Risk Factors Comparison 2024-03-20 to 2023-03-16 Form: 10-K

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

Investing in our common stock involves a high degree of risk. We have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition, results of operations and future growth prospects. Our business could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. If any of the risks actually occur, our business, financial condition, results of operations, cash flows and prospects could be materially and adversely affected. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained in this Annual Report on Form 10- K, including our financial statements and related notes. Please also see " Cautionary Notes Regarding Forward- Looking Statements. " Risk Factor Summary The risk factors summarized and detailed below could materially harm our business, operating results and / or financial condition, impair our future prospects and / or cause the price of our common stock to decline. These are not all of the risks we face **,** and other factors not presently known to us or that we currently believe are immaterial may also affect our business if they occur. Material risks that may affect our business, operating results and financial condition include, but are not necessarily limited to, those relating to: Risks Related to Our Business ● significant fluctuations in our operating results, our history of net losses and ability to achieve profitability; ● our ability to continue as a going concern; ● **risks and uncertainties arising from bankruptcy, if pursued ●** our ability to obtain additional capital on acceptable terms or at all and our significant levels of debt; ● our **ability to realize benefits from our license and collaboration agreements with Zylox- Tonbridge Medical Technology Co., Ltd. (" Zylox- Tonbridge ") or achieve the milestones related to the Zylox- Tonbridge collaboration; ● our** covenants and restrictions under and our ability to service our Loan Agreement with CRG; ● the liquidation ~~preference~~ **preferences** of our Series ~~A~~ **E preferred stock and Series F** preferred stock; ● rights of warrant and preferred option holders in the event of a fundamental transaction, ● our reliance on a limited number of products with a limited commercial history; ● our reliance on sales professionals to market and sell our products **and** ~~; ● our~~ dependence on ~~our senior management team and~~ key employees; ● our ability to demonstrate the benefits of our Lumivascular platform to physicians, hospitals, and patients and our ability to innovate successfully; ● our ~~competition~~ **competitors** ~~, which includes companies~~ that have longer operating histories, more established products, and greater resources; ● the potential for disruptions at our manufacturing facility; ● our dependence on third- party vendors, including some single- source suppliers, to manufacture some of our components, coating, and sub- assemblies; ● our intention not to devote significant resources in the near- term to market our Lumivascular platform internationally; ● ~~our ability to use our net operating loss carryforwards; ●~~ the possibility that we may acquire other companies or technologies, or be the target of strategic transactions; ● ~~Outbreaks of contagious diseases, such as the novel coronavirus, COVID- 19, and other public health crises may materially impact our business and operations; ●~~ Disruptions of our supply chain **and operations** could have a material adverse effect on our operating and financial results; ● New product development for the coronary artery disease market carries great risk; ● Adverse developments affecting the financial services industry, including events or concerns involving liquidity, defaults or non- performance by financial institutions, could adversely affect our business, financial condition or results of operations; Risks Related to Our Use of Technology and Intellectual Property ● our technology infrastructure and the potential of a cybersecurity incident or data breach; ● any future intellectual property litigation or administrative proceedings; ● any failure to adequately protect our intellection property rights and the assertion of patents held by third parties against us; Regulatory and Litigation Risks ● compliance with applicable laws and regulations and our ability to obtain necessary regulatory clearances and approvals; ● ~~any material modifications to our Lumivascular platform products, which may require new clearances or approvals; ●~~ certain limitations on our ability to market our current products in the United States; ● the success and timing of our clinical trials ~~; ● the performance of the outside parties that we engage to perform services related to certain of our clinical studies~~ ; ● our limited long- term data regarding the safety and efficacy of our Lumivascular platform products; ● our suppliers' compliance with the FDA' s QSR; ● any product recalls on our Lumivascular products; ● any changes in coverage and reimbursement for procedures using our Lumivascular products and any healthcare reform measures; ● compliance with healthcare regulations, environmental laws and regulations; ● regulations related to " conflict minerals " and any use, misuse, or off- label use of our products; ~~● the expense and availability of insurance coverage for liabilities resulting from our products; ● related composition requirements;~~ Risks Related to Our Organizational Structure ● the volatility of our stock price; ● our ability to meet guidance or expectations and receive coverage of our business by securities or industry analysts; ● any sales of substantial numbers of shares of our common stock in the public market ~~; ● the requirements and expense of being a public company~~ ; ● the possibility that Nasdaq may delist our securities from its exchange; ● anti- takeover provisions in our amended and restated certificate of incorporation, bylaws, and Delaware law; ● the forum selection clause in our amended and restated certificate of incorporation; ● ~~our anticipation that we will not pay cash dividends in the foreseeable future; ●~~ CRG **' s and Zylox- Tonbridge** ' s ability to exert significant control over certain matters ~~pursuant~~ **relating** to our **business** ~~Loan Agreement~~ ; ● the current number of authorized shares available for issuance ~~, and~~ ; **and** ● our dependence on our board of directors. Our quarterly and annual results may fluctuate significantly, may not fully reflect the underlying performance of our business and may result in decreases in the price of our common stock. Our quarterly and annual results of operations, including our revenues, profitability and cash flow, may vary significantly in the future and period- to- period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our quarterly and annual financial results may fluctuate as a result of a variety of factors, many of which

are outside our control and, as a result, may not fully reflect the underlying performance of our business. Fluctuation in quarterly and annual results may decrease the value of our common stock. Factors that may cause fluctuations in our quarterly and annual results include, without limitation: ● our ability to obtain and maintain FDA clearance and approval from foreign regulatory authorities for our products, and the timing of such clearances and approvals, particularly with respect to current and future generations of Pantheris, Tigereye and Ocelot product families; ● market acceptance of our Lumivascular platform and products, including Pantheris, Ocelot, Tigereye and Lightbox; ● the availability of reimbursement for our Lumivascular platform products; ● our ability to attract new customers and increase the amount of business we generate from existing customers; ● results of our clinical trials; ● the timing and success of new product and feature introductions by us or our competitors or any other change in the competitive dynamics of our industry, including consolidation among competitors, customers or strategic partners; ● the amount and timing of costs and expenses related to the maintenance and expansion of our business and operations; ● changes in our pricing policies or those of our competitors; ● general economic, political, industry and market conditions; ● the regulatory environment; ● the hiring, training and retention of key employees, including our sales team; ● the cost and potential outcomes of any litigation; ● our ability to obtain additional financing; and ● advances and trends in new technologies and industry standards. In addition, we rely on estimates and forecasts of our expenses and revenues to provide guidance and inform our business strategies, and some of our past estimates and forecasts have not been accurate. The evolving nature of our business makes forecasting operating results difficult. If we fail to accurately forecast our expenses and revenues, our business, prospects, financial condition and results of operations may suffer, and the value of our business may decline. If our estimates and forecasts prove incorrect, we may not be able to adjust our operations quickly enough to respond to lower- than- expected sales which, for example, could result in higher than anticipated inventory levels, or higher- than- expected expenses which, for example, could be the result of building excess capacity. Based upon the factors above and others beyond our control, we have a limited ability to forecast our future revenue, costs and expenses. If we fail to meet or exceed the operating results expectations of analysts and investors or if analysts and investors have estimates and forecasts of our future performance that are unrealistic or that we do not meet, the market price of our common stock could decline. In addition, if one or more of the analysts who cover us adversely change their recommendation regarding our stock, the market price of our common stock could decline. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities litigation. We may be the target of this type of litigation in the future, which could result in substantial costs and divert our management' s attention from other business concerns. You should consider our business in light of the risks and difficulties we may encounter, as described above and elsewhere in this " Risk Factors " section. If we fail to address the risks and difficulties that we face, our business and operating results will be adversely affected. We have a history of net losses and we may not be able to achieve or sustain profitability. We have incurred significant losses in each period since our inception in 2007. We incurred net losses of $ **18. 3 million in 2023 and $** 17. 6 million in 2022 ~~and $ 17. 4 million in 2021~~ . As of December 31, ~~2022~~ **2023** , we had an accumulated deficit of approximately $ ~~402~~ **420** . ~~4~~ **7** million. These losses and our accumulated deficit reflect the substantial investments we have made to develop our Lumivascular platform and acquire customers. We expect our losses to continue for the foreseeable future as we continue to make significant future expenditures to develop and expand our business. In addition, as a public company, we will continue to incur significant legal, accounting and other expenses. Accordingly, we cannot assure you that we will achieve profitability in the future or that, if we do become profitable, we will sustain profitability. Our failure to achieve and sustain profitability would negatively impact the market price of our common stock. ~~Our 2022 financial statements contain disclosure that there~~ **There** is substantial doubt about our ability to continue as a going concern, and we will need additional financing to execute our business plan, to fund our operations and to continue as a going concern **, and, if we are unable to obtain additional financing, may be required to pursue a reorganization proceeding under applicable bankruptcy or insolvency laws, including under Chapter 11 of the U. S. Bankruptcy Code** . Since inception, we have experienced recurring operating losses and negative cash flows and we expect to continue to generate operating losses and consume significant cash resources for the foreseeable future. There is substantial doubt regarding our ability to continue as a going concern. Our independent registered public accounting firm has expressed in its auditors' report on our ~~2022~~ **2023** financial statements, included in this Annual Report on Form 10- K, an emphasis of matter paragraph relating to our ability to continue as a " going concern, " meaning that our recurring losses from operations and negative cash flows from operations raise substantial doubt regarding our ability to continue as a going concern. We have prepared our financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. Our ~~2022~~ financial statements do not include any adjustment to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty, with the exception that all borrowings are classified as current on the balance sheets. Under our Term Loan Agreement (the " Loan Agreement ") with CRG Partners III L. P. and certain of its affiliated funds (collectively " CRG "), a " Material Adverse Change " or " Material Adverse Effect " (each as defined in the Loan Agreement) is an " Event of Default " thereunder, which gives Majority Lenders (as defined in the Loan Agreement) the right to declare amounts outstanding under the Loan Agreement immediately due and payable. Due to the substantial doubt about our ability to continue operating as a going concern and the Event of Default that could result due to a Material Adverse Change under the Loan Agreement, the entire amount of borrowings at December 31, **2023 and December 31,** 2022 **are** ~~and 2021 is~~ classified as current **. In addition, we may not be able to generate sufficient liquidity or revenue to satisfy minimum liquidity and minimum revenue covenants under the Loan Agreement. If we fail to satisfy such requirements, we will be in default under the Loan Agreement and all outstanding amounts under the Loan Agreement will become immediately due** . Majority Lenders have not purported that an Event of Default has occurred as a result of a Material Adverse Change **or breach of other financial covenants.** However, there can be no guarantee that Majority Lenders will not invoke such Event of Default in the future, or that we will not experience other Material Adverse Changes or other Material Adverse

~~Effect~~ **Effects , or otherwise breach our financial or other covenants under the Loan Agreement,** that could give rise to an Event of Default under the Loan Agreement **. If we are unable to generate sufficient revenue and liquidity to service our debt, we may be required to pursue a reorganization proceeding under applicable bankruptcy or insolvency laws, including protection (" Bankruptcy Protection ") under Chapters 7 or 11 of the U. S. Bankruptcy Code. Holders of our common stock will likely not receive any value or payments in a restructuring or similar scenario. In the event we pursue Bankruptcy Protection, we will be subject to the risks and uncertainties associated with such proceedings. In the event we file for relief under the United States Bankruptcy Code, our operations, our ability to develop and execute our business plan and our continuation as a going concern will be subject to the risks and uncertainties associated with bankruptcy proceedings, including, among others: our ability to execute, confirm and consummate a plan of reorganization; the high costs of bankruptcy proceedings and related fees; our ability to obtain sufficient financing to allow us to emerge from bankruptcy and execute our business plan post- emergence, and our ability to comply with terms and conditions of that financing; our ability to continue our operations in the ordinary course; our ability to maintain our relationships with our customers, business partners, counterparties, employees and other third parties; our ability to obtain, maintain or renew contracts that are critical to our operations on reasonably acceptable terms and conditions; our ability to attract, motivate and retain key employees; the ability of third parties to use certain limited safe harbor provisions of the United States Bankruptcy Code to terminate contracts without first seeking Bankruptcy Court approval; and the actions and decisions of our stakeholders and other third parties who have interests in our bankruptcy proceedings that may be inconsistent with our operational and strategic plans. Any delays in our bankruptcy proceedings would increase the risks of our being unable to reorganize our business and emerge from bankruptcy proceedings and may increase our costs associated with the bankruptcy process or result in prolonged operational disruption for us. Also, we would need the prior approval of the bankruptcy court for transactions outside the ordinary course of business during the course of any bankruptcy proceedings, which may limit our ability to respond timely to certain events or take advantage of certain opportunities. Because of the risks and uncertainties associated with any bankruptcy proceedings, we cannot accurately predict or quantify the ultimate impact of events that could occur during any such proceedings. There can be no guarantees that if we seek Bankruptcy Protection, we will emerge from Bankruptcy Protection as a going concern or that holders of our common stock will receive any recovery from any bankruptcy proceedings. In the event we are unable to pursue Bankruptcy Protection under Chapter 11 of the United States Bankruptcy Code, or, if pursued, successfully emerge from such proceedings, it may be necessary to pursue Bankruptcy Protection under Chapter 7 of the United States Bankruptcy Code for all or a part of our businesses. In the event we are unable to pursue Bankruptcy Protection under Chapter 11 of the United States Bankruptcy Code, or, if pursued, successfully emerge from such proceedings, it may be necessary for us to pursue Bankruptcy Protection under Chapter 7 of the United States Bankruptcy Code for all or a part of our businesses. In such event, a Chapter 7 trustee would be appointed or elected to liquidate our assets for distribution in accordance with the priorities established by the United States Bankruptcy Code. We believe that liquidation under Chapter 7 would result in significantly smaller distributions being made to our stakeholders than those we might obtain under Chapter 11 primarily because of the likelihood that the assets would have to be sold or otherwise disposed of in a distressed fashion over a short period of time rather than in a controlled manner and as a going concern** . We may not be able to secure additional financing on favorable terms, or at all, to meet our future capital needs and our failure to obtain additional financing when needed could force us to delay, reduce or eliminate our product development programs and commercialization efforts or cause us to become insolvent. **On March 5, 2024, we entered into a financing as part of a broader strategic collaboration with Zylox- Tonbridge Medical Technology Co., Ltd. (" Zylox- Tonbridge ") in which we received an aggregate of $ 7. 5 million before any commissions, legal and accounting fees, and other ancillary expenses.** We believe that our cash and cash equivalents at December 31, ~~2022~~ **2023** , together with **the aforementioned financing,** debt and **other** financing activities and expected revenues from operations, will be sufficient to satisfy our capital requirements and fund our operations through ~~at least~~ the ~~third~~ **second** quarter of ~~2023~~ **2024** . Even though we received net proceeds of approximately ~~$ 13. 0 million from the sale of our common stock in February 2021,~~ $ 6. 7 million from the sale of our Series D Convertible Preferred Stock in January 2022, $ 4. 4 million from the sale of our common stock in August 2022, and $ ~~0~~ **5** . ~~8~~ **1** million from the sale of our common stock under our at- the- market program that we entered into on May 20, 2022, we ~~may~~ **will** need to raise additional funds through future equity or debt financings in the near future to meet our operational needs and capital requirements for product development, clinical trials and commercialization **, and to regain compliance with the Equity Requirement under the Nasdaq Listing Rules** . We can provide no assurance that we will be successful in raising funds pursuant to additional equity or debt financings or that such funds will be raised at prices that do not create substantial dilution for our existing stockholders. Given the volatility of our stock price, any financing that we undertake could cause substantial dilution to our existing stockholders.

Macroeconomic challenges and volatility in capital markets could further limit our ability to raise capital when needed on terms favorable to us, or at all. In addition, while we have been able to raise capital from the sale of shares under our at- the- market program, the limitations under instruction I. B. 6 of Form S- 3, as well as possible low volume of trading in our securities, will limit our ability to continue raising funds through such program. To date, we have financed our operations primarily through sales of our products and net proceeds from the issuance of our preferred stock and debt financings, our initial public offering (" IPO "), **private offerings, strategic investment,** and our follow- on public offerings **of our securities** . We do not know when or if our operations will generate sufficient cash to fund our ongoing operations. We cannot be certain that additional capital will be available as needed on acceptable terms, or at all. In the future, we may require additional capital in order to (i) continue to conduct research and development activities, (ii) conduct post- market clinical studies, as well as clinical trials to obtain regulatory clearances and approvals necessary to commercialize our Lumivascular

platform products, (iii) expand our sales and marketing infrastructure, (iv) acquire complementary businesses technologies or products; or (v) respond to business opportunities, challenges, a decline in sales, increased regulatory obligations or unforeseen circumstances. Our future capital requirements will depend on many factors, including: ● the degree of success we experience in commercializing our Lumivascular platform products, particularly Pantheris, **Ocelot, Tigereye** and any future versions of such products; ● the costs, timing and outcomes of clinical trials and regulatory reviews associated with our future products; ● the costs and expenses of maintaining or expanding our sales and marketing infrastructure and our manufacturing operations; ● the costs and timing of developing variations of our Lumivascular platform products and, if necessary, obtaining FDA clearance of such variations **; ● the costs and timing of developing our Coronary products, timing and outcomes of clinical trials and regulatory reviews associated with this product and eventual timing and expenses related to obtaining FDA clearance** ; ● the extent to which our Lumivascular platform is adopted by hospitals for use by interventional cardiologists, vascular surgeons and interventional radiologists in the treatment of PAD; ● the number and types of future products we develop and commercialize; ● the costs of defending ourselves against future litigation; ● the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property- related claims; and ● the extent and scope of our general and administrative expenses. We may **attempt to** raise additional funds in equity or debt financings or enter into credit facilities in order to access funds for our capital needs. Any debt financing obtained by us in the future would cause us to incur additional debt service expenses and could include restrictive covenants relating to our capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and pursue business opportunities. In addition, due to our current level of debt, future equity investors may require that we convert all or a portion of our debt to equity, and our debtholders may not agree to such terms. If we raise additional funds through further issuances of equity or convertible debt securities, and / or if we convert all or a portion of our existing debt to equity, our existing stockholders could suffer significant dilution in their percentage ownership of our company, and any new equity securities we issue could have rights, preferences and privileges senior to those of holders of our common stock. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, we may terminate or delay the development of one or more of our products, delay clinical trials necessary to market our products, delay establishment of sales and marketing capabilities or other activities necessary to commercialize our products, and significantly scale back our operations, or we may become insolvent. **In addition, as described above under the risk factor " Nasdaq may delist our securities from its exchange, which could harm our business and limit our stockholders' liquidity, " if we are unable to raise capital in a manner accretive to our stockholders' equity, our common stock could be delisted from Nasdaq.** If this were to occur, our ability to continue to grow and support our business and to respond to business challenges could be significantly limited. We have **entered into a license agreement and related collaboration agreement with respect to the development and commercialization of certain of our products in the Greater China region. There can be no guarantee that such strategic partnership will be successful and we may not be able to capitalize on the market potential of our products in the Greater China region or realize other benefits from such arrangement. In March 2024, we entered into a license agreement and collaboration agreement with Zylox- Tonbridge, pursuant to which we agreed to license and distribute certain of our products to Zylox- Tonbridge in the Greater China region, including mainland China, Hong Kong, Macao, and Taiwan (the " Territory "). Zylox- Tonbridge will lead all regulatory and commercialization activities for our products in the Territory. We have limited control over the amount and timing of resources that Zylox- Tonbridge will dedicate to such efforts and there can be no guarantee that Zylox- Tonbridge will be successful in obtaining required regulatory approvals or commercializing such products in the Territory. As a result, we may never realize any royalty payments under such license agreement. In addition, as part of this strategic partnership, Zylox- Tonbridge agreed to invest $ 7. 5 million to purchase shares of a new Series G convertible preferred stock, provided that the following milestones are achieved: (i) the successful registration and listing under 21 CFR part 807 with the FDA of Zylox- Tonbridge and one of its designated affiliates to manufacture our products, and (ii) us achieving an aggregate of $ 10 million in gross revenue within any four consecutive fiscal quarters, excluding any gross revenue achieved under the license agreement. There can be no guarantee that such milestones will be achieved and, therefore, we may never receive such additional investment. Furthermore, the collaboration agreement we entered into with Zylox- Tonbridge contemplates that, after required regulatory approvals have been obtained, Zylox- Tonbridge will manufacture our products. There can be no guarantee that such regulatory approvals will be obtained and that Zylox- Tonbridge will be able to manufacture our products. Even if Zylox- Tonbridge is able to manufacture our products, there can be no guarantee that they will be able to do so at costs that will be advantageous to us. We have** a significant amount of debt, which may adversely affect our ability to operate our business and our financial position and our ability to secure additional financing in the future. As of December 31, ~~2022~~ **2023** , we had $ 14. ~~2~~ **3** million in principal, back- end fees and interest outstanding under the Loan Agreement, with CRG. Our significant amount of debt may: ● increase our vulnerability to adverse changes in general economic, industry and competitive conditions; ● require us to dedicate a substantial portion of our cash flow from operations to make payments on our debt, thereby reducing the availability of our cash flow to fund working capital, capital expenditures and other general corporate purposes; ● limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate; ● restrict us from exploiting business opportunities; ● make it more difficult to satisfy our financial obligations, including payments on the Loan Agreement; ● place us at a competitive disadvantage compared to our competitors that have less debt obligations; and ● limit our ability to borrow additional funds for working capital, capital expenditures, acquisitions, debt service requirements, execution of our business strategy or other general corporate purposes on satisfactory terms or at all. The existence of a substantial amount of debt may make it difficult for us to run our business effectively or raise the capital we need to continue our operations. Covenants under the Loan Agreement will restrict our business in many ways. The Loan Agreement contains various covenants that limit, subject to certain exceptions, our ability to, among other things: ● incur or assume liens; ●

incur additional debt or provide guarantees in respect of obligations of other persons; ● issue redeemable stock and preferred stock; ● pay dividends or make distributions on capital stock, repurchase, redeem or make payments on capital stock or repay, repurchase, redeem, retire, defease, acquire or cancel debt prior to the stated maturity thereof; ● make loans, investments or acquisitions; ● create or permit restrictions on the ability of our subsidiaries to pay dividends or make other distributions to us or to guarantee our debt, limit our or any of our subsidiaries ability to create liens, or make or pay intercompany loans or advances; ● enter into certain transactions with affiliates; ● sell, transfer, license, lease or dispose of our or our subsidiaries' assets, including the capital stock of our subsidiaries; and ● dissolve, liquidate, consolidate or merge with or into, or sell substantially all of our assets to another person. In particular, the Loan Agreement, as most recently amended in ~~August~~ **March** ~~2022~~ **2024**, includes a covenant that we maintain a minimum of $ 3. 5 million of cash and certain cash equivalents, ~~and we will have~~ **which was temporarily reduced** to ~~achieve a~~ minimum ~~revenues~~ of $ ~~8~~ **1**. 0 million ~~in~~ **until April 1,** ~~2022~~ **2024 . Thereafter**, **we will be subject to the minimum liquidity requirement of** $ **3** ~~10. 0 million in 2023, $ 14~~. 5 million ~~in 2024 and $ 17. 0 million in 2025. If we fail to meet the applicable minimum revenue target in any calendar year, the Loan Agreement provides a cure right if we prepay a portion of the outstanding principal equal to 2. 0 times the revenue shortfall. Such prepayment would use capital resources that are otherwise required for us to operate our business and, therefore, if we are required to pay such amounts our liquidity and operations could be adversely affected. In addition, if we are unable to make such required prepayment and, as a result, default on our obligations under the Loan Agreement, our business will be adversely affected~~. There can be no assurance as to our future compliance with the covenants under the Loan Agreement, as amended. **We currently anticipate that, if we are unable to raise additional capital, our cash balance will fall below the required minimum of $ 3. 5 million in the second quarter of 2024. If our cash balance falls below the required minimum and we are unable to negotiate a waiver or amendment to the Loan Agreement, we would be in default of our covenants under the Loan Agreement, which would adversely affect on our financial position and operations.** The covenants contained in the Loan Agreement could **also** adversely affect our ability to execute our business strategies by restricting our ability to make capital expenditures, engage in strategic acquisitions, refinance our outstanding indebtedness, or obtain additional financing. Such restrictions may make it difficult to plan for or react to changes in market conditions, such as future downturns in our business or the economy in general. In addition, potential sources of equity financing may decline to invest in our company given the amount of debt and the rights that debt holders have to get paid before equity holders. In order to facilitate equity investments, future equity investors may require that we convert all or a portion of our debt to equity, and our debtholders may not agree to such terms. The amount of debt could therefore affect our ability to finance our company and prevent us from obtaining necessary operating capital as a result. We may not be able to generate sufficient cash to service our obligations under the Loan Agreement. If we default on payments or otherwise fail to comply with our obligations under our Loan Agreement, the lenders thereunder may be able to accelerate amounts owed under the loan facility and may foreclose upon the assets securing our obligations. Borrowings under our Loan Agreement are secured by substantially all of our personal property, including our intellectual property. The existing collateral pledged under the Loan Agreement may prevent us from being able to secure additional debt or equity financing on favorable terms, or at all, or to pursue business opportunities, including potential acquisitions. Our ability to make scheduled payments, comply with our debt covenants, or to refinance our debt obligations depends on numerous factors, including the amount of our cash reserves and our actual and projected financial and operating performance. These amounts and our performance are subject to numerous risks, including the risks in this section, some of which may be beyond our control. We cannot assure you that we will maintain a level of cash reserves or cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our existing or future indebtedness. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness. We cannot assure you that we would be able to take any of these actions, or that these actions would permit us to meet our scheduled debt service obligations. In addition, in the event of our breach of the Loan Agreement, we may be required to repay any outstanding amounts earlier than anticipated. If we fail to comply with our obligations under the Loan Agreement, the lender would be able to accelerate the required repayment of amounts due and, if they are not repaid, could foreclose upon our assets securing our obligations under the Loan Agreement. The Series ~~A~~ **E and Series F convertible** preferred stock have a liquidation preference senior to our common stock **, Series A- 1 convertible preferred stock** and Series B **convertible** preferred stock. Our outstanding shares of Series ~~A~~ **E and Series F** preferred stock have a liquidation preference that gets paid prior to any payment on our common stock (including shares issuable upon the exercise of our outstanding warrants) **, Series A- 1** and Series B preferred stock. ~~As a result, if we were to dissolve, liquidate, merge with another company or sell our assets, the holders of our Series A preferred stock would have the right to receive up to approximately $ 60. 9 million as of December 31, 2022, plus any unpaid dividends, and, after the payment of the liquidation preference to the holders of the Series A preferred stock before any amount is paid to the holders of our Series B preferred stock or common stock or pursuant to the redemption rights in the warrants for fundamental transactions.~~ The payment of the liquidation preferences could result in common stockholders, **A- 1 and** Series ~~B~~ **E** preferred stockholders and warrant holders not receiving any consideration if we were to liquidate, dissolve or wind up, either voluntarily or involuntarily. **This liquidation preference may increase over time based on the** ~~In January 2019, December 2019, December 2020, December 2021, and December 2022, 2, 945, 3, 580, 3, 866, 4, 175 and 4, 510 additional shares of Series A preferred stock, respectively, were issued to CRG as~~ payment of dividends ~~accrued through December 31, 2022~~. The existence of the liquidation preferences may reduce the value of our common stock, make it harder for us to sell shares of common stock in offerings in the future, or prevent or delay a change of control. We have outstanding shares of convertible preferred stock, some of which contain " full- ratchet " anti- dilution protection, which may cause significant dilution to our stockholders. As of December 31, ~~2022~~ **2023**, we had outstanding ~~7~~ **1**, ~~832~~ **279**, ~~644~~ **928** shares of common stock. As of that date we had outstanding **1, 920 shares of Series E convertible preferred stock convertible into an aggregate of 178, 560 share of common stock,** 85 shares

of Series B convertible preferred stock convertible into an aggregate of ~~56~~ **14** , ~~591~~ **790** shares of common stock **;** and ~~60~~ **subsequent to December 31** , ~~876~~ **2023, we issued 10, 000** shares of Series A **- 1** convertible preferred stock convertible ~~, subject to certain conditions,~~ into an aggregate of ~~152~~ **2** , ~~190~~ **729, 258 shares of common stock and 7, 224 shares of Series F convertible preferred stock convertible into an aggregate of approximately 1, 971, 616** shares of common stock. The issuance of shares of common stock upon the conversion of such shares of preferred stock would dilute the percentage ownership interest of all stockholders, might dilute the book value per share of our common stock and would increase the number of our publicly traded shares, which could depress the market price of our common stock. The shares of Series B preferred stock contain a " full- ratchet " anti- dilution provision which, subject to limited exceptions, would reduce the conversion price of the Series B preferred stock (and increase the number of shares issuable) in the event that we in the future issue common stock, or securities convertible into or exercisable to purchase common stock, at price per share lower than the conversion price then in effect. Our outstanding 85 shares of Series B preferred stock ~~are~~ **were** convertible into ~~56~~ **14** , ~~591~~ **790** shares of common stock at a conversion price of $ ~~1~~ **5** . ~~502~~ **732** per share ~~. The certificate of designation for our Series A preferred stock,~~ as ~~amended, currently provides that shares~~ of **December 31** ~~such Series A preferred stock will not be convertible into shares of our common stock until our stockholders have approved an amendment to our Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock from 100~~ , **2023** ~~000, 000 to at least 125, 000, 000 shares. Our Board of Directors may determine to remove this requirement. If our stockholders approve such amendment to our Amended and Restated Certificate of Incorporation, shares of Series A preferred stock may be converted into shares of our common stock, which will result in dilution to our stockholders~~ . Certain of our outstanding warrants and preferred investment options include put rights upon the occurrence of a fundamental transaction, which could make it difficult for us to complete a fundamental transaction that would otherwise be beneficial to our stockholders. Certain of our outstanding warrants, including the warrants issued in February 2018, November 2018, and January 2022 and the preferred investment options issued in August 2022, include provisions that, in the event of certain fundamental transactions defined in the relevant agreements, provide the holders of such warrants and preferred investment options with the right to require us, or the successor company in such transaction, to repurchase any unexercised portion of such warrants or preferred investment options from the holder at their Black- Scholes value. In some circumstance this repurchase must be made in cash. Such Black- Scholes value may be significant and the requirement to pay such amount could prevent us from completing a transaction which would otherwise be accretive to shareholders or make such transaction more costly and reduce the value of such transaction to holders of our common stock. Our success depends in large part on a limited number of products, particularly the Pantheris product family, all of which have a limited commercial history. If these products fail to gain, or lose, market acceptance, our business will suffer. Ocelot, Ocelot PIXL, Ocelot MVRX, Tigereye, **Tigereye ST,** Lightbox 3, Pantheris ~~and ,~~ Pantheris SV **and Pantheris LV** are our only products currently cleared for sale, and our current revenues are wholly dependent on them. In addition, the long- term viability of our company is largely dependent on the successful commercialization and continued development of the Pantheris product family and we expect that sales of our other current and future Lumivascular platform products in the United States will account for substantially all of our revenues for the foreseeable future. Accordingly, our success depends on the continued and growing acceptance and use of Lumivascular platform products by the medical community. All of our products have a limited commercial history. For example, we received 510 (k) clearance from the FDA to commercialize Pantheris in October 2015 as well as a separate FDA clearance to market enhanced versions of Pantheris in March 2016 and May 2018 and those versions of Pantheris became commercially available in the United States and select international markets promptly thereafter. Pantheris SV launched in July 2019 after having received FDA clearance in April 2019. Tigereye launched in October 2020 after having received FDA clearance in September 2020 **. Tigereye ST launched in September 2023 after having received FDA clearance in April 2023. Pantheris LV is currently in a limited launch phase after having received FDA clearance in June 2023** . Our limited commercialization experience and number of approved products make it difficult to evaluate our current business and predict our future prospects. We have encountered and will continue to encounter risks and difficulties frequently experienced by companies in rapidly changing industries. Our ability to successfully market Lumivascular platform products will also be limited due to a number of factors including regulatory restrictions in our labeling. We cannot assure demand for Lumivascular platform products will continue to grow or that our products will significantly penetrate current or new markets. Market demand for our Lumivascular platform products and physician adoption of these products also may be negatively impacted by product performance issues and the need to replace certain products in accordance with our warranty policy. Utilization of our products has been less than we anticipated historically. If demand for our Lumivascular platform products does not increase and we cannot sell our products as planned, our financial results will be harmed. In addition, market acceptance may be hindered if physicians are not presented with compelling data from long- term studies of the safety and efficacy of our Lumivascular platform products compared to alternative procedures, such as angioplasty, stenting, bypass surgery or other atherectomy procedures. For example, if patients undergoing treatment with our Lumivascular platform products have retreatment rates higher than or comparable with the retreatment rates of alternative procedures, it will be difficult to demonstrate the value of our Lumivascular platform products. Any studies we may conduct comparing our Lumivascular platform with alternative procedures will be expensive, time consuming and may not yield positive results. Physicians will also need to appreciate the value of real- time imaging in improving patient outcomes in order to change current methods for treating PAD patients. In addition, demand for our Lumivascular platform products may decline or may not increase as quickly as we expect. Failure of our Lumivascular platform products to significantly penetrate current or new markets, or our failure to successfully commercialize our products, would harm our business, financial condition and results of operations. We are also aware of certain characteristics and features of our Lumivascular platform that may prevent widespread market adoption. For example, in procedures using the current model of Pantheris, some physicians may prefer to have a technician or second physician assisting with the operation of the catheter as well as a separate technician to operate the Lightbox, potentially making

it less financially attractive for physicians and their hospitals and medical facilities. It may take significant time and expense to modify our products to allow a single physician to operate the entire system and we can provide no guarantee that we will be able to make such modifications or obtain any additional and necessary regulatory clearances for such modifications. Although the OCT images created by our Lightbox may make it possible for physicians to reduce the degree to which fluoroscopy and contrast dye are used when using our Lumivascular platform products compared to competing endovascular products, physicians are still using both fluoroscopy and contrast dye in these procedures. As a result, risks of complications from radiation and contrast dye are still present and may limit the commercial success of our products. Finally, it requires training of technicians and physicians to effectively operate our Lumivascular platform products, including interpreting the OCT images created by our Lightbox, which may affect adoption of our products by physicians. Our Lumivascular products are highly complex, and the failure of relatively minor components could result in product failure or other significant performance issues that may not be discovered until after delivery to customers, which could give rise to claims from our customers or their patients. We have in the past, and may in the future, become aware of performance issues with our products. For example, prior to becoming commercially available on March 1, 2016, Pantheris had been used in clinical trials mainly in controlled situations. Since its commercialization and as more physicians have used Pantheris, we have received additional feedback on its performance, both positive and negative. We have attempted to address certain of these concerns with our current version of Pantheris. However, there can be no assurance that the changes and improvements will fully address the performance issues that have been raised by earlier versions of Pantheris. Our revenue has been adversely impacted by these product performance issues. We also had to incur additional expenses to make product changes and improvements, and to replace products in accordance with our warranty policy. If future product performance issues are not resolved and physician concerns not addressed, our reputation could suffer, which could lead to decreased sales of our products. We rely heavily on our sales professionals to market and sell our products. If we are unable to hire, effectively train, manage, improve the productivity of, and retain our sales professionals, our business will be harmed, which would impair our future revenue and profitability. Our success largely depends on our ability to hire, train, manage and improve the productivity levels of our sales professionals. Competition for sales professionals who are familiar with and trained to sell our products continues to be strong and our larger competitors are able to offer compensation and benefits that we are not able to. We have experienced and continue to experience significant turnover of our sales professionals. Significant turnover of our sales professionals makes it difficult for us to maintain an adequate presence in some markets and to preserve institutional expertise among our sales teams. While we train our new sales professionals to better understand our existing and new product technologies and how they can be positioned against our competitors' products, it takes time for the sales professionals to become productive following their hiring and training and there can be no assurance that newly hired sales professionals will reach adequate levels of productivity, or that we will not continue to experience significant levels of attrition in the future. Measures we implement to improve the productivity of our sales professionals may not be successful and may instead cause additional departures from our sales organization. Such attrition could further reduce our revenue, profitability, and harm our business and our stock price may be adversely impacted as a result. In addition, the loss of any member of our sales team' s senior management could weaken our sales expertise and harm our business, and we may not be able to find adequate replacements on a timely basis, or at all. Attrition in our senior management team over sales that have occurred over the past several years have created and likely will continue to create instability in our sales force, which could lead to further attrition in our team of sales professionals. If we are unable to retain experienced sales professionals, our ability to market and sell our products in our target markets will be adversely affected, which will adversely affect our sales and results of operations. We depend on our senior management team and the loss of one or more key employees or an inability to attract and retain highly skilled employees could harm our business. Our success largely depends upon the continued services of our executive management team and key employees and the loss of one or more of our executive officers or key employees could harm us and directly impact our financial results. Our employees may terminate their employment with us at any time. Changes in our executive management team resulting from the hiring or departure of executives could disrupt our business. For example, our Chief Financial Officer resigned from the Company effective May 12, 2022. Nabeel Subainati, our Vice President of Finance, has been designated as Principal Financial Officer and Principal Accounting Officer effective as of July 21, 2022. If we are unable to hire one or more replacement employees for officers who have departed or may depart, or otherwise fill their responsibilities, our ability to effectively manage our business could be adversely affected. We must attract and retain highly qualified personnel. Competition for skilled personnel is intense, especially for engineers with high levels of experience in designing and developing medical devices and for sales professionals. We have, from time to time, experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications. Many of the companies with which we compete for experienced personnel have greater resources than we have. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages. In addition, job candidates and existing employees, particularly in the San Francisco Bay Area, often consider the value of the stock awards they receive in connection with their employment. If the perceived value of our stock awards declines or if we do not make grants of stock-based incentive awards, it may harm our ability to recruit and retain highly skilled employees. In addition, we invest significant time and expense in training our employees, which increases their value to competitors who may seek to recruit them. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business would be harmed. Our ability to compete is highly dependent on demonstrating the benefits of our Lumivascular platform to physicians, hospitals and patients and our ability to innovate new and improved products. In order to generate sales, we must be able to clearly demonstrate that our Lumivascular platform is a more effective treatment system than the alternatives offered by our competitors. If we are unable to convince physicians that our Lumivascular platform leads to significantly lower rates of restenosis, or narrowing of the artery, and leads to fewer adverse events during treatment than those using competing technologies, our business will suffer. We

must convince hospitals and physicians that our Lumivascular platform results in significantly better patient outcomes at a competitive overall cost. For example, we may need to demonstrate that the investment hospitals must make of purchasing our Lightbox and the incremental costs of having a technician or a second individual operate Pantheris can be justified based on the benefits to patients, physicians and hospitals. If we are unable to develop robust clinical data to support these claims, we will be unable to convince hospitals and third- party payors of these benefits and our business will suffer. In addition, attrition among our sales professionals may make it difficult to maintain relationships with physicians and hospitals, which could adversely affect our sales and results of operations. Our value proposition to physicians and hospitals is largely dependent upon our contention that the rate of arterial damage when physicians are using our imaging products is lower than with non- imaging competing products. If minimizing arterial damage does not significantly impact patient outcomes, meaning either (i) that restenosis is often triggered without disrupting healthy arterial structures or (ii) arteries can be damaged during treatment without triggering restenosis, then we may be unable to demonstrate our Lumivascular platform' s benefits are any different than competing technologies. Furthermore, physicians may find our imaging system difficult to use, and we may not be able to provide physicians with adequate training to be able to realize the benefits of our Lumivascular platform. If physicians do not value the benefits of on- board imaging and the enhanced visualization enabled by our products during an endovascular intervention as compared to our competitors' products, or do not believe that such benefits improve clinical outcomes, our Lumivascular platform products may not be widely adopted. In order to remain competitive, we must also continue to develop new product offerings and enhancements to our existing Lumivascular platform products. The market for medical devices in general, and in the PAD market in particular, is highly competitive, dynamic, and marked by rapid and substantial technological development and product innovation. If we are unable to innovate successfully, our Lumivascular platform products could become obsolete, and our revenues would decline as our customers purchase our competitors' products. In addition, our innovation efforts may not result in new products that generate additional revenue. For example, we believe that our next-generation Pantheris, Pantheris SV **, Pantheris LV** and any future iterations of these products are important to our future revenues, and we are devoting a significant portion of our resources to their continued development. However, we do not yet know whether these or any other new offerings will be well received and broadly accepted by physicians, and if so, whether sales will be sufficient for us to offset costs of development, implementation, support, operation, sales and marketing. Additionally, new products may subject us to additional risks of product performance, market adoption, customer complaints and litigation. If sales of our new product offerings are lower than we expect, fail to gain anticipated market acceptance or cause us to expend additional resources to fix unforeseen problems and develop modifications, our revenues and results of operations may not improve, and our business will be adversely affected. Our ability to develop, market, and sell our products depends in part upon our working relationships with physicians, and any events that damage those relationships, or make it more difficult to build and maintain those relationships, could harm our business. The development, marketing, and sale of our products depends upon our ability to maintain strong 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 in clinical trials and 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 harm our business, financial condition and results of operations. The medical device industry' s relationship with physicians is under increasing scrutiny by the Office of Inspector General, or OIG, the Department of Justice, or DOJ, state attorneys general, and other foreign and domestic government agencies. Changes to or our failure to comply with laws, rules and regulations governing our relationships with physicians, or an investigation into our compliance by the OIG, DOJ, state attorneys general and other government agencies, could significantly harm our business by damaging our reputation among, or restricting our ability to work with, physicians. In addition, we target our sales efforts to interventional cardiologists, vascular surgeons and interventional radiologists because they are often the physicians diagnosing and treating both coronary artery disease and PAD. If these physicians are not made aware of our Lumivascular platform products, those patients may instead be surgically treated or treated with an alternative interventional procedure. In addition, there is a significant correlation between PAD and coronary artery disease, and many physicians do not routinely screen for PAD while screening for coronary artery disease. If we are not successful in educating physicians about screening for PAD and about the capabilities of our Lumivascular platform products, our ability to increase our revenues may be impaired. We compete against companies that have longer operating histories, more established products and greater resources, which may prevent us from achieving significant market penetration, increasing our revenues or becoming profitable. Our products compete with a variety of products and devices for the treatment of PAD, including other CTO crossing devices, stents, balloons and atherectomy catheters, as well as products used in vascular surgery. Large competitors in the CTO crossing, stent and balloon markets include Abbott Laboratories, AngioDyamics, Boston Scientific, Cardinal Health, Cook Medical, Becton Dickinson and Medtronic. Competitors in the atherectomy market include AngioDyamics, Boston Scientific, Cardiovascular Systems, Medtronic and Philips. Some competitors have previously attempted to combine intravascular imaging with atherectomy and may have current programs underway to do so. These and other companies may attempt to incorporate on- board visualization into their products in the future and may remain competitive with us in marketing traditional technologies. Other competitors include pharmaceutical companies that manufacture drugs for the treatment of symptoms associated with mild to moderate PAD and companies that provide products used by surgeons in peripheral and coronary bypass procedures. These competitors and other companies may introduce new products that compete with our products. Many of our competitors have significantly greater financial and other resources than we do and have well- established reputations, as well as broader product offerings and worldwide distribution channels that are significantly larger and more effective than ours. In addition, competitors with greater financial resources than ours could acquire other companies to gain enhanced name recognition and market share, as well as new technologies or products that could effectively compete with our existing products, which may cause our revenues to

decline and would harm our business. Competition with these companies could result in price- cutting, reduced profit margins and loss of market share, any of which would harm our business, financial condition and results of operations. If we are unable to effectively differentiate our products or company from those of our competitors and our business may be adversely affected. If our manufacturing facility becomes damaged or inoperable, or we are required to vacate the facility, or our electronic systems are compromised, our ability to manufacture and sell our Lumivascular platform products and to pursue our research and development efforts may be jeopardized. We currently manufacture and assemble our Lumivascular platform products in- house. Our products are comprised of components sourced from a variety of contract manufacturers, with final assembly completed at our facility in Redwood City, California. Our facility and equipment, or those of our suppliers, could be harmed or rendered inoperable by natural or man- made disasters, including fire, earthquake, terrorism, flooding and power outages. Further, our electronic systems may experience service interruptions, denial- of- service and other cyber- attacks, computer viruses or other events. Any of these may render it difficult or impossible for us to manufacture products, pursue our research and development efforts or otherwise run our business for some period of time. If our facility is inoperable for even a short period of time, the inability to manufacture our current products, and the interruption in research and development of any future products, may result in harm to our reputation, increased costs, lower revenues and the loss of customers. Furthermore, it could be costly and time- consuming to repair or replace our facilities and the equipment we use to perform our research and development work and manufacture our products. We depend on third- party vendors to manufacture some of our components, coating and sub- assemblies, including some single source suppliers, which could make us vulnerable to supply shortages and price fluctuations that could harm our business. We currently manufacture some of our components and sub- assemblies at our Redwood City facility and rely on third- party vendors for other components and sub- assemblies used in our Lumivascular platform. For several of our components and sub- assemblies we rely on single and limited source suppliers. For example, we rely on single vendors for our optical fiber, coatings and drive cables that are key components of our catheters, and we rely on single vendors for our laser and data acquisition card that are key components of our Lightbox. These components are critical to our products and there are relatively few alternative sources of supply. Further, we do not carry a significant inventory of these components. If our suppliers of these materials cease doing business, reduce their production capacity, or otherwise limit the amount of materials we can purchase, we may be unable to acquire necessary materials on favorable terms, or at all. If we are unable to purchase required inputs for our production, our business will be adversely affected. Our reliance on third- party vendors subjects us to a number of risks that could impact our ability to manufacture our products and harm our business. We rely on third- party vendors to supply us with raw materials, as well as certain components and sub- assemblies used in the manufacture of our products. Our reliance on such third parties subjects us to a number of risks that could adversely affect our operations, including: ● interruption of supply resulting from modifications to, or discontinuation of, a supplier' s operations; ● delays in shipments resulting from slowdowns in manufacturing due to **a** ~~the COVID- 19~~ pandemic or other causes, such as government restrictions on the movement of people and goods; ● delays in product shipments resulting from uncorrected defects, reliability issues or a supplier' s failure to consistently produce quality components; ● price fluctuations due to a lack of long- term supply arrangements with our suppliers for key components; ● inability to obtain adequate supply in a timely manner or on commercially reasonable terms; ● difficulty identifying and qualifying alternative or additional suppliers for components in a timely manner; ● inability of the manufacturer or supplier to comply with QSR as enforced by the FDA and state regulatory authorities; ● inability to control the quality of products manufactured by third parties; ● production delays related to the evaluation and testing of products from alternative suppliers and corresponding regulatory qualifications; and ● delays in delivery by our suppliers due to changes in demand from us or their other customers. The indirect and direct effects of the COVID- 19 pandemic, including subsequent variants, and measures taken in response by governments and businesses worldwide to contain its spread, including quarantines, facility closures, travel and logistics restrictions, border controls, and shelter in place or stay at home and social distancing orders, have **historically** adversely impacted and are **in some ways** expected to continue to adversely impact global supply chain, manufacturing, and logistics operations. Shipping and freight delays have also been increasing in response to port closures, port congestion, shipping container and ship shortages, and global conflicts. To the extent ~~the COVID- 19~~ **events such as another** pandemic ~~and~~ **or** other **disruptive** ~~events~~ **event** ~~result~~ **results the** ~~in continuation or~~ worsening of manufacturing and shipping delays and constraints, our suppliers of raw materials and other components may have difficulty obtaining and providing the materials we require to manufacture our products, which could adversely affect our ability to acquire and maintain adequate inventory and meet demand for our products. Some of our suppliers have begun requiring us to provide longer- term forecasts of our supply requirements. If our assumptions about customer demand are incorrect, the forecasts we provide to our suppliers may result in excess inventory due to reduced demand or insufficient inventory to meet demand, which would adversely affect our business and results of operations. We also compete with other manufacturers who require the same components as us, or inputs used in producing the components that we purchase. Other purchasers may be able to leverage stronger relationships or greater purchasing power than we have to gain advantages over us in the supply chain. We do not currently intend to devote significant additional resources in the near- term to market our Lumivascular platform internationally, which will limit our potential revenues from our Lumivascular platform products. Marketing our Lumivascular platform outside of the United States would require substantial additional sales and marketing, regulatory and personnel expenses. As part of our product development and regulatory strategy, we plan to expand into select international markets, but we do not currently intend to devote significant additional resources to market our Lumivascular platform internationally in order to focus our resources and efforts on the U. S. market. Our decision to market our products primarily in the United States in the near- term will limit our ability to reach all of our potential markets and will limit our potential sources of revenue. In addition, our competitors will have an opportunity to further penetrate and achieve market share outside of the United States until such time, if ever, that we devote significant additional resources to market our Lumivascular platform products or other products internationally. Our ability to utilize our net operating loss carryforwards may be limited. As

of December 31, ~~2022~~ **2023**, we had federal and state net operating loss carryforwards, or NOLs, due to prior period losses of $ ~~346~~ **357**. ~~0~~ **7** million and $ ~~209~~ **218**. ~~8~~ **7** million, respectively, which if not utilized will begin to expire in 2027 for federal purposes and ~~2023~~ **2024** for state purposes. Out of the total Federal net operating loss carryforwards, $ ~~88~~ **100**. ~~5~~ **2** million were generated in years after December 31, 2017 and have no expiration. Subject to certain limitations, NOLs can be used to offset taxable income for U. S. federal income tax purposes. However, Section 382 of the Internal Revenue Code of 1986, as amended, may limit the NOLs we may use in any year for U. S. federal income tax purposes in the event of certain changes in ownership of our company. A Section 382 " ownership change " generally occurs if one or more stockholders or groups of stockholders who own at least 5 % of our stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three- year period. Similar rules may apply under state tax laws. It is possible that prior transactions with respect to our stock may have caused, and that future issuances or sales of our stock (including certain transactions involving our stock that are outside of our control) could cause, an " ownership change. " A number of our common and preferred stock financings over the past year may affect our ability to use NOLs. If an " ownership change " occurs, Section 382 would impose an annual limit on the amount of pre- ownership change NOLs and other tax attributes we can use to reduce our taxable income, potentially increasing and accelerating our liability for income taxes, and also potentially causing those tax attributes to expire unused. Any limitation on using NOLs could (depending on the extent of such limitation and the NOLs previously used) result in our retaining less cash after payment of U. S. federal income taxes during any year in which we have taxable income (rather than losses) than we would be entitled to retain if such NOLs were available as an offset against such income for U. S. federal income tax reporting purposes, which could harm our profitability. On December 22, 2017, the Tax Cuts and Jobs Act, or Tax Act, was enacted into law with many significant changes to the U. S. tax laws. The Tax Act limits the utilization of NOLs arising in tax years beginning after December 31, 2017 to 80 % of taxable income per year. However, existing NOLs that arose in years prior to December 31, 2017 are not affected by these provisions. Our ability to utilize NOLs arising in future tax periods may be limited by the Tax Act. Outbreaks of contagious diseases, such as the novel coronavirus, COVID- 19, and other public health crises may impact our business and operations, which could materially adversely affect our financial condition and results of operations. We have **historically** experienced a disruption in procedures using our products and in our operations as a result of the COVID- 19 outbreak. Public health crises, including an outbreak of a contagious disease, such as COVID- 19, particularly to the extent it becomes a pandemic like COVID- 19, could significantly disrupt our business. The effects of such a public health crisis are difficult to predict, but may include a decrease in procedure volumes due to restrictions and guidelines implemented by facilities and governmental entities; reduced availability of physicians or lab space to treat patients using our products and / or different treatment prioritizations of those physicians; increased cost pressures and burdens on the overall healthcare infrastructure that result in reallocation of resources; changed treatment decisions by patients who may elect to defer or avoid treatment for procedures that use our products due to concerns about the potential spread of diseases in facilities; the suspension of clinical trial activity; restrictions on the ability of our personnel and personnel of our distribution partners and sales agents to travel and to access customers and medical facilities for sales activities, training and case support; delays in approvals by regulatory bodies; delays in product development efforts, which will also disrupt or delay our ability to launch affected products; reallocation of company resources from our strategic priorities; supply chain disruptions that limit, delay or prevent us from acquiring the components used to manufacture our products or ship those products once manufactured; disruptions in our relationships with our distributors and sales agents due to the impact of the outbreak on their operations; temporary closures of our facilities; loss of employee productivity; government requirements to " shelter at home " or other incremental mitigation efforts that may further impact our capacity to manufacture, sell and support the use of our products; legal actions threatened or commenced against us by employees, customers or others who allege that our actions or inactions relating to safety measures led to their exposure to COVID- 19 or other personal injury; and adverse impacts on the national and global economies. The extent of ~~the~~ **pandemics such as** COVID- 19 ~~pandemic~~ **,** may be further aggravated by the spread of new, more viral or deadly variants. Public health crises and pandemics, such as the outbreak of COVID- 19, also affect the economy generally, which may affect our stock price, our ability to borrow or raise additional capital, and the funding of health systems that purchase our products, among other potential effects. The United States and world economies could enter into periods of sustained recession or depression, which could materially adversely affect our business. The total impact of these disruptions could have a material adverse impact on our financial condition and results of operations, ~~and,~~ we cannot predict the specific extent, or duration, of the impact of **such** ~~the COVID- 19 outbreak or any~~ **an** ~~other~~ outbreak of a contagious disease or other public health crisis on our financial condition and results. Furthermore, the **extent of a** global ~~COVID- 19~~ **impact from a** pandemic **cannot** ~~continues to evolve and we do not yet know the full~~ **fully be known or quantified** ~~extent and duration of its impact~~. The full extent to which a public health crisis will directly or indirectly impact our business and results will depend on future developments that are highly uncertain and difficult to predict. Finally, to the extent a public health crisis adversely affects our business, results and prospects, it may also have the effect of heightening many of the other risks described in this section. Disruptions of supply chains could have a material adverse effect on our operating and financial results Disruption of supply chains due to trade restrictions, political instability, severe weather, natural disasters, public health crises such as the COVID- 19 pandemic, terrorism, product recalls, port closures, labor supply or stoppages, the financial or operational instability of key suppliers and carriers, government restrictions or measures, or other reasons could impair our ability to distribute our products, or cause the demand for our products to decrease. Many industries, including our own, **faced and continue to** face supply chain challenges ~~as a result~~ **resulting** ~~of~~ **from** COVID- 19 and other macroeconomic issues, including reduced freight availability and increased costs, port disruption, manufacturing facility closures, labor shortages and other supply chain disruptions. For example, hospitals reported a shortage of an iodinated contract medium used in X- rays, radiography and CT scans due to Shanghai' s lockdowns during the COVID- 19 pandemic. A shortage of such products could lead to a reduced number of surgeries and decrease the demand for our products. In addition, we have and continue to experience supply chain

challenges related to extended lead times from certain key suppliers. Should these challenges persist or worsen, we may be unable to manufacture enough inventory to meet the current demand for our Lumivascular products and consequently incur significant adverse effects on our operating and financial results. To the extent we are unable to mitigate the likelihood or potential impact of such events, there could be a material adverse effect on our operating and financial results. We may acquire other companies or technologies or be the target of strategic transactions, which could divert our management' s attention, result in additional dilution to our stockholders and otherwise disrupt our operations and harm our operating results. We may in the future seek to acquire or invest in businesses, applications or technologies that we believe could complement or expand our Lumivascular platform, enhance our technical capabilities or otherwise offer growth opportunities. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various costs and expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. We may not be able to identify desirable acquisition targets or be successful in entering into an agreement with any particular target or obtain the expected benefits of any acquisition or investment. To date, our technology and product development efforts have been organic, and we have no experience in acquiring other businesses. In any acquisition, we may not be able to successfully integrate acquired personnel, operations and technologies, or effectively manage the combined business following the acquisition. Acquisitions could also result in dilutive issuances of equity securities, the use of our available cash, or the incurrence of debt, which could harm our operating results. In addition, if an acquired business fails to meet our expectations, our operating results, business and financial condition may suffer. In addition, we sometimes receive inquiries relating to potential strategic transactions, including from third parties who may seek to acquire us. We will continue to consider and discuss such transactions as we deem appropriate. Such potential transactions may divert the attention of management, and cause us to incur various costs and expenses in investigating and evaluating such transactions, whether or not they are consummated. New product development for the coronary artery disease market may be challenging, expensive and carries no guarantee of an approved commercial product. In order to create more opportunities to grow our revenue base, we must continue to develop new product offerings and enhancements to our existing Lumivascular platform products. The market for medical devices in general, and in the CAD market, is highly competitive, dynamic, and marked by rapid and substantial technological development and product innovation. We believe that a Lumivascular product developed for the CAD market is important to our future revenues, and we are beginning to devote a significant portion of our resources to its development. Consequently, we anticipate we will need additional capital to finance this endeavor encompassing the research and development, clinical trials and eventual promotion of any new CAD product. Even if we are able to obtain additional capital, we may not be successful in the development any new CAD product. Our team may not have all the necessary qualifications and experience for the development of such a product. Therefore, we may need to attract and retain highly qualified personnel with specific experience in the coronary industry. Competition for skilled personnel is intense, especially for engineers with high levels of experience in designing and developing these types of medical devices, and we may not be successful in hiring and retaining employees with appropriate qualifications. Many of the companies with which we compete for experienced personnel have greater resources than we have. We may also may not be able to complete development of such products or choose to allocate our financial and other resources elsewhere due to unforeseen circumstances. Should we develop a CAD product, we will need to conduct a clinical trial. Clinical development is a long, expensive, and uncertain process and is subject to delays and the risk that this product may ultimately prove unsafe or ineffective in treating the indications for which they it will be designed. Completion of clinical trials may take several years or more and failure of the trial can occur at any time. We cannot provide any assurance that our clinical trials will meet their primary endpoints or that such trials or their results will be accepted by the FDA or foreign regulatory authorities. Even if we achieve positive early or preliminary results in clinical trials, these results do not necessarily predict final results, and positive results in early trials may not indicate success in later trials. Many companies in the medical device industry have suffered significant setbacks in late-stage clinical trials, even after receiving promising results in earlier trials or in the preliminary results from these late- stage clinical trials. Furthermore, we do not yet know whether any new CAD product, if developed and approved, will be well received and broadly accepted by physicians, and if so, whether sales will be sufficient for us to offset costs of development, implementation, support, operation, sales and marketing. Additionally, such products may subject us to additional risks of product performance, market adoption, customer complaints and litigation. If sales of this coronary device are lower than we expect, fail to gain anticipated market acceptance or cause us to expend additional resources to fix unforeseen problems and develop modifications, our revenues and results of operations may not improve and our business will be adversely affected. Adverse developments affecting the financial services industry, including events or concerns involving liquidity, defaults or non- performance by financial institutions, could adversely affect our business, financial condition or results of operations. Actual events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future adversely affect our liquidity. For example, on March 10, 2023, the Federal Deposit Insurance Corporation (" FDIC ") announced that Silicon Valley Bank had been closed by the California Department of Financial Protection and Innovation. At that time, all of our cash and cash equivalents were held at Silicon Valley Bank and our access to such funds was limited until the United States Department of the Treasury announced in a joint statement with the Federal Reserve and FDIC that depositors of Silicon Valley Bank will have access to all of their money starting March 13, 2023. While we have regained access to our funds at Silicon Valley Bank **, later acquired by First Citizens Bank,** and are evaluating our banking relationships, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by events such as liquidity constraints or failures, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors may also adversely affect our ability to access our cash and cash equivalents at affected financial institutions. In addition, investor concerns regarding the U.

S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on terms favorable to us, or at all. Any decline in available funding or access to our cash and liquidity resources could, among other things, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our business, financial condition or results of operations. If our technology infrastructure is compromised, damaged or interrupted by a cybersecurity incident, data security breach or other security problems, our operating results and financial condition could be adversely affected. We use technology in substantially all aspects of our business operations, and our ability to serve customers most effectively depends on the reliability of our technology systems. Cybersecurity incidents can include computer viruses, computer denial- of- service attacks, worms, and other malicious software programs or other attacks, covert introduction of malware to computers and networks, impersonation of authorized users, and efforts to discover and exploit any design flaws, bugs, security vulnerabilities or security weaknesses, as well as intentional or unintentional acts by employees or other insiders with access privileges, intentional acts of vandalism by third parties and sabotage. In addition, our technology infrastructure and systems are vulnerable to damage or interruption from natural disasters, power loss and telecommunications failures. Any such disruption to our systems, or the technology systems of third parties on which we rely, the failure of these systems to otherwise perform as anticipated, or the theft, destruction, loss, misappropriation, or release of sensitive and / or confidential information or intellectual property, could require us to notify affected individuals, federal or state agencies or media outlets of the incident and could result in business disruption, negative publicity, loss of customers, potential liability, including litigation or other legal actions against us or the imposition of penalties, fines, fees or liabilities, which may not be covered by our insurance policies, and competitive disadvantage, any or all of which would potentially adversely affect our customer service, decrease the volume of our business and result in increased costs and lower profits. Moreover, a cybersecurity breach could require us to devote significant management resources to address the problems associated with the breach and to expend significant additional resources to upgrade further the security measures we employ to protect information against cyber- attacks and other wrongful attempts to access such information, which could result in a disruption of our operations. While we have invested, and continue to invest, in technology security initiatives and other measures to prevent security breaches and cyber incidents, as well as disaster recovery plans, these initiatives and measures may not be entirely effective to insulate us from technology disruption that could result in adverse effects on our results of operations. We may in the future be a party to intellectual property litigation or administrative proceedings that could be costly and could interfere with our ability to sell our Lumivascular platform products. The medical device industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets, and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. It is possible that U. S. and foreign patents and pending patent applications or trademarks controlled by third parties may be alleged to cover our products, or that we may be accused of misappropriating third parties' trade secrets. Additionally, our products include hardware and software components that we purchase from vendors, and may include design components that are outside of our direct control. Our competitors, many of which have substantially greater resources and have made substantial investments in patent portfolios, trade secrets, trademarks, and competing technologies, may have applied for or obtained or may in the future apply for or obtain, patents or trademarks that will prevent, limit or otherwise interfere with our ability to make, use, sell and / or export our products or to use product names. They may devote substantial resources towards obtaining claims that cover the design of our atherectomy products to prevent the marketing and selling of competitive products. We may become a party to patent or trademark infringement or trade secret claims and litigation as a result of these and other third- party intellectual property rights being asserted against us. The defense and prosecution of these matters are both costly and time consuming. Vendors from whom we purchase hardware or software may not indemnify us in the event that such hardware or software is accused of infringing a third- party' s patent or trademark or of misappropriating a third- party' s trade secret. Further, if such patents, trademarks, or trade secrets are successfully asserted against us, this may harm our business and result in injunctions preventing us from selling our products, license fees, damages and the payment of attorney fees and court costs. In addition, if we are found to willfully infringe third- party patents or trademarks or to have misappropriated trade secrets, we could be required to pay treble damages in addition to other penalties. Although patent, trademark, trade secret, and other intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. We may be unable to obtain necessary licenses on satisfactory terms, if at all. If we do not obtain necessary licenses, we may not be able to redesign our Lumivascular platform products to avoid infringement. Similarly, interference or derivation proceedings provoked by third parties or brought by the U. S. Patent and Trademark Office, or USPTO, may be necessary to determine the priority of inventions or other matters of inventorship with respect to our patents or patent applications. We may also become involved in other proceedings, such as re- examination, inter partes review, or opposition proceedings, before the USPTO or other jurisdictional body relating to our intellectual property rights or the intellectual property rights of others. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our Lumivascular platform products or using product names, which would have a significant adverse impact on our business. Additionally, we may need to commence proceedings against others to enforce our patents or trademarks, to protect our trade secrets or know- how, or to determine the enforceability, scope and validity of the proprietary rights of others. These proceedings would result in substantial expense to us and significant diversion of effort by our technical and management personnel. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. We may not be able to stop a competitor from marketing and selling products that are the same or

similar to our products or from using product names that are the same or similar to our product names, and our business may be harmed as a result. We are aware of patents held by third parties that may be asserted against us in litigation that could be costly and could limit our ability to sell our Lumivascular platform products. We are aware of patent families related to catheter positioning, optical coherence tomography, occlusion cutting and atherectomy owned by third parties. With regard to atherectomy patents, one of our founders, Dr. John Simpson, founded FoxHollow Technologies prior to founding our company. FoxHollow Technologies developed an atherectomy device that is currently sold by Medtronic, and Dr. Simpson and our Chief Technology Officer, Himanshu Patel, are listed as inventors on patents covering that device that are now held by Medtronic. We are not currently aware of any claims Medtronic has made or intends to make against us with respect to Pantheris or any other product or product under development. Because of a doctrine known as " assignor estoppel, " if any of Dr. Simpson' s earlier patents are asserted against us by Medtronic, we may be prevented from asserting an invalidity defense regarding those patents, and our defense may be compromised. Medtronic has significantly greater financial resources than we do to pursue patent litigation and could assert these patent families against us at any time. Adverse determinations in any such litigation could prevent us from manufacturing or selling Pantheris or other products or products under development, which would significantly harm our business. Intellectual property rights may not provide adequate protection, which may permit third parties to compete against us more effectively. In order to remain competitive, we must develop and maintain protection of the proprietary aspects of our technologies. We rely on a combination of patents, copyrights, trademarks, trade secret laws and confidentiality and invention assignment agreements to protect our intellectual property rights. As of December 31, ~~2022~~ **2023** , we held ~~54~~ **64** issued and allowed U. S. patents, 1 U. S. pending provisional application, ~~22~~ **18** U. S. utility patent applications and ~~4~~ **3** PCT applications pending. As of December 31, ~~2022~~ **2023** , we also had ~~84~~ **83** issued and allowed patents from outside of the United States. As of December 31, ~~2022~~ **2023** , we had ~~35~~ **22** pending patent applications outside of the United States, including in Australia, Canada, China, Europe, India, Japan and Mexico. Our patents and patent applications include claims covering key aspects of the design, manufacture and therapeutic use of OCT imaging catheters, occlusion- crossing catheters, atherectomy devices and our imaging console. Our patent applications may not result in issued patents and our patents may not be sufficiently broad to protect our technology. Any patents issued to us may be challenged by third parties as being invalid, or third parties may independently develop similar or competing technology that avoids our patents. Should such challenges be successful, competitors might be able to market products and use manufacturing processes that are substantially similar to ours. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by consultants, vendors or former or current employees, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be adequate. In addition, the laws of many foreign countries will not protect our intellectual property rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to international markets or require costly efforts to protect our technology. To the extent our intellectual property protection is incomplete, we are exposed to a greater risk of direct competition. In addition, competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our Lumivascular platform, brand and business. We use certain open source software in all versions of our Lightbox. We may face claims from companies that incorporate open source software into their products or from open source licensors, claiming ownership of, or demanding release of, the source code, the open source software or derivative works that were developed using such software, or otherwise seeking to enforce the terms of the applicable open source license. These claims could result in litigation and could require us to cease offering Lightbox unless and until we can re- engineer it to avoid infringement. This re- engineering process could require significant additional research and development resources, and we may not be able to complete it successfully. These risks could be difficult to eliminate or manage, and, if not addressed, could harm our business, financial condition and operating results. Regulatory and Litigation Risks If we fail to obtain and maintain necessary regulatory clearances or approvals for our Lumivascular platform products, or if clearances or approvals for future products and indications are delayed or not issued, our commercial operations would be harmed. Our Lumivascular platform products are medical devices that are subject to extensive regulation by FDA in the United States and by regulatory agencies in other countries where we do business. Government regulations specific to medical devices are wide- ranging and govern, among other things: ● product design, development and manufacture; ● laboratory, preclinical and clinical testing, labeling, packaging, storage and distribution; ● pre- marketing clearance or approval; ● record keeping; ● product marketing, promotion and advertising, sales and distribution; and ● post- marketing surveillance, including reporting of deaths or serious injuries and recalls and correction and removals. Before a new medical device, or a new intended use for, an existing product can be marketed in the United States, a company must first submit and receive either 510 (k) clearance or pre- marketing approval from FDA, unless an exemption applies. Either process can be expensive, lengthy and unpredictable. We may not be able to obtain the necessary clearances or approvals or may be unduly delayed in doing so, which could harm our business. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. Although we have obtained 510 (k) clearance to market our Pantheris family of catheters for atherectomy, and our Ocelot and Tigereye family of catheters for crossing sub and total occlusions in the peripheral vasculature, our clearance can be revoked if safety or efficacy problems develop. Delays in obtaining clearance or approval could increase our costs and harm our revenues and growth. In addition, we are required to timely file various reports with the FDA, including medical device reports, or MDRs, if our devices may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If these MDRs are not filed timely, regulators may impose sanctions and sales of our products may suffer, and we may be subject to product liability or regulatory

enforcement actions, all of which could harm our business. If we initiate a correction or removal for one of our devices to reduce a risk to health posed by the device, we would be required to submit a publicly available Correction and Removal report to the FDA and in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall that could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our devices. Furthermore, the submission of these reports has been and could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm our reputation. The FDA and the Federal Trade Commission, or FTC, also regulate the advertising and promotion of our products to ensure that the claims we make are consistent with our regulatory clearances, that there are adequate and reasonable scientific data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or FTC determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including Warning Letters, adverse publicity, and we may be required to revise our promotional claims and make other corrections or restitutions. The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include, among other things, harm to our reputation; fines, injunctions, civil penalties, or criminal prosecution; product replacements or recalls; or rejecting our requests for future 510 (k) clearance or pre- market approval or withdrawal of a previously granted 510 (k) clearance. If any of these events were to occur, our business and financial condition would be harmed. Material modifications to our Lumivascular platform products may require new 510 (k) clearances or pre-market approvals or may require us to recall or cease marketing our Lumivascular platform products until clearances or approvals are obtained. Material modifications to the intended use or technological characteristics of our Lumivascular platform products will require new 510 (k) clearances or pre- market approvals or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained if such changes were made via the " Letter- to- File " process of internal documentation. Based on published FDA guidelines, the FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance; however, the FDA can review a manufacturer' s decision. Any modification to an FDA- cleared device that would significantly affect its safety or efficacy or that would constitute a major change in its intended use would require a new 510 (k) clearance or possibly a pre- market approval. We may not be able to obtain additional 510 (k) clearances or pre- market approvals for new products or for modifications to, or additional indications for, our Lumivascular platform products in a timely fashion, or at all. Delays in obtaining required future clearances would harm our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. We have made modifications to our Lumivascular platform products in the past and will make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop selling or marketing our Lumivascular platform products as modified, which could harm our operating results and require us to redesign our Lumivascular platform products. In these circumstances, we may be subject to significant enforcement actions. Future versions of are Lumivascular platform incorporating enhancements may require additional regulatory clearances or approvals. Our ability to market our current products in the United States is limited to use in peripheral vessels, and if we want to market our products for other uses, we will need to file for FDA clearances or approvals and may need to conduct trials to support expanded use, which would be expensive, time- consuming and may not be successful. Our current products are cleared in the United States only for crossing sub- total and chronic total occlusions and for performing atherectomy in the peripheral vasculature. These FFDCA clearances prohibits us from marketing or advertising our products for any other indication within the peripheral vasculature, which restricts our ability to sell these products and could affect our growth. Additionally, our products are contraindicated for use in the cerebral, carotid, coronary, iliac, and renal arteries. While off- label use of medical devices is common and the FDA does not regulate physicians' choice of treatments, the FDA does restrict a manufacturer' s communications regarding such off- label use. We are not allowed to actively promote or advertise our products for off- label use. In addition, we cannot make comparative claims regarding the use of our products against any alternative treatments without conducting head- to- head comparative clinical studies, which would be expensive and time consuming. If our promotional activities fail to comply with the FDA' s regulations or guidelines, we may be subject to warnings or enforcement action by the FDA and other government agencies. In the future, if we want to market a variation of Ocelot, Tigereye or Pantheris product families in the United States for use in other applications for which we do not currently have clearance, such as the coronary arteries, we will need to make modifications to these products, conduct further clinical trials and obtain new clearances or approvals from the FDA. There can be no assurance that we will successfully develop these modifications, that future clinical studies will be successful or that the expense of these activities will be offset by additional revenues. If our clinical trials are unsuccessful or significantly delayed, or if we do not complete our clinical trials, our business may be harmed. Clinical development is a long, expensive, and uncertain process and is subject to delays and the risk that products may ultimately prove unsafe or ineffective in treating the indications for which they are designed. Completion of clinical trials may take several years or more and failure of the trial can occur at any time. We cannot provide any assurance that our clinical trials will meet their primary endpoints or that such trials or their results will be accepted by the FDA or foreign regulatory authorities. Even if we achieve positive early or preliminary results in clinical trials, these results do not necessarily predict final results, and positive results in early trials may not indicate success in later trials. Many companies in the medical device industry have suffered significant setbacks in late- stage clinical trials, even after receiving promising results in earlier trials or in the preliminary results from these late- stage clinical trials. We may experience numerous unforeseen events during, or because of, the clinical trial process that could delay or prevent us from receiving regulatory clearance or approval for new products or modifications of existing products, including new indications for existing products, including: ● negative or inconclusive results that may cause us to decide, or regulators may require us, to conduct additional clinical and / or preclinical testing which may be

expensive and time consuming; ● trial results that do not meet the level of statistical significance required by the FDA or other regulatory authorities; ● findings by the FDA or similar foreign regulatory authorities that the product is not sufficiently safe for investigational use in humans; ● interpretations of data from preclinical testing and clinical testing by the FDA or similar foreign regulatory authorities that may be different from our own; ● delays or failure to obtain approval of our clinical trial protocols from the FDA or other regulatory authorities; ● delays in obtaining institutional review board approvals or government approvals to conduct clinical trials at prospective sites; ● findings by the FDA or similar foreign regulatory authorities that our or our suppliers' manufacturing processes or facilities are unsatisfactory; ● changes in the review policies of the FDA or similar foreign regulatory authorities or the adoption of new regulations that may negatively affect or delay our ability to bring a product to market or receive approvals or clearances to treat new indications; ● trouble in managing multiple clinical sites; ● delays in agreeing on acceptable terms with third- party research organizations and trial sites that may help us conduct the clinical trials; and ● the suspension or termination by us, or regulators, of our clinical trials because the participating patients are being exposed to unacceptable health risks. Failures or perceived failures in our clinical trials will delay and may prevent our product development and regulatory approval process, damage our business prospects and negatively affect our reputation and competitive position. From time to time, we engage outside parties to perform services related to certain of our clinical studies and trials, and any failure of those parties to fulfill their obligations could increase costs and cause delays. From time to time, we engage consultants to help design, monitor, and analyze the results of certain of our clinical studies and trials. The consultants we engage interact with clinical investigators to enroll patients in our clinical trials. We depend on these consultants and clinical investigators to help facilitate the clinical studies and trials and monitor and analyze data from these studies and trials under the investigational plan and protocol for the study or trial and in compliance with applicable regulations and standards, commonly referred to as good clinical practices. We may face delays in our regulatory approval process if these parties do not perform their obligations in a timely, compliant or competent manner. If these third parties do not successfully carry out their duties or meet expected deadlines, or if the quality, completeness or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical trial protocols or for other reasons, our clinical studies or trials may be extended, delayed or terminated or may otherwise prove to be unsuccessful, and we may have to conduct additional studies, which would significantly increase our costs, in order to obtain the regulatory clearances that we need to commercialize our products. We have limited long- term data regarding the safety and efficacy of our Lumivascular platform products ~~, including Pantheris~~ . Any long- term data that is generated by clinical trials involving our Lumivascular platform may not be positive or consistent with our short- term data, which would harm our ability to obtain clearance to market and sell our products. Our Lumivascular platform is a novel system, and our success depends on its acceptance by the medical community as being safe and effective, and improving clinical outcomes. Important factors upon which the efficacy of our Lumivascular platform products, including Pantheris, will be measured are long- term data on the rate of restenosis following our procedure, and the corresponding duration of patency, or openness of the artery, and publication of that data in peer- reviewed journals. Another important factor that physicians will consider is the rate of reintervention, or retreatment, following the use of our Lumivascular platform products. The long- term clinical benefits of procedures that use our Lumivascular platform products are not known. The results of short- term clinical experience of our Lumivascular platform products do not necessarily predict long- term clinical benefit. Restenosis rates typically increase over time. We believe that physicians will compare the rates of long- term restenosis and reintervention for procedures using our Lumivascular platform products against alternative procedures, such as angioplasty, stenting, bypass surgery and other atherectomy procedures. If the long- term rates of restenosis and reintervention do not meet physicians' expectations, our Lumivascular platform products may not become widely adopted and physicians may consider alternative treatments for their patients. Another significant factor that physicians will consider is acute safety data on complications that occur during the use of our Lumivascular platform products. If the results obtained from any post- market studies that we conduct or post- clearance surveillance indicate that the use of our Lumivascular platform products are not as safe or effective as other treatment options or as current short- term data would suggest, adoption of our product may suffer and our business would be harmed. In addition, we are responsible for the costs associated with conducting studies to obtain safety and efficacy data. If we are unable to obtain sufficient financing, whether through our operations or from third parties, we will not be able to conduct the studies necessary to obtain long- term data regarding the safety and efficacy of our products. Even if we believe the data collected from clinical studies or clinical experience indicate positive results, each physician' s actual experience with our products will vary. Physicians who are technically proficient participate in our clinical trials and are high- volume users of our Lumivascular platform products. Consequently, the results of our clinical trials and their experiences using our products may lead to better patient outcomes than those of physicians that are less proficient, perform fewer procedures or who use our products infrequently. If we or our suppliers fail to comply with the FDA' s QSR, our manufacturing operations could be delayed or shut down and Lumivascular platform sales could suffer. Our manufacturing processes and those of our third- party suppliers are required to comply with the FDA' s QSR, which covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our Lumivascular platform products. We are also subject to similar state requirements and licenses. In addition, we must engage in extensive recordkeeping and reporting and must make available our manufacturing facilities and records for periodic unannounced inspections by governmental agencies, including the FDA, state authorities and comparable agencies in other countries. If we fail a QSR inspection, our operations could be disrupted and our manufacturing interrupted. Failure to take adequate corrective action in response to an adverse QSR inspection could result in, among other things, a shut- down of our manufacturing operations, significant fines, suspension of marketing clearances and approvals, seizures or recalls of our device, operating restrictions and criminal prosecutions, any of which would cause our business to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays for our products and cause our revenues to decline. We have registered with the FDA as a medical device manufacturer and have obtained a

manufacturing license from the CDPH. The FDA has broad post- market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of CDPH to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our suppliers. We have undergone numerous audits, inspections, and reviews by the FDA, CDPH, and BSI, our European Notified Body, in the past, some of which resulted in the identification of instances of non- compliance which we were required to correct. We expect that we will undergo additional audits, inspections, and reviews in the future, which could result in further corrective actions. We can provide no assurance that we will continue to remain in substantial compliance with the QSR. If the FDA, CDPH or BSI inspect our facility and discover major compliance problems, we may have to shut down our facility and cease manufacturing until we can take the appropriate remedial steps to correct the audit findings. Taking corrective action may be expensive, time consuming and a distraction for management and if we experience a shutdown or delay at our manufacturing facility, we may be unable to produce our Lumivascular platform products, which would harm our business. Our Lumivascular platform products may in the future be subject to product recalls that could harm our reputation. FDA and similar governmental authorities in other countries have the authority to require the recall of commercialized products in the event of material regulatory deficiencies or defects in design or manufacture. A government mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design or labeling defects. Recalls of our Lumivascular platform products or products we commercialize in the future would divert managerial attention, be expensive, harm our reputation with customers and harm our financial condition and results of operations. A recall announcement would negatively affect our stock price. Changes in coverage and reimbursement for procedures using our Lumivascular platform products could affect the adoption of our Lumivascular platform and our future revenues. Currently, our Lumivascular platform procedure is typically reimbursed by third- party payors, including Medicare and private healthcare insurance companies, under existing reimbursement codes. These payors may change their coverage and reimbursement policies, as well as payment amounts, in a way that would prevent or limit reimbursement for our products, which would significantly harm our business. Also, healthcare reform legislation or regulation may be proposed or enacted in the future, which may adversely affect such policies and amounts. We cannot predict whether and to what extent existing coverage and reimbursement will continue to be available. If physicians, hospitals and other providers are unable to obtain adequate coverage and reimbursement for procedures performed using our Lumivascular platform products, they are significantly less likely to use our Lumivascular platform products and our business would be harmed. Healthcare reform measures could hinder or prevent our planned products' commercial success. In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system in ways that could harm our future revenues and profitability and the future revenues and profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. The current presidential administration and Congress may continue to attempt broad sweeping changes to the current healthcare laws. We face uncertainties that might result from modifications or repeal of any of the provisions of the Affordable Care Act, including as a result of current and future executive orders and legislative actions. The impact of those changes on us and potential effect on the medical device industry as a whole is currently unknown. Any changes to the Affordable Care Act are likely to have an impact on our results of operations and may have a material adverse effect on our results of operations. We cannot predict what other healthcare programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the United States may have on our business. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may harm: ● our ability to set a price that we believe is fair for our products; ● our ability to generate revenues and achieve or maintain profitability; and ● the availability of capital. If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third- party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We are subject to many healthcare fraud and abuse and patient privacy regulations by both the federal government and the states in which we conduct our business. The regulations that affect how we operate include: ● the federal healthcare program Anti- Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs; ● the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government; ● federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; ● the Sunshine Act, created under the Affordable Care Act, and its implementing regulations, which require manufacturers of drugs, medical devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid, or the Children' s Health Insurance Program to report annually to the HHS information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; ● HIPAA, as amended by the HITECH Act, which protects the security and privacy of protected 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 payor, including commercial insurers. The Affordable Care Act, among other things, amends the intent requirement of the Federal Anti- Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the Federal Anti- Kickback

Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could harm our ability to operate our business and our results of operations. In addition, the clearance or approval and commercialization of any of our products outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. Compliance with environmental laws and regulations could be expensive. Failure to comply with environmental laws and regulations could subject us to significant liability. Our research and development and manufacturing operations involve the use of hazardous substances and are subject to a variety of federal, state, local and foreign environmental laws and regulations relating to the safe storage, use, discharge, disposal, remediation of, and human exposure to, hazardous substances and the sale, labeling, collection, recycling, treatment and disposal of products containing hazardous substances, such as isopropyl alcohol and other solvents. In addition, our research and development may acquire biological waste materials, such as human and animal tissue, for the sole use of product design testing. Upon completion of the product testing, these biological wastes are safely disposed of following all federal, state, local and foreign environmental laws and regulations. These operations are permitted by regulatory authorities, and the resultant waste materials are disposed of in material compliance with environmental laws and regulations. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence. Compliance with environmental laws and regulations may be expensive and non- compliance could result in substantial liabilities, fines and penalties, personal injury and third- party property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could harm our financial condition and operating results. The use, misuse or off- label use of the products in our Lumivascular platform may result in injuries that lead to product liability suits, which could be costly to our business. We require limited training in the use of our Lumivascular platform products because we market primarily to physicians who are experienced in the interventional techniques required to use our device. If demand for our Lumivascular platform continues to grow, less experienced physicians will likely use the devices, potentially leading to more injury and an increased risk of product liability claims. The use or misuse of our Lumivascular platform products has in the past resulted, and may in the future result, in complications, including damage to the treated artery, infection, internal bleeding, and limb loss, potentially leading to product liability claims. Our Lumivascular platform products are contraindicated for use in the carotid, cerebral, iliac, or renal arteries. Our sales force does not promote the use of our products for off- label indications, and our U. S. instructions for use specify that our Lumivascular platform products are not intended for use in the carotid, cerebral, coronary, iliac or renal arteries. However, we cannot prevent a physician from using our Lumivascular platform products for these off- label applications. The application of our Lumivascular platform products to coronary arteries, as opposed to peripheral arteries, is more likely to result in complications that have serious consequences. For example, if excised plaque were not captured properly in our device, it could be carried by the bloodstream to a narrower location, blocking a coronary artery, leading to a heart attack, or blocking an artery to the brain, leading to a stroke. If our Lumivascular platform products are defectively designed, manufactured or labeled, contain defective components or are misused, we may become subject to costly litigation initiated by our customers or their patients. Product liability claims are especially prevalent in the medical device industry and could harm our reputation, divert management' s attention from our core business, be expensive to defend and may result in sizable damage awards against us. Although we maintain product liability insurance, the amount or breadth of our coverage may not be adequate for the claims that are made against us. The expense and potential unavailability of insurance coverage for liabilities resulting from our products could harm us and our ability to sell our Lumivascular platform products. We may not have sufficient insurance coverage for future product liability claims. We may not be able to obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our reputation in the industry, significantly increase our expenses, and reduce product sales. Product liability claims in excess of our insurance coverage would be paid out of cash reserves, harming our financial condition and operating results. Some of our customers and prospective customers may have difficulty in procuring or maintaining liability insurance to cover their operations and use of our Lumivascular platform products. Medical malpractice carriers are also withdrawing coverage in certain states or substantially increasing premiums. If this trend continues or worsens, our customers may discontinue using our Lumivascular platform products and potential customers may opt against purchasing our Lumivascular platform products due to the cost or inability to procure insurance coverage. Our stock price may be volatile, and purchasers of our common stock could incur substantial losses. Our stock price has fluctuated significantly since our IPO and is likely to continue to fluctuate substantially. As a result of this price fluctuation, investors may experience losses on their investments in our stock. In addition, the development stage of our operations may make it difficult for investors to evaluate the success of our business to date and to assess our future viability. The market price for our common stock may be influenced by many factors, including: ● sales of stock by our existing stockholders, including our affiliates; ● market acceptance of our Lumivascular platform and products; ● the results of our clinical trials; ● changes in analysts' estimates, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts' and our own estimates; ● the financial projections we

may provide to the public, any changes in these projections or our failure to meet these projections; ● actual or anticipated fluctuations in our financial condition and operating results; ● quarterly variations in our or our competitors' results of operations; ● general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors; ● changes in operating performance and stock market valuations of other technology companies generally, or those in the medical device industry in particular; ● the loss of key personnel, including changes in our board of directors and management; ● legislation or regulation of our business; ● lawsuits threatened or filed against us; ● the announcement or approvals of new products or product enhancements by us or our competitors; ● announcements related to patents issued to us or our competitors and to litigation; and ● developments in our industry. From time to time, our affiliates may sell stock for reasons due to their personal financial circumstances. These sales may be interpreted by other stockholders as an indication of our performance and result in subsequent sales of our stock that have the effect of creating downward pressure on the market price of our common stock. In addition, the stock prices of many companies in the medical device industry have experienced wide fluctuations that have often been unrelated to the operating performance of those companies. The market price and trading volume of our common stock has been volatile over the past year, and it may continue to be volatile. During the year ended December 31, ~~2022~~ **2023**, our common stock has closed as low as $ ~~0~~ **2**. ~~96~~ **61** and as high as $ ~~10~~ **22**. ~~20~~ **95** per share. We cannot predict the price at which our common stock will trade in the future and it may decline. The price at which our common stock trades may fluctuate significantly and may be influenced by many factors, including our financial results; developments generally affecting our industry; general economic, industry and market conditions; the depth and liquidity of the market for our common stock; investor perceptions of our business; reports by industry analysts; announcements by other market participants, including, among others, investors, our competitors, and our customers; regulatory action affecting our business; and the impact of other " Risk Factors " discussed in this Annual Report. In addition, changes in the trading price of our common stock may be inconsistent with our operating results and outlook. The volatility of the market price of our common stock may adversely affect investors' ability to purchase or sell shares of our common stock. We may fail to meet our publicly announced guidance or other expectations about our business and future operating results, which would cause our stock price to decline. We have provided in the past and may provide guidance in the future about our business and future operating results. In developing this guidance, our management must make certain assumptions and judgments about our future performance, including projected revenues and the timing of regulatory approvals. Furthermore, analysts and investors may develop and publish their own projections of our business, which may form a consensus about our future performance. Our business results may vary significantly from such guidance or that consensus due to a number of factors, many of which are outside of our control, and which could adversely affect our operations and operating results. Furthermore, if we make downward revisions of our previously announced guidance, or if our publicly announced guidance of future operating results fails to meet expectations of securities analysts, investors or other interested parties, the price of our common stock would decline. If securities or industry analysts do not publish research or reports about our business, or publish negative reports about our business, our share price and trading volume could decline. The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business, our market and our competitors. We do not have any control over these analysts. The analysts who previously published research reports on our stock following our IPO have discontinued coverage. We do not currently have analyst coverage. If analysts do not begin regularly publishing reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline. Sales of a substantial number of shares of our common stock in the public market, including by our existing stockholders, could cause our stock price to fall. Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that these sales and others may have on the prevailing market price of our common stock. We will need to raise additional funds through future equity or debt financings to meet our operational needs and capital requirements for product development, clinical trials and commercialization. We can provide no assurance that we will be successful in raising funds pursuant to additional equity or debt financings or that such funds will be raised at prices that do not create substantial dilution for our existing stockholders. Given our stock price, any financing that we undertake in the future could cause substantial dilution to our existing stockholders. On March 28, 2022, we filed a universal shelf registration statement (the " Shelf Registration Statement ") to offer up to $ 50. 0 million of our securities, which expires on March 29, 2025. On May 20, 2022, we entered into an " at- the- market " agreement pursuant to which we may offer and sell shares of our common stock pursuant to the Shelf Registration Statement. ~~On August 3, 2022, we suspended the offer and sale of our common stock under our at- the- market program but may engage in such activity in the future.~~ Due to the SEC' s " baby shelf rules, " which prohibit companies with a public float of less than $ 75 million from issuing securities under a shelf registration statement in excess of one- third of such company' s public float in a twelve- month period, we are limited in our ability to use the Shelf Registration Statement. Our directors and employees may sell our stock through 10b5- 1 trading plans or in the market during open windows under our insider trading policy without such plans in place. Sales of our common stock by our directors and employees could be perceived negatively by investors or cause downward pressure on our common stock and cause a reduction in the price of our common stock as a result. We have also registered shares of our common stock that we may issue under our employee equity incentive plans. These shares will be able to be sold freely in the public market upon issuance. The requirements of being a public company may strain our resources, divert management' s attention and affect our ability to attract and retain executive management and qualified board members. As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes- Oxley Act, the Dodd- Frank Act, the listing requirements of Nasdaq and other applicable securities laws, rules and regulations. Compliance with these laws, rules and regulations have increased our legal and financial compliance costs and will make some activities more difficult, time- consuming or costly and increase demand on our systems and resources, particularly after we are no longer an " emerging

growth company. ” The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. The Sarbanes- Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. Our management and other personnel now need to devote a substantial amount of time to these compliance initiatives. As a result, management' s attention may be diverted from other business concerns and our costs and expenses will increase, which could harm our business and operating results. We may need to hire more employees in the future or engage outside consultants to comply with these requirements, which will increase our costs and expenses. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management' s time and attention from revenue- generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. We will incur additional compensation costs in the event that we decide to pay our executive officers cash compensation closer to that of executive officers of other public medical device companies, which would increase our general and administrative expense and could harm our profitability. Any future equity awards will also increase our compensation expense. We also expect that being a public company and compliance with applicable rules and regulations will make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified executive officers and members of our board of directors, particularly to serve on our audit committee and compensation committee. As a result of disclosure of information in this Annual Report on Form 10- K and in other filings required of a public company, our business and financial condition will become more visible, which could be advantageous to our competitors and clients and could result in threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business and operating results could be harmed, and even if the claims are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and harm our business and operating results. Nasdaq may delist our securities from its exchange, which could harm our business and limit our stockholders' liquidity. Our common stock is currently listed on the Nasdaq Capital Market (“ Nasdaq ”), which has qualitative and quantitative listing criteria. However, we cannot assure you that our common stock will continue to be listed on Nasdaq in the future. In order to continue listing our common stock on Nasdaq, we must maintain certain financial, distribution and stock price levels. Generally, we must maintain a minimum amount in stockholders' equity, a minimum number of holders of our common stock and a minimum bid price. ~~In particular~~ **On April 25** , **2023, we received notice (the “ Bid Price Deficiency Letter ”) from the Listing Qualifications Department (the “ Staff ”) of The Nasdaq Stock Market, LLC (“ Nasdaq ”) notifying us that we were not in compliance with** Nasdaq Listing Rule 5550 (a) **(2) (the “ Bid Price Requirement ”), as the minimum bid price for our listed securities was less than $ 1. 00 for the previous 30 consecutive business days. We had a period of 180 calendar days, or until October 23, 2023, to regain compliance with the rule referred to in this paragraph. As part of our efforts to regain compliance with the aforementioned rule, we effected a 1- for- 15 reverse stock split on September 12, 2023. On September 27, 2023, we received a letter from Nasdaq notifying us that the Staff had determined that the closing bid price of our common stock had been at $ 1. 00 per share or greater for at least 10 consecutive business days** and **, accordingly, that we had regained compliance with the Bid Price Requirement. While we have regained compliance with the Bid Price Requirement, there can be no assurance that we will be able to maintain compliance with the Bid Price Requirement, or other continued listing requirements of Nasdaq, in the future. On May 18, 2023, we received notice (the “ Stockholders' Equity Deficiency Letter ”) from the Staff that we no longer satisfy the $ 2. 5 million stockholders' equity requirement for continued listing on The Nasdaq Capital Market, or the alternatives to that requirements – a $ 35 million market value of listed securities or $ 500, 000 in net income in the most recent fiscal year or two of the last three fiscal years – as required by Nasdaq Listing Rule** 5550 (b) (~~1~~ **the “ Equity Requirement ”**) ~~require us~~ **. As with the Bid Price Deficiency Letter, the Stockholders' Equity Deficiency Letter had no immediate effect on our continued listing on The Nasdaq Capital Market. In accordance with the Nasdaq Listing Rules, we were provided 45 calendar days, or until July 3, 2023,** to ~~maintain~~ **submit** a **plan to regain** ~~minimum stockholders' equity of $ 2. 5 million. While we are currently in~~ compliance with **the Equity Requirement (the “ Compliance Plan ”). We submitted the Compliance Plan to Nasdaq on July 3, 2023. On July 31, 2023, we received a letter from Nasdaq notifying us that the Staff had determined to grant us an extension of 180 calendar days from the date of the Staff' s notice, or November 14, 2023, to regain compliance with the Equity Requirement. On November 21, 2023, the Staff formally notified us that the Staff had determined that we were unable to demonstrate compliance with the Equity Requirement and that our securities would be delisted at the open of business on November 30, 2023, unless we timely requested a hearing before the Nasdaq Hearings Panel (the “ Panel ”). On November 28, 2023, we requested and were granted a hearing before the Panel which took place on February 20, 2024. At the hearing, we presented a plan to regain and sustain compliance with the Equity Requirement and requested an extension to do so. On March 14, 2024, the results from the hearing were rendered in which we were granted an extension by the Panel.** ~~this~~ **This** ~~rule~~ **extension stayed any further action by**

Nasdaq with respect to our continued listing until May 20, 2024. We anticipate we will need to issue additional shares of capital stock through various other financing transactions in order to regain compliance with the Equity Requirement. However , we may not be ~~able~~ **successful in executing such transactions on terms favorable** to ~~maintain~~ **us, or at all. In addition, there can be no guarantee that such efforts will succeed in helping us regain** compliance ~~in~~ **with** the ~~future~~ **Nasdaq Listing Rules** . **There can be no assurance that** ~~We have, since our inception, incurred net losses and expect~~ we will **evidence compliance within the extension period** ~~continue to incur net losses. The decline in our equity is a direct result of our net loss. As we continue to incur losses, our accumulated deficit will continue to increase, which will have a negative impact on our equity balance. Therefore, if we do not continually raise funds through various equity offerings~~ that **was granted** ~~have an accretive value to our equity, our equity balances will continue to decline. If we are unable to raise capital in a manner that provides accretive value to our equity, our stockholders' equity may decrease below the minimum required~~ by **the Panel** ~~Nasdaq, which could result in Nasdaq delisting our common stock~~ . If Nasdaq delists our common stock from trading on its exchange and we are not able to list our securities on another national securities exchange, we expect our securities could be quoted on an over- the- counter market. If this were to occur, we could face significant material adverse consequences, including: ● a limited availability of market quotations for our securities; ● reduced liquidity for our securities; ● a determination that our common stock is a " penny stock " which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities; ● a limited amount of news and analyst coverage; and ● a decreased ability to issue additional securities or obtain additional financing in the future. The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as " covered securities. " If our common stock continues to be listed on NASDAQ, our common stock will be a covered security. Although the states are preempted from regulating the sale of our securities, the federal statute does allow the states to investigate companies if there is a suspicion of fraud, and, if there is a finding of fraudulent activity, then the states can regulate or bar the sale of covered securities in a particular case. Anti- takeover provisions in our amended and restated certificate of incorporation and bylaws and Delaware law could discourage a takeover. Our amended and restated certificate of incorporation and bylaws contain provisions that might enable our management to resist a takeover. These provisions include: ● a classified board of directors; ● advance notice requirements applicable to stockholders for matters to be brought before a meeting of stockholders and requirements as to the form and content of a stockholder' s notice; ● a supermajority stockholder vote requirement for amending certain provisions of our amended and restated certificate of incorporation and bylaws; ● the right to issue preferred stock without stockholder approval, which could be used to dilute the stock ownership of a potential hostile acquirer; ● allowing stockholders to remove directors only for cause; ● a requirement that the authorized number of directors may be changed only by resolution of the board of directors; ● allowing all vacancies, including newly created directorships, to be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum, except as otherwise required by law; ● a requirement that our stockholders may only take action at annual or special meetings of our stockholders and not by written consent; ● limiting the forum for certain litigation against us to Delaware; and ● limiting the persons that can call special meetings of our stockholders to our board of directors, the chairperson of our board of directors, the chief executive officer or the president (in the absence of a chief executive officer). These provisions might discourage, delay or prevent a change in control of our company or a change in our management. The existence of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors might be willing to pay in the future for shares of our common stock. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any " interested " stockholder for a period of three years following the date on which the stockholder became an " interested " stockholder. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers or other employees to us or to our stockholders, (iii) any action asserting a claim arising pursuant to the Delaware General Corporation Law or our certificate of incorporation or bylaws (iv) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws, or (v) any action asserting a claim governed by the internal affairs doctrine. This exclusive forum provision would not apply to suits brought to enforce any liability or duty created by the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. This choice of forum provision may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers or employees. If a court were to find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could have a material adverse effect on our business, financial condition, results of operations and prospects. We have not paid cash dividends in the past and do not expect to pay cash dividends in the future, and any return on investment may be limited to the value of our stock. We have never paid cash dividends and do not anticipate paying cash dividends in the foreseeable future. The payment of dividends will depend on our

earnings, capital requirements, financial condition, prospects and other factors our board of directors may deem relevant. In addition, our Loan Agreement with CRG prohibits us from, among other things, paying any dividends or making any other distribution or payment on account of our common stock. The terms of our Series A preferred stock, Series B preferred stock and Series ~~D~~ **E** preferred stock provide that we may not pay dividends on our common stock without concurrently declaring dividends on each. If we do not pay dividends, our stock may be less valuable because a return on your investment will only occur if you sell our common stock after our stock price appreciates. For more information on restrictions governing our ability to pay dividends, see the section titled " Dividend Policy " below. CRG has the ability to exert significant control over matters pursuant to the protective provisions therein as well as the covenants and other restrictions in the Loan Agreement. **Our** ~~Even though~~ Series ~~A~~ **E** preferred stock ~~is non- voting stock, our governing documents, as~~ **has** ~~amended, have~~ protective provisions that will require CRG to consent to certain significant Company events. For example, CRG' s consent would be necessary to create additional shares of Series ~~A~~ **E** preferred stock, amend our organizational documents, or approve any merger, sale of assets, or other major corporate transaction. This consent requirement could delay or prevent any acquisition of our company on terms that other stockholders may desire, and may adversely affect the market price of our common stock **. Zylox- Tonbridge has the ability to exert significant control over our business due to their substantial interest in us, as well as their relationship with us through the license agreement and collaboration agreement previously entered into. In connection with their entry into the license agreement and collaboration agreement, Zylox- Tonbridge purchased securities, including common stock and Series F preferred stock, from us representing approximately 19. 9 % of our outstanding voting power. If stockholder approval is obtained relating to the conversion of the Series F preferred stock, their ownership interest could represent up to 49. 9 % of our outstanding voting power. In addition, we are subject to a number of covenants and agreements under the license agreement and collaboration agreement, which could allow Zylox- Tonbridge to exercise influence over our business. In addition, our Series F preferred stock has protective provisions that will require Zylox- Tonbridge to consent to certain significant Company events. For example, Zylox- Tonbridge' s consent would be necessary to create additional shares of Series F preferred stock, amend our organizational documents, or approve any merger, sale of assets, or other major corporate transaction. This consent requirement could delay or prevent any acquisition of our company on terms that other stockholders may desire, and may adversely affect the market price of our common stock. Zylox- Tonbridge' s interests may conflict with your interests as a stockholder. Zylox- Tonbridge' s ability to influence our business could make some transactions, including mergers or other changes in control, more difficult or impossible without the support of Zylox- Tonbridge and could discourage others from making tender offers, which could prevent stockholders from receiving a premium for their shares. As a result, the market price of our common stock may be affected** . We depend on our board of directors and the loss of one or more or our board members or an inability to attract and retain highly qualified members could harm our business. Our success largely depends upon the continued services and involvement of the members of our board of directors and the loss of one or more of our directors could adversely affect us. Additionally, changes in the composition of our board resulting from the addition or departure of members could disrupt our business. We must attract and retain highly qualified board members. Competition for these individuals can be intense. We have, from time to time, experienced, and we may experience in the future, difficulty in adding and retaining members of our board with appropriate qualifications. In addition, some states and other regulatory authorities, including Nasdaq, have adopted board diversity requirements, which mandate that companies have a minimum number of directors who meet specified diversity criteria, or otherwise require that companies disclose board diversity information. If we are unable to attract and retain qualified board members who meet such diversity criteria, we will be unable to comply with such requirements and could face enforcement or other regulatory actions. ~~49~~