	$ (4.58)	$ (3.44)	$ (0.75)

	Fiscal 2019 Quarter Ended (Unaudited)			
	March 31	June 30	September 30	December 31
	(in thousands, except per share amounts)			
Revenue	$ 2,491	$ 2,872	$ 2,630	$ 7,085
Gross profit	$ (5,258)	$ (4,470)	$ (5,294)	$ (2,780)
Net loss	$ (16,422)	$ (17,029)	$ (15,402)	$ (19,446)
Net loss attributable to common stockholders, basic and diluted	$ (24,292)	$ (25,057)	$ (16,666)	$ (19,446)
Net loss per share attributable to common stockholders, basic and diluted	$ (30.34)	$ (18.93)	$ (18.93)	$ (21.18)

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, and 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, 2020.

Management's Annual Report on Internal Control over Financial Reporting

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by the rules of the SEC for newly public companies.

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, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

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 2021 Annual Meeting of Stockholders within 120 days of our fiscal year ended December 31, 2020 (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*" 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.

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				
10.1†	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				
10.6†*	Form of Restricted Stock Unit Award Grant Notice and Award Agreement for Outset Medical, Inc. 2020 Equity Incentive Plan				
10.7†*	Form of Restricted Stock Award Grant Notice and Award Agreement for Outset Medical, Inc. 2020 Equity Incentive Plan				
10.8†*	Form of Performance Stock Unit Award Grant Notice and Award Agreement for Outset Medical, Inc. 2020 Equity Incentive Plan				
10.9†	Outset Medical, Inc. 2020 Employee Stock Purchase Plan	S-1/A	333-248225	10.5	September 9, 2020
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	Amended and Restated Stockholders Agreement by and among the Institutional Investors, the Other Investors, the Key Common Holders and Outset Medical, dated as of January 27, 2020	S-1	333-248225	10.9	August 21, 2020
10.14#	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
10.15#	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
10.16#	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
10.17#	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
10.18#	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
10.19#	Manufacturing Services Agreement by and between Paramit Corporation and Outset Medical, Inc. dated as of April 15, 2016	S-1	333-248225	10.15	August 21, 2020

10.20#	Amendment to Contract Manufacturer Agreement by and between Paramit Corporation and Outset Medical, Inc. dated as of January 26, 2018	S-1	333-248225	10.16	August 21, 2020
10.21#	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
10.22#	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
10.23#	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
10.24#	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
10.25#	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
10.26#	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
10.27#	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
10.28#	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
10.29#*	Amendment to Solicitation/Modification of Contract from ASPR-BARDA to Outset Medical, Inc., dated November 25, 2020				
10.30#*	Supply Agreement by and between Carlisle Interconnect Technologies, Inc. and Outset Medical, Inc., dated January 12, 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	XBRL Instance Document				
101.SCH	XBRL Taxonomy Extension Schema Document				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				

* Filed herewith

† Indicates a management contract or compensatory plan or arrangement.

Portions of the exhibit have been or will be excluded because it both (i) is not material and (ii) would be competitively harmful if publicly disclosed.

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: March 22, 2021

By: /s/ Leslie Trigg
Leslie Trigg
President and Chief Executive Officer

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Leslie Trigg and Rebecca Chambers, 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; Director (*Principal Executive Officer*)	March 22, 2021
/s/ Rebecca Chambers Rebecca Chambers	Chief Financial Officer (*Principal Financial Officer and Principal Accounting Officer*)	March 22, 2021
/s/ D. Keith Grossman D. Keith Grossman	Chairman of the Board of Directors	March 22, 2021
/s/ Karen Drexler Karen Drexler	Director	March 22, 2021
/s/ Patrick T. Hackett Patrick T. Hackett	Director	March 22, 2021
/s/ Jim Hinrichs Jim Hinrichs	Director	March 22, 2021
/s/ Ali Osman Ali Osman	Director	March 22, 2021