**Risk Factors Comparison 2024-02-21 to 2023-02-13 Form: 10-K**

**Legend:** **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

The following summarizes the principal factors that make an investment in our company speculative or risky, all of which are more fully described in the risk factors section below. This summary should be read in conjunction with the risk factors section and should not be relied upon as an exhaustive summary of the material risks facing our business. The following factors could result in harm to our business, reputation, revenue, financial results, and prospects, among other impacts: Risks Related to Our Business and Industry • Our history of net losses and expectation that we will continue to incur losses • Our ability to **achieve sustainable gross margins, including by** reduce manufacturing **and service** costs • Our ability to attain market acceptance for Tablo among providers and patients • Concentration of our revenues in a single product and concentration of a large percentage of our revenues from ~~our largest~~ **a limited number of** ~~customer~~ **customers • Financial pressures faced by our customers including capital budget constraints, staffing shortages and increased costs • Our ability to expand into the home hemodialysis market and the expansion of the home hemodialysis market itself** • Risks associated with our international manufacturing operations ~~• Our ability to expand into the home hemodialysis market and the expansion of the home hemodialysis market itself~~ • Our reliance on third- party suppliers, including single source suppliers and contract manufacturers, and our ability to overcome **any** manufacturing **or** ~~disruptions, including any~~ supply chain disruptions ~~resulting from the recent COVID- 19 pandemic • Financial pressures faced by our customers including staffing shortages and increased costs and the resulting cost- containment efforts of our current and potential customers • The impact of the recent pandemic, natural or man- made disasters and similar events on our business~~ • Our ability to continue innovating and improving Tablo, ensure strong product performance and reliability, offer high quality support, ensure proper training and use of Tablo, and increase our sales and marketing capabilities • Our ability to compete effectively with existing manufacturers and new entrants • Our ability to effectively manage privacy, information and data security risks, including our ability to adequately defend against, respond to and manage increasingly sophisticated cyberattacks in an increasingly complex cyber ecosystem • Our estimates of the sizes of the markets for Tablo • Our ability to accurately forecast customer demand and manage our inventory **• The impact of the recent pandemic, natural or man- made disasters and similar events on our business** • Potential disruptions of service provided by third parties that host our cloud- based ecosystem and information technology systems • Potential litigation, including product liability claims, and the expense and potential unavailability of insurance coverage for any liabilities resulting from Tablo • Risks related to our credit agreements, including interest rate risk and our ability to **access additional capital and / or** meet certain covenants Risks Related to Government Regulation • Our ability to recover from disruptions to our business and operations as a result of the prior shipment hold on Tablo for home use • Our compliance with FDA and other medical device regulations applicable to our products and operations, including our ability to: **resolve the warning letter we recently received from the FDA,** comply with the post- market surveillance order recently issued by the FDA for Tablo **and resume our distribution of TabloCart with Prefiltration pending the FDA' s review and clearance of the submitted 510 (k) application** ; obtain and maintain necessary FDA regulatory clearance or approvals for Tablo, related products, or any future product modifications or new products; comply with ongoing FDA requirements, including related to the manufacturing, marketing and promotion of our products, and the ability of our suppliers to so comply; and manage the risks and expenses associated any clinical trials necessary to support future product submissions to the FDA • Impact of potential changes to scope of coverage and reimbursement rates for dialysis treatments or healthcare reform measures • Impact of potential adverse medical events associated with Tablo, product failures or malfunctions, or our failure to report such events to the FDA • Our ability to comply with various laws and regulations regarding healthcare, data privacy and security, and environmental and occupational safety Risks Related to Our Intellectual Property • Our ability to obtain, maintain, protect and enforce our intellectual property rights, including our patents, copyrights, trademarks and trade secrets Risks Related to Ownership of Our Common Stock • Fluctuations in the market price of our common stock in response to numerous factors regardless of our operating performance • Influence of principal stockholders and management over matters subject to stockholder approval • Our organizational documents include certain provisions that may make a change of control more difficult, as well as exclusive forum requirements General Risks • General economic and financial market conditions • Substantial resources associated with complying with the laws and regulations affecting public companies • Our ability to attract and retain key personnel and maintain our corporate culture • Risks associated with potential future acquisitions or investments • Our ability to comply with anti- corruption, anti- bribery, anti- money laundering and similar laws • Our estimates or judgments relating to our accounting policies • Expectations relating to ESG factors The summary risk factors described above should be read together with the text of the full risk factors below and the other information set forth in this Annual Report, including our financial statements and the related notes and the section entitled " Management' s Discussion and Analysis of Financial Condition and Results of Operations ", as well as in other documents that we file with the SEC. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us, or that we currently deem to be immaterial, may also arise and materially impact our business. If any of these risks occur, our business, results of operations and financial condition could be materially and adversely affected and the trading price of our common stock could decline. Risks Related to our Business and Industry We have a history of net losses, and we expect to continue to incur losses for the foreseeable future. If we ever achieve profitability, we may not be able to sustain it. We have incurred losses since our inception and expect to continue to incur significant net losses for the foreseeable future. We have incurred net losses of $ **172. 8 million, $** 163. 0 million ~~, and~~ $ 131. 9 ~~million and $ 121. 5~~ million for the years ended December 31, **2023,** 2022, **and** 2021 ~~, and 2020~~ , respectively. As of December

31, ~~2022~~ **2023**, we had $ ~~290~~ **206**. ~~8~~ **7** million in cash, cash equivalents, restricted cash and short- term investments, and an accumulated deficit of $ ~~789~~ **961**. ~~0~~ **7** million. Based on our current planned operations, we expect our existing cash, cash equivalents and short- term investments, cash generated from revenues from our products and services, and proceeds received ~~and currently available~~ from the debt financing described in Note 7, Term Loans, to our audited financial statements included in this Annual Report, will be sufficient to meet our anticipated needs for at least the next 12 months from the date of this Annual Report. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our revenue is derived, and we expect it to continue to be derived, primarily from sales of Tablo, its associated consumables and related services. Because of its recent commercial introduction, Tablo currently has limited product and brand recognition. In addition, demand for Tablo may decline or may not increase as quickly as we expect. Our ability to generate revenue from sales of Tablo, associated consumables and related services, or from any products we may develop in the future, may not be sufficient to enable us to transition to profitability and generate positive cash flows **within the timeframe we anticipate or at all**. ~~We~~ **Over time, we** expect that our cost of service, sales and marketing, research and development, regulatory and other expenses will continue to increase as we expand our marketing efforts to increase adoption of Tablo, expand existing relationships with our customers, obtain regulatory clearances or approvals for future product enhancements to Tablo, and conduct clinical trials on Tablo. In addition, we expect our general and administrative expenses to increase **over the long- term** due to the additional costs associated with scaling our business operations and continuing to operate as a public company, including due to legal, accounting, insurance, exchange listing and SEC compliance, investor relations and other expenses. As a result, we expect to continue to incur operating losses and may never achieve profitability. We will need to generate significant additional revenue in order to achieve and sustain profitability. Even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time. If we do not achieve or sustain profitability, it will be more difficult for us to finance our business and accomplish our strategic objectives, either of which would have a material adverse effect on our business, financial condition and results of operations. Our ability to achieve sustainable gross margins depends on the success of our **various** initiatives designed to **expand gross margin** ~~reduce the costs of manufacturing and producing our products, mitigate against supply chain challenges, and drive down service costs per console~~. We have undertaken a number of initiatives designed to reduce the cost of producing our products ~~and otherwise mitigate against supply chain challenges~~. ~~We established~~ **Over the past three years, we have moved the production of Tablo consoles and** a **majority of Tablo cartridges in- house at our** manufacturing facility ~~for the production of Tablo consoles~~ in **Tijuana,** Mexico which we operate in collaboration with our outsourced business administration service provider, TACNA. ~~During 2021, we fully insourced Tablo console manufacturing at this~~ **This** ~~facility, which has lowered our costs of manufacturing and producing consoles. We continue to partner with contract manufacturers in the production of the Tablo cartridge. During 2022, we moved production of a majority of Tablo cartridges to a contract manufacturer in Mexico, while continuing to produce a portion through our contract manufacturer in Southeast Asia. We believe this transition~~ has helped ~~us achieve cost reductions through lower freight costs and mitigate against global supply chain challenges. Recently, in an effort to~~ further our long- term gross margin expansion and supply continuity strategies **while reducing the costs of Tablo console production** and ~~improve~~ **improving** the flexibility of our operations **. We plan to continue to** ~~, we initiated production of Tablo cartridges in- house~~ -- **use** ~~at~~ our **design** ~~manufacturing facility in Mexico which we operate in collaboration with TACNA~~, **engineering, supply chain,** and ~~we intend to increase the quantity of Tablo cartridges produced at this facility as we ramp our cartridge~~ manufacturing capabilities ~~during~~ **to help further advance and improve** the ~~remainder~~ **efficiency** of **our manufacturing processes, lower** the ~~year~~ **cost of parts and components, and lower our costs of production**. **However,** ~~There~~ **there** is no guarantee that we will be able to sustain cost reductions, achieve planned cost reductions, or otherwise achieve the anticipated benefits from our various initiatives. For example, we may be unable to sustain the savings associated with producing **Tablo** consoles **at** our manufacturing facility with TACNA, or the benefits we anticipate will result from insourcing Tablo cartridge production at this same facility may not materialize or be as significant as projected or realized within the timeframe we currently estimate. There may also be unforeseen occurrences that increase our costs, such as increased prices of raw materials, changes to labor costs, less favorable terms with third party suppliers, freight providers, or contract manufacturing partners, or disruptions to the operations of our contract manufacturers or third- party suppliers including as a result of the recent COVID- 19 pandemic. ~~For example, in late 2021, supply chain disruptions exacerbated by COVID- 19 outbreaks and protocols escalated, and we faced increased supply constraints, which increased freight costs associated with the transportation of Tablo cartridges. See the risk factor below entitled " We depend upon third- party suppliers, including contract manufacturers and single source suppliers, making us vulnerable to supply problems and price fluctuations. " Our ability to maintain our product pricing is dependent on our customers' recognition that the benefits outweigh the higher upfront purchase price.~~ If we are unable to reduce our costs ~~,~~ **or** if cost reductions or other anticipated benefits are less significant or less timely than projected ~~or if we are unable to maintain our product pricing~~, we will not be able to achieve sustainable gross margins, which would adversely affect our ability to invest in and grow our business and adversely impact our business, financial condition and results of operations. **Moreover, our ability to expand gross margins will also depend in part on our ability to control the average selling prices of our products and services, including by selling higher- margin accessories, consumables and services.** Our ability to ~~recognize~~ **maintain our product pricing is dependent on our customers' recognition that the benefits outweigh the higher upfront purchase price. If we are unable to maintain our product pricing** ~~our~~ **or** ~~goal of~~ **continue to sell higher- margin accessories, consumables and services at the levels we anticipate, our ability to** ~~expanding~~ -- **expand gross margins will be adversely affected, which would harm our business, financial condition and results of operations. Lastly, our ability to expand** gross margins is also dependent on the success of our initiatives to better leverage our field service team and drive down service costs per console, including through our cloud- based data system, remote monitoring, remote diagnostics and repairs, and other enhancements designed to improve the performance and reliability of Tablo. If we are unable to continuously improve the

performance and reliability of Tablo, broaden our installed base or if these initiatives are otherwise unsuccessful, we may fail to better leverage our field service team and drive down service costs per console within the ~~timeframes~~ **timeframe** we anticipate or at all, which could delay or prevent us from achieving sustainable gross margins, and adversely impact our financial condition, results of operation and future growth. The commercial success of Tablo will depend upon attaining significant market acceptance among providers and patients. Our success will depend, in part, on the acceptance of Tablo as safe, easy to learn, easy to use, clinically flexible, operationally versatile and, with respect to providers, cost effective. We began commercializing Tablo throughout the United States in 2018 and began the process to commercialize Tablo for home- based dialysis in 2020. Our **relatively** limited commercialization experience makes it **more** difficult to evaluate our current business and predict our future prospects. ~~We cannot~~ **It is difficult to** predict how quickly, if at all, providers and patients will accept Tablo or, if accepted, how frequently it will be used. These constituents must believe that Tablo offers benefits over traditional machines. The degree of market acceptance of Tablo will depend on a number of factors, including: • whether providers and others in the medical community consider Tablo to be a safe and cost- effective treatment method; • the potential and perceived advantages of Tablo over traditional machines; • the potential and perceived advantages of Tablo relative to our customers' other capital and operating purchase requirements; • the cost of treatment, maintenance and upkeep using Tablo in relation to traditional machines; • the cost of treatment, and convenience and ease of use of Tablo in the acute setting relative to outsourcing dialysis services to third- party providers; • the convenience and ease of use of Tablo relative to traditional machines; • the effectiveness of our sales and marketing efforts for Tablo; • our ability to provide incremental data that show the clinical benefits and cost effectiveness of, and operational benefits from, Tablo; • any changes to the availability of coverage and adequate reimbursement for dialysis from payors, including government authorities; • pricing pressure, including from Group Purchasing Organizations (GPOs), seeking to obtain discounts on Tablo based on the collective buying power of the GPO members; • product labeling or product insert requirements by the FDA or other regulatory authorities; and • limitations or warnings contained in the labeling cleared or approved by the FDA or other authorities. Additionally, even if Tablo achieves widespread market acceptance, it may not maintain that market acceptance over time if competing products or technologies, which are more cost effective or received more favorably, are introduced. Failure to achieve or maintain market acceptance and / or market share would limit our ability to generate revenue and would have a material adverse effect on our business, financial condition and results of operations. We currently derive substantially all of our revenue from the sale of Tablo and associated consumables and are therefore highly dependent on Tablo for our success. We derive substantially all of our revenues from sales of Tablo and its associated consumables, with the remainder of our revenues largely coming from services provided for the support and maintenance of Tablo. Accordingly, our business is exposed to risks that our revenues are concentrated in a single product. As a result, any event that adversely affects Tablo or the market for Tablo and associated consumables could adversely affect our business, financial condition and results of operation. Our customers are facing **financial pressures including capital budget constraints,** staffing shortages ~~,~~ **and** increased costs **,** ~~and other financial pressures~~ that have had, and may continue to have, a negative impact on our revenue. ~~Healthcare providers (including~~ **Beginning in the third quarter of 2023, we began to observe an increasing number of** our existing and prospective customers ~~) are facing a nationwide~~ **deferring their decisions to purchase Tablo in an environment of rising interest rates and more cautious capital spending. These deferrals served to further elongate our sales cycle and the timing of delivery and installations which in turn, contributed to an adverse impact on our bookings and revenues for the second half of 2023, and we expect these negative impacts to continue into 2024. During 2022, our existing and prospective customers faced** ~~shortage~~ **shortages** of ~~qualified~~ **skilled** nurses and other clinical personnel ~~due to long- term trends that have been exacerbated by the recent COVID- 19 pandemic. As competition for these healthcare professionals has~~ **as well as** ~~intensified, providers are facing increased difficulties attracting and retaining skilled clinical personnel, resulting in increased costs, staffing shortages, and other disruptions. These challenging labor market conditions in the healthcare industry have been heightened by the increased demand for, and demand upon, nurses and other staff resulting from the pandemic. There is a risk that the increased costs and other disruptions caused by the shortage of dialysis nurses, technicians and other staff could cause existing or prospective customers to delay continued investment in or adoption of new technologies and postpone purchasing decisions. For example, during 2022, our existing and potential customers faced increasing staffing shortages and~~ increased labor costs, combined with economic pressures resulting from general economic and financial market conditions, primarily escalating inflation, tightening hospital operating budgets and increased scrutiny of capital purchase decisions, all of which generally have the effect of lengthening the average sales cycle and elongating the timing of installations. These factors negatively impacted our customer base on pipeline development and installation schedules, which, in turn, negatively impacted our bookings, delayed our shipments and adversely impacted our revenues for 2022. If our customers continue to face prolonged **periods of rising interest rates, capital budget constraints,** volatility, uncertainty, staffing shortages, rising costs and **other** financial pressures, whether due to ~~the ongoing effects of the pandemic,~~ general macroeconomic conditions or otherwise, it could ultimately adversely impact our ability to expand existing customer relationships or attract new customers of Tablo, **timely collect amounts due, effectively manage our inventory levels,** and have a material adverse effect on our bookings, revenues, results of operations, **financial condition,** and, ultimately, our future growth and profitability. ~~We recently~~ **In 2022, we** launched a ~~new~~ pilot clinical and administrative services program designed to help bridge our healthcare provider customers, particularly those challenged by staffing shortages, as they transition from using an outsourced inpatient dialysis provider to offering on- site inpatient dialysis services on their own. In return for a fair market value service fee, we assign members of our own employed nurses on a temporary basis to support participating providers to launch and manage an inpatient dialysis program using Tablo and, as full- time staff is hired, to help train and onboard those nurses. ~~This~~ **However, our** pilot **clinical and administrative services** program ~~is in its early stages and~~ may not be successful in achieving the objectives we intend and anticipate ~~and ultimately~~ , ~~it~~ may fail to meet our customers' expectations, ~~any of which could harm our reputation and customer relationships. In addition, the program~~ may not generate sufficient returns to

justify our investment, or may result in unanticipated costs, which could **harm our reputation and customer relationships and** adversely impact our operating margins and results of operations. Our ability to generate revenue from home- based dialysis is subject to certain risks and uncertainties, including around the ~~adoption~~ **use** of Tablo in the home setting. In March 2020, Tablo was cleared by the FDA for patient use in the home of patients with acute and / or chronic renal failure, with or without ultrafiltration, and we intend to expand within the home market. However, this goal is subject to certain risks, including our ability to attract, retain and manage patients ~~, our ability to continue regaining momentum in our home commercialization and marketing and rebuilding our home patient pipeline following the release of our prior home shipment hold in 2022~~ , as well as our ability to further evolve our commercial infrastructure and sales processes as we scale our business in the home market. Our business strategy, including our pricing of Tablo, while informed by our limited history of selling Tablo in the home care setting, continues to be based in part on certain assumptions about the adoption of Tablo by home dialysis patients, as well as patient retention. If these assumptions about the home market are inaccurate and we are unable to increase our share of the home dialysis market by attracting new patients, or retain such market share once achieved, we would need to significantly change certain aspects of our business strategy, including the pricing of ~~the~~ Tablo console, associated consumables and support and maintenance, which could adversely affect our business, financial condition and results of operations. Our limited experience in the distribution, logistics and service support that relate to the use of Tablo in the home care setting may also negatively impact our ability to generate revenue from home- based dialysis. Currently, the provision of in- clinic and home dialysis is largely dominated by DaVita and Fresenius, and our expansion within the home dialysis market is dependent on our ability to grow new home programs with health systems and innovative dialysis clinic partners. In addition, patients and their care partners using Tablo for home dialysis may not successfully operate Tablo or may require increased service and support from us. Moreover, given the home dialysis market remains a relatively novel one for us, we also face the risk that we may encounter difficulties whose precise nature or magnitude we cannot accurately predict at this time, but which may have a material adverse effect on our business, financial condition or results of operations. With a significant portion of our manufacturing operations located outside of the United States, we may experience manufacturing disruptions, and be subject to additional risks associated with international manufacturing operations **, including uncertain or changing regulatory and / or labor requirements** . We **have insourced** ~~continue to rely primarily on contract manufacturing partners in Mexico and, to a lesser extent, in Southeast Asia, for~~ the production of ~~the~~ Tablo **consoles** ~~cartridge. If any of our contract manufacturing partners' facilities were disrupted~~ , ~~by labor disputes, work stoppages, public health crises such as the recent COVID- 19 pandemic, riots, terrorism, vandalism, cyber security attacks, natural disaster or otherwise, it could cause substantial delays in our operations~~ and **a majority** ~~result in our having insufficient Tablo cartridge in inventory to fulfill orders. Further, to the extent we seek to renew or renegotiate our arrangements with any~~ of ~~our contract manufacturing partners, and cannot agree to the terms and conditions of future contract manufacturing arrangements, or if any of our contract manufacturing partners terminate existing agreements with us, our ability to produce and sell~~ Tablo cartridges ~~could be delayed until an alternative manufacturing partner or arrangement is identified~~ , ~~a new contract manufacturing agreement is negotiated and new production lines are established. In addition, we have insourced the production of Tablo consoles~~ at our manufacturing facility in Tijuana, Mexico which we operate in collaboration with our outsourced business administration service provider, TACNA ~~. Recently, we also initiated production of Tablo cartridges in- house at this Mexico facility~~ , and we intend **to continue** to increase the quantity of Tablo cartridges produced at this facility ~~as we ramp our cartridge manufacturing capabilities during the remainder of the year~~ . Under our arrangement with TACNA, we control the operations, engineering, quality and materials supply functions at the facility, while TACNA provides manufacturing space, the workforce, utilities, cross- border logistics, local permits and licenses. We are subject to a number of additional risks associated with operating our Mexico- based manufacturing facility ~~and increased international manufacturing operations generally~~ , and many of these risks may heighten to the extent we **continue to** ramp our cartridge manufacturing capabilities and increase our dependence on our Mexico- based manufacturing operations. We may experience strikes, work stoppages, work slowdowns, high personnel turnover, grievances, complaints, claims of unfair labor practices, other collective bargaining disputes or other labor disputes at our new facility. Our manufacturing operations at the facility may also suffer disruptions from global or regional public health crises such as the recent COVID- 19 pandemic, natural disasters, cyber security attacks, vandalism, terrorism or other political hostilities. Any such occurrences could negatively impact our ability to produce Tablo consoles and cartridges. We are also subject to a variety of foreign laws and regulations, including trade and labor restrictions and laws relating to importation, exportation and taxation of goods, and U. S. laws and regulations relating to foreign operations, including anti- corruption, anti- bribery and anti- money laundering laws **. For example, Mexico' s Congress is considering proposals to amend Mexico' s federal labor law, including a reduction in maximum workweek hours from 48 to 40 hours. These proposed legislative changes are expected to increase our labor costs and, ultimately, could potentially negatively impact the productivity of our manufacturing operations to the extent our efforts to mitigate the impact of the changes are not successful** . In addition, because certain of our Mexico- based manufacturing operations incur costs that are denominated in Mexican Pesos (MXN), we are exposed to additional risk of currency fluctuations between the U. S. dollars (USD) and MXN, which could increase our product and labor costs, thus reducing our gross profit. Moreover, while certain members of our management team have some manufacturing experience, as an organization, we do not have any prior experience in this type of manufacturing arrangement, and we could accordingly experience other risks, the nature and magnitude of which we are unable to assess precisely at this time. Furthermore, we are subject to increased risks related to changes in export or import regulation, other trade barriers, security measures and uncertainties impacting the cost and the ability to move inventory and manufacturing equipment across the United States- Mexico border. These risks may disrupt our Mexico- based manufacturing operations, subject us to increased costs, restrict or delay our ability to deliver products to our customers and meet our customers' demand on a timely basis, and result in customer dissatisfaction, all of which would adversely impact our results of operations. **In addition, we continue to rely on contract**

**manufacturing partners in Mexico and Southeast Asia, for the production of a portion of our Tablo cartridges. If either of our contract manufacturing partners' facilities were disrupted, by labor disputes, work stoppages, public health crises such as the recent COVID- 19 pandemic, riots, terrorism, vandalism, cyber security attacks, natural disaster, regulatory action or otherwise, it could cause substantial delays in our operations and result in our having insufficient Tablo cartridge in inventory to fulfill orders. For example, in late 2021, supply chain disruptions exacerbated by COVID- 19 outbreaks and protocols escalated, and we faced increased supply constraints, which increased freight costs associated with the transportation of Tablo cartridges. Further, to the extent we seek to renew or renegotiate our arrangements with either of our contract manufacturing partners, and cannot agree to the terms and conditions of future contract manufacturing arrangements, or if either of our contract manufacturing partners terminate existing agreements with us, our ability to produce and sell Tablo cartridges could be delayed until we are able to ramp our own in- house manufacturing capabilities to meet demand, or until an alternative manufacturing partner or arrangement is identified, a new contract manufacturing agreement is negotiated and new production lines are established. We depend upon third-party suppliers, including contract manufacturers and single source suppliers, making us vulnerable to supply problems and price fluctuations.** We rely on third- party suppliers, including in some instances single source suppliers, to provide us with certain components of Tablo. The number of suppliers required for Tablo console production is in excess of 200 worldwide. We consider a discrete number of these suppliers, located in the United States, Mexico, Europe and Asia, as critical providers of components such as pumps, motors, valves and Printed Circuit Board Assembly (PCBA) boards. While we are undertaking a second source qualification process for the majority of these critical components, we may not ultimately be successful in securing second sourcing for all of them. In addition, we purchase supplies through purchase orders and do not have long- term supply agreements with, or guaranteed commitments from, our suppliers, including single source suppliers. Moreover, ~~at present~~ **while we manufacture a majority of Tablo cartridges in- house** , we rely ~~primarily~~ on contract manufacturers for the production of ~~the~~ **a portion of** Tablo ~~cartridge~~ **cartridges** . Many of our suppliers and contract manufacturers are not obligated to perform services or supply products for any specific period, in any specific quantity or at any specific price, except as may be provided in a particular purchase order. We depend on our suppliers and contract manufacturers to provide us and our customers with materials in a timely manner that meet our and their quality, quantity and cost requirements. These suppliers and contract manufacturers may encounter problems during manufacturing for a variety of reasons, including as a result of public health crises such as the recent COVID- 19 pandemic, labor disputes, work stoppages, damage or interruption from fires, severe weather or other natural disasters, vandalism, terrorism or other political hostilities, any of which could delay or impede their ability to meet our demand. These suppliers and contract manufacturers may cease producing the components we purchase from them or otherwise decide to cease doing business with us. Further, we maintain limited volumes of inventory from most of our suppliers and contract manufacturers. If we inaccurately forecast demand for finished goods, we may be unable to meet customer demand which could harm our competitive position and reputation. Further, if we fail to effectively manage our relationships with our suppliers and contract manufacturers, we may be required to change suppliers or contract manufacturers. While we believe replacement suppliers exist for all materials, components and services necessary to continue manufacturing ~~our~~ Tablo ~~system~~ , establishing additional or replacement suppliers for any of these materials, components or services could be time- consuming and expensive, may result in interruptions in our operations and product delivery, may affect the performance specifications of ~~our~~ Tablo ~~system~~ or could require that we modify Tablo' s design. Even if we are able to find replacement suppliers, we will be required to verify that the new supplier maintains facilities, procedures and operations that comply with our quality expectations and applicable regulatory requirements. Any of these events could require that we obtain a new regulatory authority approval before we implement the change, which could result in further delay and which may not be obtained at all. If our third- party suppliers fail to deliver the required commercial quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement suppliers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality on a timely basis, the continued commercialization of ~~our~~ Tablo ~~system~~ , the supply of our products to customers and the development of any future products will be delayed, limited or prevented, which could have **a** material adverse effect on our business, financial condition and results of operations. For example, **we have** ~~the COVID- 19 pandemic disrupted the operations of certain of our third- party suppliers, resulting in increased lead- times, higher component costs and lower allocations for our purchases of some components (including certain critical components) and, in certain cases, requiring us to procure materials from alternative sources or incur higher logistical expenses. We~~ worked closely with our manufacturing partners and suppliers to enable us to source key components and maintain appropriate inventory levels to meet customer demand, and have not experienced material disruptions in our supply chain to date. However, **macroeconomic factors such** ~~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 **rising inflation** ~~a result of the pandemic that impede their ability to meet our demand in a timely manner~~ , **increasing labor costs** ~~we may be unable to find alternative sources of supply~~ , **and** ~~be required to pay higher prices, or fail to meet customer demand, any of which would harm our business. Additionally,~~ surges and shifts in consumer demand ~~as the economy reopens~~ , ~~further exacerbated by COVID~~ **have disrupted the operations of certain of our third** - **party suppliers** ~~19 outbreaks and protocols~~ , **resulting** ~~have strained the global freight network and placed significant stress on air~~ , ~~ocean and ground freight carriers. This resulted~~ in ~~labor shortages~~ **some cases** , **in increased** ~~container and chassis shortages, reduced carrier capacity, carrier delays and longer~~ lead times ~~,~~ ~~shipment receiving~~ and **higher component** ~~unloading backlogs at many U. S. ports, and escalating freight~~ costs. **We** ~~During late 2021, these supply chain disruptions escalated, and, as a result, we~~ faced increased supply chain constraints **during late 2021** ,

~~notably with the transportation of Tablo cartridges from our contract manufacturing partner in Southeast Asia. As a result~~ **resulting in** ~~, we have faced, and may continue to face,~~ increased transportation and related costs ~~, and / or delays,~~ associated with delivering adequate supply of Tablo treatments to our customers **from our contract manufacturing partner in Southeast Asia** . ~~We~~ **During 2023, we saw moderation in these costs. Moreover, we** believe that ~~transitioning~~ **localizing** production of a majority of Tablo cartridges ~~during 2022~~ **in Mexico (** to ~~a~~ **our Mexico- based** contract manufacturer **and, more recently,** in ~~Mexico~~ **- house at our manufacturing facility) has** helped ~~us~~ achieve cost reductions through lower freight costs, ~~and that our recent efforts to initiate production of Tablo cartridges in- house at our manufacturing facility in Mexico which we operate in collaboration with TACNA will help~~ further our long- term gross margin expansion and supply continuity strategies **and** ~~as well as~~ improve the flexibility of our operations. However, ~~there is no assurance that~~ we **may** ~~will not continue to~~ face **increased** supply chain constraints **in** ~~. Continued escalation of these~~ -- **the future, which** ~~supply chain disruptions and a sustained rise in freight costs~~ could negatively impact our ability to meet customer demand on a timely basis, result in customer dissatisfaction and adversely impact our operating margins and results of operation. A pandemic, epidemic or..... that would otherwise be focused on the operations of our business; delays in growing..... in this " Risk Factors " section . If we fail to provide strong product performance, customer dissatisfaction could adversely affect our reputation and results of operations. We need to maintain and continuously improve the performance and reliability of Tablo to achieve our profitability objectives. Poor product performance and reliability could lead to customer dissatisfaction, adversely affect our reputation and revenues, and increase our service and distribution costs and working capital requirements. Software and hardware incorporated into Tablo may contain errors or defects, especially when first introduced and while we have made efforts to test this software and hardware extensively, we cannot assure that the software and hardware, or software and hardware developed in the future, will not experience errors or performance problems. In addition, with our **relatively recent** transition to manufacturing Tablo consoles **and a majority of Tablo cartridges** at our facility in ~~Tijuana,~~ Mexico operated in collaboration with TACNA, ~~and our plans to ramp production of Tablo cartridges in- house at this facility,~~ we are more exposed to risks relating to product quality and reliability ~~until the~~ **as we continue to refine our** manufacturing processes ~~mature~~ . Like all transitions of this nature, they could increase our costs in the near- term and accordingly adversely affect our business, financial condition and results of operations. If we are unable to continue to innovate and improve Tablo, we could lose customers or market share. Our success will depend on our ability to keep ahead of developments in the dialysis industry. It is critical to our competitiveness that we continue to innovate and make improvements to Tablo' s functionality and efficiency. If we fail to make improvements to Tablo' s functionality over time, our competitors may develop products that offer features and functionality similar or superior to those of Tablo. If we fail to make improvements to Tablo' s efficiency, our competitors may develop products that are more cost effective than Tablo. Our failure to make continuous improvements to Tablo to keep ahead of the products of our competitors could result in the loss of customers or market share that would adversely affect our business, results of operations, and financial condition. We face competition from many sources, including larger companies and new entrants, and we may be unable to compete successfully. There are a number of dialysis machine manufacturers in the United States, Europe and Asia. Notable competitors in the United States include Fresenius Medical Care AG & Co. KGaA (Fresenius), Baxter International, Inc. (Baxter) and B. Braun Medical Inc. (B. Braun). In addition, Quanta Dialysis Technologies Ltd' s (Quanta) dialysis system received FDA 510 (k) clearance for use in acute and / or chronic settings. Of these competitors, Fresenius is the largest and it supplies dialysis products, operates a significant number of dialysis clinics and provides outsourced dialysis services in many hospitals. Fresenius, Baxter and B. Braun all supply machines and supplies in both the acute and home care settings. With the exception of Quanta, all of these organizations are currently significantly larger with greater financial and personnel resources than us, enjoy significantly greater market share than ours and have greater resources than we do. As a consequence, they are able to spend more on product development, marketing, sales and other product initiatives than we can. Additionally, companies with dialysis machine development programs include Medtronic. Some of our competitors have: • substantially greater name recognition; • broader, deeper or longer- term relations with healthcare professionals, customers and third- party payors; • more established distribution networks; • additional lines of products and the ability to offer rebates or bundle products to offer greater discounts or other incentives to gain a competitive advantage; • greater experience in conducting research and development, manufacturing, clinical trials, marketing and obtaining regulatory clearance or approval for products; and • greater financial and human resources for product development, sales and marketing and patent litigation. Further, we may compete with third party providers of outsourced dialysis services, including Fresenius. These organizations are significantly larger with greater financial, personnel and other resources than us and enjoy significantly greater market share and name recognition than us. As a result, these competitors may be able to adopt more aggressive pricing policies and devote greater resources to the promotion, marketing and sales of their services. Our continued success depends on our ability to: • further penetrate the acute care market and drive utilization and fleet expansion among our existing customers in the acute care setting; • successfully expand within the home dialysis market; • maintain and widen our technology lead over competitors by continuing to innovate and deliver new product enhancements on a continuous basis; • cost- effectively manufacture Tablo and its component parts as well as drive down the cost of service; • increase adoption of Tablo in the chronic outpatient facility setting via transitional care programs within existing dialysis clinics; ~~and~~ • demonstrate Tablo' s economic, clinical, compliance and operational benefits relative to outsourcing dialysis services **; and • overcome the adverse impact in the field from the Warning Letter and our distribution pause on TabloCart with Prefiltration which created a certain amount of marketplace confusion (exacerbated, we believe, in some cases by our competitors) particularly regarding Tablo' s use in the intensive care unit (ICU)** . In addition, competitors, including those with greater financial resources than ours, could acquire, combine with or partner with other companies to gain enhanced name recognition and market share, as well as new technologies, products or services that could effectively compete with our existing solutions, which may cause our revenue to decline and would harm our business. For example, in ~~May~~ **April** ~~2022~~ **2023** , Medtronic and DaVita **launched** ~~announced a joint venture to form~~ a new

independent company focused on kidney care, and in August 2022, Fresenius Health Partners (the value- based care division of Fresenius), InterWell Health and Cricket Health, Inc. merged the three businesses into a new independent company focused on kidney care. In the future, we may also face competition from new entrants or companies spun off from our larger competitors. For example, in January 2023, Baxter announced its plans to spin off its renal care business unit into a new independent company ~~, which could ultimately result in another competitor for us~~ . Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, as well as in acquiring technologies complementary to, or necessary for, Tablo. Because of the complex and technical nature of Tablo and the dynamic market in which we compete, any failure to attract and retain a sufficient number of qualified employees could materially harm our ability to develop and commercialize Tablo, which would have a material adverse effect on our business, financial condition and results of operations. As we attain greater commercial success, our competitors are likely to develop products that offer features and functionality similar to Tablo. Improvements in existing competitive products or the introduction of new competitive products may make it more difficult for us to compete for sales, particularly if those competitive products demonstrate better reliability, convenience or effectiveness or are offered at lower prices. More generally, the development of viable medical, pharmacological and technological advances in treating or preventing kidney failure may also limit the opportunity for Tablo and our services. While kidney transplantation is the treatment of choice for most patients with ESRD, it is not currently a viable treatment for most patients. This may change, however, with the development of new medications designed to reduce the incidence of kidney transplant rejection, progress in using kidneys harvested from genetically engineered animals as a source of transplants as demonstrated by the first pig- to- human kidney transplant in ~~September~~ 2021, and other advances in kidney transplantation **. Moreover, developments in the healthcare marketplace related to new or innovative technologies, drugs and other treatments have the potential to impact the rate of growth of the ESRD patient population or otherwise reduce demand for dialysis treatments. For example, in October 2023, a pharmaceutical manufacturer announced the early termination of its study, which sought to demonstrate the effectiveness of its glucagon- like peptide (GLP- 1) receptor agonist indicated for type 2 diabetes in delaying the progression of CKD and lowering the risk of cardiovascular mortality, as a result of the study having met certain endpoints. This development generated uncertainty in the marketplace with respect to the potential impact of these or other similar classes of drugs or new classes of drugs or treatments on the rate of growth of the ESRD patient population. We believe increased adoption of GLP- 1 receptor agonists has the potential to reduce cardiovascular disease and events, which is the leading cause of mortality amongst patients with chronic kidney disease and on dialysis, resulting in lower mortality rates and likely an increase in the ESRD patient population over time. However, any sustained or significant decline in the rate of growth of the ESRD patient population or demand for Tablo, whether as a result of developments related to new or innovative technologies, drugs, treatments or otherwise, may adversely impact our business, results of operation, financial condition, cash flows and stock price** . We may face additional costs, loss of revenue, significant liabilities, harm to our brand, decreased use of our platform and business disruption if there are any security or data privacy breaches or other unauthorized or improper access. In connection with various facets of our business, we collect and use a variety of personal information as part of the Tablo data ecosystem, such as name, street address, email addresses, mobile telephone number, and prescription information. Security breaches, computer malware and computer hacking attacks have become more prevalent across industries and may occur on our systems or those of our third- party service providers, suppliers or other partners. Despite the implementation of security measures, our internal computer systems and those of our third- party service providers, suppliers and other partners are vulnerable to damage from computer viruses, hacking and other means of unauthorized access, denial of service and other attacks, natural disasters, terrorism, war and telecommunication and electrical failures. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Further, we may face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who may work remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. In addition to unauthorized access to or acquisition of personal information, confidential information, intellectual property or other sensitive information, such attacks could include the deployment of harmful malware and ransomware, and may use a variety of methods, including denial- of- service attacks, social engineering and other means, to attain such unauthorized access or acquisition or otherwise affect service reliability and threaten the confidentiality, integrity and availability of information. Any failure to prevent or mitigate security breaches or improper access to, or use or disclosure of, our data or consumers' personal information, including information hosted by third party service providers such as Amazon Web Services (AWS), could result in significant liability under applicable data protection laws, such as state breach notification laws and the HIPAA and its implementing regulations. Such an incident may also cause a material loss of revenue from the potential adverse impact to our reputation and brand, affect our ability to retain or attract new users of Tablo and potentially disrupt our business, as well as require significant expenditure of resources to contain, mitigate and remediate the incident. Because the techniques used to obtain unauthorized access, disable or degrade service or sabotage systems change frequently or may be designed to remain dormant until a predetermined or other future event and often are not recognized until launched against a target, we and our partners may be unable to anticipate these techniques or to implement adequate preventative measures. Further, we do not have any direct control over the operations of the facilities or technology of AWS or our other cloud and service providers. Our systems, servers and platforms, those of our cloud service providers, and Tablo' s two- way wireless communication system, may be vulnerable to computer viruses or physical or electronic break- ins that our or their security measures may not detect or effectively block, and may be breached due to the actions of outside parties, employee error or misconduct, malfeasance, or a combination of these and, as a result, an unauthorized party may obtain access to our data or the personal information maintained by us or on our behalf. Additionally, outside parties may attempt to fraudulently induce employees to disclose sensitive information in order to gain access to the data and personal information we

maintain **, including through phishing or smishing attacks** . Threat actors, including individuals, criminal groups, state sponsored actors or others may be able to circumvent such security measures and misappropriate our confidential or proprietary information, disrupt our operations, corrupt our data, damage our computers or otherwise impair our reputation and business. ~~We~~ **Although we currently invest in our resources and infrastructure, we** may need to expend significant resources and make significant capital investment **in the future** to protect against security breaches or to mitigate the impact of any such breaches. In addition, to the extent that our cloud and other service providers experience security breaches that result in the unauthorized or improper use of confidential information, employee information or personal information, we may not be indemnified for any losses resulting from such breaches. If we are unable to prevent or mitigate the impact of such security breaches or other cyber events that impact our operations, our ability to attract and retain new customers, patients, and other partners could be harmed, as they may be reluctant to entrust us with their data, and we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business or other adverse consequences. We may encounter difficulties in managing our growth, which could disrupt our operations. As of December 31, ~~2022~~ **2023** , we had ~~518~~ **480** full- time employees. **We may not be able** ~~Over the next several years, we expect to increase the scope of our operations, particularly in the areas of manufacturing and commercial functions, including sales and marketing and field service, as well as in research and development and general and administrative functions to support our growth. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational quality and financial systems, expand our facilities and continue~~ to recruit and train additional qualified personnel ~~. Due to~~ **and expand our operations in the timeframe that we desire for various reasons which include** our limited financial resources, ~~we~~ **the impact of macroeconomic conditions on us or our customers, or any inability to overcome the adverse impacts of regulatory, competitive or other challenges. Our growth** may ~~not be~~ **, instead, require us to leverage and optimize our existing personnel while increasing the scale of our operations in an effort to grow our revenue and expand gross margins. If we are** ~~able~~ **unable** to **effectively** manage ~~the expansion of our operations or~~ **our** ~~recruit and train additional qualified personnel in an effective manner. In addition, the physical expansion of our operations, including the establishment of our manufacturing facility in Tijuana, Mexico, may lead to significant costs and may divert our management and business development resources. Any inability to manage~~ growth ~~could delay~~ **in the face of these challenges,** the execution of our business plans **could be delayed, which would have a material adverse effect on** ~~or~~ **our** ~~disrupt our~~ **business, financial condition and results of** operations. The home hemodialysis market may not expand sufficiently to support our growth prospects. We believe a significant growth opportunity exists within the home hemodialysis market. However, home hemodialysis therapies to date have not been extensively adopted. We believe that the home hemodialysis market is sufficient to fuel our growth in the near term if we are able to capture sufficient market share; however, there can be no assurance that we will be successful in increasing our market share. Our long- term growth will require us to shift patients' and the medical community' s understanding and view of home hemodialysis and will require greater acceptance of home hemodialysis from patients as compared to current levels, physicians who are willing to prescribe home hemodialysis, and dialysis centers that are willing to support home hemodialysis growth. Most dialysis centers presently do not have the infrastructure to support a significant home hemodialysis patient population, including the availability of home hemodialysis training nurses, and may not be motivated to invest in home hemodialysis programs. The nationwide shortage of nurses and other clinical personnel ~~that has been exacerbated by the COVID- 19 pandemic~~ poses increased challenges for dialysis centers looking to retain or attract the staff necessary to support a home hemodialysis program. We will need to continue to devote significant resources to support the expansion of the home hemodialysis market, but these efforts ultimately may not be successful. We traditionally have had significant customer concentration ~~, with our largest customer accounting for a large portion of our revenues~~ . For the year ended December 31, ~~2022~~ **2023** , our largest customer accounted for ~~14~~ **13** % of revenues. There are risks whenever a large percentage of total revenues are concentrated with a limited number of customers. It is not possible for us to predict the level of demand for Tablo that will be generated by any of these customers in the future. In addition, revenues from these larger customers may fluctuate from time to time based on these customers' business needs and customer experience, the timing of which may be affected by market conditions or other factors outside of our control. Furthermore, because our business model consists of an upfront capital purchase by our customers, and relatively lower recurring revenue from future sales of consumables and services, revenues from these larger customers may not represent a substantial portion of our revenues in future periods. These customers could also potentially pressure us to reduce the prices we charge for Tablo, which could have an adverse effect on our margins and financial position and could negatively affect our revenues and results of operations. If any of our largest customers terminates its relationship with us, such termination could negatively affect our revenues and results of operations. Natural or man- made disasters and..... materially and adversely affect our business. Any failure to offer high- quality product support for Tablo may adversely affect our relationships with providers and negatively impact our reputation among patients and providers, which may adversely affect our business, financial condition, and results of operations. We operate a multichannel model, including remote and on- site product support to respond to and resolve issues reported to us by providers and nurses on behalf of their patients. In implementing and using Tablo, providers depend on our support to resolve product quality- and performance- related issues in a timely manner. We may be unable to respond quickly enough to accommodate short- term increases in demand for customer support. Increased customer demand for product support could increase costs and adversely affect our business, financial condition and results of operations. Our sales are highly dependent on our reputation and on positive recommendations from our existing patients, care partners and providers. Any failure to maintain high- quality customer support for our products, or a market perception that we do not maintain high- quality customer support for our products, could adversely affect our reputation, our ability to sell Tablo, and in turn our business, results of operations, and financial condition. Our results of operations will be materially harmed if we are unable to accurately forecast customer demand for, and utilization of, Tablo and manage our inventory. To ensure adequate inventory supply, we must forecast inventory needs and manufacture ~~the~~ Tablo ~~console~~ **consoles** and ~~the~~ Tablo ~~cartridge~~

**cartridges** based on our estimates of future demand for Tablo. Our ability to accurately forecast demand for Tablo could be negatively affected by many factors, including our failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for Tablo or for products of our competitors, our failure to accurately forecast customer acceptance of new products, potential disruption in our supply chain from regional or global public health crises ~~including~~ **such as** the recent COVID- 19 pandemic, unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions. Inventory levels in excess of customer demand may result in inventory write- downs or write- offs, which would cause our gross margin to be adversely affected and could impair the strength of our brand. Conversely, if we underestimate customer demand for Tablo, our supply chain, manufacturing partners and / or internal manufacturing team may not be able to deliver components and products to meet our requirements, and this could result in damage to our reputation and customer relationships. In addition, if we experience a significant increase in demand, additional supplies of raw materials or additional manufacturing capacity may not be available when required on terms that are acceptable to us, or at all, or suppliers may not be able to allocate sufficient capacity in order to meet our increased requirements, which will adversely affect our business, financial condition and results of operations. ~~a material adverse effect on our long- term business.~~ 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** ~~such as~~ the recent COVID- 19 pandemic,power outages and other infrastructure failures,which may render it difficult or impossible for us to operate our business for some period of time.Our facilities would likely be costly to repair or replace,and any such efforts would likely require substantial time.Any disruptions in our operations could adversely affect our business and results of operations and harm our reputation.Moreover,although we have disaster recovery plans,they may prove inadequate.We may not carry sufficient business insurance to compensate for losses that may occur.Any such losses or damages could have a material adverse effect on our business and results of operations.In addition,our facility in Mexico and the facilities of our suppliers and manufacturers may be harmed or rendered inoperable by such natural or man- made disasters,which may cause disruptions,difficulties or otherwise materially and adversely **affect our business.** Inadequate training of, and improper use of Tablo by, nurses, dialysis technicians, care partners and patients may lead to negative patient outcomes, affect ~~adoption~~ **use** of Tablo and adversely affect our business. The success of Tablo depends in part on the proper training and use of Tablo by nurses and dialysis technicians in the acute setting ~~or~~ **and** patients and care partners in the home setting. We train nurses and dialysis technicians on the appropriate use of Tablo, as well as how to train other users, including patients and care partners who use Tablo in the home setting, on the appropriate use of Tablo. If nurses and dialysis technicians, including those we train directly and those trained by others, or patients and care partners, who are not trained by us directly, use Tablo inappropriately or incorrectly, or with supplies that are not compatible with Tablo or without adhering to or completing training sessions, patient outcomes may not be consistent with expected results. This may result in adverse events, including reduced treatment efficacy, and may negatively impact the perception of patient benefit and safety and limit adoption of Tablo, which would have a material adverse effect on our business, financial condition and results of operations. In addition, we may face liability for inadequate training and training materials for nurses and other providers who use our products. Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide. Our quarterly and annual results of operation, including our revenue, gross margin, profitability and cash flows, may fluctuate significantly, which makes it difficult for us to predict our future operating results. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our quarterly and annual operating results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. These fluctuations may occur due to a variety of factors, including, but not limited to: • the level of demand for Tablo, which may vary significantly, our ability to accurately forecast and meet customer demand and the timing of customer orders and installation schedules; • the cost of manufacturing Tablo, which may vary depending on the quantity of production, the terms of our agreements with third- party suppliers and manufacturers, costs of raw materials and components, and any related foreign currency impact; • expenditures that we may incur to acquire, develop or commercialize additional products and technologies; • unanticipated pricing pressures; • the ~~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 **public health crises such as** the recent COVID- 19 pandemic may have on our operations, financial results and the number of patients treated; • the timing and cost of, and level of investment in, research, development, licenses, regulatory approval, commercialization activities, acquisitions and other strategic transactions, or other significant events relating to Tablo, which may change from time to time; • **our ability to leverage and optimize our existing sales force, and the speed at which any newly hired salespeople become effective, and the cost and level of investment therein; •** the timing and cost of obtaining and maintaining regulatory approvals or clearances for **our products or product enhancements, or** ~~the~~ **other** ~~current version of Tablo,~~ **regulatory actions with respect to our products (such** as ~~well as planned~~ **the Warning Letter we received in July 2023 and** ~~or~~ **our** ~~future improvements or enhancements to Tablo~~ **subsequent pause on the distribution of TabloCart with Prefiltration)** ; • pricing

and discounts for Tablo or competing products; • legal, accounting and other expenses we may incur as a result of operating as a public company, including costs related to compliance with new compliance initiatives and requirements; • future accounting pronouncements or changes in our accounting policies; and • general economic and financial market conditions or political instability, including changes in tariff or trade laws and policies, as well as inflationary pressures (such as current inflation related to global supply chain disruptions). The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual financial results. As a result, comparing our operating results on a period- to- period basis may not be meaningful. Further, our historical results are not necessarily indicative of results expected for any future period, and quarterly results are not necessarily indicative of the results to be expected for the full year or any other period, and accordingly should not be relied upon as indicative of future performance. This variability and unpredictability could also result in our failure to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, it will negatively affect our business, financial condition and results of operations. The sizes of the markets for Tablo in the acute and home settings have not been established with precision and may be smaller than we estimate and may decline. Our estimates of the annual total addressable market for Tablo are based on a number of internal and third- party estimates, including, without limitation, the assumed prices at which we can sell Tablo in the acute and home markets. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual total addressable market for Tablo in different settings may prove to be incorrect. If the actual number of patients who would benefit from Tablo, the price at which we can sell Tablo, or the total addressable market for Tablo is smaller than we have estimated, it may impair our sales growth and negatively affect our business, financial condition and results of operations. We use Amazon Web Services to support Tablo' s cloud connectivity and any disruption of service could interrupt or delay our ability to receive and deliver ~~critical~~ **certain** treatment and reporting information from and to providers and patients. We currently use AWS to host our cloud- based ecosystem. We also use other cloud service providers in our operations. We do not have direct control over the operations of the facilities of AWS or of our other cloud service providers and these facilities are vulnerable to damage or interruption from earthquakes, hurricanes, floods, fires, cyber security attacks, terrorist attacks, power losses, telecommunications failures and similar events. The occurrence of a natural disaster or an act of terrorism, a decision by AWS or another cloud service provider to close the facilities without adequate notice, or other unanticipated problems could result in lengthy interruptions in, or curtailment of, Tablo' s functionality and our ability to provide software updates or analyze patient and machine data. The facilities also could be subject to break- ins, computer viruses, sabotage, intentional acts of vandalism and other misconduct. The continuing and uninterrupted performance of Tablo is critical to our success. Because our customer- facing software platform is used by providers to gain insight into treatment performance, it is critical that our customer facing software platform be accessible without interruption or degradation of performance or data. Providers and patients may become dissatisfied by any system failure that interrupts our ability to provide the full suite of Tablo capabilities to them. Outages could lead to the triggering of our service level agreements and the issuance of credits to our clients, in which case, we may not be fully indemnified for such losses pursuant to our agreement with AWS or our agreements with our other cloud service providers. We may not be able to easily switch our AWS operations to another cloud provider if there are sustained disruptions or interference with our use of AWS. Repeated or prolonged system failures may reduce the attractiveness of Tablo to providers and patients and result in a decreased demand for Tablo, thereby adversely affecting our business, financial condition and results of operations. Moreover, negative publicity arising from these types of disruptions could damage our reputation and may adversely impact use of Tablo. AWS and our other cloud service providers are not obligated to renew agreements with us on commercially reasonable terms, or at all. If we are unable to renew our agreements with AWS or our other cloud service providers on commercially reasonable terms, if our agreements with AWS or our other cloud service providers are prematurely terminated, or if in the future we add additional data providers, we may experience costs or downtime in connection with the transfer to, or the addition of, new providers. If these providers were to increase the cost of their services, we may have to increase the price of Tablo or take other measures to offset such cost increases, which could have a material adverse effect on our business, financial condition and results of operations. If we experience significant disruptions in our information technology systems, our business may be adversely affected. We depend on our information technology systems for the efficient functioning of our business, including the manufacture, distribution and maintenance of Tablo, as well as for accounting, data storage, compliance, purchasing and inventory management. We do not have redundant information technology in all aspects of our systems at this time. Our information technology systems may be subject to computer viruses, ransomware or other malware, attacks by computer hackers or malicious insiders, failures during the process of upgrading or replacing software, databases or components thereof, power outages, damage or interruption from fires or other natural disasters, hardware failures, telecommunication failures and user errors, among other malfunctions. We could be subject to an unintentional event that involves a third party gaining unauthorized access to our systems, which could disrupt our operations, corrupt our data or result in release of our confidential information. Technological interruptions or malfunction would disrupt our operations, including our ability to timely ship and track Tablo orders, project inventory requirements, ensure the integrity of our data analytics services, manage our supply chain and otherwise adequately service our customers or disrupt our customers' ability to use Tablo. In the event we experience significant disruptions, we may be unable to repair our data or systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our business, financial condition and results of operations. Currently, we carry business interruption coverage to mitigate certain potential losses but this insurance is limited in amount, and we cannot be certain that such potential losses will not exceed our policy limits. We are increasingly dependent on complex information technology to manage our infrastructure. Our information systems require an ongoing commitment of significant

resources to maintain, protect and enhance our existing systems. Failure to maintain or protect our information systems and data integrity effectively could have a material adverse effect on our business, financial condition and results of operations. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit or halt the marketing and sale of Tablo. The expense and potential unavailability of insurance coverage for liabilities resulting from Tablo could harm us and our ability to sell Tablo. We face an inherent risk of product liability as a result of the marketing and sale of Tablo. For example, we may be sued if Tablo or any of its component parts causes, or is perceived to cause, injury or is found to be otherwise unsuitable during manufacturing, marketing or sale. Any such product liability claim may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. In addition, we may be subject to claims against us even if the apparent injury is due to the actions of others or the pre- existing health conditions of the patient. For example, nurses, dialysis technicians, care partners and patients operate Tablo. If these nurses, dialysis technicians, care partners or patients are not properly trained, are negligent or use Tablo incorrectly, the capabilities of Tablo may be diminished or the patient may suffer critical injury. We may also be subject to claims that are caused by the activities of our suppliers, such as those who provide us with components and sub- assemblies, or manufacturers who produce Tablo consoles and cartridges. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or halt the marketing and sale of Tablo. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: • decreased demand for Tablo; • harm to our reputation; • initiation of investigations by regulators, which could result in enforcement action against us or our contract manufacturers; • costs to defend the related litigation; • a diversion of management' s time and our resources; • substantial monetary awards to trial participants or patients; • product recalls, withdrawals or labeling, marketing or promotional restrictions; • loss of revenue; and • exhaustion of any available insurance and our capital resources. We believe we have adequate product liability insurance, but it may not prove to be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain or obtain insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our insurance policy contains various exclusions, and we may be subject to a product liability claim for which we have no coverage. The potential inability to obtain sufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or inhibit the marketing and sale of Tablo. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts, which would have a material adverse effect on our business, financial condition and results of operations. In addition, any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our reputation in the industry, significantly increase our expenses and reduce product sales. We expect to continue to incur net losses for the next several years and we may require substantial additional capital to finance our planned operations, which may include future equity and debt financings. This additional capital may not be available to us on acceptable terms or at all. Our failure to obtain additional financing when needed on acceptable terms, or at all, could force us to delay, limit, reduce or eliminate our commercialization, sales and marketing efforts, product development programs or other operations. We may require additional financing to fund working capital and pay our obligations. While we ~~have~~ entered into two senior secured credit facilities ~~in~~ **on** November **3,** 2022 ~~that~~ **, which** provide for **(i)** up to ~~a~~ $ 250. 0 million **of** term **loans (the SLR Term Loan Facility) pursuant to a** loan and **security agreement with certain lenders and SLR Investment Corp., as agent (the SLR Loan Agreement) and (ii)** up to a $ 50. 0 million asset- based revolving credit facility **(the SLR Revolver , together with the SLR Term Loan Facility, the SLR Credit Facilities) pursuant to a credit agreement with Gemino Healthcare Finance, LLC d / b / a SLR Healthcare ABL, as lender (the SLR Revolving Credit Agreement, together with the SLR Loan Agreement, the SLR Credit Facility Agreements),** we ~~only~~ have ~~access to~~ **already borrowed** $ 200. 0 million of **term loans** ~~such borrowings since an~~ **and the** additional $ 100. 0 million ~~of such~~ borrowings **under the SLR Credit Facilities** is subject to us achieving certain **net revenue** milestones and obtaining lenders' credit approval. We may seek to raise any necessary additional capital through a combination of public or private equity offerings or debt financings. There can be no assurance, however, that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable to us. If adequate funds are not available on acceptable terms when needed, we may be required to significantly reduce operating expenses, which may negatively affect our business, financial condition and results of operations. If we do raise additional capital through public or private equity or convertible debt offerings, **such offerings could result in dilution, including potentially significant dilution, of** the ownership interest of our existing stockholders ~~will be diluted~~, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing (including through refinancing our existing debt), we may be subject to **, among other things, an increase in our interest expense which may negatively affect our cash flow and** covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Additional capital may not be available on reasonable terms, or at all. The terms of our credit agreement require us to meet certain operating and financial covenants, place restrictions on our operating and financial flexibility and subject us to interest rate risk **, and our ability to access additional borrowings is subject to us achieving certain net revenue milestones and obtaining lenders' credit approval** . We entered into ~~two senior secured credit facilities (~~ the SLR Credit Facilities ~~)~~ on November 3, 2022 **,** ~~(the Closing Date)~~ which provide for **(i)** up to ~~a~~ $ 250. 0 million **of** term ~~loan~~ **loans** ~~(the SLR Term Loan Facility)~~ pursuant to ~~a loan and security agreement with certain lenders and SLR Investment Corp., as agent (~~ the SLR Loan Agreement **and (ii )** ~~and~~ up to a $ 50. 0 million asset- based revolving credit facility ~~(the SLR Revolver, together with the SLR Term Loan Facility, the SLR Credit Facilities)~~ pursuant to ~~a credit agreement with Gemino Healthcare Finance, LLC d / b / a SLR Healthcare ABL, as lender (~~ the SLR Revolving Credit Agreement ~~, together with the SLR Loan Agreement, the SLR Credit Facility Agreements)~~ . ~~While~~ **We have already borrowed**

**$ 200. 0 million of term loans and the additional $ 100. 0 million of borrowings under** the SLR Credit Facilities ~~provide for borrowings of up to $ 300. 0 million, we only have access to $ 200. 0 million of such borrowings as of the Closing Date and the additional $ 100. 0 million of such borrowings~~ is subject to us achieving certain net revenue milestones and obtaining lenders' credit approval. If we achieve a certain net revenue milestone, calculated on a trailing six- month basis (First Revenue Milestone), on or before June 30, 2024 and the additional tranche under the SLR Revolver has been approved, we will be permitted to borrow up to **an additional** $ ~~250~~ **50** . 0 million under the SLR Credit Facilities. If we achieve a subsequent additional net revenue milestone, calculated on a trailing six- month basis (Second Revenue Milestone, and together with First Revenue Milestone, the Revenue Milestones), on or before June 30, 2025 and obtain lenders' credit approval, we will be permitted to **further** borrow up to **an additional** $ ~~300~~ **50** . 0 million under the SLR Credit Facilities. If we fail to achieve either or both of these Revenue Milestones or obtain lenders' credit approval, we will not be able to access the ~~full~~ **remaining** $ ~~300~~ **100** . 0 million **of** ~~borrowing~~ **borrowings** ~~amounts~~ under the SLR Credit Facilities. The SLR Credit Facilities are secured by substantially all of our assets, including all of ~~the capital stock held by us, if any, (subject to a 65 % limitation on pledges of voting capital stock of foreign subsidiaries), and all of~~ our intellectual property, subject to certain exceptions. The SLR Credit Facility Agreements contain a number of restrictive covenants, and the terms may restrict our current and future operations, particularly our ability to respond to certain changes in our business or industry or take future actions. In addition, as principal amounts outstanding under each of the SLR Term Loan Facility and the SLR Revolver accrue interest at variable interest rates tied to SOFR, any borrowings under the facilities will be subject to interest rate risk. An adverse change in interest rates for our borrowings could increase our future borrowing costs which may restrict our access to capital in the future and, ultimately, could adversely affect our financial condition and results of operations. See the section titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Debt Obligations – SLR Debt Financing. " The SLR Credit Facility Agreements contain customary representations and warranties and affirmative covenants and also contain certain restrictive covenants, including, among others, limitations on: the incurrence of additional debt, liens on property, acquisitions and investments, loans and guarantees, mergers, consolidations, liquidations and dissolutions, asset sales, dividends and other payments in respect of our capital stock, prepayments of certain debt, transactions with affiliates and changes to our type of business, management of the business, control of the business or business locations. The SLR Credit Facility Agreements also include a financial covenant that, beginning with the fiscal quarter ending December 31, 2023, requires us to either (i) maintain certain levels of cash and cash equivalents in accounts subject to control agreements in favor of Agent and ABL Lender of at least **the sum of (a)** 50 % of ~~the sum of (a)~~ the outstanding obligations under the SLR Term Loan Facility and (b) the amount of the Company' s accounts payable that have not been paid within 120 days from the invoice date thereof or (ii) generate net product and product related revenue ~~(or~~ **in excess of specified amounts and** maintain gross profit margins ~~)~~ in excess of specified ~~amounts (or~~ percentages ~~)~~**, in each case,** for applicable measuring periods. The SLR Credit Facility Agreements also contain customary events of default. If we fail to comply with such covenants, payments or other terms of either SLR Credit Facility Agreement, our agent or lender, as applicable, could declare an event of default, which would give it the right to declare all borrowings outstanding, together with accrued and unpaid interest and fees, to be immediately due and payable. In addition, our agent or lender, as applicable, would have the right to proceed against the assets we provided as collateral pursuant to the SLR Loan Agreement or SLR Revolving Credit Agreement, as applicable. If the debt under either SLR Credit Facility Agreement was accelerated, we may not have sufficient cash or be able to sell sufficient assets to repay this debt, which would harm our business and financial condition. Performance issues, service interruptions or price increases by our shipping carriers and warehousing providers could adversely affect our business and harm our reputation and ability to provide our services on a timely basis. Expedited, reliable shipping and secure warehousing are essential to our operations. We rely heavily on providers of transport services for reliable and secure point- to- point transport of ~~our~~ Tablo ~~system~~ to our customers and for tracking of these shipments, and from time to time require warehousing for our products. Should a carrier encounter delivery performance issues such as loss, damage or destruction of any systems, it would be costly to replace such systems in a timely manner and such occurrences may damage our reputation and lead to decreased demand for ~~our~~ Tablo ~~system~~ and increased cost and expense to our business. In addition, any significant increase in shipping or warehousing rates could adversely affect our operating margins and results of operations. For example, in late 2021, surges and shifts in consumer demand as the economy reopened, further exacerbated by COVID- 19 outbreaks and protocols, strained the global freight network and placed significant stress on air, ocean and freight ground carriers, resulting in increased freight costs associated with our transportation of Tablo cartridges. If freight costs ~~continue to~~ escalate and / or remain high for a sustained period of time, our operating margins and results of operations would be adversely impacted. Similarly, strikes, severe weather, natural disasters or other service interruptions affecting delivery or warehousing services we use would adversely affect our ability to process orders for ~~our~~ Tablo ~~system~~ on a timely basis. We bear the risk of warranty claims on ~~our~~ Tablo ~~system~~ . We bear the risk of warranty claims on ~~our~~ Tablo ~~system~~ . We may not be successful in claiming recovery under any warranty or indemnity provided to us by our suppliers or vendors in the event of a successful warranty claim against us by a customer or any recovery from such vendor or supplier may not be adequate. In addition, warranty claims brought by our customers related to third- party components may arise after our ability to bring corresponding warranty claims against such suppliers expires, which could result in costs to us. Cost- containment efforts of our customers, purchasing groups and governmental organizations could have a material adverse effect on our sales and profitability. In an effort to reduce costs, many hospitals in the United States are members of GPOs and Integrated Delivery Networks (IDNs). GPOs and IDNs negotiate pricing arrangements with medical device companies and distributors and then offer these negotiated prices to affiliated hospitals and other members. GPOs and IDNs typically award contracts on a category- by- category basis through a competitive bidding process. Bids are generally solicited from multiple providers with the intention of driving down pricing or reducing the number of vendors. Due to the highly competitive nature of the GPO and IDN contracting processes, we may not be able to obtain new, or maintain existing, contract positions with major

GPOs and IDNs. Furthermore, the increasing leverage of organized buying groups may reduce market prices for Tablo, thereby reducing our revenue and margins. While having a contract with a GPO or IDN for a given product category can facilitate sales to members of that GPO or IDN, such contract positions can offer no assurance that any level of sales will be achieved, as sales are typically made pursuant to individual purchase orders. Even when a provider is the sole contracted supplier of a GPO or IDN for a certain product category, members of the GPO or IDN are generally free to purchase from other suppliers. Furthermore, GPO and IDN contracts typically are terminable without cause by the GPO or IDN upon 60 to 90 days' notice. Accordingly, the members of such groups may choose to purchase alternative products due to the price or quality offered by other companies, which could result in a decline in our revenue. If we fail to retain **our** 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 **, leverage** and ~~grow~~ **optimize** our direct sales force will negatively affect our business, financial condition and results of operations. The members of our direct sales force are highly trained and possess substantial technical expertise, which we believe is critical in increasing adoption of Tablo. The members of our U. S. sales force are at- will employees. The loss of these personnel to competitors, or otherwise, will negatively affect our business, financial condition and results of operations. If we are unable to retain our direct sales force personnel or replace them with individuals of equivalent technical expertise and qualifications, or if we are unable to successfully instill such technical expertise in replacement personnel, it may negatively affect our business, financial condition and results of operations. In addition, our services revenue is dependent in part on our FSEs, and any failure to maintain ~~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 **and optimize** our sales and marketing infrastructure to increase the number of customers that adopt Tablo. In addition, identifying and recruiting qualified sales and marketing personnel and training them on Tablo, on applicable federal and state laws and regulations and on our internal policies and procedures requires significant time, expense and attention. It often takes several months or more before a sales representative is fully trained and productive. Our sales force may subject us to higher fixed costs than those of companies with competing techniques or products that utilize independent third parties, which could place us at a competitive disadvantage. It will negatively affect our business, financial condition and results of operations if our efforts to expand and train our sales force do not generate a corresponding increase in revenue, and our higher fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for Tablo. In addition, our ability to generate revenue growth depends on the success of our efforts to further evolve our commercial infrastructure and sales processes to support the growth of our business in the home and acute markets. Any failure to hire, develop and retain talented sales personnel, to achieve desired productivity levels in a reasonable period of time or timely reduce fixed costs, or to evolve and scale our commercial infrastructure and sales processes, could negatively affect our business, financial condition and results of operations. Our ability to increase our customer base and achieve broader market acceptance of Tablo will depend to a significant extent on our ability to expand our marketing efforts. We plan to dedicate significant resources to our marketing programs. It will negatively affect our business, financial condition and results of operations if our marketing efforts and expenditures do not generate a corresponding increase in revenue. In addition, we believe that developing and maintaining broad awareness of Tablo in a cost- effective manner is critical to achieving broad acceptance of Tablo. Promotion activities may not generate patient or physician awareness or increase revenue, and even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain and protect our brand, we may fail to attract or retain the physician acceptance necessary to realize a sufficient return on our brand building efforts, or to achieve the level of brand awareness that is critical for broad adoption of Tablo. Litigation and other legal proceedings may adversely affect our business. From time to time we may become involved in legal proceedings relating to patent and other intellectual property matters, product liability claims, employee claims, tort or contract claims, federal regulatory investigations, securities class action and other legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. For example, on July 8, 2022, a purported stockholder class action lawsuit was filed against the Company, our Chief Executive Officer, Chief Financial Officer and former Chief Financial Officer, in the U. S. District Court for the Northern District of California alleging that the defendants violated federal securities laws by making false or misleading statements regarding the Company' s regulatory studies of ~~the~~ Tablo ~~Hemodialysis System~~ for at home use and the Company' s prospects related to the sale of the system for at home use. On September 7, 2022, the plaintiff filed a notice of voluntary dismissal of this action without prejudice, and this action is now concluded ~~. For further information, see the section entitled " Litigation " in Note 6, Commitments and Contingencies, to our audited financial statements included in this Annual Report~~. Litigation is inherently unpredictable and can result in excessive or unanticipated verdicts and / or injunctive relief that affect how we operate our business. We could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. There may be an increase in the scope of these matters or there may be additional lawsuits, claims, proceedings or investigations in the future, which could have a material adverse effect on our business, financial condition and results of operations. Adverse publicity about regulatory or legal action against us could damage our reputation and brand image, undermine our customers' confidence and reduce long- term demand for Tablo, even if the regulatory or legal action is unfounded or not material to our operations. We may seek strategic alliances, joint ventures or collaborations, or enter into licensing or partnership arrangements in the future and may not be successful in doing so, and even if we are, we may not realize the benefits or costs of such relationships. We may form or seek strategic alliances, make minority investments, create joint ventures or collaborations or enter into licensing or partnership arrangements with third parties that we believe will compliment or augment our sales and marketing and / or product development efforts with respect to Tablo. We may not be successful in our efforts to establish such collaborations for Tablo. Any of these relationships may require us to incur non-

recurring and other charges, increase our near and long- term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time- consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic alliance or other alternative arrangements for Tablo. We cannot be certain that, following a strategic alliance or similar arrangement, we will achieve the revenue, cash flows or specific net income that justifies such transaction. In addition, any potential future collaborations may be terminable by our collaborators, and we may not be able to adequately protect our rights under these agreements. Any termination of collaborations we enter into in the future, or delays in entering into new strategic partnership agreements could delay our sales and marketing efforts, which would harm our business prospects, financial condition and results of operations. To the extent we enter into foreign markets, we would be subject to additional regulatory burdens and other risks and uncertainties. To the extent we enter into foreign markets in the future, we would face additional risks and uncertainties. We are not permitted to market or promote Tablo before we receive regulatory approval from the applicable regulatory authority in that foreign market, and we may never receive such regulatory approval for Tablo. To obtain separate regulatory approvals in other countries we may be required to comply with numerous and varying regulatory requirements of such countries regarding the safety and efficacy of Tablo and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product, and we cannot predict success in these jurisdictions. Such activities may result in incremental expenses and diversion of management' s time and attention, and we may not ultimately obtain the requisite approvals in a timely manner or at all. If we obtain approval of Tablo and sell Tablo in foreign markets, we would be subject to additional risks and uncertainties in those markets, including: • foreign currency exchange rate fluctuations and currency controls; • increased costs associated with maintaining compliance, sales and marketing, and service for customers outside the United States, especially as we establish ourselves in these markets; • economic weakness, including inflation, or political instability in particular economies and markets; • potentially adverse and / or unexpected tax consequences, including penalties due to the failure of tax planning or due to the challenge by tax authorities on the basis of transfer pricing and liabilities imposed from inconsistent enforcement; • the burden of complying with complex and changing regulatory, tax, accounting and legal requirements, many of which vary between countries; • different medical practices and customs in multiple countries affecting acceptance of medical products in the marketplace; • differing payor reimbursement regimes, governmental payors or patient self- pay systems and price controls; • tariffs, trade barriers, import or export licensing requirements or other restrictive actions; • compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; • reduced or loss of protection of intellectual property rights in some foreign countries; and • becoming subject to the different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations. Our ability to utilize our net operating loss carryforwards and research and development credit may be limited. As of December 31, ~~2022~~ **2023**, we had U. S. federal and state net operating loss (NOL) carryforwards of $ ~~526~~ **643**. ~~8~~ **4** million and $ ~~298~~ **380**. ~~1~~ **2** million, respectively. If not utilized, our U. S. federal NOLs generated in taxable years beginning before 2018 will begin to expire in 2024 and our state NOLs ~~will begin~~ **began** to expire in ~~2023~~ **2024**. Deductibility of U. S. federal NOLs generated in taxable years beginning after 2017 and used in taxable years beginning after 2020 do not expire but are limited to 80 % of our taxable income before the deduction of such NOLs. As of December 31, ~~2022~~ **2023**, we also had U. S. federal and state research and development credits of $ ~~7~~ **8**. 8 million and $ ~~6~~ **7**. ~~4~~ **5** million, respectively. Our U. S. federal research and development credits **will** begin to expire in 2030. State research and development credits do not expire. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code) a corporation that undergoes an ownership change, generally defined as a greater than 50 % change by value in its equity ownership over a three- year period, is subject to limitations on its ability to utilize its pre- change net operating losses and its research and development credit carryforwards to offset future taxable income. Our existing NOLs and research and development credit carryforwards may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change, our ability to utilize NOLs and research and development credit carryforwards could be further limited by Sections 382 and 383 of the Code. Similar rules may apply under state tax laws. In addition, our ability to deduct net interest expense may be limited if we have insufficient taxable income for the year during which the interest is incurred, and any future carryovers of such disallowed interest would be subject to the limitation rules similar to those applicable to NOLs and other attributes. Future changes in our stock ownership, some of which might be beyond our control, could result in an ownership change under Section 382 of the Code. For these reasons, in the event we experience a change of control, we may not be able to utilize a material portion of the existing NOLs, research and development credit carryforwards or future disallowed interest expense carryovers, even if we attain profitability. Any limitation on using NOLs could adversely impact operating results and result in our retaining less cash after payment of U. S. federal and state income taxes. Risks Related to Governmental Regulation ~~While we resumed marketing and shipping~~ **We are subject to risks related to** the **warning letter we recently received from the FDA and the pause we recently implemented on the distribution of TabloCart with Prefiltration. In July 2023, we received a warning letter (the " Warning Letter ") from the FDA that raised two observations. The first observation asserts that certain content reviewed by the FDA and found on our website promotes CRRT, a modality outside of the current indications for** Tablo **. The second observation asserts that TabloCart with Prefiltration requires prior** ~~System for home use following the FDA' s clearance of the related~~ 510 (k) ~~submission~~ **clearance for marketing authorization. TabloCart with Prefiltration is an accessory to Tablo launched in the third quarter of 2022. We believe the concern raised by the first observation regarding CRRT promotion has been effectively addressed through a thorough review of existing promotional materials and practices. We believe the concern raised by the second observation regarding TabloCart with Prefiltration has been effectively addressed with two actions. First , although we evaluated TabloCart with Prefiltration prior to marketing and distributing the product and concluded that no marketing authorization was necessary, we paused distribution of TabloCart with Prefiltration pending the FDA' s review and clearance of a 510 (k) application. Second, we submitted to the FDA a 510 (k) application**

**for TabloCart with Prefiltration in September 2023, and have been engaged in constructive interactive review with the FDA reviewing team. In addition, we have provided monthly updates to the FDA as to the status of these Warning Letter- related workstreams since July 2023, and believe we have taken appropriate measures to resolve the matters raised in the Warning Letter. While we remain committed to fully cooperating with the FDA to expeditiously and completely resolve the Warning Letter, we cannot guarantee that the FDA will be satisfied with our response or the remedial measures we have taken, nor can we give any assurances as to the timing of the resolution of such matters, including the clearance of the 510 (k) application and our resumption of distribution of TabloCart with Prefiltration. Failure to promptly and fully address the matters raised in the Warning Letter to the FDA' s satisfaction or to comply with FDA regulations in general could result in further regulatory and enforcement actions being initiated by the FDA. These actions may include, among other things, additional inspections, requirements to implement additional remedial measures, recommending or requiring that we cease manufacturing or producing TabloCart with Prefiltration or that we withdraw or recall the product from the marketplace, until clearance is obtained (which may not happen in a timely manner or at all), as well as product seizures, injunctions, civil monetary penalties, fines, or criminal prosecution. In addition, although we have paused distribution of TabloCart with Prefiltration pending the FDA' s review and clearance of the submitted 510 (k) application, the FDA could specifically mandate that we do so, which would result in the resumption of such distribution being outside of our sole control. Any such actions could materially and adversely disrupt and harm** our business ~~and~~ **, reputation, financial condition, results of** operations **and future growth. In addition, while we have submitted a 510 (k) application for TabloCart with Prefiltration, we cannot predict with certainty when the FDA will complete its review of our application, whether the FDA will ultimately grant clearance of our application, or when we will resume distribution of the product. Based on the results of the FDA' s review, we may be required to take additional actions, which may include making changes to the product, temporarily withdrawing or recalling TabloCart with Prefiltration until clearance is obtained (which may not happen in a timely manner or at all), and / or we may be subject to other enforcement actions or proceedings and litigation, any of which could materially and adversely disrupt and harm our business and future growth. Moreover, even if we are able to expeditiously and definitively resolve the Warning Letter, we will continue to incur incremental expenses relating to doing so, and we have experienced and expect to continue to experience related disruptions to our business, including reputational harm, customer uncertainty regarding the matters addressed in the Warning Letter and diversion of management' s time and attention. Furthermore, our business and operations have experienced and** may continue to experience disruptions as a result of **our pause on the distribution of TabloCart with Prefiltration, including reputational harm and adverse impacts on our bookings and revenues, and may experience further disruptions which could include adverse impacts on our backlog, our ability to expand customer relationships or attract new customers, as well as reduced demand for TabloCart and / or, potentially, Tablo. Any of** ~~the~~ **these** ~~prior~~ **factors** ~~our bookings and revenue for the last three quarters of 2022,as well as on our pipeline of potential new deals.Following the most recent 510 (k) clearance,we have resumed marketing and shipping Tablo for home use.However,we may continue to experience disruptions to our home and acute business and operations that~~ could materially and adversely ~~impact~~ **affect** our results of operations,financial condition and growth prospects ~~as~~ **.For example,beginning in the third quarter of 2023,** we **observed more customers than we anticipated choosing to defer their Tablo console purchasing and installation until TabloCart with Prefiltration becomes available again,and we also experienced marketplace confusion in relation to the Warning Letter (exacerbated,we believe,in some cases by our competitors),particularly regarding Tablo' s use in the ICU.These factors,combined with other macroeconomic factors,served to elongate our sales cycle and the timing of delivery and installations which,in turn,had an adverse impact on our bookings and revenues for the second half of 2023.We anticipate that the negative impacts from the Warning Letter and our distribution pause will** continue ~~recovering from~~ **into 2024.Moreover,** ~~the~~ **these risks** ~~interruption to,~~ and ~~loss~~ **adverse impacts will be exacerbated if the FDA' s review** of ~~momentum in,~~ **our pending 510 (k) application for TabloCart with Prefiltration and the current distribution pause (** ~~our~~ **or** ~~home commercialization and marketing,related disruptions to our acute business,and~~ any ~~negative effects to~~ **mandated distribution pause by the FDA) continues for an extended period of time,** ~~our~~ **or if** ~~reputation as a result of~~ the ~~hold~~ **FDA ultimately does not grant clearance of our 510 (k) application** .As we continue to modify Tablo from time to time,such modifications may require new clearances or approvals from the FDA,which we may not be able to obtain on a timely basis or at all.Although we currently market our products exclusively under 510 (k) clearances,modifications to Tablo and associated consumables may require new regulatory approvals or clearances,including additional 510 (k) clearances,de novo classification,or approval of PMAs or PMA supplements.As we continue to modify Tablo from time to time,we may determine that such modifications could significantly affect safety and effectiveness of the device or represent a major change in its intended use and thereby require new 510 (k) clearances.Further,even in instances where we determine modifications to Tablo do not require a new 510 (k) clearance or a PMA,the FDA may review our decision and disagree,or otherwise determine on its own initiative that a new clearance or approval is required.In this case,we may ultimately be required to make additional changes to ~~the~~ Tablo ~~System~~ ,we may need to submit a new 510 (k) application or a PMA and obtain clearance or approval,we may be required to temporarily suspend ~~shipment of,withdraw or recall Tablo until such clearance or approval is obtained (which may not happen in a timely manner or at all),and / or we may be subject to other enforcement actions or proceedings and litigation,all of which would materially and adversely disrupt and harm our business and future growth.Where we determine that modifications to Tablo do require a new 510 (k) clearance from the FDA or PMA approval,we may not be able to obtain such clearance or approval in a timely manner~~ shipment ~~hold~~ **of, withdraw or recall Tablo until such clearance or approval is obtained (which may not happen in a timely manner or at all), and / or we may be subject to other enforcement actions or proceedings and litigation, all of which would materially and adversely disrupt and harm our business and future growth** . ~~.~~ Where we determine that

modifications to Tablo do require a new 510 (k) clearance from the FDA or PMA approval,we may not be able to obtain such clearance or approval in a timely manner,or at all.Obtaining clearances or approvals can be a time- consuming and costly process,which may in some cases require us to conduct clinical trials,and delays in obtaining required future clearances or approval could adversely affect our ability to make updates and enhancements to Tablo in a timely manner,which in turn would harm our future growth. ~~Since Tablo~~ **For example, ~~Since~~ since** Tablo' s original clearance by the FDA for home use in March 2020, we have made certain changes to the device over time **and, where appropriate, have submitted 510 (k) applications for certain modifications to Tablo** . In May 2021, we submitted a 510 (k) application to the FDA covering the design changes for patient use in the home. In May 2022, after further discussions with the FDA and receiving indications that the clearance of this 510 (k) application would be delayed beyond our original expectations, we implemented a shipment hold on the distribution and marketing of Tablo for use in the home environment pending the FDA' s review and clearance of this 510 (k) application. In late July 2022, the FDA cleared this 510 (k) application of Tablo for patient use in the home and we resumed marketing and shipping Tablo for home use . The shipment hold on Tablo for..... and harm our business and future growth . Changes to the reimbursement rates for dialysis treatments and measures to reduce healthcare costs may adversely impact our business. Our customers depend upon reimbursement by government and other third- party insurance payors for dialysis services using our products. With a vast majority of U. S. patients with ESRD covered by Medicare, the Medicare reimbursement rate is an important factor in a customer' s decision to use Tablo and limits the prices we may charge for our products. For patients with Medicare fee- for- service coverage, virtually all payments for renal dialysis services are currently made under a single bundled payment rate which provides a fixed payment rate to encompass virtually all goods and services provided during the dialysis treatment. The bundled payment rate is also adjusted for certain patient characteristics, a geographic wage index, and other factors. The ESRD PPS is subject to rebasing, which can have a positive financial effect, or a negative one if the government fails to rebase in a manner that adequately addresses the costs borne by dialysis facilities. For example, on ~~October 31~~ **November 6** , ~~2022~~ **2023** , CMS issued a final rule updating the PPS to, among other things, increase the base rate from $ **265.** ~~257~~ - **57** ~~. 90~~ to $ ~~265~~ **271** . ~~57~~ **02** , an increase that CMS projects will increase the total payments to all ESRD facilities by ~~3~~ **2** . 1 % in CY ~~2023~~ **2024** . Additionally, reimbursement rates and coverage policies under Medicare Advantage plans may also be subject to change. We cannot anticipate whether the government and / or Medicare Advantage plans will decrease payment rates in the coming years or if any future rate increases will adequately cover facilities' costs, which could adversely harm our business. Additionally, federal regulations provide for transitional add- on payment adjustments under the Medicare ESRD PPS for certain TPNIES. For home dialysis equipment, CMS provided a pathway for CRA to secure TPNIES. We applied for and received CRA TPNIES in connection with the **use of** Tablo ~~Hemodialysis System use~~ by one patient per one machine in the home, pursuant to which Medicare **paid** ~~will pay~~ 65 % of the Medicare Administrative Contractor- determined pre- adjusted per treatment amount for two calendar years beginning with CY 2022. **However** ~~In a final rule issued on November 7~~ , ~~2022, CMS confirmed that it will continue Tablo' s eligibility for TPNIES through CY 2023. Though~~ our TPNIES approval ~~may~~ **, which temporarily** ~~increase~~ **increased** provider reimbursement ~~over the short term and positively affect our revenues as a result~~ , **expired on December 31** ~~such increased reimbursement is temporary and~~ , **2023** ~~thus, may not be sufficient to cause healthcare providers to adopt Tablo at rates we expect~~ . **We** ~~Accordingly, we~~ cannot fully assess the impact of the **expiration of our** TPNIES approval on our financial performance. CMS rules limit the number of hemodialysis treatments paid for by Medicare Part B to three times a week, unless there is medical justification provided by the dialysis facility based on information from the patient' s physician for additional treatments. To the extent that over three treatments per week are prescribed for Tablo patients and Medicare contractors determine they will not pay for additional treatments, adoption of ~~the~~ Tablo ~~System~~ could be impaired. As there is not a uniform national standard for what constitutes medical justification, a clinic' s decision as to how much it is willing to spend on home dialysis equipment and services will be at least partly dependent on the number of weekly treatments prescribed for home dialysis, and if greater than three, the level of confidence the center has in the predictability of receiving reimbursement from Medicare for additional treatments per week based on submitted claims for medical justification. Although most ESRD patients are currently covered by traditional Medicare, beginning January 1, 2021, when changes from the 21st Century Cures Act entered into effect, more dialysis patients were eligible to enroll in Medicare Advantage managed care plans. While Medicare Advantage plans must provide at least the same level of coverage for Medicare beneficiaries as traditional Medicare, reimbursement to dialysis facilities is most often higher than traditional Medicare with a wide range of variability in payment rates to providers. Reimbursement rates depend on each Medicare Advantage plan' s contracts and network agreements with each dialysis facility **. In March 2023, CMS released the Announcement of CY 2024 Medicare Advantage Capitation Rates and Payment Policies. Among other changes, this announcement includes information about future Medicare Advantage rate increases and updates certain policies associated with risk adjustments** . Many ESRD patients have Medicaid coverage that is supplemental to Medicare coverage, and some ESRD patients may have Medicaid as their primary coverage. Because Medicaid is a state- administered program, Medicaid reimbursement for dialysis services varies by state. Changes in state Medicaid or other non- Medicare government- based programs or payment rates could have an adverse effect on our customers' business. Additionally, some patients may have coverage through private insurance, for example through a marketplace plan set up under the Affordable Care Act or through an employer or union group health plan. Private insurance reimbursement is generally higher than government reimbursement, but it varies by sponsor and plan. Commercial payment rates are negotiated between our customers and insurers or other third- party administrators, and commercial payors may also exert downward pressure on payment rates for dialysis services. Recent litigation regarding payor coverage of ESRD services may also affect our business. Specifically, on June 21, 2022, in the case of Marietta v. DaVita, the Supreme Court of the United States addressed the question of whether a group health plan that provides limited benefits for outpatient dialysis – but does so uniformly for all plan participants – violates the MSPA, a law which makes Medicare a " secondary " payer to an individual' s existing insurance plan for certain medical services, including dialysis, when that plan already covers the same

services. Specifically, the Supreme Court held that because the Plan' s terms apply uniformly to all covered individuals, the Plan does not " differentiate in the benefits it provides " to individuals with ESRD or " take into account " whether an individual is entitled to or eligible for Medicare, and thus does not violate the MSPA. We cannot anticipate what the impact of the Court' s decision will be on our business, including whether adverse ESRD coverage actions may be taken by health plans or whether regulatory guidance or new legislation may be issued limiting ESRD coverage. Any reduction in reimbursement rates for dialysis treatments may adversely affect our customers' businesses and cause them to enact cost reduction measures that may result in reducing the scope of their home hemodialysis programs, which could result in reduced demand for our product or additional pricing pressures. Healthcare reform measures could hinder or prevent the commercial success of Tablo. In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that may harm our future revenues and profitability and the demand for Tablo. As discussed in the section titled " Business – Government Regulation – United States Health Reform " above, federal and state lawmakers regularly propose and, at times, enact legislation and propose and finalize regulations that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services, improve quality and / or expand access. Current and future legislative or regulatory proposals to further reform healthcare or reduce healthcare costs may limit coverage of and / or lower reimbursement for the procedures associated with the use of Tablo. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of Tablo. By way of example, in the United States, the Affordable Care Act substantially changed the way healthcare is financed by both governmental and private insurers, and continues to significantly impact our industry. The Affordable Care Act contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which impact existing government healthcare programs and have resulted in the development of new programs. As discussed in the section titled " Business – Government Regulation – United States Health Reform " above, there have been, and continue to be, judicial and Congressional challenges to several elements of the Affordable Care Act, as well as efforts by both the executive and legislative branches of the federal government to modify certain aspects of the Affordable Care Act. It is unclear how these and other efforts to challenge or modify, or alter the implementation or interpretation of the Affordable Care Act will affect our business, financial condition and results of operations. In addition, as discussed in the section titled " Business – Government Regulation – United States Health Reform " above, other legislative and executive actions have encouraged the development of new payment and care models for ESRD patients. Changes to the models of patient care, including an increased focus on treatments earlier in disease progression, may adversely affect our customers' businesses and potentially decrease the demand for our product or result in additional pricing pressures. Further, with home dialysis as a growing trend in the industry and the **implementation of the** ETC Model ~~final rule~~ , a failure to implement our expansion into home dialysis could have a material adverse impact on our business. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may harm our ability to set a price that we believe is fair for Tablo, our ability to generate revenue and achieve or maintain profitability, and the availability of capital. We believe that there will continue to be proposals and other actions by legislators and other policymakers at both the federal and state levels, and by regulators and third- party payors to reduce costs and / or expand individual healthcare coverage. We cannot predict what other healthcare policies will ultimately be proposed or implemented at the federal or state level or the effect of any future legislation or regulation in the United States on our business, financial condition and results of operations. Future changes in healthcare policy could increase our costs and subject us to additional legislative and regulatory requirements that may interrupt commercialization of our current and future solutions, decrease our revenue and impact sales of and pricing for our current and future products. We must comply with anti- kickback, fraud and abuse, false claims, transparency, and other healthcare laws and regulations. Our current and future operations are subject to various federal and state healthcare laws and regulations. These laws affect our sales, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with dialysis providers, hospitals, physicians or other potential purchasers or users, including patients, of medical devices and services. They also impose additional administrative and compliance burdens on us. In particular, these laws influence, among other things, how we structure our sales and rental offerings, including discount practices, customer support, education and training programs and physician consulting and other service arrangements. These laws include, but are not limited to, the healthcare fraud and abuse laws described in the section titled " Business – Government Regulation – Healthcare Fraud and Abuse Laws " above, and the Federal Food, Drug, and Cosmetic Act, which governs, among other things, the misbranding and adulteration of medical devices. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, compliance oversight and reporting requirements and the curtailment or restructuring of our operations. Moreover, any investigation into our practices could cause adverse publicity and require a costly and time- consuming response. Tablo and our operations are subject to extensive government regulation and oversight in the United States. If we fail to obtain or maintain necessary regulatory approvals for Tablo and related products, or if approvals or clearances for future products are delayed or not issued, it will negatively affect our business, financial condition and results of operations. Tablo is a medical device subject to extensive regulation in the United States and elsewhere, including by the FDA and its foreign counterparts. Government regulations specific to medical devices are wide ranging and govern, among other things: • product design, development, manufacture, and release; • laboratory and clinical testing, labeling, packaging, storage and distribution; • product safety and efficacy; • premarketing clearance or approval; • service operations; • record keeping; • product marketing, promotion and advertising, sales and distribution; • post- marketing surveillance, including reporting of deaths or serious injuries and recalls and correction and removals; • post- market approval studies; and • product import and export. We have obtained 510 (k)

clearances to market Tablo for use in patients with acute and / or chronic renal failure, with or without ultrafiltration, in the settings of an acute or chronic care facility and the home. ~~However, Tablo is not cleared by the FDA for CRRT.~~ The FDA or other regulators could delay, limit, or deny clearance or approval of a device for many reasons, including: • our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that ~~the~~ Tablo ~~System~~, or any other future device, and any accessories are substantially equivalent to a legally marketed predicate device or safe or effective for their proposed intended use; • the disagreement of the FDA with the design or implementation of any clinical trials or the interpretation of data from preclinical studies or clinical trials; • serious and unexpected adverse device effects experienced by participants in our clinical trials; • the insufficiency of the data from preclinical studies or clinical trials to support clearance or approval, where required; • our inability to demonstrate that the clinical and other benefits of the device outweigh the risks; • the failure of our manufacturing process or facilities to meet applicable requirements; and • the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval. The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. The FDA enforces these regulatory requirements through, among other means, periodic unannounced inspections. We do not know whether we will be found compliant in connection with any future regulatory inspections. Moreover, the FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by any such agency, which may include any of the following sanctions: • adverse publicity, warning letters **(such as the Warning Letter we received in July 2023)** , untitled letters, it has come to our attention letters, fines, injunctions, consent decrees and civil penalties; • repair, replacement, refunds, recall or seizure of Tablo; • operating restrictions, partial suspension or total shutdown of production; • denial of our requests for regulatory clearance or PMA approval of new products or services, new intended uses or modifications to existing products or services; • withdrawal of regulatory clearance or PMA approvals that have already been granted; or • criminal prosecution. If any of these events were to occur, it would negatively affect our business, financial condition and results of operations. Our future success depends on our ability to develop, receive regulatory clearance or approval for, and introduce new products that will be accepted by the market in a timely manner. There is no guarantee that the FDA will grant 510 (k) clearance or PMA approval of our future products on a timely basis, if at all, and failure to obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business. It is important to our business that we build a pipeline of product offerings that address limitations of current dialysis products. As such, our success will depend in part on our ability to develop and introduce new products. However, we may not be able to successfully develop and obtain regulatory clearance or approval for product enhancements, or new products for any number of reasons, including due to the cost associated with certain regulatory approval requirements, or these products may not be accepted by physicians or users. The success of any new product offering or enhancement to an existing product will depend on a number of factors, including our ability to, among others: • identify and anticipate physician and patient needs properly; • develop and introduce new products or product enhancements in a timely manner; • avoid infringing upon the intellectual property rights of third parties; • demonstrate, if required, the safety and efficacy of new products with data from clinical studies; • obtain the necessary regulatory clearances or approvals for new products or product enhancements; • comply fully with the FDA and applicable foreign regulations on marketing of new products or modified products; and • provide adequate training to potential users of Tablo. If we do not develop new products or product enhancements in time to meet market demand or if there is insufficient demand for these products or enhancements, or if our competitors introduce enhanced or new products with functionalities that are superior to ours, our results of operations will suffer. Some of our future products will require FDA clearance of a 510 (k). Other products may require the approval of a PMA. In addition, some of our future products may require clinical trials to support regulatory approval and we may not successfully complete these clinical trials. The FDA may not approve or clear these products for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510 (k) clearance or PMA approval of new products. Failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business. If we or our suppliers fail to comply with ongoing FDA or other foreign regulatory authority requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market. Even though we have obtained 510 (k) clearance for Tablo, it and any other product for which we obtain clearance or approval, and the manufacturing processes, post- market surveillance, post- approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight, requirements, and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our suppliers are required to comply with FDA' s QSR and other regulations enforced outside the United States which cover the manufacture of our products and the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of medical devices. The QSR requires that each manufacturer establish a quality systems program by which the manufacturer monitors the manufacturing process and maintains records that show compliance with FDA regulations and the manufacturer' s written specifications and procedures relating to the devices. QSR compliance is necessary to receive and maintain FDA clearance or approval to market new and existing products. Regulatory bodies, such as the FDA, enforce the QSR and other regulations through periodic audits and inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions: • FDA untitled letters, FDA Form 483s, FDA warning letters, it has come to our attention letters, fines, injunctions, consent decrees and civil penalties; • unanticipated expenditures to address or defend such actions • customer notifications for repair, replacement, refunds; • recall, detention or seizure of our products; • operating restrictions or partial suspension or total shutdown of production; • refusing or delaying our requests for 510 (k) clearance or

PMA approval of new products or modified products; • withdrawal of 510 (k) clearances or PMA approvals that have already been granted; • refusal to grant export approval for our products; or For example, ~~in the first quarter of 2023,~~ the FDA conducted their first quality system inspection of our San Jose, California facility **which concluded in February 2023** . At completion, the FDA issued a Form FDA- 483 identifying four inspectional observations. We ~~intend to provide~~ **provided our** ~~a complete~~ response **plan** to the FDA **in March 2023** and **have since completed the associated remediation workstreams** to **fully** ~~implement a corrective action plan to~~ address these observations **. We continue to provide the FDA** ~~within~~ -- **with monthly updates as to the status of** ~~the~~ **these** ~~requisite timeframe~~ **483- related workstreams** . Although we believe we are in material compliance with the QSR and **have** ~~will be able to address~~ **addressed** the observations identified in the Form- 483 ~~in a timely manner~~ , there is no guarantee that subsequent inspections of our facility by the FDA or other regulatory authorities will not result in similar observations with respect to our quality system, which could adversely affect our business. The FDA can also publish Safety Communications or Letters to Health Care Providers when the agency becomes aware of new issues involving a specific product or, or more broadly, a product family. These communications are posted on the FDA' s website and describe the FDA' s analysis of a current issue and provide specific regulatory approaches and clinical recommendations for patient management. If any of these actions were to occur it would harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements which could result in our failure to produce our products on a timely basis and in the required quantities, if at all. In addition, we are required to conduct costly post- market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products ~~. For example, the FDA previously issued to us a post- market surveillance order under Section 522 of the FDCA which required that we conduct a human factors study, as well as conduct a detailed analysis of adverse events and complaints from home users. While the FDA recently placed this 522 study requirement on hold because the original order specifically pertained to a prior version of Tablo, the FDA may decide to issue a new 522 order applicable to the current version of Tablo or extend the requirements of the prior 522 study order to apply to the version of Tablo that is the subject of the recently cleared 510 (k)~~ . Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects. For example, in May 2022, the FDA published a Letter to Healthcare Providers entitled" Potential Risk of Exposure to Toxic Compounds When Using Certain Hemodialysis Machines Manufactured by Fresenius Medical Care – Letter to Health Care Providers." In that communication, the agency stated that it is evaluating the potential risk of exposure to NDL PCBA and NDL PCBs with certain hemodialysis machines marketed in the United States. The FDA stated that the source of the NDL PCBAs and NDL PCBs is from the silicone tubing used as a part of the hydraulics in those machines and the dialysate lines. Although ~~the~~ Tablo ~~Hemodialysis System~~ was not the subject of the FDA' s Letter to Healthcare Providers, the FDA reached out to Outset regarding the tubing used in ~~the~~ Tablo. In a series of discussions with the FDA, the agency requested that we conduct a targeted analysis and a screening analysis on the tubing **currently** used in ~~the~~ Tablo ~~Hemodialysis System~~ . ~~The~~ **After aligning with the** FDA ~~is requesting data~~ on ~~three specific compounds of PCB / PCBA as well as screening for other toxins and PCB / PCBAs. We are cooperating fully with the agency and are in the process of finalizing~~ testing and screening protocols ~~for submission to the FDA~~ , **we are concluding our** ~~and plan to perform the~~ analysis ~~in the first half~~ of ~~2023. Based on~~ the ~~results of this testing~~ **data. In parallel** , **we filed** ~~Outset may be required to take additional actions including submission of~~ a 510 (k) application **, and received subsequent 510 (k) clearance from the FDA** for ~~modified~~ **, PCB- free** silicone tubing **in December 2023. During the first quarter of 2024** , ~~if necessary~~ **we intend to proactively initiate a workstream to replace the remaining few silicone segments in new and existing Tablo consoles with the new** , ~~or even~~ **PCB- free, silicone tubing. While we intend to continue to partner with the FDA on next steps and take appropriate action with respect to this matter, there is no assurance that the FDA will not publish a safety notice specific to Tablo, classify this action as a recall, require us to** conduct a recall of previously marketed products **, or subject us to other enforcement actions, any of which could damage our reputation and harm our business** . Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us. We are subject to the FDA' s medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. Manufacturers are also expected to maintain certain policies, procedures, and records regarding complaints and medical device reporting. If we fail to comply with our reporting and recordkeeping obligations, the FDA could take action, including warning letters, untitled letters, it has come to our attention letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance or approval, seizure of our products or delay in clearance or approval of future products. The

FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA' s authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. For example, in January 2022 we proactively initiated a recall to replace a component in Tablo consoles at customer sites due to the possibility of heat- related damage to the device as a result of the component. A government- mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future. Depending on the corrective action we take to redress a product' s deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new clearances or approvals for the device before we may market or distribute the corrected device. Seeking such clearances or approvals may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines. Our products, such as Tablo, may in the future be subject to product recalls that could harm our reputation, business and financial results. Medical devices can experience performance problems in the field that require review and possible corrective action. The occurrence of component failures, manufacturing errors, software errors, design defects or labeling inadequacies affecting a medical device could lead to a government- mandated or voluntary recall by the device manufacturer, in particular when such deficiencies may endanger health. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, will distract management from operating our business and may harm our reputation and financial results. We may be subject to regulatory or enforcement actions if we engage in improper marketing or promotion of Tablo. Our educational and promotional activities and training methods must comply with FDA and other applicable laws, including the prohibition of the promotion of a medical device for a use that has not been cleared or approved by the FDA. Use of a device outside of its cleared or approved indications is known as " off- label " use. Physicians may use Tablo off- label in their professional medical judgment, as the FDA does not restrict or regulate a physician' s choice of treatment within the practice of medicine. However, if the FDA determines that our educational and promotional activities or training constitutes promotion of an off- label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of warning letters, untitled letters, fines, penalties, injunctions, or seizures, any of which could have an adverse impact on our reputation and financial results. **For example, one of the observations raised in the Warning Letter we received in July 2023 asserted that certain content reviewed by the FDA and found on our website promotes CRRT, a modality outside of the current indications for Tablo. We believe this concern has been effectively addressed through a thorough review of existing promotional materials and practices, however, there is no guarantee that the FDA will not issue similar warning letters to us or subject us to other regulatory or enforcement actions for marketing or promotion of Tablo that the agency deems improper in the future.** It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our educational and promotional activities or training methods to constitute promotion of an off- label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged, and adoption of the products could be impaired. Although our policy is to refrain from statements that could be considered off- label promotion of Tablo, the FDA or another regulatory agency could disagree and conclude that we have engaged in off- label promotion. It is also possible that other federal, state or foreign enforcement authorities might take action, including, but not limited to, through a whistleblower action under the FCA, if they consider our business activities to constitute promotion of an off- label use, which could result in significant penalties, including, but not limited to, criminal, civil or administrative penalties, treble damages, fines, disgorgement, exclusion from participation in government healthcare programs, reporting requirements and compliance oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, and the curtailment or restructuring of our operations. In addition, the off- label use of Tablo may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management' s attention, result in substantial damage awards against us, and harm our reputation. Legislative or regulatory reforms may make it more difficult and costly for us to obtain regulatory clearance or approval of any future products **or product enhancements** and to manufacture, market and distribute our products after clearance or approval is obtained. From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval or clearance of our future products under development or impact our ability to modify our currently cleared products on a timely basis. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of planned or future products **or product enhancements** . It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be. FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may

significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain clearance or approval for, manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to obtaining clearance or approval; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping. The FDA' s and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay regulatory clearance or approval of our product candidates **or enhancements** . We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. Any change in the laws or regulations that govern the clearance and approval processes relating to our current, planned and future products **or product enhancements** could make it more difficult and costly to obtain clearance or approval for new products or to produce, market and distribute existing products. Significant delays in receiving clearance or approval or the failure to receive clearance or approval for any new products **or enhancements** would have an adverse effect on our ability to expand our business. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing clearance that we may have obtained and we may not achieve or sustain profitability **. For example, medical device cybersecurity continues to be an area of focus for and evolving guidance from the FDA. Specifically, the FDA recently finalized new cybersecurity guidance for medical device manufacturers, which we anticipate may necessitate additional time and cost for product development, submission and approval or clearance** . Clinical trials may be necessary to support future product submissions to the FDA. The clinical trial process is lengthy and expensive with uncertain outcomes, and often requires the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Delays or failures in our clinical trials will prevent us from commercializing any modified or new products and will adversely affect our business, operating results and prospects. Initiating and completing clinical trials necessary to support any future PMAs, and additional safety and efficacy data beyond that typically required for a 510 (k) clearance, for our possible future product candidates, will be time- consuming and expensive and the outcome uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product we advance into clinical trials may not have favorable results in later clinical trials. The results of preclinical studies and clinical trials of our products conducted to date and ongoing or future studies and trials of our current, planned or future products may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Our interpretation of data and results from our clinical trials do not ensure that we will achieve similar results in future clinical trials. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in preclinical studies and earlier clinical trials have nonetheless failed to replicate results in later clinical trials. Products in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical trials. Failure can occur at any stage of clinical testing. Our clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non- clinical testing in addition to those we have planned. The initiation and completion of any of clinical studies may be prevented, delayed, or halted for numerous reasons. We may experience delays in our ongoing clinical trials for a number of reasons, which could adversely affect the costs, timing or successful completion of our clinical trials, including related to the following: • we may be required to submit an IDE application to the FDA, which must become effective prior to commencing certain human clinical trials of medical devices, and the FDA may reject our IDE application and notify us that we may not begin clinical trials; • regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials; • regulators and / or an IRB, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site; • we may not reach agreement on acceptable terms with prospective contract research organizations (CROs), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs; • the number of subjects or patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate; • our third- party contractors, including those manufacturing products or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; • we might have to suspend or terminate clinical trials for various reasons, including the withdrawal of approval of an IDE by the FDA based on, for example, a finding that the subjects are being exposed to unacceptable health risks; • we may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB and / or regulatory authorities for re- examination; • regulators, IRBs, or other parties may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements; • the cost of clinical trials may be greater than we anticipate; • clinical sites may not adhere to the clinical protocol or may drop out of a clinical trial; • we may be unable to recruit a sufficient number of clinical trial sites; • regulators, IRBs, or other reviewing bodies may fail to approve or subsequently find fault with our manufacturing processes or facilities of third- party manufacturers with which we enter into agreement for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical trials may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; • approval policies or regulations of the FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for approval; • our current or future

products may have undesirable side effects or other unexpected characteristics; and • impacts of regional or global public health crises ~~including~~ **such as** the recent COVID- 19 pandemic could adversely affect any clinical trials we are conducting or plan to conduct, including delays or difficulties in enrolling or onboarding patients, initiating clinical sites, or obtaining the requisite regulatory approvals, interruption of key clinical trial activities, or supply chain disruptions that delay or make it more difficult or costly to obtain the supplies and materials we need for clinical trials. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Clinical trials must be conducted in accordance with applicable laws and regulations of the FDA and other regulatory authorities' applicable legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. Conducting successful clinical studies will require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow- up depends on many factors, including the size of the patient population, the nature of the trial protocol, the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects, the availability of appropriate clinical trial investigators, support staff, and proximity of patients to clinical sites and able to comply with the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post- treatment procedures or follow- up to assess the safety and effectiveness of our products or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. We depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with good clinical practice (GCP) requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both. In addition, clinical trials that are conducted in countries outside the United States may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non- U. S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening and medical care. Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required and we may not adequately develop such protocols to support clearance and approval. Further, the FDA may require us to submit data on a greater number of patients than we originally anticipated and / or for a longer follow- up period or change the data collection requirements or data analysis applicable to our clinical trials. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays in the approval and attempted commercialization of our products or result in the failure of the clinical trial. In addition, despite considerable time and expense invested in our clinical trials, the FDA may not consider our data adequate to demonstrate safety and efficacy. Such increased costs and delays or failures could adversely affect our business, operating results and prospects. If the third parties on which we rely to conduct our clinical trials and to assist us with pre- clinical development do not perform as required or expected, we may not be able to obtain regulatory clearance or approval for or commercialize our products. We may not have the ability to independently conduct our pre- clinical and clinical trials for our future products and we may need to rely on third parties, such as CROs, medical institutions, clinical investigators and contract laboratories to conduct such trials. We would depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with GCP requirements, and other regulatory requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, including on account of the outbreak of infectious disease, such as the COVID- 19 pandemic, or otherwise, we may be affected by increased costs, program delays or both, any resulting data may be unreliable or unusable for regulatory purposes, and we may be subject to enforcement action. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre- clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected. The results of our clinical trials may not support our product candidate claims or may result in the discovery of adverse side effects. We cannot be certain that the results of our future clinical trials will support our future product claims or that the FDA will agree with our conclusions regarding them. Success in pre- clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre- clinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the future product' s profile. Changes in funding or disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes, and other events that may otherwise affect the FDA' s ability to perform routine functions. Average review times at the agency have

fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new product applications to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, the U. S. government could shut down causing certain regulatory agencies, including the FDA, to furlough critical employees and stop critical activities. Separately, in response to the COVID- 19 pandemic, the FDA postponed most inspections of foreign and domestic manufacturing facilities. Although inspections have resumed to near pre- pandemic levels, the FDA could amend its priorities with respect to inspections at any time, and those changes could have a material effect on our regulatory submissions and on our business. Our use, disclosure, and other processing of personally identifiable information, including health information, is subject to HIPAA and other federal, state, and data privacy and security regulations, and our failure to comply with those regulations or to adequately secure the information we hold could result in significant liability or reputational harm and, in turn, a material adverse effect on our client base, member base and revenue. Numerous state and federal laws and regulations govern the collection, dissemination, use, privacy, confidentiality, security, availability, integrity, and other processing of PHI and PII. These laws and regulations include HIPAA. HIPAA establishes a set of national privacy and security standards for the protection of PHI (as defined in HIPAA) by health plans, healthcare clearinghouses and certain healthcare providers, referred to as covered entities, and the business associates with whom such covered entities contract to provide specified services or perform a function for or on behalf of such covered entities. We are a business associate under HIPAA **,** and ~~we~~ **it is our policy to** execute business associate agreements with our clients **and our sub- business associates** . HIPAA requires covered entities and business associates, such as us, to develop and maintain policies with respect to the protection, use and disclosure of electronic PHI, including the adoption of administrative, physical and technical safeguards to protect such information, and imposes certain notification and reporting requirements in the event of a data breach. Violations of HIPAA may result in significant civil and criminal penalties. HIPAA also authorizes state attorneys general to file ~~suit~~ **suits** on behalf of their residents. Courts may award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI. OCR has recently increased its enforcement efforts on compliance with HIPAA, including the security regulations (Security Rule), bringing actions against entities which have failed to implement security measures sufficient to reduce risks to electronic protected health information or to conduct an accurate and thorough risk analysis, among other violations. HIPAA enforcement actions may lead to monetary penalties and costly and burdensome corrective action plans. We are also required to report known breaches of PHI consistent with applicable breach reporting requirements set forth in applicable laws and regulations. In addition, HIPAA mandates that the Secretary of HHS conduct periodic compliance audits of HIPAA covered entities and business associates. With regard to business associates, those audits assess the business associate' s compliance with the HIPAA Privacy and Security Rules. Such audits are conducted randomly and after an entity experiences a breach affecting more than 500 individuals' data. Undergoing an audit can be costly, can result in fines or onerous obligations, and can damage a business associate' s reputation. Finally, on December 10, 2020, OCR issued a proposed rule aimed at reducing regulatory burdens that may exist in discouraging coordination of care, including creating an exception to the minimum necessary standard for healthcare coordination, among other changes. While a final rule has not yet been issued, if adopted, these proposed changes may require us to update our HIPAA policies and procedures to comply with the new requirements. In addition to HIPAA, numerous other federal and state laws and regulations protect the confidentiality, privacy, availability, integrity and security of PHI and other types of PII. Some of these laws and regulations may be preempted by HIPAA with respect to PHI, or may exclude PHI from their scope but impose obligations with regard to PII that is not PHI, and in some cases, can impose additional obligations with regard to PHI. These laws and regulations are often uncertain, contradictory, and subject to changed or differing interpretations, and we expect new laws, rules and regulations regarding privacy, data protection, and information security to be proposed and enacted in the future. ~~For example, the CCPA, became effective on January 1, 2020. The CCPA gives California residents new rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined) and provide such consumers new ways to opt- out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation.~~ Although ~~the~~ **these other** ~~law~~ **laws** ~~includes~~ **include** limited exceptions, including for PHI maintained by a covered entity or business associate, ~~it~~ **they** may regulate or impact our processing of personal information depending on the context ~~,~~ and ~~the CCPA may~~ increase our compliance costs and potential liability. Additionally, our machine learning and data analytics offerings may be subject to laws and evolving regulations regarding the use of artificial intelligence, controlling for data bias, and antidiscrimination ~~. Other states, including Nevada, Virginia, Colorado, and Utah have passed data protection laws, or are considering passing legislation, similar to CCPA. To the extent these laws apply to our operations, they may impose organizational requirements and grant individual rights that are comparable to those established in the CCPA. Additionally, a ballot initiative, the CPRA, passed in November 2020 in California. The CPRA amendments to the CCPA impose additional data protection obligations on companies doing business in California, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. The amendments also created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions went into effect on January 1, 2023, and additional compliance investment and potential business process changes will be required~~ . Additionally, the FTC and many state attorneys general are interpreting existing federal and state consumer protection laws to impose evolving standards for the

online collection, use, dissemination and security of health- related and other personal information. Courts may also adopt the standards for fair information practices promulgated by the FTC, which concern consumer notice, choice, security and access. Consumer protection laws require us to publish statements that describe how we handle personal information and choices individuals may have about the way we handle their personal information. If such information that we publish is considered untrue, we may be subject to government claims of unfair or deceptive trade practices, which could lead to significant liabilities and consequences. Furthermore, according to the FTC, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair or deceptive acts or practices in violation of Section 5 of the FTC Act. The FTC expects a company' s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC' s guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule. Enforcement by the FTC under the FTC Act can result in civil penalties or enforcement actions. This complex, dynamic legal landscape regarding privacy, data protection, data analytics and information security creates significant compliance issues for us and our clients and potentially exposes us to additional expense, adverse publicity and liability. While we have implemented data privacy and security measures in an effort to comply with applicable laws and regulations relating to privacy and data protection, some PHI and other PII or confidential information is transmitted to us by third parties, who may not implement adequate security and privacy measures, and it is possible that laws, rules and regulations relating to privacy, data protection, or information security may be interpreted and applied in a manner that is inconsistent with our practices or those of third parties who transmit PHI and other PII or confidential information to us. If we or these third parties are found to have violated such laws, rules or regulations, it could result in government- imposed fines, orders requiring that we or these third parties change our or their practices, or criminal charges, which could adversely affect our business. Complying with these various laws and regulations could cause us to incur substantial costs or require us to change our business practices, systems and compliance procedures in a manner adverse to our business ~~. We regularly monitor, defend against and respond to attacks to our networks and other information security incidents. Despite our information security efforts, our facilities, systems, and data, as well as those of our third- party service providers, may be vulnerable to privacy and information security incidents such as data breaches, viruses or other malicious code, coordinated attacks, data loss, phishing attacks, ransomware, denial of service attacks, or other security or IT incidents caused by threat actors, technological vulnerabilities or human error. If we, or any of our vendors that support our IT or have access to our data, fail to comply with laws requiring the protection of personal information, or fail to safeguard and defend personal information or other critical data assets or IT systems, we may be subject to regulatory enforcement and fines as well as private civil actions. We may be required to expend significant resources in the response, containment, mitigation of cybersecurity incidents as well as in defense against claims that our information security was unreasonable or otherwise violated applicable laws or contractual obligations~~ . Our employees, collaborators, independent contractors and consultants may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk that our employees, collaborators, independent contractors and consultants may engage in fraudulent or other illegal activity with respect to our business. Misconduct by these persons could include intentional, reckless and / or negligent conduct or unauthorized activity that violates: • FDA requirements, including those laws requiring the reporting of true, complete and accurate information to the FDA authorities; • manufacturing standards; • federal and state healthcare fraud and abuse laws and regulations; or • laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commissions, customer incentive programs and other business arrangements. Misconduct by these parties could also involve individually identifiable information, including, without limitation, the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Any incidents or any other conduct that leads to an employee, contractor, or other agent, or our company, receiving an FDA debarment or disqualification from clinical trials, or exclusion by OIG could result in penalties, a loss of business from third parties, and severe reputational harm. It is not always possible to identify and deter misconduct by our employees and other agents, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, treble damages, monetary fines, disgorgement, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, reporting requirements and compliance oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, and curtailment of our operations. We must comply with environmental and occupational safety laws. Our research and development programs as well as our manufacturing operations involve the controlled use of hazardous materials. Accordingly, we are subject to federal, state and local laws, as well as the laws of foreign countries, governing the use, handling and disposal of these materials. In the event of an accident or failure to comply with environmental or occupational safety laws, we could be held liable for resulting damages, and any such liability could exceed our insurance coverage and may accordingly adversely affect our business, financial condition or results of operations. Risks Related to our Intellectual Property We have to protect our intellectual property. Our commercial success will depend in part in our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our technology. We rely on patent protection, as well as a combination of copyright, trade secret

and trademark laws, to protect our proprietary technology and prevent others from duplicating Tablo. However, these means may afford only limited protection and may not prevent our competitors from duplicating Tablo, prevent our competitors from gaining access to our proprietary information and technology, or permit us to gain or maintain a competitive advantage. Any of our patents, including those we may license, may be challenged, invalidated, rendered unenforceable or circumvented. We may not prevail if our patents are challenged by competitors or other third parties. The U. S. federal courts or equivalent national courts or patent offices elsewhere may invalidate our patents, find them unenforceable, or narrow their scope. Furthermore, competitors may be able to design around our patents, or obtain patent protection for more effective technologies, designs or methods for treating kidney failure. If these developments were to occur, Tablo may become less competitive and sales of Tablo may decline. We have filed numerous patent applications seeking protection of products and other inventions originating from our research and development. Our patent applications may not result in issued patents, and any patents that are issued may not provide meaningful protection against competitors or competitive technologies. Further, the examination process may require us to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The scope of a patent may also be reinterpreted after issuance. The rights that may be granted under our future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we are unable to obtain and maintain patent protection for our technology, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize products similar or superior to ours, and our competitive position may be adversely affected. It is also possible that we will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them. In addition, the patent prosecution process is expensive, time- consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. Additionally, while software and other of our proprietary works may be protected under copyright law, we have chosen not to register any copyrights in these works, and instead, primarily rely on protecting our software with patents and as a trade secret. In order to bring a copyright infringement lawsuit in the United States, the copyright must be registered. Accordingly, the remedies and damages available to us for unauthorized use of our software may be limited. We may be subject to claims challenging the ownership or inventorship of our patents and other intellectual property and, if unsuccessful in any of these proceedings, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms, or at all, or to cease the development, manufacture and commercialization of Tablo. We may be subject to claims that current or former employees, collaborators or other third parties have an interest in our patents, trade secrets or other intellectual property as an inventor or co- inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing Tablo. Litigation may be necessary to defend against these and other claims challenging inventorship of our patents, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to Tablo. If we were to lose exclusive ownership of such intellectual property, other owners may be able to license their rights to other third parties, including our competitors. We also may be required to obtain and maintain licenses from third parties, including parties involved in any such disputes. Such licenses may not be available on commercially reasonable terms, or at all, or may be non- exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture and commercialization of Tablo. The loss of exclusivity or the narrowing of our patent claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position may be harmed. In addition to seeking patent protection for Tablo, we also rely upon unpatented trade secrets, know- how and continuing technological innovation to develop and maintain a competitive position. We seek to protect such proprietary information, in part, through confidentiality agreements with our employees, collaborators, contractors, advisors, consultants and other third parties and invention assignment agreements with our employees. We also have agreements with some of our consultants that require them to assign to us any inventions created as a result of their working with us. The confidentiality agreements are designed to protect our proprietary information and, in the case of agreements or clauses containing invention assignment, to grant us ownership of technologies that are developed through a relationship with employees or third parties. We cannot guarantee that we have entered into such agreements with each party that has or may have had access to our trade secrets or proprietary information. Additionally, despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to, or independently developed by, a competitor or other third party, our competitive position would be materially and adversely harmed. Furthermore, we expect these trade secrets, know- how and proprietary information to over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology and the movement of personnel from academic to industry scientific positions. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known, or be

independently discovered by, competitors. To the extent that our employees, consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know- how and inventions, which could have a material adverse effect on our business, financial condition and results of operations. We may be subject to claims that we or our employees have misappropriated the intellectual property of a third party, including trade secrets or know- how, or are in breach of non- competition or non- solicitation agreements with our competitors and third parties may claim an ownership interest in intellectual property we regard as our own. Many of our employees and consultants were previously employed at or engaged by other medical device, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and contractors, may have executed proprietary rights, non- disclosure and non- competition agreements in connection with such previous employment. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know- how or trade secrets of others in their work for us, we may be subject to claims that we or these individuals have, inadvertently or otherwise, misappropriated the intellectual property or disclosed the alleged trade secrets or other proprietary information, of these former employers or competitors. Additionally, we may be subject to claims from third parties challenging our ownership interest in intellectual property we regard as our own, based on claims that our employees or consultants have breached an obligation to assign inventions to another employer, to a former employer, or to another person or entity. Litigation may be necessary to defend against any other claims, and it may be necessary or we may desire to enter into a license to settle any such claim; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to Tablo, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate technologies or features that are important or essential to our product could have a material adverse effect on our business, financial condition and results of operations, and may prevent us from selling Tablo. In addition, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our product, which could have an adverse effect on our business, financial condition and results of operations. Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future products. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In 2011, the Leahy- Smith America Invents Act (Leahy- Smith Act) was signed into law. The Leahy- Smith Act includes a number of significant changes to U. S. patent law. These include provisions that affect the way patent applications are prosecuted and also may affect patent litigation. These also include provisions that switched the United States from a first- to- invent system to a first- to- file system, allow third- party submission of prior art to the USPTO during patent prosecution and set forth additional procedures to attack the validity of a patent by the USPTO administered post grant proceedings. Under a first- to- file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy- Smith Act, and many of the substantive changes to patent law associated with the Leahy- Smith Act, and in particular, the first to file provisions, only became effective in 2013. Accordingly, it is not clear what, if any, impact the Leahy- Smith Act will have on the operation of our business. The Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition and results of operations. In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications. Furthermore, the U. S. Supreme Court and the U. S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U. S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future. If our trademarks and tradenames are not adequately protected, then we may not be able to build name recognition in our markets and our business may be adversely affected. Our trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be violating or infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners and customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement or dilution claims brought by owners of other trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names or other intellectual property may be ineffective, could result in substantial costs and diversion of resources and could adversely affect our business, financial condition and results of operations. We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time- consuming and unsuccessful. Competitors may infringe our patents, or we may be required to enforce patents issued or licensed to us, to protect our trade secrets or know- how, to defend against claims of infringement of the rights of others or to determine the scope and validity of the proprietary rights of others. In addition, our patents also may become involved in inventorship, priority or validity disputes. To counter or defend against such

claims can be expensive and time- consuming and could divert our attention from other functions and responsibilities. In an infringement proceeding, a court may decide that a patent owned by us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover such technology. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, even if our patents are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages and / or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer' s competition in the market. Adverse determinations in litigation could subject us to significant liabilities to third parties, require us to seek licenses from third parties and prevent us from manufacturing, selling or using the product, any of which could severely harm our business. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our management and other personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on our common stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Any of the foregoing could have a material adverse effect on our business, financial condition or results of operations. Our use of " open source " software could subject our proprietary software to general release, adversely affect our ability to sell Tablo and subject us to possible litigation. A portion of the products or technologies licensed, developed and / or distributed by us incorporate so- called " open source " software and we may incorporate open- source software into other products in the future. Such open- source software is generally licensed by its authors or other third parties under open- source licenses. Some open- source licenses contain requirements that we disclose source code for modifications we make to the open- source software and that we license such modifications to third parties at no cost. In some circumstances, distribution of our software in connection with open- source software could require that we disclose and license some or all of our proprietary code in that software, as well as distribute our software that uses particular open- source software at no cost to the user. We monitor our use of open- source software in an effort to avoid uses in a manner that would require us to disclose or grant licenses under our proprietary source code; however, there can be no assurance that such efforts will be successful. Open- source license terms are often ambiguous and such use could inadvertently occur. There is little legal precedent governing the interpretation of many of the terms of these licenses, and the potential impact of these terms on our business may result in unanticipated obligations regarding Tablo and our technologies. Companies that incorporate open- source software into their products have, in the past, faced claims seeking enforcement of open- source license provisions and claims asserting ownership of open- source software incorporated into their product. If an author or other third party that distributes such open- source software were to allege that we had not complied with the conditions of an open- source license, we could incur significant legal costs defending ourselves against such allegations. In the event such claims were successful, we could be subject to significant damages or be enjoined from the distribution of Tablo. In addition, if we combine our proprietary software with open- source software in certain ways, under some open- source licenses, we could be required to release the source code of our proprietary software, which could substantially help our competitors develop products that are similar to or better than ours and otherwise adversely affect our business. These risks could be difficult to eliminate or manage, and, if not addressed, could harm our business, financial condition and results of operations. Intellectual property rights do not necessarily address all potential threats. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example: • others may be able to make products that are similar to Tablo or utilize similar technology but that are not covered by the claims of our patents or that incorporate certain technology in Tablo that is in the public domain; • we, or our future licensors or collaborators, might not have been the first to make the inventions covered by the applicable issued patent or pending patent application that we own now or may own or license in the future; • we, or our future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; • it is possible that our current or future pending patent applications will not lead to issued patents; • issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties; • our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • we may not develop additional proprietary technologies that are patentable; • the patents of others may harm our business; and • we may choose not to file a patent in order to maintain certain trade secrets or know- how, and a third party may subsequently file a patent covering such intellectual property. 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. The market price of our common stock has been and may continue to be volatile and may decline steeply or suddenly regardless of our operating performance, which could result in substantial losses for holders of our common stock, and we may not be able to meet investor or analyst expectations. The market price of our common stock has been and may continue to be highly volatile and may continue to fluctuate or decline significantly in response to numerous factors, many of which are beyond our control, including: • actual or anticipated changes in our operating results, and variations between our actual operating results and the expectations of securities analysts, investors and the financial community; • any forward- looking financial or operating information we may provide to the public or securities analysts, any changes in this information or our failure to meet expectations based on this information; • actions of securities analysts who initiate or maintain coverage of us, changes in financial estimates by any securities analysts who follow our company or our failure to meet these estimates or the expectations of investors; • additional shares of our common stock being sold into the market by us or our existing stockholders, or the anticipation of such sales; • hedging activities by market participants; • regulatory actions with respect to our products or our competitors' products **, or announcements by us in relation to such regulatory actions (for example, the Warning Letter we received in July 2023 and our subsequent pause on the distribution of TabloCart with Prefiltration)** ; • announcements by us or our competitors of significant products or features, technical innovations, acquisitions, strategic partnerships, joint ventures or capital commitments; • changes in operating performance and stock market valuations of companies in our industry, including our competitors; • price and volume fluctuations in the overall stock market, including as a result of trends in the economy as a whole; • lawsuits threatened or filed against us; • developments in new legislation and pending lawsuits or regulatory actions, including interim or final rulings by judicial or regulatory bodies; and • other events or factors, including those resulting from political conditions, election cycles, war or incidents of terrorism, or responses to these events **. In addition, developments in the healthcare marketplace related to new or innovative technologies, drugs and other treatments have the potential to impact the rate of growth of the ESRD patient population or otherwise reduce demand for dialysis treatments, and uncertainty surrounding the development of such new technologies, drugs and other treatments may drive volatility in our stock price. For example, in October 2023, a pharmaceutical manufacturer announced the early termination of its study, which sought to demonstrate the effectiveness of its GLP- 1 receptor agonist indicated for type 2 diabetes in delaying the progression of CKD and lowering the risk of cardiovascular mortality, as a result of the study having met certain endpoints. This development generated uncertainty in the marketplace with respect to the potential impact of these or other similar classes of drugs or new classes of drugs or treatments on the rate of growth of the ESRD patient population. The release of further information on GLP- 1 receptor agonists and their potential application to kidney care, or the release of other information regarding current or future new or innovative technologies, drugs and other treatments may continue to drive volatility in our stock price** . In addition, extreme price and volume fluctuations in the stock markets have affected and continue to affect many life sciences and technology companies' stock prices. Stock prices often fluctuate in ways unrelated or disproportionate to the companies' operating performance. In the past, stockholders have filed securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and seriously harm our business. Moreover, because of these fluctuations, comparing our operating results on a period- to- period basis may not be meaningful. You should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failure to meet the expectations of industry or financial analysts or investors for any period. If our revenues or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings forecasts that we may provide. We do not intend to pay dividends for the foreseeable future and, as a result, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock. We have never declared or paid any cash dividends on our common stock and do not intend to pay any cash dividends in

the foreseeable future. We anticipate that we will retain all of our future earnings for use in the development of our business and for general corporate purposes. Any determination to pay dividends in the future will be at the discretion of our board of directors. In addition, the terms of the SLR Credit Facility Agreements restrict our ability to pay dividends to limited circumstances. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments. If securities or industry analysts either do not publish research about us or publish inaccurate or unfavorable research about us, our business or our market, or if they change their recommendations regarding our common stock adversely, the trading price or trading volume of our common stock could decline. The trading market for our common stock is influenced in part by the research and reports that securities or industry analysts may publish about us, our business, our market or our competitors. If one or more analysts initiate research with an unfavorable rating or downgrade our common stock, provide a more favorable recommendation about our competitors or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If any analyst who may cover us were to cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the trading price or trading volume of our common stock to decline. Our principal stockholders and management own a significant percentage of our stock and are able to exercise significant influence over matters subject to stockholder approval. Based on available information, we believe that, as of December 31, ~~2022~~ **2023**, our executive officers, directors and 5 % stockholders beneficially owned approximately ~~52~~ **59** % of the outstanding shares of capital stock. In addition, as of December 31, ~~2022~~ **2023**, our executive officers and directors held options to purchase an aggregate of 1, ~~892~~ **470**, ~~625~~ **776** shares of our common stock at a weighted- average exercise price of $ ~~10~~ **12**. ~~95~~ **41** per share, and ~~622~~ **1**, ~~145~~ **049, 341** restricted stock units, which would give our officers and directors ownership of approximately ~~5~~ **6** % of our outstanding common stock as of December 31, ~~2022~~ **2023** if such awards were fully vested and exercised or settled in full (assuming over-achievement of any performance conditions). Therefore, these stockholders have the ability to influence us through this ownership position. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could attempt to delay or prevent a change in control of us, even if such change in control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of us or our assets and might affect the prevailing market price of our common stock due to investors' perceptions that conflicts of interest may exist or arise. As a result, this concentration of ownership may not be in the best interests of our other stockholders. Future securities issuances could result in significant dilution to our stockholders and impair the market price of our common stock. Future issuances of shares of our common stock, or the perception that these sales may occur, could depress the market price of our common stock and result in dilution to existing holders of our common stock. Also, to the extent outstanding options to purchase shares of our common stock are exercised or options, restricted stock units or other stock- based awards are issued or become vested, there will be further dilution. The amount of dilution could be substantial depending upon the size of the issuances or exercises. Furthermore, we may issue additional equity securities that could have rights senior to those of our common stock. As a result, purchasers of our common stock bear the risk that future issuances of debt or equity securities may reduce the value of our common stock and further dilute their ownership interest. Delaware law and provisions in our amended and restated certificate of incorporation and bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock. Our amended and restated certificate of incorporation and bylaws contain provisions that could depress the trading price of our common stock by acting to discourage, delay or prevent a change of control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions include the following: • establish a classified board of directors so that not all members of our board of directors are elected at one time; • permit the board of directors to establish the number of directors and fill any vacancies and newly- created directorships; • provide that directors may only be removed for cause and only by the affirmative vote of the holders of at least a majority of the voting power of all then outstanding shares of our capital stock; • require super-majority voting to amend some provisions in our amended and restated certificate of incorporation and bylaws; • authorize the issuance of " blank check " preferred stock that our board of directors could use to implement a stockholder rights plan; • prohibit stockholders from calling special meetings of stockholders; • prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders; • provide that the board of directors is expressly authorized to make, alter or repeal our bylaws; • restrict the forum for certain litigation against us to Delaware; and • establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at annual stockholder meetings. Any provision of our amended and restated certificate of incorporation or bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock. Our amended and restated certificate of incorporation designates a state or federal court located within the State of Delaware as the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to choose the judicial forum for disputes with us or our directors, officers or employees. Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf under Delaware law, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action arising pursuant to any provision of the Delaware General Corporation Law (DGCL), our amended and restated certificate of incorporation or bylaws, (4) any other action asserting a claim that is governed by the internal affairs doctrine, or (5) any other action asserting an " internal corporate claim, " as defined in Section 115 of the DGCL, shall be the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) in all cases subject to the court having jurisdiction over indispensable parties named as defendants. These exclusive- forum provisions do not apply to claims under the Securities Act or

the Exchange Act. To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. However, our amended and restated certificate of incorporation contains a federal forum provision which provides that unless the company consents in writing to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to this provision. This exclusive forum provision may limit a stockholder' s ability to bring a claim in a judicial forum of its choosing for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find the exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could harm our results of operations. General economic and financial market conditions may exacerbate our business risks. Global macroeconomic conditions and the world' s financial markets remain susceptible to significant stresses, including global geopolitical instability (such as the current conflict between Russia and Ukraine and related economic and other retaliatory measures taken by the United States, European Union and others **or the ongoing conflict between Israel and Hamas and in the Red Sea as well as the potential escalation or geographic expansion of such conflicts** ), pandemics (such as the recent COVID- 19 pandemic), inflationary pressures (such as current inflation related to global supply chain disruptions), extreme weather conditions and natural disasters, market declines and uncertainty, fluctuating interest and foreign currency rates and credit availability, government austerity measures, fluctuating fuel and other energy costs, fluctuating commodity prices, and general uncertainty regarding the overall future economic environment. **The** ~~In particular, the~~ ultimate impact of ~~the~~ **these** ~~conflict~~ **conflicts** ~~in Ukraine~~ on fuel prices, inflation, volatility of global financial markets, the global supply chain and other macroeconomic conditions is unknown and could materially adversely affect the availability and cost of materials, access to capital, global economic growth, consumer confidence and demand for our products and services. Our customers may respond to such economic pressures by reducing or deferring their capital spending or reducing staff. Furthermore, unfavorable changes in foreign exchange rates versus USD could increase our product and labor costs, thus reducing our gross profit. We are highly dependent on our senior management team and key personnel, and our business could be harmed if we are unable to attract and retain personnel necessary for our success in a cost-effective manner. We are highly dependent on our senior management, including our chief executive officer, Leslie Trigg, and other key personnel. Our success will depend on our ability to retain senior management and to attract and retain qualified personnel in the future, including sales and marketing professionals, scientists, clinical specialists, engineers and other highly skilled personnel and to integrate current and additional personnel in all departments. The loss of members of our senior management, sales and marketing professionals, scientists, clinical and regulatory specialists and engineers could result in delays in product development and harm our business. If we are not successful in attracting and retaining highly qualified personnel, or if we are unable to do so in a cost- effective manner, it would have a material adverse effect on our business, financial condition, and results of operations. Competition for skilled personnel in our market is intense and has recently intensified further due to industry trends in many areas where our employees are located. Further, the increased availability of hybrid or remote working arrangements has expanded the pool of companies that can compete for our employees and employment candidates. Such competition may limit our ability to hire and retain highly qualified personnel on acceptable terms, or at all. We may experience higher compensation costs to retain senior management and experienced personnel that may not be offset by improved productivity **. Moreover, the restructuring of our organization which we substantially completed in the fourth quarter of 2023, and any future restructurings intended to improve operational efficiencies and operating expenses, may adversely affect our ability to attract and retain employees** . To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have issued and may continue to issue equity awards that vest over time. The value to employees of equity awards that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Our employment arrangements with our employees provide for at- will employment, which means that any of our employees could leave our employment at any time, with or without notice. We also do not maintain " key man " insurance policies on the lives of these individuals or the lives of any of our other employees. We will continue to incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies in the United States, which may harm our business. We have incurred and will continue to incur substantial legal, accounting and other expenses as a result of operating as a public company. In addition, changing laws, regulations, and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and The Nasdaq Stock Market, may increase legal and financial compliance costs and make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations, and standards, and this investment may result in increased general and administrative expenses and a diversion of management' s time and attention from revenue- generating activities to compliance activities. If, notwithstanding our efforts, we fail to comply with new laws, regulations, and standards, regulatory authorities may initiate legal proceedings against us and our business may be harmed. ~~Based on the market value of our common stock held by non- affiliates as of the last business day of our fiscal second quarter ended June 30, 2021, we ceased to be an " emerging growth company " as defined in the Jumpstart our Business Startups Act of 2012 as of December 31, 2021. As a result, we have experienced and expect to continue to~~

~~experience, additional costs associated with being a public company, including costs associated with the auditor attestation requirement of Section 404 of the Sarbanes- Oxley Act, the adoption of certain Accounting Standard Updates upon losing such status, and additional disclosure requirements. As part of these requirements, we have made changes to our corporate governance practices and will need to maintain effective disclosure and financial controls that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC' s rules and forms, and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our principal executive and financial officers. Any failure to maintain effective controls could adversely affect the results of periodic management evaluations.~~ Any failure to comply with applicable rules and regulations may make it more expensive for us to obtain director and officer liability insurance. Given recent developments in the market for such coverage, we expect to incur substantially higher costs to obtain and maintain the same or similar coverage. These factors could also make it more difficult for us to attract and retain qualified executive officers and members of our board of directors. If our internal control over financial reporting or our disclosure controls and procedures are not effective, we may not be able to accurately report our financial results, prevent fraud or file our periodic reports in a timely manner, which may cause investors to lose confidence in our reported financial information. We are a " large accelerated filer " under the Exchange Act, which requires us to comply with the requirements of Section 404 of the Sarbanes- Oxley Act. Section 404 of the Sarbanes- Oxley Act requires that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluations, document our controls and perform testing of our key controls over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. We have incurred significant expense and devoted substantial management effort to complying with the requirements of Section 404 of the Sarbanes- Oxley Act, which we expect will continue. We may hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge, or incur expense associated with consultants, to support future growth. If we are not able to comply with the requirements of Section 404 of the Sarbanes- Oxley Act or if we encounter difficulties in the timely and accurate reporting of our financial results, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, our investors could lose confidence in our reported financial information, the market price of our stock may decline and we could be subject to lawsuits, sanctions or investigations by regulatory authorities, which would require additional financial and management resources. Our corporate culture has contributed to our success, and if we cannot maintain this culture as we grow, we could lose the innovation, creativity and teamwork fostered by our culture and our business may be harmed. We believe that our culture has been and will continue to be a critical contributor to our success ~~. We expect to continue to hire aggressively as we expand, and we believe our corporate culture has been crucial in our success~~ and our ability to attract highly skilled personnel. If we do not continue to develop our corporate culture or maintain and preserve our core values as we grow and evolve, we may be unable to foster the innovation, curiosity, creativity, focus on execution, teamwork and the facilitation of critical knowledge transfer and knowledge sharing we believe we need to support our growth ~~. Our anticipated headcount growth and our public company status may result in a change to our corporate culture, which could harm our business~~ . We may acquire other businesses which could require significant management attention, disrupt our business, dilute stockholder value and adversely affect our results of operations. As part of our business strategy, we may in the future make acquisitions or investments in complementary companies, products or technologies that we believe fit within our business model and can address the needs of our customers and potential customers. In the future, we may not be able to acquire and integrate other companies, products or technologies in a successful manner. We may not be able to find suitable acquisition candidates, and we may not be able to complete such acquisitions on favorable terms, if at all. In addition, the pursuit of potential acquisitions may divert the attention of management and cause us to incur additional expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. If we do complete acquisitions, we may not ultimately strengthen our competitive position or achieve our goals, including increases in revenue, and any acquisitions we complete could be viewed negatively by our customers, investors and industry analysts. Future acquisitions may reduce our cash available for operations and other uses and could result in amortization expense related to identifiable assets acquired. We may have to pay cash, incur debt or issue equity securities to pay for any such acquisition, each of which could adversely affect our financial condition or the value of our common stock. The sale or issuance of equity to finance any such acquisitions would result in dilution to our stockholders. The incurrence of indebtedness to finance any such acquisition would result in fixed obligations and could also include covenants or other restrictions that could impede our ability to manage our operations. In addition, our future results of operations may be adversely affected by the dilutive effect of an acquisition, performance earn- outs or contingent bonuses associated with an acquisition. Furthermore, acquisitions may require large, onetime charges and can result in increased debt or contingent liabilities, adverse tax consequences, additional stock- based compensation expenses and the recording and subsequent amortization of amounts related to certain purchased intangible assets, any of which items could negatively affect our future results of operations. We may also incur goodwill impairment charges in the future if we do not realize the expected value of any such acquisitions. Also, the anticipated benefit of any strategic alliance, joint venture or acquisition may not materialize, or such strategic alliance, joint venture or acquisition may be prohibited. In November 2022, we entered into the SLR Credit Facility Agreements which also restrict our ability to pursue certain acquisitions, mergers, or consolidations that we may believe to be in our best interest. Additionally, future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write- offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results. If we fail to comply with anti- corruption, anti- bribery, anti- money laundering and similar laws, we could suffer severe penalties. We are subject to the U. S. Foreign Corrupt Practices Act which

generally prohibits U. S. companies from engaging in bribery or other prohibited payments to foreign officials for the purpose of obtaining or retaining business and requires companies to maintain accurate books and records and internal controls, including at foreign controlled subsidiaries. We are also subject to requirements under the U. S. Treasury Department' s Office of Foreign Assets Control, U. S. domestic bribery laws and other anti- corruption, anti- bribery and anti- money laundering laws. While we have policies and procedures in place designed to promote compliance with such laws, our employees or other agents may nonetheless engage in prohibited conduct under these laws for which we or our executives might be held responsible. If our employees or other agents are found to have engaged in such practices, we could suffer severe penalties and other consequences that may have an adverse effect on our business, financial condition and results of operations. If our estimates or judgments relating to our accounting policies prove to be incorrect, our results of operations could be adversely affected. The preparation of financial statements in conformity with the United States generally accepted accounting principles (U. S. GAAP) and our key metrics require management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes and amounts reported in our key metrics. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, as provided in the section titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations. " The results of these estimates form the basis for making judgments about the carrying values of assets, liabilities and equity and the amount of revenue and expenses that are not readily apparent from other sources. Significant assumptions and estimates used in preparing our financial statements include those related to allowance for ~~doubtful accounts~~ **credit losses** , assessment of the useful life and recoverability of long- lived assets, warranty obligations, fair values of stock- based awards, warrants, contingent consideration, and income taxes. Our results of operations may be adversely affected if our assumptions change or if actual circumstances differ from those in our assumptions, which could cause our results of operations to fall below the expectations of securities analysts and investors, resulting in a decline in the trading price of our common stock. Expectations relating to ESG factors may impose additional costs and expose us to new risks. There is increasing focus from certain investors, customers and other stakeholders on ESG factors, including greenhouse gas emissions and climate- related risks; diversity, equity, and inclusion; responsible sourcing and supply chain; human rights and social responsibility; and corporate governance and oversight. Some investors may use ESG factors to guide their investment strategies and, in some cases, may choose not to invest in us if they believe our policies and actions relating to ESG matters are inadequate. Third party providers of ESG ratings and reports on companies have increased in number to meet growing investor demand for measurement of ESG performance, resulting in varied and in some cases inconsistent standards. In addition, the criteria by which companies' ESG practices are assessed are evolving, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Alternatively, if we elect not to or are unable to satisfy such new criteria, some investors may conclude that our policies with respect ESG matters are inadequate. We may face reputational damages in the event that our ESG procedures or standards do not meet the standards set by various constituencies. Furthermore, if our competitors' ESG performance is perceived to be better than ours, potential or current investors may elect to invest with our competitors instead. Further, increased public awareness and concern regarding ESG factors may result in new or enhanced legal requirements. For example, new regulations relating to ESG matters, including human capital, diversity, sustainability, climate change and cybersecurity, are under consideration or being adopted. Such regulations may impose additional reporting obligations and increase our compliance costs. In addition, climate change initiatives and legislation could also disrupt our operations by impacting the availability and cost of materials within our supply chain, and could also increase our operating costs. In addition, from time to time, we communicate certain initiatives and goals related to ESG matters. For example, in ~~October~~ **June** ~~2021~~ **2023** , we published our ~~inaugural~~ **second full** ESG Report, including updates on our ESG programs, priorities, initiatives, goals and performance ~~, which we updated with a supplemental ESG report in September 2022~~ . We could fail, or be perceived to fail, in our achievement of such initiatives or goals, or we could fail in fully and accurately reporting our progress on such initiatives and goals. In addition, we could be criticized for the scope of such initiatives or goals or perceived as not acting responsibly in connection with these matters. Our business could be negatively impacted by such matters. If we fail to satisfy the ESG- related expectations of investors, customers and other stakeholders or our initiatives or goals are not executed or achieved as planned, our reputation and financial results could be materially and adversely affected.