Risk Factors Comparison 2024-03-28 to 2023-03-31 Form: 10-K

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In addition to the other information contained in this **Annual** Report and the exhibits hereto, the following risk factors should be considered carefully in evaluating our business. Our business, financial condition, cash flows or results of operations could be materially adversely affected by any of these risks. Additional risks not presently known to us or that we currently deem immaterial may also adversely affect our business, financial condition, cash flows or results of operations. The following discussion of risk factors contains forward- looking statements as discussed on page 1. Our business routinely encounters and addresses risks, some of which may cause our future results to be different – sometimes materially different – than we presently anticipate. Risk Factor Summary Risks Relating to Our Business Operations • We have incurred losses for a number of years and anticipate that we will incur continued losses for the foreseeable future. • ~~Our results of~~ **Public health epidemics or pandemics may affect our ability to develop, market and sell our products, disrupt regulatory activities or have other adverse effects on our business and** operations ~~have been, and may continue to be, negatively impacted by COVID- 19 or other future outbreak of any other highly infectious or contagious diseases~~ . • We may not be able to maintain an uninterrupted supply of the gases used to power our lasers, as the Russia- Ukraine War has disrupted supplies of rare gases. • We may ~~acquire other assets or businesses, or form collaborations or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense. • We may~~ not be able to successfully integrate newly acquired businesses, joint ventures and other partnerships into our operations or achieve expected profitability from our acquisitions. • Our laser treatments of psoriasis, vitiligo, atopic dermatitis and leukoderma and / or any of our future products or services may fail to gain market acceptance or be impacted by competitive products, services or therapies which could adversely affect our competitive position. • The success of our products depends on third- party reimbursement of patients ~~'~~ **'** costs, which could result in potentially reduced prices or reduced demand and adversely affect our revenues and business operations ~~. • The continuing development of our products depends upon our developing and maintaining strong working relationships with physicians~~ . • Any failure in our customer education efforts could have a material adverse effect on our revenue and cash flow. • If revenue from significant distributors declines, we may have difficulty replacing the lost revenue, which would negatively affect our results and operations. • If we fail to manage our sales and marketing force or to market and distribute our products effectively, we may experience diminished revenues and profits. • We are reliant on a limited number of suppliers for production of our products. • Our indebtedness could materially adversely affect our financial condition and our ability to operate our business, react to changes in the economy or industry or pay our debts and meet our obligations under our debt and could divert our cash flow from operations for debt payments. • If our actual liability for state sales and use taxes is higher than our accrued liability, it could have a material impact on our financial condition ~~. • Our failure to respond to rapid changes in technology and other applications in the medical devices industry or the development of a cure for skin conditions treated by our products could make our treatment system obsolete. • Our customers, or physicians and technicians, as the case may be, may misuse certain of our products, and product liability lawsuits and other damages imposed on us may exceed our insurance coverage, or we may be subject to claims that are not covered by insurance~~ . • We must comply with complex statutes prohibiting fraud and abuse, and both we and physicians utilizing our products could be subject to significant penalties for noncompliance. • We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws. • If the effectiveness and safety of our devices are not supported by long- term data, and the level of acceptance of our products by dermatologists does not increase or is not maintained, our revenues could decline. • Our failure to obtain or maintain necessary FDA clearances and approvals, or to maintain continued clearances, or equivalents thereof in the U. S. and relevant foreign markets, could hurt our ability to distribute and market our products **, and our products are subject to recall by such agencies** . • If required, clinical trials necessary to support a 510 (k) notice or PMA application, for new or modified products, will be expensive and will require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit ~~. • Our medical device operations are subject to FDA regulatory requirements~~ . • Healthcare policy changes may have a material adverse effect on us. • Our market acceptance in international markets requires regulatory approvals from foreign governments and may depend on third party reimbursement of participants' cost. • We face substantial competition, which may result in others discovering, developing or commercializing products more successfully than us. • ~~Consolidation in the medical device industry could have an adverse effect on our revenue and results of operations. •~~ We actively employ social media as part of our marketing strategy, which could give rise to regulatory violations, liability, breaches of data security or reputational damage. • Social media companies on which we rely for advertising may change their policies limiting our ability to reach our target markets. • We may become subject to claims of infringement or misappropriation of the intellectual property rights of others, which could prohibit us from shipping affected products, require us to obtain licenses from third parties or to develop non- infringing alternatives, and subject us to substantial monetary damages and injunctive relief. Our patents may also be subject to challenge on validity grounds, and our patent applications may be rejected. • If we or our third- party manufacturers or suppliers fail to comply with the FDA' s Quality System Regulation or any applicable state equivalent, our manufacturing operations could be interrupted and our potential product sales and operating results could suffer. • If ~~we fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems with products, these products could be subject to restrictions or withdrawal from the market. • Our medical products may in the future be subject to product recalls that could harm our reputation, business and financial results. • If~~ any of our medical products cause or contribute to a death or a serious injury, or malfunction in certain

ways, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions. • We may have a need for additional funds in the future and there is no guarantee that we will be able to generate those funds from our business ~~. • If~~ **, and if** we do not have enough capital to fund operations, then we will have to cut costs or raise funds. • We may be subject to disruptions or failures in our information technology systems and network infrastructures, including through cyber- attacks or other third- party breaches that could have a material adverse effect on our business. • Environmental and health safety laws may result in liabilities, expenses and restrictions on our operations. Risks Relating to Our Common Stock • Our shares of common stock could be delisted from the Nasdaq Capital Market which could result in, among other things, a decline in the price of our common stock and less liquidity for holders of shares of our common stock. • Your percentage ownership will be further diluted. • In the event of certain contingencies, the investors in the May 2018 Equity Financing may receive additional shares issued pursuant to the Retained Risk Provisions as defined in the purchase agreements. • Our stock price may be volatile, meaning purchasers of our common stock could incur substantial losses. • Our charter documents and Delaware law may inhibit a takeover that stockholders consider favorable and could also limit the market price of our stock. **We** ~~Risks Relating to Our Business OperationsWe~~ have incurred losses for a number of years and anticipate that we will incur continued losses for the near future. Since 2015, we have devoted substantially all of our resources in the commercialization and sales of the XTRAC products. Our net loss for the year ended December 31, ~~2022~~ **2023** was approximately $ ~~5~~ **10** . ~~5~~ **8** million, and as of December 31, ~~2022~~ **2023** , we had an accumulated deficit of approximately $ ~~227~~ **238. 1** million. Our losses, among other things, have had and may continue to have an adverse effect on the adequacy of our capitalization and cash flow. ~~We believe that~~ **Public health epidemics** ~~our~~ **or pandemics may affect** ~~cash and cash equivalents as of December 31, 2022, combined with the anticipated revenues from the sale of~~ our **ability to develop, market and sell our** ~~product~~ **products** ~~and operating expense management~~ , **disrupt regulatory activities** ~~will be sufficient to satisfy our~~ **or have** ~~working capital needs, lasers placed- in- service, capital asset purchases, outstanding commitments and~~ other **adverse effects on** ~~liquidity requirements associated with~~ our ~~existing~~ **business and** operations ~~through at least the next 12 months following the filing of this Report~~ . In **addition** ~~December 2019~~ , ~~a novel strain of coronavirus (~~ **public health epidemics or pandemics may adversely impact economies worldwide, which could result in adverse effects on our business, operations and prospects. Our business and operations could be adversely affected by public health epidemics or pandemics, including the recent** COVID- 19 ~~) was reported to~~ **pandemic, impacting the markets and industries in which we and our collaborators operate. We and our partners** have ~~surfaced~~ ~~---~~ **faced and may** in **the future face disruptions that affect our ability** ~~Wuhan, China. COVID- 19 has since spread~~ to ~~over 100 countries~~ **operate due to various factors** , including **: •** ~~every state in~~ the ~~United States. In the last 36 months, the United States and the world have experienced various levels of government shutdowns, closures and quarantines. The outbreak of COVID- 19 has severely impacted global economic activity and caused significant volatility and negative pressure in financial markets, global supply chains, labor supply and inflation. This outbreak has triggered a period of global economic slowdown and a change in the behavior of the ultimate consumer of our products and services, which could continue for some time which cannot be predicted. COVID- 19 or another pandemic has or could have material and adverse effects on our~~ ability to **source raw materials and supplies;** ~~successfully operate our business due to, among other factors: •~~ a general decline in business activity; • the destabilization of the markets and negative impacts on the healthcare system globally **, which** could negatively impact our ability to market and sell our products, including through the disruption of health care activities in general and elective health care procedures in particular, the inability of our sales team to contact and / or visit doctors in person, patients' interest in starting or continuing procedures involving our products and our ability to support patients that presently use our products; **and** • difficulty accessing the capital and credit markets on favorable terms, or at all, and a severe disruption and instability in the global financial markets, or deteriorations in credit and financing conditions which could affect our access to capital necessary to fund business operations ~~; •~~ **. Further, the Biden Administration ended the public health emergency declarations related to the COVID- 19 pandemic in May 2023 and the FDA ended a number of COVID- related policies. The FDA has retained a number of COVID- 19- related policies but with appropriate changes, as applicable. It is unclear how, if at all, these policies will impact our efforts to develop and commercialize our products. We may in the future face impediments or delays to regulatory meetings and approvals due to any pandemic measures. We cannot be certain what the overall impact of such pandemics will be on our business, although for the reasons described above such pandemics have** the potential ~~negative impact on the health of our employees, especially if a significant number of them are impacted; • the impact of the pandemic on our customers, which may result in a decrease in the use of our products and services as well as an increase in past due accounts receivable, write- offs and customer bankruptcies; and • a deterioration in our ability~~ to ~~ensure~~ **adversely affect our** business ~~continuity during a disruption~~ **, financial condition, results of operations and prospects** . Prior to the outbreak of the Russia- Ukraine War, Ukraine was the world' s largest exporter of noble gases including neon, krypton and xenon. Historically, Ukraine has been the source of a significant amount of gas supplied to the Company by our contract suppliers. Neon gas is essential to the proper functioning of our lasers. Our suppliers have been resourceful in continuing to supply gases to us but cannot assure us that the supply will remain uninterrupted. The reduced supply and war have ~~raised~~ **also impacted** the price of gas ~~significantly~~ worldwide. Additionally, the Creating Helpful Incentives to Produce Semiconductors and Science Act of 2022 has led to a further tightening of rare gas supplies as chip manufacturers reconfigure their supply chains to address the need to secure their own supplies of rare gases for use in the manufacture of computer chips, while struggling with the disruption caused by this war. We may acquire other assets or businesses, or form collaborations or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense. As part of our business strategy, we may pursue acquisitions of assets, including preclinical, clinical or commercial stage products or product candidates, or businesses, or strategic alliances and collaborations, to expand our existing technologies and operations. We may not identify or complete these transactions in a timely manner, on a cost- effective basis, or at all, and

we may not realize the anticipated benefits of any such transaction, any of which could have a detrimental effect on our financial condition, results of operations and cash flows. We have limited experience with acquiring other companies, products or product candidates, and limited experience with forming strategic alliances and collaborations. We may not be able to find suitable acquisition candidates, and if we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business and we may incur additional debt or assume unknown or contingent liabilities in connection therewith. Integration of an acquired company or assets may also disrupt ongoing operations, require the hiring of additional personnel and the implementation of additional internal systems and infrastructure, especially the acquisition of commercial assets, and require management resources that would otherwise focus on developing our existing business. We may not be able to find suitable strategic alliances or collaboration partners or identify other investment opportunities, and we may experience losses related to any such investments. To finance any acquisitions or collaborations, we may choose to issue debt or equity securities as consideration. Any such issuance of shares would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other assets or companies or fund a transaction using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings ~~.~~ **, and such** ~~Additional~~ **additional** funds may not be available on terms that are favorable to us, or at all ~~. We may not be able to successfully integrate newly acquired businesses, joint ventures and other partnerships into our operations or achieve expected profitability from our acquisitions~~ . If we cannot successfully integrate acquisitions (including the Pharos and TheraClear businesses), joint ventures and other partnerships on a timely basis, we may be unable to generate sufficient revenue to offset acquisition costs, we may incur costs in excess of what we anticipate, and our expectations of future results of operations, including certain cost savings and synergies, may not be achieved. Acquisitions involve substantial risks, including: • unforeseen difficulties in integrating operations, technologies, services, accounting and personnel; • diversion of financial and management resources from existing operations; • unforeseen difficulties related to entering geographic regions where we do not have prior experience; • risks relating to obtaining sufficient equity or debt financing; and • potential loss of customers. In addition, if we finance acquisitions by issuing equity securities or securities convertible into equity securities, our existing stockholders' interests would be diluted, which, in turn, could adversely impact the market price of our stock. Moreover, we could finance an acquisition with debt, resulting in higher leverage and interest costs and could increase losses and losses per share which could impact the price of our stock. Our laser treatments of psoriasis, vitiligo, atopic dermatitis and leukoderma and / or any of our future products or services may fail to gain market acceptance or be impacted by competitive products, services or therapies which could adversely affect our competitive position. We have generated limited worldwide commercial distribution for our products. In the United States, our XTRAC systems are placed at physician offices at no upfront charge to the physician and we are generally paid on a per- usage method where we retain ownership of the system. We cannot assure you that our products and services will find sufficient acceptance in the marketplace under our sales strategies. We also face a risk that other companies in the market for dermatological products and services may be able to provide dermatologists a higher overall financial return and therefore compromise our ability to increase our installed base of users and ensure they engage in optimal usage of our products. If, for example, such other companies have products or medical devices that require less time commitment from the dermatologist and yield an attractive return on a dermatologist' s time and investment, we may find that our efforts to increase our base of users are hindered. We also face a risk that the overall cost of systemic or biologic medications or treatment modalities become less expensive through the development of generics or other means. We may be faced with pressure to reduce our costs to be competitive which may negatively impact our business. In addition, our business could be negatively impacted if these medications are prescribed for less severe cases of the diseases or if new, more effective or less expensive medications are developed. ~~CPT codes for all procedures are subject to continued reevaluation. Should CMS reduce reimbursement for the CPT codes for XTRAC treatment or raise reimbursement for competitive products we may see a decline in our recurring revenue business as well as a decline in new XTRAC installations.~~ Whether a treatment may be delegated to non- physician staff members and, if so, to whom and to what extent, are matters that may vary state by state, as these matters are within the province of the state medical boards. In states that may be more restrictive in such delegation, a physician may decline to adopt the XTRAC system into his or her practice, deeming it to be fraught with too many constraints and finding other outlets for the physician' s time and staff' s time to be more remunerative. There can be no assurance that we will be successful in persuading such medical boards that a liberal standard for delegation is appropriate for the XTRAC system, based on its design for ease and safety of use. If we are not successful, we may find that even if a geographic region has wide insurance reimbursement, the region' s physicians may decline to adopt the XTRAC system into their practices. We therefore cannot assure you that the marketplace will be receptive to our excimer laser technology over competing products, services and therapies or that a cure will not be found for the underlying diseases we are focused on treating. Failure of our products to achieve market acceptance could have a material adverse effect on our business, financial condition and results of operations. In addition, while this introduction is specifically for those patients that might not be able to avail themselves of in- office treatments, it may be viewed by our partner clinics as a channel conflict and cause a deterioration in our relationships with our current partners or negatively impact our ability to grow the number of partner clinics. The success of our products depends on third- party reimbursement of patients ~~2~~ **'** costs, which could result in potentially reduced prices or reduced demand and adversely affect our revenues and business operations. Our ability to market our products successfully, especially XTRAC treatments, depends in large part on the extent to which various third parties are willing to reimburse patients or providers for the costs of medical procedures utilizing such products. These third parties include government authorities, private health insurers and other organizations, such as health maintenance organizations, whose patterns of reimbursement may change as a result of new standards for reimbursement determined by these third parties or because of the programs and policies enacted under the ACA. Third- party payers are systematically challenging the prices charged for medical products and services. They may deny reimbursement if they determine that a prescribed device is not used in accordance with cost- effective treatment

methods as determined by the payer, or is experimental, unnecessary or inappropriate. Further, although third parties may approve reimbursement, such approvals may be under terms and conditions that discourage use of the XTRAC system. Accordingly, if less costly drugs or other treatments are available, third- party payers may not authorize or may limit reimbursement for the use of our products, even if our products are safer or more effective than the alternatives. In addition, medical insurance policies and treatment coverage have been and may be affected by the parameters of the ACA or successor policies enacted by the current or any new administration. While the ACA' s stated purpose is to expand access to coverage, it also mandates certain requirements regarding the types and limitations of insurance coverage. There can be no guarantee that the changes in coverage under the ACA will not affect the type and level of reimbursement for our products. **CPT codes for all procedures are subject to continued reevaluation. Should CMS reduce reimbursement for the CPT codes for XTRAC treatment or raise reimbursement for competitive products, we may see a decline in our recurring revenue business as well as a decline in new XTRAC installations.** Although we have received reimbursement approvals from a majority of private healthcare plans for the XTRAC system, we cannot give assurance that these private plans will continue to adopt or maintain favorable reimbursement policies or accept the XTRAC system in its clinical role as a second- line therapy in the treatment of psoriasis. Additionally, third- party payers may require further clinical studies or changes to our pricing structure and revenue model before authorizing or continuing reimbursement. As of December 31, ~~2021~~ **2023** ~~, we estimate~~ , based on published coverage policies and ~~on~~ payment practices of private and Medicare insurance plans, **we estimate** that more than 86 % of the insured population in the U. S. is covered by insurance coverage or payment policies that reimburse physicians for using the XTRAC system for treatment of psoriasis. We can give no assurance that health insurers will not adversely modify their reimbursement policies for the use of the XTRAC system in the future. Currently, there is little insurance reimbursement coverage for acne treatments, such as those provided by TheraClear. In order for TheraClear to be successful, patients and decision makers will need to be able to pay for treatments without insurance reimbursement. The continuing development of our products depends upon our developing and maintaining strong working relationships with physicians. The research, development, marketing and sale of our current products and any potential new and improved products or future product indications for which we receive regulatory clearance or approval depend upon our maintaining working relationships with physicians. We rely on these professionals to provide us with considerable knowledge and experience regarding the development, marketing and sale of our products. Physicians assist us as researchers, marketing and product consultants and public speakers. If we cannot maintain our strong working relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could have a material adverse effect on our business, financial condition, and results of operations. At the same time, companies in the medical device industry are under increasing scrutiny by the U. S. Department of Health and Human Services Office of Inspector General, or OIG, and the U. S. Department of Justice, or DOJ for improper relationships with physicians. Our failure to comply with requirements governing the industry' s relationships with physicians, including the reporting of certain payments to physicians under the National Physician Payment Transparency Program (Open Payments) or an investigation into our compliance by the OIG or the DOJ, could have a material adverse effect on our business, financial condition, and results of operations. ~~Any failure in our customer education efforts could have a material adverse effect on our revenue and cash flow.~~ It is important to the success of our marketing efforts to educate physicians and technicians how to properly use our products. We rely on physicians to spend their time and money to participate in our pre- installation educational sessions. Moreover, if physicians and technicians use our products improperly, they may have unsatisfactory patient outcomes or, in the case of the XTRAC system, cause patient injury, which may give rise to negative publicity or lawsuits against us, any of which could have a material adverse effect on our reputation, revenues and profitability ~~. If revenue from significant distributors declines, we may have difficulty replacing the lost revenue, which would negatively affect our results and operations~~ . We depend on several key distributors for a material portion of our sales, especially in our international business. While we no longer rely upon a single master distributor for our international sales, we now rely upon several in- country distributors in connection with this business. If, for example, a distributor finds that the financial incentives underlying the distributor relationship are no longer attractive, we may need to reduce our margins in order to continue the relationship or identify a new distributor, which could take a significant amount of time. This could have a significant negative effect on our results and our operations **, including, but not limited to, failing to comply with a financial covenant in our credit facility with MidCap** . There are significant risks involved in managing our sales and marketing force and marketing our products, including our ability: • to hire, as needed, a sufficient number of qualified sales and marketing personnel with the aptitude, skills and understanding to market our products; • to adequately train our sales and marketing force in the use and benefits of all our products and services, thereby making them more effective promoters; • to manage our sales and marketing force and our ancillary channels (e. g., telesales) such that variable and semi- fixed expenses grow at a lesser rate than our revenues; and • to set the prices and other terms and conditions for treatments using the XTRAC system in a complex legal environment so that treatments will be accepted as attractive skin health and appropriate alternatives to conventional modalities and treatmentsTo increase acceptance and utilization of our products, we may expand our sales and marketing programs in the U. S. While we may be able to draw on currently available personnel within our organization to meet this need, we also expect that we will have to increase the number of representatives devoted to the sales and marketing programs and to broaden, through such representatives, the talents we have at our disposal. In some cases, we may look outside our organization for assistance in marketing our products. ~~We are reliant on a limited number of suppliers for production of our products.~~ Production of our products requires specific component parts obtained from our suppliers. While we believe that we could find alternate suppliers, in the event that our current suppliers fail to meet our needs, a change in suppliers or any significant delay in our ability to have access to such resources could have a material adverse effect on our delivery schedules, business, operating results and financial condition. Moreover, in the event we can no longer utilize this supplier or acquire this resource and must identify a new supplier or substitute a different resource, such change may trigger an obligation for us to

comply with additional FDA regulatory requirements including, but not limited to, premarketing authorization and Quality System Requirements (" QSR "). Our indebtedness could materially adversely affect our financial condition and our ability to operate our business, react to changes in the economy or industry or pay our debts and meet our obligations ~~under our debt~~ and could divert our cash flow from operations for debt payments. In September 2021, we entered into **a** ~~an $ 8. 0 million~~ secured borrowing facility **with MidCap Financial Trust (" MidCap "), which was amended in January 2022, September 2022 and June 2023** (the " Senior Credit Facility ") ~~with MidCap~~. ~~The~~ **On February 20, 2024, we amended the** Senior Credit Facility **to** ~~bears interest at LIBOR plus 7. 50 %~~, **among** ~~with a LIBOR floor of 0. 50 %, and matures on September 1, 2026. In September 2022, we amended the~~ **other things** ~~Senior Credit Facility to transition~~, ~~upon~~ **revise** the **applicable minimum net revenue threshold financial covenant** ~~cessation of LIBOR, to one- month Secured Overnight Financing Rate~~ (**the** " ~~SOFR~~ **Amendment** ") ~~,~~**. Because we were not in compliance with the applicable minimum net revenue financial threshold covenant** ~~or~~ **for** ~~such~~ **the period ended December 31, 2023, MidCap and the lenders in the Amendment agreed to, among** other **things** ~~applicable period~~, **grant** ~~plus 0. 10 %, with~~ a ~~floor~~ **limited waiver** of ~~0. 50 %. We are obligated to make interest- only payments through September 2024. From October 2024 to Maturity, we will make principal payments in 24 equal installments. The loan is senior to all other~~ -- **the foregoing** ~~indebtedness and is secured by substantially all of our assets. We are subject to customary affirmative and negative covenants including a financial covenant based on minimum revenue thresholds. Upon an~~ event **that had occurred prior to the effectiveness** of **the Amendment** ~~default, including a covenant violation, all principal~~ and ~~interest are due on demand~~ **of any right the lenders may have to exercise any of their rights against us as a result**. See " Management ~~'~~**'** s Discussion and Analysis of Financial Condition and Results of Operations- Liquidity and Capital Resources " for discussion included in Item 7 of this Annual Report on Form 10- K. In addition, subject to restrictions in the agreements governing our credit facilities, we may incur additional debt. Our indebtedness could have negative consequences, including the following: • it may be difficult for us to satisfy our obligations, including debt service requirements under our outstanding debt, resulting in possible defaults on and acceleration of such indebtedness; • our ability to obtain additional financing for working capital, capital expenditures, debt service requirements, acquisitions or other general corporate purposes may be impaired; • a substantial portion of cash flow from operations may be dedicated to the payment of principal and interest on our debt, therefore reducing our ability to use our cash flow to fund our operations, capital expenditures, future business opportunities, acquisitions and other purposes; • we are more vulnerable to economic downturns and adverse industry conditions and our flexibility to plan for, or react to, changes in our business or industry is more limited; • our ability to capitalize on business opportunities and to react to competitive pressures, as compared to our competitors, may be compromised due to our high level of debt; and • our ability to borrow additional funds or to refinance debt may be limited. Furthermore, all of our debt under the Senior Credit Facility bears interest at variable rates. As these rates increase as they did in ~~2022~~ **2023**, our debt service obligations increase even though the amount borrowed remains the same, and our net income and cash flows, including cash available for servicing our indebtedness, correspondingly decrease. If interest rates continue to increase, we will see a corresponding increase in these obligations. Accordingly, our ability to borrow additional funds may be reduced and risks related to our indebtedness would intensify. Each quarter- point increase in the variable interest rates would increase interest expense on our current variable rate debt by approximately $ ~~20 thousand~~ **38, 000** during ~~2023~~ **2024**. The Financial Conduct Authority (the authority that regulates the London Interbank Offer Rate (" LIBOR ") announced it intended to stop compelling banks to submit rates for the calculation of LIBOR after June 30, 2022. ~~As discussed above, we~~ **We transitioned to the one month Secured Overnight Financing Rate (" SOFR ") in connection with the** amended ~~the~~ Senior Credit Facility ~~to transition to SOFR upon such occurrence~~. SOFR is a daily index of the interest rate banks and hedge funds pay to borrow money overnight, secured by U. S. Treasury securities. We also anticipate that we may use SOFR as the interest rate index in future agreements. SOFR differs fundamentally from LIBOR. For example, SOFR is a secured overnight rate, while LIBOR is an unsecured rate that represents interbank funding over different maturities. In addition, because SOFR is a transaction- based rate, it is backward- looking, whereas LIBOR is forward- looking. Because of these and other differences, there can be no assurance that SOFR will perform in the same way as LIBOR would have done at any time, and there is no guarantee that it is a comparable substitute for LIBOR. ~~If our actual liability for state sales and use taxes is higher than our accrued liability, it could have a material impact on our financial condition.~~ Included in accrued state sales and use taxes are certain known and estimated sales and use taxes and related penalties and interest to taxing authorities. In our recurring revenue model, we place the XTRAC system in the physician' s office under an arrangement for no upfront charge and generate our revenue on a per- use basis. In the ordinary course of business, we are, from time to time, subject to audits performed by state taxing authorities. These actions and proceedings are generally based on the state' s position that the arrangements entered into by the Company are subject to state sales and use tax rather than exempt from applicable law. We are currently under audit by two taxing jurisdictions as it pertains to state sales and / or use tax. The State of New York has assessed us, in ~~two~~ **three** assessments, an aggregate amount of $ ~~1~~ **2**. ~~5~~ **7** million ~~for~~ **including penalties and interest. The audits cover** the period from March 2014 through ~~February~~ **November** ~~2020~~ **2022** ~~including penalties and interest~~. In January 2021, we received notification that the administrative judge in this jurisdiction had issued an opinion finding in favor of us that the sale of XTRAC treatment codes were not taxable as sales tax with respect to the first assessment **, which amounted to $ 1. 4 million**. The relevant taxing authority filed an appeal of the administrative law judge' s finding and, following the submission of legal briefs by both sides and an oral argument held in January 2022 ~~and~~, on May 6, 2022, we received a written decision from the State of New York ~~Tax~~ Appeals Tribunal (~~the~~ " Tribunal ") overturning the favorable sales tax determination of the administrative law judge. We ~~filed an appeal~~ **appealed** ~~of~~ the Tribunal' s decision **to** ~~, and posted the required appellate bond, with~~ the New York State Appellate Division **(" Appellate Division "), and posted the required appellate bond in the form of cash collateral. Oral argument was held by the Appellate Division on January 18, 2024**. We are **in** ~~waiting for~~ the **administrative process of appeal with respect to the remaining $ 1. 3 million of assessments in the State of New York. On March 8, 2024, we**

received a decision from the ~~appellate~~ **Appellate Division ruling against us in the matter of** ~~court~~ -- **our sales tax appeal, affirming the Tribunal' s ruling that our sale of XTRAC treatment codes is subject** to **sales tax** ~~set a briefing and oral argument schedule~~ . The ~~second jurisdiction~~ **Appellate Division concluded that, through the usage arrangements, our customers had possession of the laser devices and had a license and ability to use the laser devices. The Appellate Division also agreed with the Tribunal that the primary function analysis was not applicable in this matter. We will be filing a motion to appeal the Appellate Division' s decision. The State of California** has made ~~an~~ **aggregate** ~~assessment~~ **assessments** of $ ~~0~~ **1** . ~~7~~ **2** million **including penalties and interest. The audits cover the period** from June ~~2015~~ **2018** through **June** ~~March 2018 plus interest of $ 0. 2 million through April 2020~~ **2022** . We are in the administrative appeal process in this jurisdiction as well ~~and the timing has been impacted by the COVID- 19 pandemic~~ . In the event there is a determination that the true object of the delivery of phototherapy under the recurring revenue model is a sale or lease of property and it is not a prescription medication, or we do not have other defenses where we prevail, we may be subject to state sales taxes in those particular states for previous years and in the future, plus interest and penalties for failure to pay such taxes. If it was determined that our recurring revenue model was not exempt from sales taxes in all states where we do business, and taxes and penalties were imposed in each of those states for the entire period through the expiration of each state' s statute of limitations, state sales and use tax, penalties and interest for such period would have a material negative impact on our financial condition and cash flow. As of December 31, **2023 and** 2022 ~~and 2021~~ , we have estimated our sales and use tax liability to be approximately $ 4. **3 million and $ 4.** 0 ~~million and $ 3. 7~~ million, respectively. We believe our sales and use tax accruals have properly recognized that if our arrangements with customers are deemed more likely than not that we would not be exempt from sales tax in a particular state are the basis for measurement of the state sales and use tax is calculated in accordance with ASC 405, Liabilities, as a transaction tax. While we believe we have strong positions that our recurring revenue is exempt from sales tax, if it is found that we are subject to sales tax in those particular states where we believe it is more likely than not that we would be exempt from sales tax, then potential tax liabilities including interest and penalties would be higher than accrued amounts. **The** ~~If and when we are successful in defending ourselves or in settling the sales tax obligation for a lesser amount, the reversal of this liability is to be recorded in the period the settlement is reached. However, the~~ precise scope, timing and time period at issue, as well as the final outcome of any audit and actual settlements **,** remain uncertain. Our failure to respond to rapid changes in technology and other applications in the medical devices industry or the development of a cure for skin conditions treated by our products could make our treatment system obsolete. The medical device industry is subject to rapid and substantial technological development and product innovations. To be successful, we must respond to new developments in technology, new applications of existing technology and new treatment methods. Our financial condition and operating results could be adversely affected if we fail to be responsive on a timely and effective basis to competitors' new devices, applications, treatments or price strategies. For example, the development of a cure for psoriasis, vitiligo, atopic dermatitis or leukoderma would eliminate the need for our XTRAC system for these diseases and would require us to focus on other uses of our technology, which could have a material adverse effect on our business and prospects. As we develop new products or improve our existing products, we may accelerate the economic obsolescence of the existing, unimproved products and their components. The obsolete products and related components may have little to no resale value, leading to an increase in the reserves we have against our inventory. Likewise, there is a risk that the new products or improved existing products may not achieve market acceptance and therefore may also lead to an increase in the reserves against our inventory. Our customers, or physicians and technicians, as the case may be, may misuse certain of our products, and product liability lawsuits and other damages imposed on us may exceed our insurance coverage, or we may be subject to claims that are not covered by insurance. We face an inherent risk of product liability as a result of the marketing and sale of our products. For example, we may be sued if our products cause or are perceived to cause injury or are 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 breach of warranty. Our products are highly complex, and some are used to treat delicate skin conditions on and near a patient' s face. In addition, the clinical testing, manufacturing, marketing and use of certain of our products and procedures may also expose us to product liability, FDA regulatory and / or legal actions, or other claims. If a physician elects to apply an off- label use and the use leads to injury, we may be involved in costly litigation. In addition, the fact that we train technicians whom we do not supervise in the use of our XTRAC system during patient treatment may expose us to third- party claims if we are accused of providing inadequate training. We may also be subject to claims against us even if the apparent injury is due to the actions of others or the pre- existing health of the patient. For example, we rely on physicians in connection with the use of our products on patients. If these physicians are not properly trained or are negligent, the capabilities and safety features of our products may be diminished or the patient may suffer critical injury. We may also be subject to claims that are caused by the actions of our suppliers, such as those who provide us with components and sub- assemblies. We presently maintain liability insurance with coverage limits of at least $ 5. 0 million per occurrence and overall aggregate, which we believe is an adequate level of product liability insurance, but product liability insurance is expensive and we might not be able to obtain product liability insurance in the future on acceptable terms or in sufficient amounts to protect us, if at all. Our insurance policy contains various exclusions, and we may be subject to a product liability claim for which we have no coverage. A successful claim brought against us in excess of our insurance coverage could have a material adverse effect on our business, results of operations and financial condition. Even successful defense would require significant financial and management resources. In addition, continuing insurance coverage may also not be available at an acceptable cost, if at all. Therefore, we may not be able to obtain insurance coverage that will be adequate to satisfy a liability that may arise. Regardless of merit or eventual outcome, product liability claims may result in decreased demand for a product, harm to our reputation, withdrawal of clinical trial volunteers, initiation of investigations by regulators, costs to defend the related litigation, diversion of management' s time and our resources, monetary awards to trial participants or patients, product recalls, withdrawals or labeling,

marketing or promotional restrictions, exhaustion of any available insurance and our capital resources, a resulting decline in the price of our common stock and loss of revenues. As a result, regardless of whether we are insured, a product liability claim or product recall may result in losses that could result in the FDA taking legal or regulatory enforcement action against us and / or our products including recall, and could have a material adverse effect upon our business, financial condition and results of operations ~~. We must comply with complex statutes prohibiting fraud and abuse, and both we and physicians utilizing our products could be subject to significant penalties for noncompliance~~ . There are extensive federal and state laws and regulations prohibiting fraud and abuse in the healthcare industry that can result in significant criminal and civil penalties. These federal laws include: • the anti- kickback statute which prohibits certain business practices and relationships, including the payment or receipt of remuneration for the referral of patients whose care will be paid by Medicare or other federal healthcare programs, as modified by the ACA; • the physician self- referral prohibition, commonly referred to as the Stark Law; • the anti- inducement law, which prohibits providers from offering anything to a Medicare or Medicaid beneficiary to induce that beneficiary to use items or services covered by either program; the Civil False Claims Act, which prohibits any person from knowingly presenting or causing to be presented false or fraudulent claims for payment by the federal government, including the Medicare and Medicaid programs; and • the Civil Monetary Penalties Law, which authorizes HHS to impose civil penalties administratively for fraudulent or abusive acts. Sanctions for violating these federal laws include criminal and civil penalties that range from punitive sanctions, damage assessments, monetary penalties, and imprisonment, denial of Medicare and Medicaid payments, or exclusion from the Medicare and Medicaid programs, or both. As federal and state budget pressures continue, federal and state administrative agencies may also continue to escalate investigation and enforcement efforts to root out waste and to control fraud and abuse in governmental healthcare programs. Private enforcement of healthcare fraud has also increased, due in large part to amendments to the Civil False Claims Act in 1986 that were designed to encourage private persons to sue on behalf of the government. A violation of any of these federal and state fraud and abuse laws and regulations could have a material adverse effect on our liquidity and financial condition. An investigation into the use of our products by physicians may dissuade physicians from either purchasing or using our products and could have a material adverse effect on our revenues ~~. We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws~~ . While we do not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third- party payers, many healthcare laws and regulations apply to our business. For example, we could be subject to healthcare fraud and abuse and patient privacy regulation and enforcement by both the federal government and the states in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include: • the federal healthcare programs' anti- kickback laws, as modified by the ACA, which prohibits, among other things, persons or entities from soliciting, receiving, offering or providing remuneration, directly or indirectly, in return for or to induce either the referral of an individual for, or the purchase order or recommendation of, any item or service for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs; • federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third- party payers that are false or fraudulent, or are for items or services not provided as claimed and which may apply to entities like us to the extent that our interactions with customers may affect their billing or coding practices; • HIPAA, which established new federal crimes for knowingly and willfully executing a scheme to defraud any healthcare benefit program or making false statements in connection with the delivery of or payment for healthcare benefits, items or services, as well as leading to regulations imposing certain requirements relating to the privacy, security and transmission of individually identifiable health information; and • state law equivalents of each of the above federal laws, such as anti- kickback and false claims laws which may apply to items or services reimbursed by any third- party payer, including commercial insurers, and state laws governing the privacy of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. The medical device industry has been under heightened scrutiny as the subject of government investigations and regulatory or legal enforcement actions involving manufacturers who allegedly offered unlawful inducements to potential or existing customers in an attempt to procure their business, including arrangements with physician consultants. If our operations or arrangements are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs and the curtailment or restructuring of its operations. Any penalties, damages, fines, exclusions, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. The risk of us being found in violation of these laws is increased by the fact that many of these laws are broad and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against that action and the underlying alleged violations, could cause us to incur significant legal expenses and divert our management' s attention from the operation of our business. If the physicians or other providers or entities with whom we do business are found to be non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on our business. If the effectiveness and safety of our devices are not supported by long- term data, and the level of acceptance of our products by dermatologists does not increase or is not maintained, our revenues could decline. Our products may not be accepted in the market if we do not produce clinical data supported by the independent efforts of clinicians. We received clearance from the FDA for the use of the XTRAC system to treat psoriasis based upon our study of a limited number of patients. Safety and efficacy data presented to the FDA for the XTRAC system was based on studies on these patients. For the treatment of vitiligo, atopic dermatitis and leukoderma, we have received clearance from the FDA for the use of the XTRAC system based primarily on a showing of substantial equivalence to other previously cleared predicate devices. However, we may discover that physicians will expect clinical data on such treatments with the XTRAC system. We also may find that data from longer- term psoriasis patient follow- up studies may be inconsistent with those indicated by our relatively short- term data. If longer- term

patient studies or clinical experience indicate that treatment with the XTRAC system does not provide patients with sustained benefits or that treatment with our product is less effective or less safe than our current data suggests, our revenues could decline. In addition, the FDA could then bring legal or regulatory enforcement actions against us and / or our products including, but not limited to, recalls or requirements for premarket 510 (k) authorizations. We can give no assurance that our data will be substantiated in studies involving more patients. In such a case, we may never achieve significant revenues or profitability. Our failure to obtain or maintain necessary FDA clearances and approvals, or to maintain continued clearances, or equivalents thereof in the U. S. and relevant foreign markets, could hurt our ability to distribute and market our products. In both our U. S. and foreign markets, we are affected by extensive laws, governmental regulations, administrative determinations, court decisions and similar constraints. Such laws, regulations and other constraints may exist at the federal, state or local levels in the U. S. and at analogous levels of government in foreign jurisdictions. In addition, the formulation, manufacturing, packaging, labeling, distribution, importation, sale and storage of our products are subject to extensive regulation by various federal agencies, including, but not limited to, the FDA and the FTC, State Attorneys General in the U. S., as well as by various other federal, state, local and international regulatory authorities in the countries in which our products are manufactured, distributed or sold. If we or our manufacturers fail to comply with those regulations, we could become subject to significant penalties or claims, which could harm our results of operations or our ability to conduct our business. In addition, the adoption of new regulations or changes in the interpretations of existing regulations may result in significant compliance costs or discontinuation of product sales and may impair the marketing of our products, resulting in significant loss of net sales. Our failure to comply with federal or state regulations, or with regulations in foreign markets that cover our product claims and advertising, including direct claims and advertising by us, may result in enforcement actions and imposition of penalties or otherwise harm the distribution and sale of its products. Further, our businesses are subject to laws governing our accounting, tax and import and export activities. Failure to comply with these requirements could result in legal and / or financial consequences that might adversely affect our sales and profitability. Each medical device that we wish to market in the U. S. must first receive either 510 (k) clearance or PMA from the FDA unless an exemption applies. Either process can be lengthy and expensive. The FDA' s 510 (k) clearance process may take from three to 12 months, or longer, and may or may not require human clinical data. The PMA process is much more costly and lengthy. It may take from 11 months to three years, or even longer, and will likely require significant supporting human clinical data. Delays in obtaining regulatory clearance or approval could adversely affect our revenues and profitability. Although we have obtained 510 (k) clearances for our XTRAC system for use in treating psoriasis, vitiligo, atopic dermatitis and leukoderma, these approvals and clearances may be subject to revocation if post- marketing data demonstrates safety issues or lack of effectiveness. Many medical devices, such as medical lasers, are also regulated by the FDA as " electronic products. " In general, manufacturers and marketers of " electronic products " are subject to certain FDA regulatory requirements intended to ensure the radiological safety of the products. These requirements include, but are not limited to, filing certain reports with the FDA about the products and defects / safety issues related to the products as well as complying with radiological performance standards. The medical device industry is now experiencing greater scrutiny and regulation by federal, state and foreign governmental authorities. Companies in our industry are subject to more frequent and more intensive reviews and investigations, often involving the marketing, business practices, and product quality management. Such reviews and investigations may result in civil and criminal proceedings; the imposition of substantial fines and penalties; the receipt of warning letters, untitled letters, demands for recalls or the seizure of our products; the requirement to enter into corporate integrity agreements, stipulated judgments or other administrative remedies, and result in our incurring substantial unanticipated costs and the diversion of key personnel and management' s attention from their regular duties, any of which may have an adverse effect on our financial condition, results of operations and liquidity, and may result in greater and continuing governmental scrutiny of our business in the future. Additionally, federal, state and foreign governments and entities have enacted laws and issued regulations and other standards requiring increased visibility and transparency of our interactions with healthcare providers. For example, the U. S. Physician Payment Sunshine Act, now known as Open Payments, requires us to report to the Centers for Medicare & Medicaid Services, or CMS, payments and other transfers of value to all U. S. physicians and U. S. teaching hospitals, with the reported information made publicly available on a searchable website. Effective January 2022 we are also required to collect and report information on payments or transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse- midwives. Failure to comply with these legal and regulatory requirements could impact our business, and we have had and will continue to spend substantial time and financial resources to develop and implement enhanced structures, policies, systems and processes to comply with these legal and regulatory requirements, which may also impact our business and which could have a material adverse effect on our business, financial condition, and results of operations. International regulatory approval processes may take more or less time than the FDA clearance or approval process. If we fail to comply with applicable FDA and comparable non- U. S. regulatory requirements, we may not receive regulatory clearances or approvals or may be subject to FDA or comparable non- U. S. enforcement actions. We may be unable to obtain future regulatory clearance or approval in a timely manner, or at all, especially if existing regulations are changed or new regulations are adopted. For example, the FDA clearance or approval process can take longer than anticipated due to requests for additional clinical data and changes in regulatory requirements. A failure or delay in obtaining necessary regulatory clearances or approvals would materially adversely affect our business, financial condition, and results of operations. Further, more stringent regulatory requirements or safety and quality standards may be issued in the future with an adverse effect on our business. We have ceased manufacturing and marketing MelaFind but must still maintain records for FDA and foreign regulatory purposes. If required, clinical trials necessary to support a 510 (k) notice or PMA application, for new or modified products, will be expensive and will require 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 a 510 (k) notice or a PMA application 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 early or later clinical trials. 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 depend 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 patients enrolled as subjects, the availability of appropriate clinical trial investigators, support staff, and proximity of patients to clinical sites and ability 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. Patients may also not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competitive products. In addition, patients participating in clinical trials may die before completion of the trial or suffer adverse medical events unrelated to investigational products. Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy may be 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 for any 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. 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. Our medical device operations are subject to FDA regulatory requirements. Medical devices regulated by the FDA are subject to " general controls " which include: registration with the FDA; listing commercially distributed products with the FDA; complying with good manufacturing practices under the quality system regulations; filing reports with the FDA and keeping records relative to certain types of adverse events associated with devices under the medical device reporting regulation; assuring that device labeling complies with device labeling requirements; reporting certain device field removals and corrections to the FDA; and obtaining premarket notification 510 (k) clearance for devices prior to marketing. Some devices known as " 510 (k)- exempt " can be marketed without prior marketing clearance or approval from the FDA. In addition to the " general controls, " some Class II medical devices are also subject to " special controls, " including adherence to a particular guidance document and compliance with the performance standard. Instead of obtaining 510 (k) clearance, some Class III devices are subject to PMA. In general, obtaining PMA to achieve marketing authorization from the FDA is a more onerous process than seeking 510 (k) clearance. The medical device industry is now experiencing greater scrutiny and regulation by federal, state and foreign governmental authorities. Companies in our industry are subject to more frequent and more intensive reviews and investigations, often involving the marketing, business practices, and product quality management including standards for device recalls and product labeling. Such reviews and investigations may result in civil and criminal proceedings; the imposition of substantial fines and penalties; the receipt of warning letters, untitled letters, demands for recalls or the seizure of our products; the requirement to enter into corporate integrity agreements, stipulated judgments or other administrative remedies, and result in our incurring substantial unanticipated costs and the diversion of key personnel and management' s attention from their regular duties, any of which may have an adverse effect on our financial condition, results of operations and liquidity, and may result in greater and continuing governmental scrutiny of our business in the future. We must also have the appropriate FDA clearances and / or approvals from other governmental entities in order to lawfully market devices and / or drugs. The FDA, federal, state or foreign governments and agencies may disagree that we have such clearance and / or approvals for all of our products and may take action to prevent the marketing and sale of such devices until such disagreements have been resolved. Additionally, federal, state and foreign governments and entities have enacted laws and issued regulations and other standards requiring increased visibility and transparency of our interactions with healthcare providers. For example, the U. S. Physician Payment Sunshine Act requires us to disclose payments and other transfers of value to all U. S. physicians and U. S. teaching hospitals at the U. S. federal level made. Failure to comply with these legal and regulatory requirements could impact our business, and we have had and will continue to spend substantial time and financial resources to develop and implement enhanced structures, policies, systems and processes to comply with these legal and regulatory requirements, which may also impact our business. Healthcare ~~policy changes may have a material adverse effect on us. Healthcare~~ costs have risen significantly over the past decade. As a result, there have been and continue to be proposals by federal, state and foreign governments and regulators as well as third- party insurance providers to limit the growth of these costs. Among these proposals are regulations that could impose limitations on the prices we will be able to charge for our products, the amounts of reimbursement available for our products from governmental agencies or third- party payers, requirements regarding the usage of comparative studies, technology assessments and healthcare delivery structure reforms to determine the effectiveness and select the products and therapies used for treatment of patients. While we believe our products provide favorable clinical outcomes, value and cost efficiency, the resources necessary to demonstrate this value to our customers, patients, payers, and regulators is significant and may require longer periods of time and effort in which to obtain acceptance of our products. There is no assurance that our efforts will be successful, and these limitations could have a material adverse effect on our financial position and results of operations. These changes and additional proposed changes in the future could adversely affect the demand for our products as well as the way in which we conduct our business. For example, the ACA was enacted into law in the U. S. in March 2010. They imposed on medical device manufacturers, a requirement to research into the effectiveness of treatment modalities and institute changes to the reimbursement and payment systems for patient treatments. In addition, governments and regulatory agencies continue to study

and propose changes to the laws governing the clearance or approval, manufacture and marketing of medical devices, which could adversely affect our business and results of operations. FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. The FDA is currently exploring ways to modify its 510 (k) clearance process. In addition, due to changes at the FDA in general, it has become increasingly more difficult to obtain 510 (k) clearance as data requirements have increased. 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. However, any changes could make it more difficult for us to maintain or attain clearance or approval to develop and commercialize our products and technologies. Various healthcare reform proposals have also emerged at the state level. We cannot predict what healthcare initiatives, if any, will be implemented at the federal or state level, or the effect any future legislation or regulation will have on us. Furthermore, an expansion in government' s role in the U. S. healthcare industry may lower reimbursements for our products, reduce medical procedure volumes and adversely affect our business, possibly materially. In addition, if the excise taxes contained in the House or Senate health reform bills are enacted into law, our loss from continuing operations resulting from such an excise tax and results of operations would be materially and adversely affected. ~~Our market acceptance in international markets requires regulatory approvals from foreign governments and may depend on third party reimbursement of participants' cost.~~ We have introduced our XTRAC and VTRAC products into markets in more than 30 countries in Europe, the Middle East, Asia, Australia, South Africa and parts of Central and South America through distributors. We cannot be certain that our salesforce and distributor network will be successful in marketing our products in these or other countries or that our distributors will purchase XTRAC or VTRAC systems beyond their current contractual obligations or in accordance with our expectations. Our TheraClear device has historically been sold in several foreign countries and is subject to similar international regulatory approval requirements. Even if we obtain and maintain the necessary foreign regulatory registrations or approvals, market acceptance of our products in international markets may be dependent, in part, upon the availability of reimbursement within applicable healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country, and include both government- sponsored healthcare and private insurance. We may seek international reimbursement approvals for our products, but we cannot assure you that any such approvals will be obtained in a timely manner, if at all. Failure to receive international reimbursement approvals in any given market could have a material adverse effect on the acceptance or growth of our products in that market or others ~~. We face substantial competition, which may result in others discovering, developing or commercializing products more successfully than us~~ . The medical device industry is intensely competitive and subject to rapid and significant technological change. Many of our competitors have significantly greater financial, technical and human resources. Smaller and early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our competitors in medical device or pharmaceutical industries may also develop products that are more effective, more convenient, more widely used, less costly, or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products. 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, our programs. Competition for these people in the medical device industry is intense and we may face challenges in retaining and recruiting such individuals if, for example, other companies may provide more generous compensation and benefits, more diverse opportunities, and better chances for career advancement than we do. Some of these advantages may be more appealing to high- quality candidates and employees than those we have to offer. In addition, the decline in our stock price has created additional challenges by reducing the retention value of our equity awards. Because of the complex and technical nature of our systems 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 our technology, which would have a material adverse effect on our business, financial condition, and results of operations. Consolidation in the medical device industry could have an adverse effect on our revenue and results of operations. Many medical device industry companies are consolidating to create new companies with greater market power. As the medical device industry consolidates, competition to provide goods and services to industry participants will become more intense. These industry participants may try to use their market power to bundle the sale of more products to our customers in return for lower prices. If we reduce our prices because of consolidation in the healthcare industry, our revenue would decrease and our earnings, financial condition, or cash flows would suffer, which would have a material adverse effect on our business, financial condition, and results of operations ~~. We actively employ social media as part of our marketing strategy, which could give rise to regulatory violations, liability, breaches of data security or reputational damage~~ . Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us, our employees or our customers to communicate about our products or business may cause us to be found in violation of applicable requirements, including requirements of regulatory bodies such as the FDA and Federal Trade Commission. For example, promotional communications and endorsements on social media that, among other things, promote our products for uses or in patient populations that are not described in the product' s approved labeling (known as " off- label uses "), do not contain a fair balance of information about risks associated with using our products, make comparative or other claims about our products that are not supported by sufficient evidence, and / or do not contain required disclosures could result in enforcement actions against us. In addition, adverse events, product complaints, off-label usage by physicians, unapproved marketing or other unintended messages posted on social media could require an active response from us, which may not be completed in a timely manner and could result in regulatory action by a governing body. Further, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our corporate policies or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal information of our employees, clinical trial patients, customers and others. Furthermore, negative posts or comments about us or our products in social media could seriously damage

our reputation, brand image and goodwill, which would have a material adverse effect on our business, financial condition, and results of operations. ~~Social media companies on which we rely for advertising may change their policies limiting our ability to reach our target markets.~~ We rely on social media companies, such as Facebook and Twitter, to reach our target markets. Facebook has announced that beginning in January 2022 it will limit the ability of advertisers to target certain markets. Any restrictions by Facebook or any other social media platform on which we depend to reach our target market could have a significant impact on our ability to develop customer awareness and generate new users for our physician partners. We may become subject to claims of infringement or misappropriation of the intellectual property rights of others, which could prohibit us from shipping affected products, require us to obtain licenses from third parties or to develop non- infringing alternatives, and subject us to substantial monetary damages and injunctive relief. Our patents may also be subject to challenge on validity grounds, and our patent applications may be rejected. Third parties could, in the future, assert infringement or misappropriation claims against us with respect to our current or future products. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Therefore, we cannot be certain that we have not infringed the intellectual property rights of such third parties. Our potential competitors may assert that some aspect of our products infringes their patents. There also may be existing patents of which we are unaware that one or more components of our products may inadvertently infringe. Any infringement or misappropriation claim could cause us to incur significant costs, could place significant strain on our financial resources, divert management' s attention from our business and harm our reputation. If the relevant patents were upheld as valid and enforceable and we were found to infringe, we could be prohibited from selling our product unless we could obtain licenses to use the technology covered by the patent or are able to design around the patent. We may be unable to obtain a license on terms acceptable to us, if at all, and we may not be able to redesign the affected product to avoid infringement. A court could order us to pay compensatory damages for such infringement, plus prejudgment interest and could, in addition, treble the compensatory damages and award attorney fees. These damages could be substantial and could harm our reputation, business, financial condition and operating results. A court also could enter orders that temporarily, preliminarily or permanently enjoin us and our customers from making, using, selling, offering to sell or importing our products, and / or could enter an order mandating that we undertake certain remedial activities. Depending on the nature of the relief ordered by the court, we could become liable for additional damages to third parties. We rely on our patents, patent applications and other intellectual property rights to give us a competitive advantage. Whether a patent is valid, or whether a patent application should be granted, is a complex matter of science and law. Therefore, we cannot be certain that, if challenged, our patents, patent applications and / or other intellectual property rights would be upheld. If one or more of those patents, patent applications and other intellectual property rights are invalidated, rejected or found unenforceable, those outcomes could reduce or eliminate any competitive advantage we might otherwise have had. If we or our third- party manufacturers or suppliers fail to comply with the FDA' s Quality System Regulation or any applicable state equivalent, our manufacturing operations could be interrupted and our potential product sales and operating results could suffer. We and some of our third- party manufacturers and suppliers are required to comply with some or all of the FDA' s Good Manufacturing Practices or its QSR, which delineates the design controls, document controls, purchasing controls, identification and traceability, production and process controls, acceptance activities, nonconforming product requirements, corrective and preventive action requirements, labeling and packaging controls, handling, storage, distribution and installation requirements, records requirements, servicing requirements, and statistical techniques potentially applicable to the production of our medical devices. We and our manufacturers and suppliers are also subject to the regulations of foreign jurisdictions regarding the manufacturing process if we market its products overseas. The FDA enforces the QSR through periodic and announced or unannounced inspections of manufacturing facilities. Our facilities have been inspected by the FDA and other regulatory authorities, and we anticipate that we and certain of our third- party manufacturers and suppliers will be subject to additional future inspections. If our facilities or those of our manufacturers or suppliers are found to be in non- compliance or fail to take satisfactory corrective action in response to adverse QSR inspectional findings, FDA could take legal or regulatory enforcement actions against us and / or our products, including but not limited to the cessation of sales or the recall of distributed products, which could impair our ability to produce our products in a cost- effective and timely manner in order to meet our customers' demands. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits. Current regulations depend heavily on administrative interpretation. If the FDA does not believe that we are in substantial compliance with applicable FDA regulations, the agency could take legal or regulatory enforcement actions against us and / or our products. We are also subject to periodic inspections by the FDA, other governmental regulatory agencies, as well as certain third- party regulatory groups. Future interpretations made by the FDA or other regulatory bodies made during the course of these inspections may vary from current interpretations and may adversely affect our business and prospects. The FDA' s and foreign regulatory agencies' statutes, regulations, or policies may change, and additional government regulation or statutes may be enacted, which could increase post- approval regulatory requirements, or delay, suspend, prevent marketing of any cleared / approved products or necessitate the recall of distributed products. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U. S. or abroad. The medical device industry has been under heightened FDA scrutiny as the subject of government investigations and enforcement actions. If our operations and activities are found to be in violation of any FDA laws or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and other legal and / or agency enforcement actions. Any penalties, damages, fines, or curtailment or restructuring of our operations or activities could adversely affect our ability to operate our business and our financial results. The risk of us being found in violation of FDA laws is increased by the fact that many of these laws are broad and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend ourselves against that action and its underlying allegations, could cause us to incur significant legal expenses and divert management' s attention from the operation of our business. Where

there is a dispute with a federal or state governmental agency that cannot be resolved to the mutual satisfaction of all relevant parties, we may determine that the costs, both real and contingent, are not justified by the commercial returns to us from maintaining the dispute or the product. Various claims, design features or performance characteristics of our medical devices, that we regarded as permitted by the FDA without marketing clearance or approval, may be challenged by the FDA or state regulators. The FDA or state regulatory authorities may find that certain claims, design features or performance characteristics, in order to be made or included in the products, may have to be supported by further studies and marketing clearances or approvals, which could be lengthy, costly and possibly unobtainable. If we fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems with products, these products could be subject to restrictions or withdrawal from the market. We are also subject to similar state requirements and licenses. Failure by us to comply with statutes and regulations administered by the FDA and other regulatory bodies, 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, or failure to adequately respond to any FDA observations concerning these issues, could result in, among other things, any of the following actions: • warning letters or untitled letters issued by the FDA; • fines, civil penalties, injunctions and criminal prosecution; • unanticipated expenditures to address or defend such actions; • delays in clearing or approving, or refusal to clear or approve, our products; • withdrawal or suspension of clearance or approval of our products by the FDA or other regulatory bodies; • product recall or seizure; • orders for physician or customer notification or device repair, replacement or refund; • interruption of production; and • operating restrictions. If any of these actions were to occur, it would harm our reputation and adversely affect our business, financial condition and results of operations. Our medical products may in the future be subject to product recalls that could harm our reputation, business and financial results. The FDA has the authority to require the recall of commercialized medical device products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government- mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to the FDA within ten working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted. If any of our medical products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions. Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. If we fail to report these events to the FDA within the required timeframes, or at all, the FDA could take enforcement action against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require our time and capital, distract management from operating our business, and may harm our reputation and financial results. We may have a need for additional funds in the future and there is no guarantee that we will be able to generate those funds from our business. Our existing cash position and ability to borrow funds and future revenue may not be sufficient to support the expenses of our operations in the near term ~~, although based upon our cash and cash equivalents, current budgeting and projected cash flow models, we believe that we will be able to support our operations for at least the next 12 months following the filing of this Report~~ . We plan to fund operations by the recurring revenue generated by the use of the XTRAC lasers and the TheraClear Acne Therapy System in the U. S. and international markets, as well as domestic and international sales of our products. If revenues from the sale and use of our existing products are inadequate to fund our operations, we may need to raise additional financing. We cannot assure you that we will be able to raise additional capital or secure alternate financing to fund operations, if necessary, or that we will be able to raise additional capital under terms that are favorable to us. Further, we cannot assure that an acquisition will in any way negate or mitigate our need for future capital. Any additional financing may dilute the ownership interest of our existing stockholders and could adversely affect the market price of our common stock. If we do not have enough capital to fund operations, then we will have to cut costs or raise funds. If we are unable to raise additional funds, if necessary, under terms acceptable to us and in the interests of our stockholders, then we will have to take measures to cut operating costs or obtain funds using alternative methods, such as: • Sell or license some of our technologies that we would not otherwise sell or license if we were in a stronger financial position; • Sell or license some of our technologies under terms that are less favorable than they otherwise might have been if we were in a stronger financial position; and • Consider further business combination transactions with other companies or positioning ourselves to be acquired by another company. If it became necessary to take one or more of the above- listed actions, then our perceived valuation may be lower, which could impact the market price of our stock. Further, the effects on our operations, financial performance and stock price may be significant if we do not or cannot take one or more of the above- listed actions in a timely manner and when needed, and our ability to do so may be limited significantly due to the instability of the global financial markets and the resulting limitations on available financing to us and to potential licensees, buyers and investors. Additionally, these options may not be available to us as all of our assets have been pledged as security for the various

financings. We may be subject to disruptions or failures in our information technology systems and network infrastructures, including through cyber- attacks or other third- party breaches that could have a material adverse effect on our business. We rely on efficient and uninterrupted operation of complex information technology systems and network infrastructures to operate our business. We also hold data in various data center facilities upon which our business depends. A disruption, infiltration or failure of our information technology systems or any of our data centers as a result of software or hardware malfunctions, system implementations or upgrades, computer viruses, third- party security breaches, employee error, theft or misuse, malfeasance, power disruptions, natural disasters or accidents could cause breaches of data security, loss of intellectual property and critical data and the release and misappropriation of sensitive competitive information. While we have implemented a number of protective measures, including firewalls, antivirus, patches, data encryption, log monitors, routine back- ups with offsite retention of storage media, system audits, data partitioning, routine password modifications and disaster recovery procedures, such measures may not be adequate or implemented properly to prevent or fully address the adverse effect of such events. If our systems were to fail or we are unable to successfully expand the capacity of these systems, or we are unable to integrate new technologies into our existing systems, our operations and financial results could suffer. We have also outsourced significant elements of our information technology infrastructure and as a result we depend on third parties who are responsible for maintaining significant elements of our information technology systems and infrastructure and who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of our third- party vendors, make such systems potentially vulnerable to service interruptions and security breaches from inadvertent or intentional actions by its employees, partners or vendors. These systems are also vulnerable to attacks by malicious third parties, and may be susceptible to intentional or accidental physical damage to the infrastructure maintained by us or by third parties. A breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information, or other confidential information, whether as a result of theft, hacking, fraud, trickery or other forms of deception, or for any other cause, could enable others to produce competing products, use our proprietary technology or information, and / or adversely affect our business. Further, any such interruption, security breach, loss or disclosure of confidential information could result in financial, legal, business, and reputational harm to us and could have a material adverse effect on our business, results of operations and financial condition. ~~Environmental and health safety laws may result in liabilities, expenses and restrictions on our operations.~~ Federal, state, local and foreign laws regarding environmental protection, hazardous substances and human health and safety may adversely affect our business. Using hazardous substances in our operations exposes us to the risk of accidental injury, contamination or other liability from the use, storage, importation, handling, or disposal of hazardous materials. If our or our suppliers' operations result in the contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and fines, and any liability could significantly exceed our insurance coverage and have a material adverse effect on our business, financial condition, and results of operations. Future changes to environmental and health and safety laws could cause us to incur additional expenses or restrict our operations, which could have a material adverse effect on our business, financial condition, and results of operations **. Unfavorable global economic conditions could adversely affect our business, financial condition, stock price and results of operations. Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets and uncertainty about economic stability. The global economy and financial markets may also be adversely affected by the current or anticipated impact of military conflict, including the ongoing conflict between Israel and Hamas, the ongoing war between Russia and Ukraine, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the sanctions relating to Russia, may also adversely impact the financial markets and the global economy, and the economic countermeasures by the affected countries or others could exacerbate market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for our products and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could impair our ability to achieve our growth strategy, could harm our financial performance and stock price and could require us to delay or abandon development plans. In addition, there is a risk that our current or future service providers, manufacturers or other collaborators may not survive such difficult economic times, which could directly affect our ability to attain our operating goals. We cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business** . Our shares of common stock could be delisted from the Nasdaq Capital Market which could result in, among other things, a decline in the price of our common stock and less liquidity for holders of shares of our common stock. Our common stock is **currently** listed on the Nasdaq Capital Market **. To maintain the listing of our common stock on the Nasdaq Capital Market, we are required to meet certain listing requirements, including, among others,** (**i** ~~" Nasdaq CM "~~) ~~, which imposes, among other requirements,~~ a minimum **closing bid price of** $ 1. 00 per share **,** ~~bid price requirement for continued inclusion on the Nasdaq CM pursuant to Nasdaq Listing Rule 5550~~ (~~a~~ **ii**) **a market value of publicly held shares** (~~2~~ **excluding shares held by our executive officers, directors and 10 % or more stockholders**) **of** ~~(the " Bid Price Requirement "). The closing bid price for our common stock must remain~~ at **least** ~~or above~~ $ 1 **million and (iii) either: (x) stockholders' equity of at least $ 2** . **5 million;** ~~00 per share to comply with the Bid Price Requirement for~~ **or** ~~continued listing~~ **(y) a total market value of listed securities of at least $ 35 million** . On ~~October 26~~ **June 29** , ~~2022~~ **2023** , we received a **notification** ~~deficiency letter (the " Notice ")~~ from the Listing ~~Qualifications~~ Department of ~~the~~ Nasdaq **indicating** ~~Stock Market, LLC (" Nasdaq ") notifying us~~ that **during** ~~, for~~ the preceding 30 consecutive ~~trading~~ **business** ~~days~~

day period , the closing ~~bid~~ price of our common stock was below **$ 1. 00 per share. In accordance with Nasdaq Listing Rule 5810 (c) (3) (A), we had 180 calendar days, or until December 26, 2023, to regain compliance. To regain compliance,** the ~~Bid~~ **closing bid** ~~Price~~ **price** ~~Requirement~~ **of our common stock must be at least $ 1. 00 per share for a minimum of ten consecutive business days. In order to regain compliance, we proposed, and, on October 26, 2023, our stockholders approved, a proposal to effect a reverse stock split of our common stock at a ratio of not less than 1 for 5 and no greater than 1 for 25, with the exact ratio, if effected at all, to be set within that range approved at the discretion of our board of directors and publicly announced by April 26, 2024 without further approval or authorization of our stockholders** . On ~~February~~ **December** 27, 2023, we ~~announced~~ **received written notice from Nasdaq** that we ~~had~~ **have been granted a 180- day extension, or until June 24, 2024, to** ~~regained~~ -- **regain** compliance with ~~the Bid~~ **Nasdaq' s minimum bid** ~~Price~~ **price** ~~Requirement~~ **rule** . ~~Given~~ **Even if a reverse stock split is effected, there can be no assurance that the** market ~~volatility and business conditions, we~~ **price per share of our common stock will remain in excess of the $ 1. 00 minimum bid price for a sustained period of time. The continuing effect of a reverse stock split on the market price of our common stock** cannot ~~assure you~~ **be predicted with any certainty, and the history of similar stock split combinations for companies in like circumstances is varied. It is possible** that ~~we~~ **the per share price of our common stock after a reverse stock split** will ~~continue~~ **not rise in proportion** to ~~maintain compliance under~~ **the reduction in the number of shares of common stock outstanding resulting from a reverse stock split, effectively reducing our market capitalization, and** ~~the~~ **there** ~~current economic climate~~ **can be no assurance that the market price per post- reverse split share will either exceed or remain in excess of the $ 1. 00 minimum bid price for a sustained period of time. The market price of our common stock may vary based on other factors that are unrelated to the number of shares outstanding, including our future performance. If we do not meet the minimum stockholders' equity, minimum closing bid price requirements, or any other listing requirements, we would be subject to delisting from the Nasdaq Capital Market. The delisting of our common stock from a national exchange could impair the liquidity and market price of the common stock. It could also materially, adversely affect our access to the capital markets, and any limitation on market liquidity or reduction in the price of the common stock as a result of that delisting could adversely affect our ability to raise capital on terms acceptable to us, or at all** . Your percentage ownership will be further diluted in the future. Your percentage ownership in our common stock will be diluted in the future because of equity awards that we expect will be granted to our directors, officers and employees. Our Equity Incentive Plan provides for the grant of equity- based awards, including restricted stock, restricted stock units, stock options, stock appreciation rights and other equity- based awards to our directors, officers and other employees, advisors and consultants. In ~~September 2021~~ **connection with the Senior Credit Facility, as amended** , we issued a warrant to MidCap Financial Trust to purchase ~~373~~ **800** , ~~626~~ **000** shares of our common stock, with an exercise price of $ ~~1~~ **0** . ~~82~~ **88** per share. We also maintain a shelf- registration statement that provides us with the ability, from time to time, to offer and sell up to $ 25. 0 million in securities, including selling up to $ 11. 0 million of our common stock in registered " at- the- market " offerings pursuant to an equity distribution agreement entered into with Ladenburg Thalmann & Co. Inc. in October 2021. As a result of shares sold or issued under the circumstances described above, your percentage ownership in our common stock will be diluted in the future. In the event of certain contingencies, the investors in the May 2018 Equity Financing may receive additional shares issued pursuant to the Retained Risk Provisions as defined in the purchase agreements. In the event of certain contingencies, the investors in the May 2018 equity financing may receive additional shares issued pursuant to the Retained Risk Provisions as defined in the Stock Purchase Agreements. At the closing, the Company determined certain contingencies had been met and, in July 2018, the Company issued 153, 004 shares associated with those contingencies. There were additional contingencies included in the SPAs that expired in May 2020 and did not result in the issuance of shares. Our stock price ~~may be volatile, meaning purchasers of our common stock could incur substantial losses. Our stock price~~ has been and is likely to continue to be volatile. The stock market in general and the market for medical technology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The following factors, in addition to other risk factors described in this section and general market and economic conditions, may have a significant impact on the market price of our common stock: • failure of any of our products to achieve or continue to have commercial success; • the timing of regulatory approval for our future products; • adverse regulatory determinations with respect to our existing products; • results of our research and development efforts and our clinical trials; • the announcement of new products or product enhancements by us or our competitors; • regulatory developments in the U. S. and foreign countries; • our ability to manufacture our products to commercial standards; • developments concerning our clinical collaborators, suppliers or marketing partners; • changes in financial estimates or recommendations by securities analysts; • public concern over our products; • developments or disputes concerning patents or other intellectual property rights; • product liability claims and litigation against us or our competitors; • the departure of key personnel; • the strength of our balance sheet and any perceived need to raise additional funds; • variations in our financial results from expected financial results or those of companies that are perceived to be similar to us; • changes in the structure of third- party reimbursement in the U. S. and other countries; • changes in accounting principles or practices; • general economic, industry and market conditions; and • future sales of our common stock. A decline in the market price of our common stock could cause you to lose some or all of your investment, limit your ability to sell your shares of stock and may adversely impact our ability to attract and retain employees and raise capital. In addition, stockholders have, and may in the future, initiate securities class action lawsuits if the market price of our stock drops significantly. Whether or not meritorious, litigation brought against us could result in substantial costs and could divert the time and attention of our management. Our insurance to cover claims of this sort may not be adequate ~~. Our charter documents and Delaware law may inhibit a takeover that stockholders consider favorable and could also limit the market price of our stock~~ . Provisions of our restated certificate of incorporation and bylaws and applicable provisions of Delaware law may make it more difficult for or prevent a third party from acquiring control of us without the approval of our board of directors. These

provisions: • limit who may call a special meeting of stockholders; • establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon at stockholder meetings; • do not permit cumulative voting in the election of our directors, which would otherwise permit less than a majority of stockholders to elect directors; • prohibit stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders; and • provide our board of directors the ability to designate the terms of and issue a new series of preferred stock without stockholder approval. In addition, Section 203 of the Delaware General Corporation Law generally limits our ability to engage in any business combination with certain persons who own 15 % or more of our outstanding voting stock or any of our associates or affiliates who at any time in the past three years have owned 15 % or more of our outstanding voting stock. In connection with the financing in May 2018, our board of directors exempted AGP SPVI, L. P. from the application of this provision in connection with its investment. These provisions may have the effect of entrenching our management team and may deprive you of the opportunity to sell your shares to potential acquirers at a premium over prevailing prices. This potential inability to obtain a control premium could reduce the price of our common stock. ITEM 1B. UNRESOLVED STAFF COMMENTS