

Risk Factors Comparison 2025-03-27 to 2024-03-26 Form: 10-K

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

~~Investing~~ You should carefully consider the following risk factors in evaluating our business. Such risks could cause our actual results to differ materially from those that are expressed ~~our~~ or implied by the forward- looking statements contained herein. Some risks relate principally to our business and the industry in which we operate. Others relate principally to the ~~securities~~ market and ownership involves a high degree of our common stock. The risk risks and uncertainties described below are not the only ones we face. Before you decide to invest in ~~Additional risks and uncertainties of which we are unaware, our~~ or securities that we currently deem immaterial, you also may become important factors that affect us. Any of the following risks could result in material adverse impacts on our business, financial condition, or results of operations. You also should consider carefully the risks described below, together with the other information ~~contained~~ included in this Annual Report on Form 10- K, including our financial statements and the related notes appearing at the end of this Annual Report on Form 10- K. ~~We believe,~~ as well as our ~~the~~ other filings with the SEC. **Summary of Risk Factors Our business is subject to numerous risks described, which are discussed more fully below are.** **The following is a summary of the principal risks- risk that are factors we deem material to us our business as of the date of this Annual Report on Form 10- K.** ~~If any of the following risks actually occur,~~ **which summary is not exhaustive** our business, results of operations and financial condition would likely be materially and adversely affected. • In these circumstances, the market price of our securities could decline, and you may lose part or all of your investment. **Risks Related to the Development and Commercialization of Our Products** ~~We~~ **have incurred losses to date and** expect to incur losses for the foreseeable future, ~~our~~. **Our** ability to achieve and maintain profitability depends on the commercial success of the Allurion Balloon, and we expect our revenues to continue to be driven primarily by sales of the Allurion Balloon. • **We have a limited operating history and may face difficulties encountered by companies early in their commercialization in competitive and rapidly evolving markets.** • **The failure of the Allurion Balloon or our new compounded GLP- 1 program to achieve and maintain market acceptance could result in achieving sales or profitability below our expectations, which would cause our business, financial condition, and operating results to be materially and adversely affected.** • **There is no guarantee that the FDA or non- U. S. regulatory agencies will grant approval or clearance for our current or future products, and failure to obtain regulatory approvals or clearances in the United States and international jurisdictions, or revocation of approvals or clearances in those jurisdictions, will prevent us from marketing and selling our products.** • **The Allurion Balloon is not currently approved for commercial sale in the United States. Obtaining such approval is costly and time consuming, and we may not obtain the regulatory approval required to sell the Allurion Balloon in the United States.** • **The weight loss and obesity- management industries are highly competitive. We also compete with companies that make weight loss drugs and other weight loss solutions outside the medical device industry.** • **If our competitors are able to develop and market products, whether medical devices or otherwise, that are safer, more effective, easier to use, or more readily adopted by patients and health care providers, our commercial opportunities will be reduced or eliminated.** • **Our current international operations and any expansion of our business internationally expose us to business, regulatory, political, operational, financial, and economic risks associated with doing business internationally.** • **We depend on a limited number of single source suppliers to manufacture components, sub- assemblies, and materials, which makes us vulnerable to supply shortages and price fluctuations.** • **The regulatory approval process is expensive, time consuming, and uncertain, and may prevent us from obtaining approvals for the commercialization of the Allurion Balloon or other products.** • **Even if we receive regulatory approval for the Allurion Balloon in the United States and elsewhere, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to penalties if we fail to comply with applicable regulatory requirements.** • **If patients using our products experience adverse events or other undesirable side effects, regulatory authorities could withdraw or modify our regulatory approvals, which would adversely affect our reputation and commercial prospects and / or result in other significant negative consequences.** • **The medical device industry is characterized by patent litigation and we could become subject to adversarial proceedings or litigation that could be costly, result in the diversion of management' s time and efforts, result in a loss of our intellectual property, require us to pay damages, or prevent us from marketing our existing or future products.** • **If we are not able to obtain and maintain intellectual property protection for our products and technologies, if the scope of our patents is not sufficiently broad, if our patents are invalidated, or if competitors gain broader patent protection, we may not be able to effectively maintain our market leading technology position.** • **We have incurred net operating losses in the past and expect to incur net operating losses for the foreseeable future.** • **We have a significant amount of debt, which may affect our ability to operate our business and secure additional financing in the future.** • **We may need additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all, which would force us to delay, reduce, or suspend our planned development and commercialization efforts. Raising additional capital may subject us to unfavorable terms, cause dilution to our existing stockholders, restrict our operations, or require us to relinquish rights to our products and technologies.** • **We receive the majority of our revenue from sales to health care providers and other third- party distributors, and the failure to collect receivables from them could adversely affect our financial position and results of operations.** • **Our share price may be volatile, and purchasers of our securities could incur substantial losses.** **Risks Related to the Development and Commercialization of Our Products** We expect to incur

losses for the foreseeable future, our ability to achieve and maintain profitability depends on the commercial success of the Allurion Balloon, and we expect our revenues to continue to be driven primarily by sales of the Allurion Balloon. We have incurred losses to date and expect to continue to incur losses for the foreseeable future. Sales of the Allurion Balloon and related accessories, which have occurred outside of the U. S. because we have not yet obtained the regulatory approval required to sell our products within the U. S., accounted for substantially all of our revenues for the years ended December 31, **2024 and 2023 and 2022**, and we expect our revenues to continue to be driven primarily by sales of the Allurion Balloon. In order to achieve and sustain profitability, our revenues from sales of the Allurion Balloon will need to grow beyond the levels we have achieved in the past. If health care providers and / or patients do not perceive our products to be competitive in features, efficacy and safety when compared to other products in the market, or if demand for the Allurion Balloon or for weight loss procedures and programs in general decreases, we may fail to achieve sales levels that provide for future profitability. Our ability to successfully market the Allurion Balloon and our other current and future product and service offerings depends on numerous factors, including but not limited to: **outcomes of current and future clinical trials of, and trials involving, the Allurion Balloon;** **acceptance of the Allurion Balloon as safe and effective by patients, caregivers and the medical community;** **an acceptable safety profile of the Allurion Balloon in markets where we have obtained regulatory approvals ;** **successful completion of remediation programs to resume sales of the Allurion Balloon in any country that suspends sales of our products;** **outcomes of current and future clinical trials of, and trials involving, the Allurion Balloon ;** **whether key thought leaders in the medical community accept that such clinical trials are sufficiently meaningful to influence their or their patients' choices of product;** **maintenance of our existing regulatory approvals and expansion of the geographies in which we have regulatory approvals;** **establishment and maintenance of** commercially viable processes at a scale sufficient to meet anticipated demand at an adequate cost of manufacturing, and that are compliant with ISO 13485 Quality Management System requirements and / or good manufacturing practice (“GMP”) requirements, as set forth in the FDA’s QSR and other international regulations; **our success in educating health care providers and patients about the benefits, administration and use of the Allurion Balloon;** **the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;** **the willingness of patients to pay out- of- pocket for the Allurion Balloon and / or Allurion VCS in the absence of coverage and reimbursement for such treatment;** **the success of our internal sales and marketing organization and the sales forces of our distributors;** and **continued demand for weight loss using balloon products, which may be adversely affected by events involving our products or those of our competitors, among other things.** Some of these factors are beyond our control. If we are unable to continue to commercialize the Allurion Balloon and our other current and future products and services, or are unable to obtain **a distributor distributors or partner partners** to commercialize them, we may not be able to produce any incremental revenues related to the Allurion Balloon and our other current and future products and services. This would result in an adverse effect on our business, financial condition, results of operations and growth prospects. **We have a limited operating history and may face difficulties encountered by companies early in their commercialization in competitive and rapidly evolving markets.** The Allurion Balloon has been marketed in countries outside of the United States since 2016, and as such, we have a limited operating history upon which to evaluate our business and forecast our future revenue and operating results. In assessing our business prospects, you should consider the various risks and difficulties frequently encountered by companies early in their commercialization in competitive markets, particularly companies that develop and sell medical devices. These risks include our ability to: **implement and execute our business strategy;** **expand and improve the productivity of our direct sales force, distributors and marketing programs to grow sales of our existing and proposed products and services;** **increase awareness of our brand and build loyalty among health care providers and patients;** **manage growth and expanding operations;** **respond effectively to competitive pressures and developments;** **enhance our existing products and develop new products;** **obtain regulatory approval or clearance for to enhance our existing products and to enhance our existing products, and commercialize new products, including any label expansions for use of our products in adolescents or lower BMI levels ;** **respond to changing regulations associated with medical devices across all geographies;** **perform clinical trials with respect to our existing products and any new products, including products under development and the combination of our products with other therapies, including GLP- 1s ;** **attract, retain , and motivate qualified personnel in various areas of our business;** and **obtain and maintain coverage and adequate levels of reimbursement for our products in the future .** Due to our limited operating history, we may not have the institutional knowledge or experience to be able to effectively address these and other risks that we may face. In addition, we may not be able to develop insights into trends that could emerge and negatively affect our business and may fail to respond effectively to those trends. As a result of these or other risks, we may not be able to execute key components of our business strategy, and our business, financial condition and operating results may suffer. We do not expect that health care providers or patients will receive third- party reimbursement for treatment with our products. As a result, we expect that our success will depend on the ability and willingness of health care providers to adopt self- pay practice management infrastructure and of patients to pay out- of- pocket for treatment with our products. Certain elective treatments, such as an intragastric balloon, are typically not covered by insurance. Accordingly, we do not expect that any third- party payors will cover or reimburse health care providers or patients for the Allurion Program. As a result, we expect that our success will depend on the ability and willingness of health care providers that may not have historically operated a self- pay practice to adopt the policies and procedures needed to successfully operate such a practice. Our sales and marketing efforts have historically targeted bariatric surgeons, gastroenterologists, plastic surgeons and other health care providers. Although many of these health care providers are accustomed to selling cash- pay services in their practices, some are primarily accustomed to providing services that are reimbursed by third- party payors. As a result, these health care providers may need to augment their administrative staff and billing procedures to address the logistics of a self- pay practice. If health care providers are unable or unwilling to make such changes, adoption of our products may be slower than anticipated. Our success will also depend on the ability and willingness of patients to pay out- of- pocket for treatment with our products. Adverse changes in the

economy, including from heightened inflation, higher interest rates, and geopolitical conflicts such as the Russia- Ukraine war and the Israel- Hamas war, may cause consumers to reassess their spending choices and reduce the demand for elective treatments and could have an adverse effect on consumer spending. This shift could have an adverse effect on our revenues and operating results. In addition, the operations of the medical device distributors upon whom we rely to sell our products may be negatively impacted by any such adverse economic changes. If our distributors are unable to maintain their operations and effectively market and sell our products, our results of operations and business may suffer. Furthermore, consumer preferences and trends may shift due to a variety of factors, including changes in demographic and social trends, public health initiatives and product innovations, which may reduce consumer demand for our products. The decision by a patient to elect to undergo treatment with the Allurion Balloon may be influenced by a number of additional factors, such as: • the success of any sales and marketing programs, including direct- to- consumer marketing efforts, that we, or any third parties we engage, undertake; • the extent to which health care providers offer the Allurion Balloon to their patients; • the extent to which the Allurion Balloon satisfies patient expectations; • the cost, safety, comfort, tolerability, ease of use, and effectiveness of the Allurion Program as compared to other treatments; and • general consumer confidence, which may be impacted by economic and political conditions. Our financial performance will be materially harmed if we cannot generate significant customer demand for the Allurion Balloon. Changes in coverage and reimbursement for obesity treatments and procedures could affect the adoption of the Allurion Program and our future revenues. Historically, intragastric balloon products are not reimbursed by third- party payors, although a very limited number of balloon procedures have ~~recently~~ been subject to reimbursement in the U. K. market. We do not currently plan on submitting any requests to any third- party payor for coverage or billing codes specific to our products other than ~~our partnership with~~ **as allowed by** the National Health Service in the United Kingdom. However, payors may change their coverage and reimbursement policies for intragastric balloon products as a category and / or for other obesity treatments and procedures, and these changes could negatively impact our business. For example, healthcare reform legislation or regulation that may be proposed or enacted in the future that results in a favorable change in coverage and reimbursement for competitive products and procedures in weight loss and obesity could also negatively impact adoption of our products and our future revenues, and our business could be harmed as we would be at an economic disadvantage when competing for customers. For more information, see section entitled " **Business - Government Regulation- Other U. S. Healthcare Laws** - Coverage, Reimbursement and Healthcare Reform." The failure of the Allurion Balloon to achieve and maintain market acceptance could result in us achieving sales below our expectations, which would cause our business, financial condition and operating results to be materially and adversely affected. Our current business and growth strategy is highly dependent on the Allurion Balloon achieving and maintaining market acceptance. In order for us to sell our products to healthcare providers and, ultimately, weight loss patients, we must convince them that our products are an attractive alternative to competitive treatments for patients who are obese and overweight, including traditional pharmaceutical therapies and more aggressive bariatric surgical treatments, such as gastric bypass and sleeve gastrectomy. Market acceptance and adoption of the Allurion Balloon depends on educating health care providers on its safe and appropriate use, as well as the cost, safety, comfort, tolerability, ease of use, and effectiveness of the Allurion Program compared to other treatments. If we are not successful in convincing existing and potential customers of the benefits of our product, or if we are not able to achieve the support of health care providers for our product, our sales may decline or we may achieve sales below our expectations. Market acceptance of our products could be negatively impacted by many factors, including: • the ~~willingness~~ **unwillingness** of patients to pay out- of- pocket for the Allurion Program in the absence of coverage and reimbursement for such program; • the failure of our products to achieve and maintain wide acceptance among patients who are obese and overweight, their health care providers, third- party payors and key opinion leaders in the weight loss treatment community; • lack of evidence supporting the safety, ease- of- use or other perceived benefits of the Allurion Balloon over competitive products or other currently available weight loss treatment alternatives; • perceived risks or uncertainties, or actual adverse events or other undesirable side effects, associated with the use of our gastric ~~balloons-~~ **balloon**, or components thereof, or of similar products or technologies of our competitors; • any adverse legal action, including products liability litigation, against us or our competitors relating to the Allurion Balloon or similar products or technologies; • the withdrawal or modification of any regulatory approvals for our products; and • results of clinical studies relating to the Allurion Balloon or similar competitive products. In addition, the rapid evolution of technology and treatment options within our industry may cause consumers to delay the purchase of our products in anticipation of advancements or breakthroughs, or the perception that advancements or breakthroughs could occur, in our products or the products offered by our competitors. It is also possible that consumers interested in purchasing any of our future products currently under development may delay the purchase of one of our current products. In addition, customers may delay their purchasing decisions, or health care providers may refrain from providing our products, as a result of a global pandemic or unfavorable changes in general economic conditions. If the Allurion Balloon, or any other therapy or product that we may develop, does not achieve and maintain widespread market acceptance, we may fail to achieve sales consistent with our projections, in which case our business, financial condition and operating results could be materially and adversely affected. A substantial proportion of our sales are through third- party distributors, and we do not have direct control over the efforts these distributors may use to sell our products. If our relationships with these distributors deteriorate, or if these distributors fail to sell our products or engage in activities that harm our reputation, or fail to adhere to medical device regulations, our financial results may be negatively affected. Historically, our sales model has been to sell primarily through distributors rather than through our own sales force, but recently we have begun to transition certain territories to both a direct sales model and a hybrid sales model that includes both distributors and a direct sales effort. We believe that our reliance on distributors improves the economics of our business, as we do not carry the high fixed costs of a large direct sales force in many of the countries in which the Allurion Balloon is commercially available. If we are unable to maintain or enter into such distribution arrangements on acceptable terms, or at all, we may not be able to successfully commercialize our products in certain countries. Furthermore, distributors can choose the level of effort that they apply to selling our products

relative to others in their portfolio. The selection, training, and compensation of distributors' sales personnel are within the distributor's control rather than our own and may vary significantly in quality from distributor to distributor. In addition, although our contract terms require our distributors to comply with all applicable laws regarding the sale of our products, including anti-competition, anti-money laundering, sanctions laws and FDA and other health care regulations, we may not be able to ensure proper compliance. If our distributors fail to effectively market and sell our products in full compliance with applicable laws, our results of operations and business may suffer. In certain large markets, we engage in direct sales efforts. We may fail to maintain and develop our direct sales force, and our revenues and financial outcomes could suffer as a result. Furthermore, our direct sales personnel may not effectively sell our products. We **currently** engage in direct sales efforts in **19 over 20** countries. We ~~have~~ **must hire** ~~hire~~, and will need to retain and motivate a significant number of sales and marketing personnel in order to support our ~~anticipated~~ **existing operations and any future** growth in these and other new countries. There is significant competition for quality personnel experienced in such activities, including from companies with greater financial resources than ~~ours~~ **Allurion**. If we are not successful in our efforts to continue recruiting, retaining, and motivating such personnel, we may not be able to increase our revenues, or we may increase our expenses in greater measure than our revenues, negatively impacting our operating results. We are also working on creating a direct sales structure and strategy in certain markets, **including implementing**. We are working to put in place the correct legal and business ~~structure~~ **structures** to comply with taxation and operational requirements. These structures may not ultimately be implemented or, if implemented, be successful or effective, and may not be able to increase our revenues or improve our gross margins. In addition, our expenses or tax-related costs may increase in greater measure than our revenues, negatively impacting our operating results. Furthermore, our sales force may operate independently with limited day-to-day oversight from management. They may engage in sales practices that increase certain risks to our business, including the risk of scrutiny from regulatory authorities and the risk that we violate anti-corruption regulations in one or more countries. These and other independent actions may result in unexpected costs, news that might impair our reputation or revenues, **actions by regulatory authorities**, litigation ~~in various jurisdictions~~, and / or sanctions. Any of these could impair the trading price of our ~~Common~~ **common Stock** ~~stock~~ and adversely impact our results. The effectiveness and safety of the Allurion Balloon depends critically on our ability to educate health care providers on its safe and proper use. If we are unable to do so, we may not achieve our expected growth and may be subject to risks and liabilities. In addition to educating health care providers on the clinical benefits of the Allurion Balloon, we must also train health care providers on the safe and appropriate use of the Allurion Balloon. If we are unable to provide an adequate training program with respect to the Allurion Balloon, product misuse may occur that could lead to serious adverse events. Many health care providers may be unfamiliar with such treatments or find it more complex than competitive products or alternative treatments. As such, there is a learning process involved for health care providers to become proficient in the use of our products and it may take several procedures for a health care provider to be able to use the Allurion Balloon comfortably. In addition, it is also critical for health care providers to be educated and trained on best practices in order to achieve optimal results, including patient selection and eligibility criteria **and patient follow-up**, as well as complementary methods of use such as diet or behavioral modification programs. Convincing health care providers to dedicate the time and energy necessary for adequate training is challenging, and we cannot assure you that we will be successful in these efforts. This training process may also take longer than we expect. In the event that health care providers are not properly trained in the use of the Allurion Balloon **and Allurion Program generally**, they may misuse or ineffectively use our products for the treatment of patients. As a result, patients may experience adverse events or not be able to enjoy the benefits of our program or achieve the weight loss outcomes they expect, leading to dissatisfaction and market rejection of our products. In addition, misuse of our products in any stage of the treatment may result in, among other things, patient injury, adverse side effects, negative publicity or lawsuits against us. Any of these events could have an adverse effect on our business and reputation. The misuse or off-label use of our products may harm our image in the marketplace, result in injuries that lead to product liability suits or result in costly investigations and sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business. The Allurion Balloon has been approved or cleared by regulatory authorities in the countries in which we sell it or in which we conduct our operations for specific indications. We do not promote the Allurion Balloon for uses outside of approved or cleared indications for use, known as "off-label uses." We cannot, however, prevent a health care provider from using our product off-label, when in the health care provider's independent professional medical judgment he or she deems it appropriate. There may be increased risk of injury to patients if health care providers attempt to use our product off-label. Furthermore, the use of our product for indications other than those approved or cleared by regulatory authorities may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients. Health care providers may also misuse our products, use improper techniques, ignore or disregard product warnings, contraindications or other information provided in training materials or product labeling, fail to obtain adequate training, fail to inform patients of the risks associated with procedures that utilize our product or fail to solicit sufficient information from patients regarding their health status or medical histories, any of which may potentially lead to injury and an increased risk of product liability claims. If our product is misused or used with improper techniques or insufficient information, we may become subject to costly litigation by our health care providers or their patients. Moreover, if patients fail to disclose medical conditions or to follow the pre- and post-placement instructions, medication program, and dietary guidelines in connection with their treatment with the Allurion ~~balloon~~ **Balloon**, there is the risk of injury. Such patients may also fail to achieve their desired results, which could harm our image in the marketplace. There is no guarantee that the FDA or non-U.S. regulatory agencies will grant approval or clearance for our current or future products, including the Allurion Balloon. Failure to obtain regulatory approvals or clearances in the United States and other international jurisdictions, or revocation of approvals or clearances in those jurisdictions, will prevent us from marketing **and selling** our products in such jurisdictions. We intend to seek regulatory approval or clearance of our current and future products in the United States and certain non-U.S. jurisdictions. We have obtained a CE Mark for the Allurion

Balloon and are therefore authorized to sell in the EU; however, in order to market in regions such as the United States, the Asia Pacific region and many other jurisdictions, we must obtain separate regulatory approvals or clearances. The procedures for approval vary among countries and can involve additional clinical testing, and the time required to obtain approval or clearance may differ from that required to obtain the CE Mark or FDA approval. As a result of the United Kingdom leaving the EU, since January 1, 2021, the regulatory framework and regimes for medical devices in the United Kingdom and the EU have diverged. In particular, a new UKCA Mark was introduced for medical devices placed on the Great Britain market (which includes England, Scotland and Wales), and Northern Ireland adopted a hybrid approach as a result of the divergence in accordance with the Northern Ireland Protocol. Of note, on June 30, 2023, the UK Government introduced legislation, confirming that, subject to certain conditions, general medical devices compliant with the MDD with a valid declaration and CE mark can be placed on the Great Britain market up until the sooner of the expiry of the CE certificate or June 30, 2028, and general medical devices compliant with the MDR with a valid declaration and CE mark can be placed on the Great Britain market up until June 30, 2030. Moreover, clinical studies or manufacturing processes conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more international regulatory authorities does not ensure approval by regulatory authorities in other countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. An international regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain regulatory approvals on a timely basis, if at all. We may not be able to submit **applications** for regulatory approvals or clearances and, even if we submit, we may not receive necessary approvals or clearances to commercialize **and sell** our products in any market. Before obtaining regulatory approval or clearance for the sale of a product, we may be required to conduct extensive preclinical studies and clinical trials to demonstrate the safety and efficacy of our planned products in human patients. Preclinical studies and clinical trials can be expensive, difficult to design and implement, can take many years to complete, and are uncertain as to outcome. A failure of one or more of our trials could occur at any stage of testing. In connection with the initiation of a clinical trial in the U. S., we filed an investigational device exemption application, which was approved by the FDA in 2016. After we conducted that trial and submitted a premarket approval application to the FDA, in 2020, the FDA requested additional data. Therefore, we withdrew the PMA, and in 2021 submitted an IDE application for our AUDACITY trial, which the FDA approved in 2021. We **recently completed the AUDACITY** ~~are currently conducting that clinical trial~~ **and expect to file the fourth and final module of the PMA based on its results**. Numerous unforeseen events during, or as a result of, preclinical and clinical trials could occur, which would delay or prevent our ability to receive regulatory approval or commercialize the Allurion Balloon or any of our future products, including the following: • preclinical studies and clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional studies or abandon product development programs; • the number of patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, or patients may drop out of these clinical studies at a higher rate than we anticipate; • the cost of preclinical studies and clinical trials may be greater than we anticipate; • third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; • we might suspend or terminate clinical trials of our products for various reasons, including a finding that our products have unanticipated serious side effects or other unexpected characteristics, or that the trial subjects are being exposed to unacceptable health risks; • regulators may not approve our proposed clinical development plans; • regulators or independent institutional review boards ("IRBs") may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; • regulators or IRBs may require that we, or our investigators, suspend or terminate clinical studies for various reasons, including non-compliance with regulatory requirements; • regulators in countries where our products are currently marketed may require that we suspend commercial distribution if there is non-compliance with regulatory requirements or safety concerns; • the supply or quality of our products or other materials necessary to conduct clinical studies of our products may be insufficient or inadequate; and • the enactment of new regulatory requirements in the EU under the **Medical Device Regulation ("MDR")** effective since May 26, 2021 may make approval times longer and standards more difficult to pass. In particular, manufacturers are required to: **(i) assign or assign a unique device identification ("UDI")** to a medical device before it is placed on the EU market in order to improve traceability of the medical device; and **(ii) register or register** themselves, the medical device and the UDI, among other things, with a new European medical device database. If we or any future collaboration or distribution partner are required to conduct additional clinical trials or other testing of the Allurion Balloon or any future products, those clinical studies or other testing may not be successfully completed. If the results of these studies or tests are not positive, or are only modestly positive or if they raise safety concerns, we may: • be delayed in obtaining marketing approvals for the Allurion Balloon or our future products; • not obtain marketing approval at all; • obtain approval for indications that are not as broad as desired; • have a product removed from the market after obtaining marketing approval; or • be subject to restrictions on how the product is distributed or used. Even if we obtain regulatory approvals or clearances in a jurisdiction, our products may be removed from the market due to a variety of factors, including adverse events, recalls, suspension of regulatory clearance to sell, or other factors. **For example, on August 6, 2024, we announced that the French regulatory authority ANSM had suspended sales of the Allurion Balloon in France, and we withdrew the Allurion Balloon from the French market pending implementation of a remediation plan to reduce certain risks associated with the advertising, follow-up program, and adverse events for the Allurion Balloon. While the ANSM has since lifted its suspension following our completion of a remediation plan, other regulatory authorities may in the future take action with respect to our products, and there is no guarantee that we will be able to successfully implement a remediation plan or other remedial measures to the satisfaction of any such regulatory authority, which could delay or prevent us from resuming sales of the Allurion Balloon in the affected territory as a result. In addition, a withdrawal from the market in one country may have a negative effect on the regulatory approval process and ability to sell and**

commercialize, and the market acceptance of, the Allurion Balloon in other countries. Although we launched the Allurion Balloon commercially in January 2016 and have placed over ~~430~~ **150**, 000 units to date in various countries outside the U. S., we do not have as much post- market surveillance data as our competitors and may not have clearly identified all possible or actual risks of our products. Furthermore, if our clinical trials do not produce patient data that compares favorably with products that are already on the market, health care providers and patients may opt not to use our products, and our business would suffer. Our product development costs will also increase if we experience delays to our clinical trials or approvals. Significant clinical trial delays also could allow our competitors to bring products to market before we do, which would impair our ability to commercialize our products and harm our business and results of operations. The Allurion Balloon is not currently approved for commercial sale in the United States. Obtaining such approval is costly and time consuming, and we may not obtain the regulatory approval required to **market and** sell our products in the U. S. Neither we, nor any future collaboration or distributor partner, can commercialize the Allurion Balloon in the **United States U.S.** without first obtaining regulatory approval from the FDA. Extensive preclinical and clinical testing is required to support FDA approval. The FDA approval process is expensive ~~and will, typically take~~ **takes** at least several years to complete, and FDA approval may never be obtained. We must also demonstrate that our manufacturing facilities, processes and controls are adequate to support FDA approval and that our clinical investigators complied with good clinical practices in the conduct of the Allurion Balloon clinical trial. The FDA has substantial discretion in the approval process. Despite the time and expense exerted, failure may occur at any stage, and we could encounter problems that cause us to abandon or repeat clinical trials. The FDA can delay, limit, or deny approval of a product for many reasons, including, but not limited, to: • a product may not be deemed to be safe and effective; • the FDA may not find the data from clinical trials and preclinical studies sufficient; • the opportunity for bias in the clinical trials as a result of the open- label design may not be adequately handled and may cause our trial to fail; • the FDA may not approve suppliers' processes or facilities; or • the FDA may change its approval policies or adopt new regulations. If the Allurion Balloon or our future products fail to demonstrate safety and efficacy in further **or new** clinical trials that may be required for FDA approval, or do not gain regulatory approval, our business and results of operations will be harmed. Additionally, we expect that the initial FDA approval of the Allurion Balloon, if obtained, will be subject to a lengthy and expensive follow- up period, during which we must monitor patients enrolled in clinical studies and collect data on their safety outcomes. Even if FDA approval is obtained, the FDA has authority to impose post- market approval conditions, which can include (i) restrictions on the device' s sale, distribution, or use, (ii) continuing evaluation of the device' s safety and efficacy, (iii) additional warning / hazard labeling requirements, (iv) significant record management, (v) periodic reporting requirements, and (vi) any other requirements the FDA determines necessary to provide reasonable assurance of the device' s safety and effectiveness. Completion of this follow- up trial, in a manner which results in data sufficient to maintain FDA approval, is subject to multiple risks, many of which are outside of our control. These include, but are not limited to, our ability to fund the ongoing trial from our operations or via additional fundraising; trial participants' willingness and ability to return for follow- up trial visits; and maintenance of a suitable trial database over a long period of time. Even if completed and appropriately evaluated, the trial follow- up may reveal safety or other issues that impact the approved labeling, or may result in withdrawal of the Allurion Balloon from the marketplace in the U. S. or elsewhere. Even if clinical trials demonstrate acceptable safety and efficacy for the Allurion Balloon in some patient populations, the FDA or similar regulatory authorities outside the U. S. may not approve the marketing of the Allurion Balloon or may approve it with restrictions on the label, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. It is possible the FDA or similar regulatory authorities may not consider the results of our clinical trials to be sufficient for approval of the Allurion Balloon for our desired indications for use. Moreover, even if the FDA or other regulatory authorities approve the marketing of the Allurion Balloon, the approval may include additional restrictions on the label that could make the Allurion Balloon less attractive to health care providers and patients compared to other products that may be approved for broader indications, which could limit potential sales of the Allurion Balloon. If we fail to obtain FDA or other regulatory approval of the Allurion Balloon, or if the approval is narrower than what we seek, it could impair our ability to realize value from the Allurion Balloon, and therefore may have a material adverse effect on our business, financial condition, results of operations and growth prospects. The results of preclinical studies and earlier clinical trials may not be predictive of the results of later preclinical studies and clinical trials, and the results of our current and future clinical trials may not satisfy the requirements of the FDA or other comparable regulatory authorities. If we cannot replicate the positive results from our preclinical studies or earlier clinical trials of the Allurion Balloon in our current or future clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our current or future product candidates. We will be required to demonstrate **with sufficient valid scientific evidence** through well- controlled clinical trials, that our product candidates are safe and effective for their intended uses before we can seek marketing approvals for their commercial sale. Positive results from our preclinical studies of the Allurion Balloon, and any positive results we may obtain from our early clinical trials of our current or future product candidates, may not necessarily be predictive of the results from subsequent preclinical studies and clinical trials. Similarly, even if we are able to complete our planned preclinical studies or any clinical trials of the Allurion Balloon according to our current development timeline, the positive results from such preclinical studies and clinical trials of the Allurion Balloon may not be replicated in subsequent preclinical studies or clinical trial results. Additionally, several of our past, planned and ongoing clinical trials utilize an " open- label " trial design. An " open- label " clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate. Open- label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open- label clinical trials are aware when they are receiving treatment. Open- label clinical trials may be subject to a " patient bias " where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open- label clinical trials may be subject to an " investigator bias " where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment

and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results with any of our product candidates for which we include an open-label clinical trial when studied in a controlled environment with a sham procedure. Many companies in the pharmaceutical, biotechnology and medical device industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless ~~failed~~ **fail** to obtain approval from the FDA or a comparable foreign regulatory authority. ~~If we fail to produce in the FDA's judgment the results of the AUDACITY trial are not positive results in our~~ **or sufficient to warrant approval at this time** ~~planned preclinical studies or clinical trials of the Allurion Balloon~~, the development timeline and regulatory approval and commercialization prospects for the Allurion Balloon, and, correspondingly, our business and financial prospects, would be materially adversely affected. Thus, even if the results from ~~the AUDACITY trial~~ **our initial research and preclinical activities** appear positive, we do not know whether ~~the FDA~~ **subsequent clinical trials we may conduct** will **determine that such results** demonstrate adequate efficacy and safety ~~and grant to result in~~ regulatory approval to market the Allurion Balloon. Commercial success of the Allurion Balloon in the United States or elsewhere depends on our ability to accurately forecast customer demand and manufacture sufficient quantities of product that patients and health care providers request, and to manage inventory effectively. The failure to do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects. Manufacturing of the Allurion Balloon requires capital expenditures and a highly-skilled workforce. There is a significant lead time to build and certify a new manufacturing facility. Although we believe our current facilities will give us adequate manufacturing capacity to meet demand for at least the next two years, we have, in the past, been unable to fill all incoming orders to meet growing demand. If we obtain FDA approval, we intend to rely on our existing manufacturing facilities to supply products in the **United States** ~~U.S.~~ If demand increases faster than we expect, or if we are unable to produce the quantity of goods that we expect with our current facilities, we may not be able to grow revenue at an optimal rate. There may be other negative effects from supply shortages, including loss of our reputation in the marketplace and a negative impact on our relationships with our distributors, which could have a material adverse effect on our business, financial condition, results of operations, and growth prospects. **We may also need to engage others to assist with the manufacture our products, a process which requires extensive time and resources, and we cannot guarantee that any manufacturing partner would be able to manufacture our products to our specifications and quality standards.** On the other hand, if demand for our products declines, or if market supply surpasses demand, we may not be able to reduce manufacturing expenses or overhead costs proportionately. We have invested significantly in our manufacturing capacity. If an increase in supply outpaces the increase in market demand, or if demand decreases, the resulting oversupply could adversely impact our sales and result in the underutilization of our manufacturing capacity, higher inventory carrying costs and associated working capital, changes in revenue mix, and / or price erosion, any of which would lower our margins and adversely impact our financial results, which could have a material adverse effect on our business, financial condition, results of operations, and growth prospects. Our business depends on maintaining our brand, reputation, and ongoing demand for our products and services, and a significant reduction in sentiment or demand could affect our results of operations. Our success depends on **the reputation and** ~~awareness and the reputation~~ of our brand, which ~~depends~~ **depend** on factors such as the safety and quality of our products, our communication activities, including marketing and education efforts, customer acquisition and retention strategies, and our management of our health care provider and patient experience. Maintaining, promoting and positioning our brand is important to expanding our customer base. This will depend largely on the success of our education and marketing efforts and our ability to provide a consistent, high-quality experience to health care providers and patients. If we do not successfully **continue conduct** our education and marketing efforts, particularly to health care systems and large institutions, or if existing users decrease their level of engagement, our revenue, financial results and business may be significantly harmed. A decrease in customer retention, growth or engagement with our products may have a material and adverse impact on our revenue, business, financial condition and results of operations. Any number of factors could negatively affect customer retention, growth and engagement, including: • customers increasingly engaging with competing products; • inability to maintain high quality products, including any failure to introduce new and improved products; • inability to continue to develop or maintain applications for mobile devices that customers find engaging, that work with a variety of mobile operating systems and networks, and that achieve a high level of market acceptance; • changes in customer sentiment about the safety, quality or usefulness of our products, including concerns related to privacy and data sharing, security or other factors; • inability to manage and prioritize information to ensure customers are presented with content that is engaging, useful and relevant to them; • adverse changes in our products that are mandated by legislation or regulatory agencies, both in the United States and internationally; or • technical or other problems preventing us from delivering products in a rapid and reliable manner or otherwise affecting the user experience. We may need to make substantial investments in the areas of education and marketing in order to maintain and enhance our brand and awareness of our products. Ineffective marketing, negative publicity, significant discounts by our competitors, product defects, serious adverse events and related liability litigation, failure to obtain regulatory approval or clearance for our products, counterfeit products, unfair labor practices and failure to protect our intellectual property rights are some of the potential threats to the strength of our business. We may need to make substantial expenditures to mitigate the impact of such threats. We believe that maintaining and enhancing awareness of our products and brand in the countries in which we currently sell our products and in new countries where we have limited awareness or brand recognition is important to expanding our customer base. As such, our growth will depend on the further development and commercialization of our current

products, and marketing authorization of our future products, **all in compliance with applicable laws and regulations**. If we are unable to increase awareness of our products or enhance the strength of our brand in the countries in which we currently sell our products and in new countries in a timely **and compliant** manner, then our growth strategy could be adversely affected.

Risks Related to our Business and Industry The weight loss and obesity management industries are highly competitive. We also compete with companies that make weight loss drugs and other weight loss solutions outside the medical device industry, **including compounded drugs**. If our competitors are able to develop and market products that are safer, more effective, easier to use or more readily adopted by patients and health care providers, our commercial opportunities will be reduced or eliminated. The weight loss and obesity management industries are highly competitive, subject to rapid change and significantly affected by new product introductions, results of clinical research, corporate combinations, actions by regulatory bodies, changes by public and private payers, and other factors relating to our industry. We compete both with companies that offer medical devices as a weight loss therapy as well as companies that make weight loss drugs and other weight loss solutions outside the medical device industry. Because of the market opportunity and the high growth potential of the non-surgical device market for weight loss and obesity, in particular recent pharmaceutical therapies known as GLP-1s, competitors and potential competitors have historically dedicated, and will continue to dedicate, significant resources to aggressively develop and commercialize their products. Any one of these factors could reduce the demand for our devices or services or require substantial resources and expenditures for research, design and development to avoid technological or market obsolescence. Outside the **United States** ~~U.S.~~, we compete with a variety of local and regional competitive intragastric balloon manufacturers including SC MedSil, Medicone and Spatz Laboratories. In the **United States** ~~U.S.~~, there are three manufacturers with an intragastric balloon approved by the FDA at this time: Boston Scientific Corporation, ReShape Lifesciences, Inc. and Spatz FGIA Inc. All of these balloons require endoscopy and anesthesia for placement and / or removal. We also compete against the manufacturers of pharmaceuticals that are directed at treating weight loss, such as NovoNordisk A / S, Eli Lilly & Co., Roche Holding AG, GlaxoSmithKline plc, Arena Pharmaceuticals, Inc., VIVUS, Inc. and Orexigen Therapeutics, Inc. At any time, these or other competitors may introduce new or alternative products that compete directly or indirectly with our products and services. They may also develop and patent products and processes earlier than we can or obtain regulatory clearance or approvals before we are able to obtain required approvals, which could impair our ability to develop and commercialize similar products or services. If clinical outcomes of procedures performed with our competitors' products are, or are perceived to be, superior to the outcomes of treatments performed with our products, sales of our products could be negatively affected and our business, results of operations and financial condition could suffer. Our success will depend on our ability to enhance our current products and technologies and develop or acquire and market new products and technologies to keep pace with technological developments and evolving industry standards, while responding to changes in customer needs. A failure to adequately develop or acquire device enhancements or new devices that will address changing technologies and customer requirements adequately, or to introduce such devices on a timely basis, may have a material adverse effect on our business, financial condition and results of operations. Many of our competitors, or their parent companies, have significantly greater financial and other resources than we do, as well as:

- well-established reputations and name recognition with key opinion leaders and health care provider networks;
- an established base of long-time customers with strong brand loyalty;
- products supported by long-term data;
- longer operating histories;
- significantly larger installed bases and distributors and established distribution channels;
- greater existing market share in the obesity and weight management market;
- broader product offerings;
- greater ability to cross-sell products;
- the ability to offer rebates or bundle products to offer higher discounts or incentives; and
- more experience in conducting research and development, manufacturing, performing clinical trials and obtaining regulatory approvals or clearances.

We might have insufficient financial resources to improve existing devices, advance technologies, develop new devices, and market them at competitive prices. Technological advances by one or more competitors or future entrants into the field may result in our current devices becoming non-competitive or obsolete, which may decrease revenues and profits and adversely affect our business and results of operations. Competition with these companies could result in significant price-cutting, reduced profit margins and loss of market share, any of which would harm our business, financial condition and results of operations. 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 and future products, which may cause our revenues to decline and harm our business. In addition, many of our competitors are well-established manufacturers with significant resources and may engage in aggressive marketing tactics. Competitors may also possess the ability to commercialize additional lines of products, bundle products or offer higher discounts and incentives to customers in order to gain a competitive advantage. If the prices of competing products are lowered as a result, we may not be able to compete effectively. ~~Continued international expansion of our business will expose us to business, regulatory, political, operational, financial and economic risks associated with doing business internationally.~~ Our products are registered to be sold in over 50 countries, and we operate subsidiaries in Australia, France, the United Arab Emirates, ~~Hong Kong~~, the United Kingdom, **the United States**, Italy, Spain, ~~Australia~~ and Mexico. Our business strategy contemplates continued international ~~expansion operations~~ in key markets, including partnering with medical device distributors and introducing the Allurion Balloon and other products outside the **United States** ~~U.S.~~. The sale and shipment of our products internationally, as well as the purchase of components from international sources, subjects us to potential trade, export, import and customs, and economic sanctions regulations and laws. Compliance with these regulations and laws is costly and exposes us to penalties for non-compliance. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export or import privileges, seizure of shipments, restrictions on certain business activities, and exclusion or debarment from government contracting. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our shipping and sales activities. In addition, several of the countries in which we

sell our products or conduct our operations are, to some degree, subject to political, economic or social instability. Doing business in other countries outside the **United States U.S.** involves a number of other risks, including: • compliance with the free zone regime regulations under which **the manufacturing sites we and our partners** operate; • different regulatory requirements for device approvals in international markets; • multiple, conflicting and changing laws and regulations such as tariffs and tax laws, export and import restrictions, **employment laws**, and other **regulatory requirements and** governmental approvals, permits and licenses; • potential failure by us or our distributors to obtain and / or maintain regulatory approvals for the sale or use of our products in various countries; • difficulties in managing global operations; • logistics and regulations associated with shipping products, including infrastructure conditions and transportation delays; • limits on our ability to penetrate international markets if our distributors do not execute successfully; • governmental price controls, differing reimbursement regimes, and other market regulations; • financial risks, such as longer payment cycles, **and** difficulty enforcing contracts and collecting accounts receivable; • reduced protection for intellectual property rights, or lack of **them such rights** in certain jurisdictions, forcing more reliance on our trade secrets, if available; • economic weakness, political and economic instability, (including wars, terrorism and political unrest), such as attacks on commercial ships by Houthi rebels), outbreak of disease, boycotts, curtailment of trade, and other business restrictions; • failure to comply with the Foreign Corrupt Practices Act (the “FCPA”), including its books and records provisions and its anti-bribery provisions, by **failing to maintaining---** **maintain** accurate information and control over sales activities and distributors’ activities; • **unexpected changes in tariffs, trade barriers and regulatory requirements**; • compliance with tax, employment, immigration and labor laws; • taxes, including withholding of payroll taxes; • currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; • workforce uncertainty in countries where labor unrest is more common than in the **United States U.S.**; • production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and • business and shipping interruptions resulting from natural or other disasters including earthquakes, volcanic activity, hurricanes, floods and fires, **or other events outside our control**. Any of these risks, if encountered, could harm our future international expansion and operations and, consequently, have an adverse effect on our financial condition, results of operations and cash flows. We depend on a limited number of single source suppliers to manufacture our components, sub- assemblies and materials, which makes us vulnerable to supply shortages and price fluctuations. We rely on single source suppliers for some of the components, sub- assemblies and materials for our products. These components, sub- assemblies and materials are critical and, for certain items, there are relatively few alternative sources of supply. These single source suppliers may be unwilling or unable to supply the necessary materials and components reliably and at the levels we anticipate or that are required by the market. We also have two suppliers with which we do not maintain a formal contractual relationship. We typically have at least a six-month supply of the materials provided by each of these suppliers but we cannot guarantee that we could find an alternative before our inventory ran out and therefore the loss of these relationships could cause a substantial disruption to our business. We would also have little to no recourse if one of these two suppliers became unwilling or unable to continue to supply materials. While our suppliers have generally met our demand for their products and services on a timely basis in the past, we cannot guarantee that they will in the future be able to meet our demand for their products, either because of an increase in the level of such demand, acts of nature, the nature of our agreements with those suppliers or our relative importance to them as a customer. Our suppliers may decide in the future to discontinue or reduce the level of business they conduct with us. We have not qualified or obtained necessary regulatory approvals for additional suppliers for some of these components, sub- assemblies and materials, but we do carry a significant inventory of these items ourselves. While we believe that alternative sources of supply or sterilization may be available, we cannot be certain whether they will be available if and when we need them, or that any alternative suppliers or providers would be able to provide the quantity and quality of components, materials and sterilization that we would need to manufacture and ship our products if our existing suppliers and providers were unable to satisfy our requirements. To utilize other sources, we would need to identify and qualify new providers to our quality standards and obtain any additional regulatory approvals required to change providers, which could result in manufacturing delays and increase our expenses. Our dependence on third parties subjects us to a number of risks that could impact our ability to manufacture our products and harm our business, including: • interruption of supply or sterilization resulting from modifications to, or discontinuation of, a third party’s operations; • delays in product shipments resulting from uncorrected defects, reliability issues or a third party’s failure to produce components or complete sterilizations that consistently meet our quality specifications; • price fluctuations due to a lack of long- term supply arrangements with our third parties for key components or sterilization requirements; • inability to obtain adequate supply or services in a timely manner or on commercially reasonable terms; • difficulty identifying and qualifying alternative third parties for the supply of components; • inability of third parties to comply with applicable provisions of the FDA’s QSR, or other applicable laws or regulations enforced by the FDA, foreign and state regulatory authorities; • inability to ensure the quality of products manufactured or sterilization conducted by third parties; • production delays related to the evaluation and testing of products and services from alternative third parties and corresponding regulatory qualifications; and • delays in delivery by our suppliers and service providers. Although we require our third- party suppliers and providers to supply us with components and services that meet our specifications and other applicable legal and regulatory requirements in our agreements and contracts, and we perform incoming inspection, testing or other acceptance activities to ensure the components meet our requirements, there is a risk that these third parties will not always act consistently with our best interests, and may not always supply components or provide services that meet our requirements or in a timely manner. Negative publicity, product defects and any resulting litigation concerning our products or our competitors’ products could harm our reputation and reduce demand for the Allurion Balloon, either of which could negatively impact our financial results. The responses of potential patients, health care providers, the media, legislative and regulatory bodies and others to information about complications or alleged complications of our products, or products liability litigation against us or our competitors, could result in negative publicity and could materially reduce

market acceptance of our products. These responses or any investigations and potential resulting negative publicity may have a material adverse effect on our business and reputation and negatively impact our financial condition, results of operations or the market price of our common stock. In addition, significant negative publicity could result in an increased number of product liability claims against us. **Moreover, if we, the FDA or a comparable foreign regulatory authority discover previously unknown problems with our products, such as adverse events of unanticipated severity or frequency, or problems with the facilities where our products are manufactured, or if a regulatory authority disagrees with the promotion, marketing or labeling of our products, a regulatory authority may impose restrictions relative to such product, the manufacturing facility or us, including requesting a recall or requiring withdrawal of the product from the market or suspension of manufacturing. For example, on August 6, 2024, the ANSM suspended sales of the Allurion Balloon in France due to adverse events, and we withdrew the Allurion Balloon from the French market, pending implementation of a remediation plan. While the ANSM has since lifted its suspension following our completion of a remediation plan, other regulatory authorities may in the future take action with respect to our products, and there is no guarantee that we will be able to successfully implement a remediation plan or other remedial measures to the satisfaction of any such regulatory authority, and we could be delayed or prevented from resuming sales of the Allurion Balloon in the affected territory as a result. A withdrawal from the market in a country, and the risks identified by the applicable regulatory authority, could negatively affect the market acceptance of the Allurion Balloon.** 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. Although we have entered into employment agreements with some of our executive officers and key employees, each of them 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. **We For example, on November 7, 2024, Christopher Geberth, our former Chief Financial Officer, notified us of his decision to resign effective as of November 13, 2024, to pursue other interests. These types of changes in our management team could experience disruptions cause retention and morale concerns among current employees, as well as operational risks** each of these individuals begins to integrate into the business and build his or her respective departments. In addition, our Chief Executive Officer, Shantanu Gaur, has been with us since inception and has been instrumental in building operational capabilities, raising capital and guiding product development and regulatory strategy. If Dr. Gaur was no longer working at our company, our industry credibility and operational capabilities would be harmed. To execute our growth plan, 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 executives. We have, from time to time, experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize medical devices. 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 often consider the value of the stock awards they receive in connection with their employment. If the perceived value of our stock awards declines, either because we are a public company or otherwise, 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 and future growth prospects would be harmed. We may acquire other businesses or form joint ventures or make investments in other companies or technologies in the future. If we are not successful in integrating these businesses, as well as identifying and controlling risks associated with the past operations of these businesses, we may incur significant costs, receive penalties or other sanctions from various regulatory agencies, and / or incur significant diversions of management time and attention. We believe our business growth will be enhanced if we continually seek opportunities to enhance and broaden our product offerings. As part of our business strategy, we may pursue acquisitions or licenses of assets, or acquisitions of businesses. We also may pursue strategic alliances and joint ventures that leverage our core technology and industry experience to expand our product offerings or sales and distribution resources. However, we may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could have an adverse effect on our financial condition, results of operations and cash flows. Integration of an acquired company may also disrupt ongoing operations and require management resources that would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could have a negative effect on our results of operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, license, strategic alliance or joint venture. To finance such a transaction, we may choose to issue our common stock, par value \$ 0.0001 per share, as consideration, which would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our common stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings, royalty or

debt financings. Additional funds may not be available on terms that are favorable to us, or at all. We do not know whether we will be able to successfully integrate any acquired business, product or technology. The success of any given acquisition may depend on our ability to retain any key employees related thereto, and we may not be successful at retaining or integrating such key personnel. Integrating any business, product or technology we acquire could be expensive and time-consuming, disrupt our ongoing business, impact our liquidity, and / or distract our management. If we are unable to integrate any acquired businesses, products or technologies effectively, our business may suffer. Whether as a result of unsuccessful integration, unanticipated costs, including those associated with assumed liabilities and indemnification obligations, negative accounting impact, or other factors, we may not realize the economic benefits we anticipate from acquisitions. In addition, any amortization or charges resulting from the costs of acquisitions could increase our expenses. If changes in the economy and / or consumer spending, consumer preference and other trends reduce consumer demand for our products, our sales and profitability would suffer. We are subject to the risks arising from adverse changes in general economic and market conditions. Certain elective procedures, including those for weight loss, are typically not covered by insurance. Adverse changes in the economy may cause consumers to reassess their spending choices, which could have an adverse effect on consumer spending, reduce the demand for these procedures, and therefore have an adverse effect on our revenues. Furthermore, consumer preferences and trends may shift due to a variety of factors, including changes in demographic and social trends, public health initiatives and product innovations, which may reduce consumer demand for our products. Our overall performance depends, in part, on worldwide economic conditions. In recent quarters, we have observed increased economic uncertainty in the **United States U.S.** and abroad. Impacts of such economic weakness include: • falling overall demand for goods and services, leading to reduced profitability; • reduced credit availability; • higher borrowing costs; • reduced liquidity; • volatility in credit, equity and foreign exchange markets; and • bankruptcies. These developments could lead to supply chain disruption, inflation, higher interest rates, and uncertainty about business continuity, which may adversely affect our business and our results of operations. As our customers react to global economic conditions and the potential for a global recession, we may see them reduce spending on our products and take additional precautionary measures to limit or delay expenditures and preserve capital and liquidity. Reductions in spending on our products, delays in purchasing decisions, failure to complete the Allurion Program, and inability to attract new customers, as well as pressure for extended billing terms or pricing discounts, would limit our ability to grow our business and negatively affect our operating results and financial condition. Changes in our business and operations have placed, and may continue to place, significant demands on our management team and infrastructure. If we fail to manage these demands effectively, we may be unable to execute our business plan, maintain high levels of customer and patient satisfaction, or address competitive challenges adequately. Our business, headcount, and operations have ~~grown~~ **both expanded and contracted**, in the United States and abroad, since our inception, and we anticipate operational changes in the future as we enhance our product development efforts and refine our marketing and distribution strategies. While we expect to continue to grow headcount and operations over the long- term, in January 2024 we announced a restructuring plan designed to more closely align our cost structure with near- term revenue expectations, improve our capital structure, and accelerate the path to profitability (the “~~Plan~~”). The ~~January 2024 Plan~~ **plan anticipates anticipated** a total reduction of approximately 30 % of our global workforce **as of December 2023. Additionally, on November 6, 2024, the Board approved a restructuring plan to reduce operating costs and better align its workforce with the needs of our business. Under the November 2024 restructuring plan, we anticipate reducing our workforce by approximately 113 roles (approximately 50 % of the total workforce). The majority of the November 2024 restructuring plan was completed in the fourth quarter of 2024. We** may be unable to manage effectively the changes to the business and potential disruption occasioned by such reductions. The implementation of ~~the Plan~~ **our restructuring efforts**, including the impact of a leaner organization, may result in delays in delivering our products and services, declines in customer and patient satisfaction, loss of customers, or difficulties in executing new strategies such as new sales and marketing strategies. We may experience employee attrition, decreased employee morale, and difficulty recruiting and retaining new employees in the future, all of which will require the time and attention of our management team. In addition, our ability to complete the restructuring ~~plan~~ **plans** and achieve the anticipated benefits from the ~~Plan~~ **plans** within the expected time frame, or at all, are subject to successful execution of management’s estimates and assumptions and may vary materially from our expectations, including as a result of factors that are beyond our control. If we do not realize the expected benefits of the ~~Plan~~ **restructuring plans** on a timely basis, or at all, our business, results of operations and financial condition could be adversely affected. Furthermore, following completion of the ~~Plan~~ **restructuring plans**, our business may not be more efficient or flexible than prior to implementation. **We may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the workforce reductions.** In the future, should demand for our products and services significantly increase, including as a result of regulatory approvals in the United States and elsewhere, we may need to increase the number of our employees and the scope of our operations, particularly in the areas of regulatory affairs and sales and marketing. We also intend, now and in the future, to continue to improve our operational, financial and management controls and reporting systems and procedures, which may require additional personnel and capital investments and will increase our costs. Such business growth could place a strain on our existing administrative and operational infrastructure, and we may not be able to make improvements to our personnel infrastructure in an efficient or timely manner, or at all. In addition, we may discover deficiencies in existing systems and controls. Some new personnel likely would be operating in countries outside the jurisdiction of our corporate headquarters, which adds additional complexity, and may require us to expand our facilities. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Managing personnel across a global enterprise requires expertise and resources and places a strain on our management, administrative and financial infrastructure. Our failure to effectively manage change and accomplish any of these tasks could delay the execution of our business plans or disrupt our operations, and prevent us from growing successfully. We may also be exposed or subject to additional unforeseen or undisclosed liabilities as well as increased

levels of indebtedness. We may be subject to substantial warranty or product liability claims or other litigation in the ordinary course of business that may adversely affect our business, financial condition and operating results. We face an inherent risk of product liability exposure related to the sale of the Allurion Balloon and any products in clinical trials. The marketing, sale and use, misuse or off-label use of the Allurion Balloon and our other current and future products could lead to the filing of product liability claims against us if someone alleges that our products failed to perform as designed or caused significant adverse events in patients. We may also be subject to liability for a misunderstanding of, or inappropriate reliance upon, the information we provide. If we cannot successfully defend ourselves against claims that the Allurion Balloon or our other current or future products caused injuries, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any products we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of patients from clinical trials or cancellation of trials;
- significant costs to defend the related litigation and distraction to our management team;
- substantial monetary awards to plaintiffs;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We currently hold \$ 5. 0 million in product liability insurance coverage, which may not be adequate to cover all liabilities we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Any future collaboration agreements (including with respect to product distribution or commercialization) we may enter into with respect to our current or future products may place the development or commercialization of such products outside our control, or may otherwise be on terms unfavorable to us. We may enter into ~~additional~~ collaboration agreements with third parties with respect to our current or future products, including for distribution or commercialization in or outside the **United States U. S.** Our likely collaborators for any distribution, marketing, licensing or other collaboration arrangements include large and mid-size medical device and diagnostic companies, regional and national medical device and diagnostic companies, and distribution or group purchasing organizations. We will have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our products. Our ability to generate revenue from these arrangements will depend in part on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We rely on third parties to conduct certain components of our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, which could interfere with or delay our ability to get regulatory approval or commercialize our products. We rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions and clinical investigators, to perform various functions for our clinical trials. Our reliance on third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. We remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the International Council for Harmonization and the FDA require us to comply with standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to ensure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of patients in clinical trials are protected. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our planned products and will not be able to, or may be delayed in our efforts to, successfully commercialize our planned products. The failure of third parties to meet their contractual, regulatory, and other obligations could adversely affect our business. We rely on suppliers, vendors, outsourcing partners, consultants, alliance partners and other third parties to research, develop, manufacture and commercialize our products and manage certain parts of our business. Using these third parties poses a number of risks, such as:

- (i) they may not perform to our standards or legal requirements;
- (ii) they may not produce reliable results;
- (iii) they may not perform in a timely manner;
- (iv) they may not maintain confidentiality of our proprietary information;
- (v) disputes may arise with respect to ownership of rights to technology developed with our partners; and
- (vi) disagreements could cause delays in, or termination of, the research, development or commercialization of our products or result in litigation or arbitration.

Moreover, some third parties are located in markets subject to political and social risk, corruption, infrastructure problems and natural disasters, in addition to country-specific privacy and data security risk given current legal and regulatory environments. Failure of third parties to meet their contractual, regulatory, and other obligations may materially affect our business. We have significant exposure to the economic and political situations in emerging market countries, and developments in these countries could materially impact our financial results, or our business more generally. Many of the countries in which our products are sold are emerging markets. Our global growth strategy contemplates the expansion of our existing sales activities in Latin America, the Middle East, Africa and the Asia-Pacific region. Our exposure to emerging markets has increased in recent years, as have the number and importance of our distributor arrangements. Economic and political developments in the emerging markets, including economic crises, currency inflation, or political instability, have had in the past, and may have in the future, a material adverse effect on our financial condition and results of operations. Moreover, as these markets continue to grow, competitors may seek to enter these markets and existing market participants will likely try to aggressively protect or increase their market shares. Increased competition may result in price reductions, reduced margins and our inability to gain or hold market share, which could have an adverse effect on our financial condition and results of operations. Increasing scrutiny and changing expectations from investors with respect to our environmental, social and governance practices may impose additional costs on us or expose us to reputational or other risks. Investors have increased their emphasis on the environmental, social and governance ("**ESG**") practices of companies across all industries, including the environmental impact of operations and human capital management. Certain stockholders use third-party benchmarks or scores to measure a company's ESG practices and decide whether to invest in its common stock or engage with the company to require changes to its practices. A failure to comply with investor expectations and standards, which are evolving and vary considerably, or the perception that we have not

responded appropriately to the growing concern for ESG issues, could result in reputational harm to our business and could have an adverse effect on us. Risks Related to Government Regulation The regulatory approval process is expensive, time consuming and uncertain, and may prevent us from obtaining approvals for the commercialization of the Allurion Balloon or our planned products. The research, testing, **approval**, manufacturing, labeling ~~approval~~, selling, import, export, marketing and distribution of medical devices are subject to extensive regulation by the FDA and other regulatory authorities in the **United States U.S.** and other countries, where regulations differ from country to country. Our products are registered to be sold in over 50 countries, but we are not permitted to market our products in the **United States U.S.** until we receive the requisite approval or clearance from the FDA; we have not received such FDA approval to date. In addition, failure to comply with FDA and other applicable U. S. and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions, including the following: • warning or untitled letters; • civil or criminal penalties and fines; • injunctions; • suspension or withdrawal of regulatory approval; • suspension of any ongoing clinical trials; • voluntary or mandatory product recalls and publicity requirements; • refusal to accept or approve applications for marketing approval of new devices or supplements to approved applications filed by us; • restrictions on operations, including costly new manufacturing requirements; or • seizure or detention of our products or import bans. Prior to receiving approval to commercialize any of our products in the **United States U.S.** or abroad, we may be required to demonstrate with substantial evidence from preclinical and well- controlled clinical trials, to the satisfaction of the FDA or other regulatory authorities abroad, that such products are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our products are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering any of our products to humans may produce undesirable side effects, which could interrupt, delay or cause suspension of clinical trials of our planned products and result in the FDA or other regulatory authorities denying approval of our products for any or all targeted indications. Regulatory approval from the FDA is not guaranteed, and the approval process is expensive and **may can** take several years. The FDA also has substantial discretion in the approval process. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon or repeat clinical trials, or perform additional preclinical studies and clinical trials. For example, we previously conducted a clinical trial on the Allurion Balloon and submitted a PMA **application** based on data from that trial. When the FDA requested additional data, we withdrew the PMA **application** and sought FDA approval to conduct our AUDACITY trial, which the FDA granted in 2021 **and which** ~~We are currently conducting that clinical trial~~ **we recently completed**. The number of preclinical studies and clinical trials that will be required for FDA approval varies depending on the product, the indication that the product is designed to address and the regulations applicable to any particular product. The FDA can delay, limit or deny approval of a planned product for many reasons, including, but not limited to, the following: • a planned product or one or more of its features may not be deemed safe or effective; • the FDA may not find the data from preclinical studies and clinical trials sufficient; • the FDA might not approve our manufacturing or our third- party supplier' s processes or facilities; or If the Allurion Balloon or any of our other products fail to demonstrate safety and efficacy in preclinical studies and clinical trials or do not gain requisite regulatory approval, our business and results of operations will likely be harmed. Inadequate funding for the FDA, the SEC and other government agencies, including from government shutdowns, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and / or approved by necessary government agencies, which could adversely affect our business. If **there are significant employee reductions at the FDA or** a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, **future reductions in force and** government shutdowns **could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. For example, over the last several years the U. S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. Currently, federal agencies in the U. S. are operating under a continuing resolution that is set to expire on September 30, 2025. In addition, federal employees recently have been subject to termination in connection with cost reduction efforts by the federal government. If a prolonged government shutdown or significant reduction in force of federal employees occurs, including those working for the FDA, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns and cost- cutting efforts** could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. Upon receipt of regulatory approval to market the Allurion Balloon in a given jurisdiction, we are (or will be) subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to penalties if we fail to comply with applicable regulatory requirements. When a regulatory approval is obtained, the approved product and its manufacturer are subject to continual review by regulatory authorities (including, if applicable, the FDA). Our non- U. S. regulatory approvals for the Allurion Balloon, as well as any future regulatory approval that we receive for the Allurion Balloon or for any of our other products, may be subject to limitations on the indicated uses for which the product may

be marketed. Future approvals may contain requirements for potentially costly post- marketing follow- up trials to monitor the safety and efficacy of the approved product. In addition, we are subject to extensive and ongoing regulatory requirements by the FDA and other regulatory authorities with regard to the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for our products. In addition, we are required to comply with regulations regarding the manufacture of the Allurion Balloon, which include requirements related to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory authorities must inspect these manufacturing facilities and determine they are in compliance with FDA good manufacturing practice requirements as set forth in the QSR before the products can be approved. These facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with the QSR and similar regulations. If we or a third party discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturer or us, including requiring withdrawal of the product from the market or suspension of manufacturing. ~~If patients using our products experience adverse events or other undesirable side effects, regulatory authorities could withdraw or modify our regulatory approvals, which would adversely affect our reputation and commercial prospects and / or result in other significant negative consequences.~~ Undesirable side effects caused by the Allurion Balloon could : cause us, the FDA or other applicable regulatory authorities to interrupt, delay or halt clinical trials, ~~and could~~ result in more restrictive labeling than originally required, cause the FDA ~~or other regulatory authorities~~ to subsequently withdraw or modify our PMA **should, if we obtain receive** approval, or ~~other regulatory approvals, or~~ result in the delay ~~or,~~ denial **or withdrawal** of regulatory approval by **other** regulatory authorities. For example, in the 1980s and early 1990s, the FDA required post- market safety and efficacy data be collected on an earlier version of an intragastric balloon after patients suffered severe side effects and complications with the device, which ultimately resulted in the withdrawal of the PMA approval. As of December 31, ~~2023~~ **2024**, we had sold over ~~130-150~~, 000 units of the Allurion Balloon in international markets. In our commercial experience, the serious adverse event ("**SAE**") rate has been less than 0. 2 % and has been similar to the SAE profile reported in the literature. If we are unable to demonstrate that any adverse events are not related to our product, the FDA or other regulatory authorities could order us to cease further development of, require more restrictive indications for use and / or additional warnings, precautions and / or contraindications in the labeling than originally required, or delay or deny approval of any of our products. Even if we are able to do so, such event (s) could affect patient recruitment or the ability of enrolled patients to complete ~~the any future trial trials~~. Moreover, if we elect, or are required, to not initiate, delay, suspend or terminate any future clinical trial of any of our products, the commercial prospects of such product may be harmed and our ability to generate product revenues from our product may be delayed or eliminated. Any of these occurrences may harm our ability to develop other products, and may harm our business, financial condition and prospects significantly. In addition, we or others may later identify undesirable side effects caused by the product (or any other similar product), resulting in potentially significant consequences, including: • regulatory authorities may withdraw or limit their approval of the product; • regulatory authorities may require the addition of labeling statements, such as a contraindication; • we may be required to change the way the product is distributed or administered, conduct additional clinical trials or change the labeling of the product; • we may be required to correct or remove the product from the marketplace or decide to conduct a voluntary recall; • we may decide to alert physicians through customer notifications; • regulatory authorities may use publicity such as a press release to alert our customers and the public of the issue; • health care providers and patients may be dissatisfied, seek refunds and refuse to use our products; • we could be sued and held liable for injury caused to individuals using our product; and • our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of the Allurion Balloon and could substantially increase the costs of commercializing our product and significantly impact our ability to successfully commercialize our product and generate product sales. Health care reform measures could hinder or prevent our planned products' commercial success. In the **United States U. S.**, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the health care system in ways that could affect our future revenue and future profitability and the future revenue and future profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation, that could result in significant changes to the health care system, some of which are intended to contain or reduce the costs of medical products and services. For example, one of the most significant health care reform measures in decades, **the** ACA, was enacted in 2010. The ACA contains a number of provisions, including those governing enrollment in federal health care programs, reimbursement changes and fraud and abuse measures, all of which ~~will have impact impacted~~ existing government health care programs and ~~will result~~ **resulted** in the development of new programs. For more information, see section entitled " Business – **Government Regulation- Other U. S. Healthcare Laws-** Coverage, Reimbursement and Healthcare Reform. " There have been judicial and Congressional challenges to certain aspects of the ACA, as well as executive efforts to repeal or replace certain aspects of the ACA. The Tax Cuts and Jobs Act passed in 2017 included a provision that would repeal one of the primary pillars of the law, the ACA' s individual mandate penalty, which essentially assessed a monetary penalty or fine on certain individuals who fail to maintain qualifying health coverage for all or part of a year. ~~The~~ **While not successful, the** U. S. Congress may consider other legislation to repeal or replace elements of the ACA on a provision- by- provision basis. We cannot assure you that the ACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results and we cannot predict how future federal or state legislative or administrative changes relating to health care reform will affect our business. We cannot predict the impact that such actions against the ACA or other health care reform under the **Biden- Trump** administration will have on our business, and there is uncertainty as to what health care programs and regulations may be implemented or changed at the federal and / or state level in the **United States U. S.**, or the effect of any future legislation or regulation. However, it is possible that such initiatives could have an adverse effect on our ability to obtain approval and / or successfully commercialize products in the **United States U. S.** in the future. For example, any changes that reduce, or impede the ability to

obtain, reimbursement for the type of products we intend to commercialize in the **United States** U.S. (or our products more specifically, if approved) or reduce medical procedure volumes could adversely affect our business plan to introduce our products in the U. S. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011 and subsequent legislation resulted in reductions to Medicare payments to providers of up to 2 % per fiscal year to 2031 unless additional Congressional action is taken. In addition, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers, cancer centers and other treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We cannot predict whether any additional legislative changes will affect our business. There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of health care. The implementation of cost- containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from our products and product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop future product candidates. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care services to contain or reduce costs of health care may adversely affect: • the demand for our product (s) and product candidates, if approved; • our ability to set a price that we believe is fair for our products; • our ability to generate revenue and achieve or maintain profitability; and • the availability of capital. **In addition, the U. S. Supreme Court’ s June 2024 decision in Loper Bright Enterprises v. Raimondo overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies’ reasonable interpretations of ambiguous federal statutes. The Loper decision could result in additional legal challenges to regulations and guidance issued by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the Loper decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action or as a result of legal challenges, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our business could be materially harmed. Our business could be adversely affected by a disruption to our contractual relationships for the provision of telehealth services. The corporate practice of medicine doctrine prohibits non- licensed individuals from practicing medicine, including by employing physicians or other licensed professionals to provide clinical services, directing the clinical practice of physicians and clinical professionals, or holding an ownership interest in an entity that employs or contracts with physicians and other licensed professionals. Certain jurisdictions also prohibit licensed professionals from splitting professional fees with non- licensed professionals. Through our Virtual Care Suite platform, our customers gain access to one or more licensed health care providers for telehealth consultations. We contract with third parties who maintain a separate clinical environment through which customers can access telehealth consultations, and we contract with additional groups that employ or contract with licensed health care providers to deliver telehealth services and consultations in the same clinical environment (collectively, the “ Contracted Telehealth Groups ”). Our contractual arrangements are structured to comply with applicable law and to help ensure providers delivering telehealth services to our customers retain exclusive authority for the provision of telehealth services and exercise independent professional judgment in performing weight- loss consults, supervising nurse practitioners and physician assistants, and writing prescriptions for patients, as applicable. We cannot guarantee that government entities or courts would determine our approach is consistent with the corporate practice of medicine, fee splitting laws, or other laws governing the delivery of clinical services via telehealth. Furthermore, the foregoing laws, and the enforcement landscape, are subject to change based upon political, regulatory, and other influences. If our arrangements for the delivery of telehealth services on the platform are deemed to be unlawful, providers accessing our platform could be subject to penalties (e. g., fines or license suspension), which could discourage providers from entering arrangements with the Contracted Telehealth Groups and delivering services to our customers. Such enforcement actions could result in lawsuits by providers — against the Contracted Telehealth Groups or us — and could require us to restructure or terminate our arrangements with Contracted Telehealth Groups. These consequences, along with any other disputes that may arise with the Contracted Telehealth Groups related to the delivery of telehealth services to our customers, could impair our ability to offer telehealth services on our platform and materially affect our business, financial condition, and results of operations. Our and the Contracted Telehealth Groups’ activities are subject to laws governing the provision of telehealth services, which could be subject to changes that result in additional operational complexity or increase costs. The Contracted Telehealth Groups and their providers are subject to laws governing the provision of telehealth services and the delivery of professional healthcare services more broadly. For example, some states limit the modality through which telehealth services are delivered, such as requiring synchronous (i. e. “ live ”) communication or curtailing asynchronous (or “ store- and- forward ”) communication for certain telehealth services (e. g., prescribing certain types of medications). Although we believe our contractual arrangements with the Contracted Telehealth Groups are structured to comply with laws governing the provision of telehealth services, these laws are evolving at a rapid pace and are subject to changing political, regulatory, and other influences. Due to the rapidly evolving regulatory climate, we cannot assure that our contractual arrangements and telehealth activities, if challenged, will be deemed compliant, nor can we assure that a new or existing law will not be implemented, enforced, or changed, with little or no notice, in manner that requires us to modify our business model at a material expense. Evolving**

government regulations and enforcement activities may require increased costs or adversely affect our results of operations. Our contractual arrangements with our Contracted Telehealth Groups are structured to comply with all applicable material laws, but, due to the uncertain regulatory environment and enforcement discretion, government regulators or enforcement agencies may determine that we or our Contracted Telehealth Groups are in violation of their laws and regulations. If we must remedy such violations, we or the Contracted Telehealth Groups may be required to modify business operations and services in a manner that undermines our ability to retain or acquire new customers, or we — or our Contracted Telehealth Groups — may be subject to fines or other burdensome enforcement actions that may result in our termination of operations in certain jurisdictions. If so, our revenue may decline and our business, financial condition, and results of operations could be adversely affected. Moreover, the laws applicable to our operations are subject to change or reinterpretation, and continued compliance may require us to change our practices at significant expense. Additional expenses may increase future overhead, which could have a material adverse effect on our results of operations. Additionally, modifications to our platform and the products, services and solutions we offer may require us to comply with additional laws and regulations, obtain necessary licenses or certifications, or materially alter our operations — any of which may require incurring significant expenses to ensure compliance. The failure to adequately comply with these future laws and regulations may delay or possibly prevent our products or services from being offered to customers, which could have a material adverse effect on our business, financial condition, and results of operations. Our AllurionMeds program offers patients access to compounded semaglutide. Compounded drugs, including compounded semaglutide, have been subject to increased scrutiny by the FDA, state governmental agencies, and other third- parties, and may expose us to a variety of risks that could result in an adverse impact on our business or reputation. We have developed and market a program, AllurionMeds, which offers patients access to compounded injectable semaglutide, a GLP- 1 prescription medication, that is prescribed by the patient’ s practitioner. The compounded semaglutide is prepared by a third- party 503B outsourcing facility (“ Semaglutide Compounding Facility ”) and dispensed via a state- licensed pharmacy. The FDA regulates 503B outsourcing facilities, which are required to comply with certain FDA requirements, including current good manufacturing practice requirements, product labeling requirements, restrictions on compounding drugs that are essentially a copy of an FDA- approved drug, and restrictions on compounding from bulk drug substances. 503B outsourcing facilities are also subject to analogous state laws and regulations. 503B outsourcing facilities have experienced both facility and product quality issues and have been subject to increased scrutiny by the FDA and state governmental agencies. If the Semaglutide Compounding Facility or any of its compounded products do not comply with applicable regulatory requirements or if there are quality issues with compounded semaglutide, FDA or state governmental agencies could pursue regulatory or enforcement action against the Semaglutide Compounding Facility, which could interrupt or halt the facility’ s operations. Any such action could impact the ability of the Semaglutide Compounding Facility to supply compounded semaglutide, which could have an adverse effect on our business. Additionally, if we are found to have manufactured, distributed, marketed, sold, or labeled any products in violation of applicable regulatory requirements, we may face significant penalties which may result in a material adverse effect on our business, financial condition, and results of operations. Certain 503B outsourcing facilities have been subject to negative media coverage, governmental inquiries and actions, and litigation in recent years, including with respect to compounded GLP- 1s. For example, manufacturers of branded GLP- 1 medications have brought lawsuits against 503B outsourcing facilities offering compounded GLP- 1s as well as the prescribers of such medications, including telehealth providers. Any negative media coverage, governmental inquiries or actions, or litigation against us or the Semaglutide Compounding Facility could have an adverse effect on our reputation or business. 503B outsourcing facilities are permitted to compound from bulk drug substances if the product appears on the FDA’ s drug shortage list. Semaglutide was previously listed on the FDA drug shortage list in 2022 but, in February 2025, the FDA issued a declaratory order in which the FDA determined that such shortage was resolved and removed semaglutide from the FDA drug shortage list. As part of the declaratory order, the FDA stated that 503B outsourcing facilities will be permitted to compound injectable semaglutide until May 22, 2025. Following such date, 503B outsourcing facilities, including the Semaglutide Compounding Facility, will be restricted in their ability to compound semaglutide. Additionally, on October 22, 2024, Novo Nordisk submitted a nomination for semaglutide to be included on FDA’ s list of drug products that present demonstrable difficulties for compounding. If added to this list, 503B outsourcing facilities would be prohibited from producing compounded semaglutide, even if semaglutide is on the drug shortage list. If any of these events occurs, we cannot guarantee that we will be able to continue offering these products in the same manner, to the same extent, or at all, due to a variety of factors outside our control, including supply chain, intellectual property, regulatory and resource allocation matters. If our ability to offer these products is constrained in the future, supply may be limited, the price of these offerings may increase significantly, which could decrease new customer demand, cause existing customers to cancel their subscriptions, and reduce our revenues and / or gross profit, which could harm our brand, reputation, and results of operations. If we fail to comply with health care 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 health care services or bill directly to Medicare, Medicaid or other third- party payors, certain federal and state health care laws and regulations pertaining to fraud and abuse and patients’ rights may be applicable to our business. If we are approved by the FDA to market our products in the U. S., we could be subject to health care fraud and abuse, transparency, and patient privacy regulation by both the federal government and the states in which we conduct our business. For more information, see the section entitled “ Business – Other U. S. Healthcare Laws. ” Similar regulations would also apply to our business in countries where we have direct sales operations where there are different regulations at European and national levels. There is a high degree of complication in complying with the different levels of regulation and the singular

differences in the different countries and markets. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in Medicare, Medicaid and other federal health care programs, additional reporting and government oversight, if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations. Any such penalties or curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal, state or international privacy, security and fraud laws may prove costly. We have obtained the authorization to distribute our products in regions / countries through the certification of our Quality System by the corresponding regulatory entities. Failing to demonstrate that our Quality System is in place and consistently and systematically ensures compliance with regulations from such regions / countries might imply losing the certifications and as such, the rights to freely distribute the products which would adversely impact our revenue and reputation. We have not historically maintained a compliance policy relating to U. S. or foreign economic sanctions, export controls or anti-corruption laws and regulations, and failure to comply with these regimes creates the potential for significant liabilities, penalties and reputational harm. We have not historically maintained a compliance policy relating to U. S. economic sanctions, export controls or anti-corruption laws and regulations. Failure to comply with such laws and regulations creates the potential for significant liabilities, penalties and reputational harm. We are subject to a number of laws and regulations governing commercial activities with and payments and contributions to third parties, including restrictions imposed by the FCPA, as well as trade sanctions and export control laws administered by the U. S. Department of the Treasury's Office of Foreign Assets Control ("OFAC"), the U. S. Department of Commerce and the U. S. Department of State. The FCPA, among other things, prohibits bribery of foreign governments and their officials and political parties and requires U. S. public companies to keep books and records that accurately and fairly reflect those companies' transactions. OFAC, the U. S. Department of Commerce and the U. S. Department of State administer and enforce various export control laws and regulations and economic sanctions based on U. S. foreign policy and national security goals against targeted foreign states, organizations and individuals. Similar laws in non-U. S. jurisdictions, such as UK sanctions, EU sanctions or the U. K. Bribery Act, as well as other applicable anti-bribery, anti-corruption, anti-money laundering, sanctions or export control laws, may also impose stricter or more onerous requirements than U. S. economic sanctions, export controls, and anti-corruption laws and regulations, and implementing compliance measures may disrupt our business or cause us to incur significantly more costs. Different laws may also contain conflicting provisions, making compliance more difficult. If we fail to comply with these laws and regulations, we could be exposed to claims for damages, civil or criminal financial penalties, reputational harm, incarceration of our employees, restrictions on our operations and other liabilities, which could materially and adversely affect our business, results of operations and financial condition. While we have implemented policies and procedures designed to promote compliance by us and our personnel with the FCPA and other anti-corruption laws, they may not be effective in all instances to prevent violations. Any determination that we have violated the FCPA or other applicable anti-corruption, sanctions or export control laws could subject us to, among other things, civil and criminal penalties, material fines, profit disgorgement, injunctions on future conduct, securities litigation and a general loss of investor confidence, any one of which could adversely affect our business, financial condition and results of operations.

Unstable global economic and geopolitical conditions Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business, operations and financial condition, stock price, and results of operations. **Actual** The global economy and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, inflation, declines in economic growth, global supply chain disruptions, and uncertainty about economic stability. The global economy and financial markets also may be adversely affected by the potential for significant changes in U. S. policies or regulatory environment given the new administration, current or anticipated impact of military conflict, including the ongoing conflicts between Russia and Ukraine, and in the Middle East, terrorism or other geopolitical events. Sanctions imposed by the United States and involving limited liquidity, defaults, non-performance or other countries in response to such conflicts may adversely impact the financial markets and the global economy, and the economic countermeasures by the affected countries or others could exacerbate market and economic instability. There can be no assurance that affect further deterioration in credit and financial institutions, transactional counterparties markets and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand other companies in the financial services industry or for the financial services industry generally, or concerns or rumors about any events of these kinds product candidates we may develop and or our ability other similar risks, have in the past and may in the future lead to raise additional capital when needed on acceptable terms market-wide liquidity problems. On March 10, if March 12, and May 1, 2023, the Federal Deposit Insurance Corporation ("FDIC") took control and was appointed receiver of Silicon Valley Bank ("SVB"), Signature Bank, and First Republic Bank, respectively, after each bank was unable to continue its operations. We are unable to predict the extent or nature of the impacts of the failures of SVB, Signature Bank and First Republic Bank and related circumstances at all this time. Similarly, A weak or declining economy could also strain our suppliers, we cannot possibly resulting in supply disruption. If the equity and predict credit the impact that the high market markets volatility and instability of the banking sector deteriorate, it may make any necessary equity or debt financing more broadly difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and

stock price and could require us to delay, scale back or discontinue the clinical development of one or more of our product candidates, and our operations in general. In addition, there is a risk that our current or future service providers, manufacturers or other collaborators may not survive such difficult economic activity and times, which could directly affect our business in particular ability to attain our operating goals on schedule and on budget. The failure We cannot anticipate all of other -- the banks ways in which the current economic climate and financial market conditions institutions and measures taken, or not taken, by governments, businesses and other organizations in response to these events could adversely impact our business, financial condition and results of operations. Although we assess our banking relationships as we believe necessary Furthermore, changes in U. S. federal policy that affect the geopolitical landscape could give rise to circumstances outside or our control that could have negative impacts on appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or our capitalize our current and projected future business operations. For example, the new administration has imposed and announced plans to impose broad-based tariffs on imports from many countries, including China, Mexico, and Canada, as well as countries of the European Union and Japan. Historically, tariffs have led to increased trade and political tensions between the United States and countries in the international community. In response to tariffs, other countries have implemented retaliatory tariffs on U. S. goods. Political tensions as a result of trade policies could reduce trade volume be significantly impaired by factors that affect us, investment the financial institutions with which we have credit agreements or arrangements directly, technological exchange and or the financial services industry or economy in general. These factors could include, among others-- other economic activities between major international economies, events such as liquidity constraints or failures, resulting in a material adverse effect on global economic conditions and the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability -- stability of global in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. Any changes in political These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also trade, regulatory, and economic conditions, include including factors involving financial markets or the financial services industry generally. In addition, investor concerns regarding the U. S. trade policies 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 acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and / or 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 a material adverse impacts effect on our liquidity and our current and / or projected business operations and financial condition and results of operations. We may be affected by regulatory responses to climate-related issues. The Biden Administration has made climate change and the limitation of greenhouse gas (" GHG ") emissions one of its primary objectives. Several states and other geographic regions in the United States have also adopted legislation and regulations to reduce emissions of GHGs. On In March 6, 2024, the SEC finalized new rules for public companies that will require extensive climate-related disclosures and significant analysis of the impact of climate-related issues on our business strategy, results of operations, and financial condition (the " SEC Climate Disclosure Rules "), although the SEC recently stayed the reporting requirements. The new If such rules are eventually effective, they will require us to disclose our material climate-related risks and opportunities, GHG emissions inventory, climate-related targets and goals, and financial impacts of physical and transition risks. As a result of the SEC Climate Disclosure Rules, and our legal, accounting, and other compliance expenses may increase significantly, and to ensure our compliance; compliance efforts may also divert management time and attention. We may also be exposed to legal or regulatory action or claims as a result of these new regulations, should they become effective. All of these risks could have a material adverse effect on our business, financial position, and / or stock price.

Risks Related to Intellectual Property

The medical device industry is characterized by patent litigation and we could become subject to litigation that could be costly, result in the diversion of management's time and efforts, require us to pay damages or prevent us from marketing our existing or future products. Patent litigation is prevalent in the medical device and diagnostic sectors. Our commercial success depends in part upon our ability and that of our distributors, contract manufacturers, and suppliers to manufacture, market, and sell our planned products, and to use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary rights or intellectual property of third parties. We are, and in the future may become, party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology. Third parties may assert infringement claims against us based on existing or future intellectual property rights. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that we may be accused of infringing. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Accordingly, third parties may assert infringement claims against us based on intellectual property rights that exist now or arise in the future. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. Medical device and diagnostic industries have produced a significant number of patents and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use or manufacture. The scope of protection afforded by a patent is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that the relevant product or methods of using the product either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable and we may not be able to do this. Proving invalidity is difficult. For example, in the U. S., proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed

by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources, and we may not have sufficient resources to bring these actions to a successful conclusion. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third-party to continue developing and marketing our products and technology. We may also elect to enter into such a license in order to settle pending or threatened litigation. However, we may not be able to obtain any required license on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us, and could require us to pay significant royalties and other fees. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our planned products in commercially important territories, or force us to cease some of our business operations, which could harm our business. **Our** Many of our employees **were** **may have been** previously employed at, and many of our current advisors and consultants are employed by, universities or other biotechnology, medical device or pharmaceutical companies, ~~including our competitors or potential competitors~~. Although we instruct our employees, advisors and consultants not to, and otherwise endeavor to ensure that they do not, use or disclose the proprietary information or know-how of others in their work for us, we may be subject to claims that we, or these service providers, have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such service providers' current or former employer or other third party. These and other claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our business to the infringement claims discussed above. Even if we are successful in defending against intellectual property claims, litigation or other legal proceedings relating to such claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of litigation or other intellectual property related proceedings could have a material adverse effect on our ability to compete in the marketplace. Changes in U. S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products. The ~~U. S. enacted and implemented the America Invents Act of 2011, a wide-ranging patent reform legislation. Further, the~~ U. S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain future patents, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U. S. Congress, the federal courts and the U. S. Patent and Trademark Office ("USPTO"), the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents or future patents. If we fail to comply with our obligations in our intellectual property agreements, we could lose intellectual property rights that are important to our business. We are a party, and expect to become party in the future, to certain intellectual property agreements that impose various obligations on us. If we fail to comply with these obligations, any licensor may have the right to terminate such agreements, in which event we may not be able to develop and market any product that is covered by such agreements. Termination of such agreements, or reduction or elimination of our rights under such agreements, may result in our having to negotiate new or reinstated arrangements on less favorable terms, or our not having sufficient intellectual property rights to operate our business. The occurrence of such events could harm our business and financial condition. The risks described elsewhere in this Annual Report on Form 10-K pertaining to our intellectual property rights also apply to any intellectual property rights that we may license, and any failure by us or any future licensor to obtain, maintain, defend and enforce these rights could have a material adverse effect on our business. If we are not able to obtain and maintain intellectual property protection for our products and technologies, ~~or~~ if the scope of our patents is not sufficiently broad, **or our patents are invalidated,** we may not be able to effectively maintain our market leading technology position. As of December 31, ~~2023~~ **2024**, we own or have rights to ~~18-19~~ issued and ~~five~~ **six** pending patents in the United States related to various aspects of the Allurion Balloon such as a swallowable, self-deflating and naturally passing gastric balloon, improvements to the fill and release valves therein, methods for deploying and releasing a gastric balloon within the body, and next generation fill and release valves. In addition, we have ~~36~~ **42** issued and ~~four~~ **five** patents pending outside of the United States. Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the U. S. and in other countries with respect to our proprietary technology and products. The patent position of medical device and diagnostic companies generally is highly uncertain and involves complex legal and factual questions which are dependent upon the current legal and intellectual property context, extant legal precedent and interpretations of the law by individuals, and for which legal principles remain unresolved. In recent years, patent rights have been the subject of significant litigation. As a result, the issuance, scope, validity, enforceability and commercial value of the patent rights we rely on are highly uncertain. Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Pending and future patent applications may not result in patents being issued at all, may not result in patents being issued in a manner which protect our technology or products, or may not result in patents being issued which effectively prevent others from commercializing competitive technologies and products. Assuming the other

requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the U. S., the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U. S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we or were the first to file for patent protection of such inventions. If third parties have filed prior patent applications on inventions claimed in our patents or applications that were filed on or before March 15, 2013, an interference proceeding in the U. S. can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third parties have filed such prior applications after March 15, 2013, a derivation proceeding in the U. S. can be initiated by such third parties to determine whether our invention was derived from theirs. The determination that a patent application or patent claim meets all the requirements for patentability is a subjective determination based on the application of law and jurisprudence. The ultimate determination by the USPTO, or by a court or other trier of fact in the U. S., or corresponding foreign national patent offices or courts, on whether a claim meets all requirements of patentability cannot be assured. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our owned (jointly or fully) or licensed- in patents or patent applications. We cannot provide assurances that any invention that is the subject of our patent applications, whether licensed- in or owned jointly or completely by us, will be found to be patentable, including over our own prior art publications or patent literature, or any such that application will result in an issued patent. We cannot make assurances as to the scope of any claims that may issue from our pending and future patent applications or to the outcome of any proceedings by any potential third parties that could challenge the patentability, validity or enforceability of our patents and patent applications in the U. S. or foreign jurisdictions. Any such challenge, if successful, could limit patent protection for our technology and products and / or materially harm our business. Even if the patent applications we rely on issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and the patents we rely on may be challenged in the courts or patent offices in the U. S. and abroad. There is no assurance that all the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it may be used to invalidate a patent, or may prevent a patent from issuing from a pending patent application. For example, such patent filings may be subject to a third- party submission of prior art to the USPTO or to other patent offices around the world. Alternately or additionally, we may become involved in post- grant review procedures, oppositions, derivation proceedings, ex parte re-examinations, inter partes review, supplemental examinations, or interference proceedings or challenges in district court, in the U. S. or in various foreign patent offices, including both national and regional, challenging patents or patent applications in which we have rights, including patents on which we rely to protect our business. Patents that may be issued or in- licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage. An adverse determination in any such challenge may result in loss of the patent or in patent application or patent claims being narrowed, invalidated or held unenforceable, in whole or in part, or in denial of the patent application or loss or reduction of the scope of one or more claims of the patent or patent application, any of which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. As another example, a European Unified Patent Court ("UPC") has entered into force on June 1, 2023. The UPC is a common patent court to hear patent infringement and revocation proceedings effective for member states of the European Union ("EU"). This could enable third parties to seek revocation of any of our European patents or licensed- in European patents in a single proceeding at the UPC rather than through multiple proceedings in each of the jurisdictions in which any such European patent is validated. Any such revocation and loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and products. Moreover, the controlling laws and regulations of the UPC will develop over time, and may adversely affect our ability to enforce our European patents, whether owned or licensed- in, or defend the validity thereof. We, or any future licensor, may decide to opt out our European patents and patent applications from the UPC. If certain formalities and requirements are not met, however, these European patents and patent applications could be challenged for non- compliance and brought under the jurisdiction of the UPC. We cannot be certain that our owned (jointly or fully) or licensed- in European patents or European patent applications will avoid falling under the jurisdiction of the UPC, if we, or any future licensor, decide to opt out of the UPC. Our competitors, who may have greater resources and may have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, and sell our technologies and products. Given the amount of time required for the development, testing and regulatory review of new planned products, patents protecting such products might expire before or shortly after such products are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage. Changes in either the patent laws or interpretation of the patent laws in the U. S. and other countries may diminish the value of the patents we rely on or narrow the scope of our patent protection. The laws of other countries may not protect our rights to the same extent as the laws of the U. S. For example, patent laws in various jurisdictions, including jurisdictions covering significant commercial markets, such as the European Patent Office, China and Japan, restrict the patentability of methods of treatment of the human body more than U. S. law does. If these developments were to occur, they could have a material adverse effect on our ability to generate revenue. There may be significant pressure on the U. S. government and international governmental bodies to limit the scope of patent protection both inside and outside the U. S. for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns. Countries other than the U. S. may have patent laws less favorable to patentees than those upheld by U. S. courts,

allowing foreign competitors a better opportunity to create, develop, and market competing products. Countries other than the U. S. may, under certain circumstances, force us to grant a license under our patents to a competitor, thus allowing the competitor to compete with us in that jurisdiction or forcing us to lower the price of our product in that jurisdiction. Furthermore, the degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example: • it is possible that one or more of our pending patent applications will not become an issued patent or, if issued, that the patent (s) claims will have sufficient scope to protect all of our planned products, provide us with commercially viable patent protection or provide us with any competitive advantages; • if our pending applications issue as patents, they may be challenged by third parties as invalid or unenforceable under U. S. or foreign laws; • we may not successfully commercialize all of our planned products, if approved, before our relevant patents expire; • we may not be the first to make the inventions covered by each of our patents and pending patent applications; or • we may not develop additional proprietary technologies or products that are separately patentable. In addition, to the extent that we are unable to obtain and maintain patent protection for our technologies or product, or in the event that such patent protection expires, it may no longer be cost- effective to extend our portfolio by pursuing additional development of any future products. If our trademarks and tradenames are not adequately protected, then we may not be able to build name recognition in our markets and our business may be adversely affected. We rely on trademarks, service marks, tradenames and brand names to distinguish our products from the products of our competitors, and have registered or applied to register these trademarks. We cannot assure you that our trademark applications will be approved. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources towards advertising and marketing new brands. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. Certain of our current or future trademarks may become so well known by the public that their use becomes generic and they lose trademark protection. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business, financial condition and results of operations may be adversely affected. We may be subject to claims that we or our employees have misappropriated the intellectual property of a third party, including trade secrets or know- how, or are in breach of non-competition or non- solicitation agreements with our competitors. **Our Many of our employees and consultants were may have been** previously employed at or engaged by other medical device, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and contractors may have executed proprietary rights, non- disclosure and non- competition agreements in connection with such employment. Although we instruct our employees and consultants not to, and otherwise endeavor to ensure that they do not, use or disclose the intellectual property, proprietary information, know- how or trade secrets of others in their work for us, we may be subject to claims that we or these individuals have, inadvertently or otherwise, misappropriated the intellectual property or disclosed the alleged trade secrets or other proprietary information of such employers or competitors. Additionally, we may be subject to claims from third parties challenging our ownership interest in intellectual property we regard as our own, based on claims that our employees or consultants have breached an obligation to assign inventions to another employer, to a former employer, or to another person or entity. Litigation may be necessary to defend against any other claims, and it may be necessary or we may desire to enter into a license to settle any such claim; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate technologies or features that are important or essential to our products could have a material adverse effect on our business, financial condition and results of operations, and may prevent us from selling our products. In addition, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could have an adverse effect on our business, financial condition and results of operations. Others may challenge inventorship or claim an ownership interest in our intellectual property which could expose us to litigation and have a significant adverse effect on our prospects. Determinations of inventorship can be subjective. While we undertake to accurately identify correct inventorship of inventions made on our behalf by our employees, consultants and contractors, an employee, consultant or contractor may disagree with our determination of inventorship and assert a claim of inventorship. Any disagreement over inventorship could result in our being forced to defend our determination of inventorship in a legal action, which could result in substantial costs and be a distraction to our senior management and scientific personnel. While we typically require employees, consultants and contractors who may develop intellectual property on our behalf to execute agreements assigning such intellectual property to us, we may be unsuccessful in obtaining execution of assignment agreements with each party who in fact develops intellectual property that we regard as our own. If we are unsuccessful in obtaining assignment agreements from an employee, consultant or contractor who develops intellectual property on our behalf, the employee, consultant or contractor may later claim ownership of the invention. Any disagreement over ownership of intellectual property could result in our losing ownership, or exclusive ownership, of the contested intellectual property, paying monetary damages and / or being enjoined from clinical testing, manufacturing and

marketing of the affected product candidate (s). Even if we are successful in defending against such claims, a dispute could result in substantial costs and be a distraction to our senior management and scientific personnel. We may become involved in legal proceedings to protect or enforce our intellectual property rights, which could be expensive, time consuming, or unsuccessful. Competitors may infringe or otherwise violate the patents we rely on, or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. In addition, in an infringement proceeding, a court may decide that a patent we are asserting is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the patents we are asserting do not cover the technology in question. With respect to a counterclaim of invalidity, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. An adverse result in any litigation proceeding could put one or more patents at risk of being invalidated or interpreted narrowly, prevent us from stopping the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. If any of our patents are found invalid or unenforceable, or construed narrowly, our ability to stop the other party from launching a competitive product would be materially impaired. Further, such adverse outcomes could limit our ability to assert those patents against future competitors. Loss of patent protection would have a material adverse impact on our business. Even if we establish infringement of any of our patents by a competitive product, a court may decide not to grant an injunction against further infringing activity, thus allowing the competitive product to continue to be marketed by the competitor. It is difficult to obtain an injunction in U. S. litigation and a court could decide that the competitor should instead pay us a “reasonable royalty” as determined by the court, and / or other monetary damages. A reasonable royalty or other monetary damages may or may not be an adequate remedy. Loss of exclusivity and / or competition from a related product would have a material adverse impact on our business. Litigation often involves significant amounts of public disclosures. Such disclosures could have a materially adverse impact on our competitive position or our stock prices. During any litigation, we would be required to produce voluminous records related to our patents and our research and development activities in a process called discovery. The discovery process may result in the disclosure of some of our confidential information. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. Litigation is inherently expensive, and the outcome is often uncertain. Any litigation likely would substantially increase our operating losses and reduce our resources available for development activities. Further, we may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. As a result, we may conclude that even if a competitor is infringing any of our patents, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of us or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. Concurrently with an infringement litigation, third parties may also be able to challenge the validity of our patents before administrative bodies in the **United States**, U.S., or abroad. Such mechanisms include re-examination, post grant review and equivalent proceedings in foreign jurisdictions, e. g., opposition proceedings. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover our products, potentially negatively impacting any concurrent litigation. Interference or derivation proceedings provoked by third parties or brought by the USPTO or any other patent authority may be necessary to determine the priority of inventions or other matters of inventorship with respect to patents and patent applications. In addition to challenges during litigation, third parties can challenge the validity of our patents in the U. S. using post-grant review and inter partes review proceedings, which some third parties have been using to cause the cancellation of selected or all claims of issued patents of competitors. For a patent filed March 16, 2013 or later, a petition for post-grant review can be filed by a third party in a nine-month window from issuance of the patent. A petition for inter partes review can be filed immediately following the issuance of a patent if the patent has an effective filing date prior to March 16, 2013. A petition for inter partes review can be filed after the nine-month period for filing a post-grant review petition has expired for a patent with an effective filing date of March 16, 2013 or later. Post-grant review proceedings can be brought on any ground of invalidity, whereas inter partes review proceedings can only raise an invalidity challenge based on published prior art and patents. These adversarial actions at the USPTO review patent claims without the presumption of validity afforded to U. S. patents in lawsuits in U. S. federal courts and use a lower burden of proof than used in litigation in U. S. federal courts. Therefore, it is generally considered easier for a competitor or third party to have a U. S. patent invalidated in a USPTO post-grant review or inter partes review proceeding than invalidated in a litigation in a U. S. federal court. If any of our patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we or any future licensors or collaborators will be successful in defending the patent, which may result in a loss of the challenged patent right to us. We may become involved in proceedings, including oppositions, interferences, derivation proceedings inter partes reviews, patent nullification proceedings, or re-examinations, challenging our patent rights or the patent rights of others, and the outcome of any such proceedings are highly uncertain. An adverse determination in any such proceeding could reduce the scope of, or invalidate, important patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Our business also could be harmed if a prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may also become involved in disputes with others regarding the ownership of intellectual property rights. If we are unable to resolve these disputes, we could lose valuable intellectual property rights. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical or management personnel from their normal responsibilities. In addition,

there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace. If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected, harming our business and competitive position. In addition to our patented technology and products, we rely upon confidential proprietary information, including trade secrets, unpatented know-how, technology and other proprietary information, to develop and maintain our competitive position. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in the market. Although we have taken steps to protect our confidential proprietary information, in part, by confidentiality agreements with our employees and our collaborators, consultants, vendors and advisors, we cannot provide assurances that all such agreements have been duly executed. Third parties may still obtain this information or may come upon this or similar information independently, and we cannot be certain that our trade secrets and other confidential information will not be disclosed or that competitors will not otherwise gain access to our trade secrets, or that technology relevant to our business will not be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees, consultants, collaborators, vendors or advisors that are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could be disclosed, misappropriated or otherwise become known or be independently discovered by our competitors. In addition, intellectual property laws in foreign countries may not protect trade secrets and confidential information to the same extent as the laws of the U. S. If we are unable to prevent disclosure of the intellectual property related to our technologies to third parties, we may not be able to establish or maintain a competitive advantage in our market, which would harm our ability to protect our rights and have an adverse effect on our business. We may not be able to protect or enforce our intellectual property rights throughout the world. Filing, prosecuting and defending patents on all of our planned products throughout the world may be prohibitively expensive to us. The requirements for patentability may differ in certain countries, particularly in developing countries; thus, even in countries where we do pursue patent protection, there can be no assurance that any patents will issue with claims that cover our products. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the **United States U.S.** and Europe do not afford intellectual property protection to the same extent as the laws of the **United States U.S.** and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the U. S. and Europe or from selling or importing products made from our inventions in and into the U. S. or other jurisdictions. Consequently, competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as in the **United States U.S.** These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in international jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Further, such proceedings could put our patents (in that or other jurisdictions) at risk of being invalidated, held unenforceable or interpreted narrowly; put our pending patent applications at risk of not issuing; and provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Furthermore, we cannot ensure that we will be able to initiate or maintain the same level or quality of patent protection in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. Changes in the interpretation of patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products. In the **United States U.S.**, the U. S. Congress is responsible for passing laws establishing patentability standards, and, as with any laws, implementation is left to federal agencies and the federal courts based on their interpretations of the laws. In the U. S., interpretation of patent standards can vary significantly within the USPTO, and across the various federal courts, including the U. S. Supreme Court. Recently, the U. S. Supreme Court has ruled on several patent cases, generally limiting the types of inventions that can be patented. Further, there are open questions regarding interpretation of patentability standards that the U. S. Supreme Court has yet to decisively address. Absent clear guidance from the U. S. Supreme Court, the USPTO has become increasingly conservative in its interpretation of patent laws and standards. Similar tensions between government administrations and judicial interpretation of patent laws in other jurisdictions may result in changes to the scope or validity of our patents in such jurisdictions. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, the legal landscape in the U. S. and outside the U. S. has created uncertainty with respect to the value of patents. Depending on any actions by applicable legislating bodies, and future decisions by the entities implementing such laws, the laws and regulations governing patents could change in unpredictable ways and could weaken our

ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents or applications will be due to be paid by us to the USPTO and various governmental patent agencies outside of the U. S. in several stages over the lifetime of the patents or applications. The USPTO and various non- U. S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. Though we use commercially reasonable efforts to comply with all applicable maintenance requirements, we may fail to do so on occasion. In many cases, such an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance, whether intentional or not, can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to use our technologies and this circumstance would have a material adverse effect on our business. We may need to acquire or license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms. A third party may hold intellectual property, including patent rights, that we may determine are important or necessary to the development of our technology and products. In addition, it may be necessary for us to use the patented or proprietary technology of one or more third parties to commercialize our current and future products. The licensing and acquisition of third- party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third- party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. If we determine to license or acquire third- party intellectual property and we are unable to acquire such intellectual property outright, or obtain licenses to such intellectual property from such third parties when needed or on commercially reasonable terms, our ability to commercialize our products at such time would likely be delayed or we may have to abandon development of that product or program and our business and financial condition could suffer. If we in- license additional technologies or products in the future, we might become dependent on proprietary rights from third parties with respect to those technologies or products. Any termination of such licenses could result in the loss of significant rights and would cause material adverse harm to our ability to develop and commercialize any product subject to such licenses. Disputes may also arise between us and any future licensors regarding intellectual property subject to a license agreement. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product (s). The risks described elsewhere pertaining to our intellectual property rights also apply to the intellectual property rights that we may determine to in- license, and any failure by us or any future licensors to obtain, maintain, defend and enforce such rights could have an adverse effect on our business. In some cases we may not have control over the prosecution, maintenance or enforcement of the patents that we determine to license, and may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents, and potential future licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend and enforce the licensed patents. The Allurion VCS and other products or services contain third- party open source software components. Certain use of such open source components with our proprietary software could adversely affect our ability to charge fees for, or otherwise protect the value of, our offerings. The Allurion VCS and our other products and services contain software licensed to us by third- party authors under “ open source ” licenses. Use of such software may entail greater risks than use of non- open source third- party commercial software, as open source licensors generally do not provide support, warranties, indemnification or other contractual protections regarding infringement claims or the quality of the code. Although we seek to monitor our use of open source software to avoid such consequences and to comply with the terms thereof, the terms of many open source licenses have not been interpreted by U. S. or foreign courts, and there is a risk that these licenses could be construed in a way that could impose unanticipated conditions or restrictions on our ability to provide or distribute our platform. If we are held to have breached the terms of an open source software license, we could face liability which may result in an injunction against providing our offering, or be required to seek costly licenses from third parties to continue providing our offerings on terms that are not economically feasible, to re- engineer our platform, to discontinue or delay the provision of our offerings if re- engineering could not be accomplished on a timely basis or to make generally available, in source code form, our proprietary code, any of which could adversely affect our business, financial condition and results of operations. Our internal computer systems, or those used by third parties which we rely on, may fail or suffer security breaches. Despite the implementation of security measures, our internal computer systems, or those used by third parties which we rely on, are vulnerable to damage from computer viruses and unauthorized access, malware, natural disasters, fire, terrorism, war, telecommunication failures, electrical failures, cyber- attacks or cyber- intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. Although our information security program is in compliance with the global ISO 27001: 2013 standards, it does not yet fully comply with all of the additions and changes in the updated ISO 27001: 2022 version of the standards, which we anticipate complying with prior to the required transition date of October 31, 2025 to maintain ISO 27001 security certification. If our security measures are breached, whether due to failure to comply with the ISO 27001: 2022 version of the standards or otherwise, or if design flaws in our software or information systems are exposed and exploited, and, as a result, a third party obtains unauthorized access to any of our or our customer’ s data, our relationships with our customers and distributors may be damaged, and we could incur significant liability and reputational harm. The risk of a security breach or disruption, particularly through cyber- attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. While we have not experienced any

such material system failure or security breach to our knowledge to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of data from completed, ongoing or future trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our current and future products could be delayed. We rely on internet infrastructure, bandwidth providers, third- party computer hardware and software and other third parties for providing services to our customers and patients, and any failure or interruption in the services provided by these third parties could expose us to litigation and negatively impact our relationships with customers and patients, adversely affecting our operating results. Our ability to deliver our internet- based services depends on the development and maintenance of the infrastructure of the internet by third parties. This includes maintenance of a reliable network backbone with the necessary speed, data capacity, bandwidth capacity and security. Our services are designed to operate without interruption. However, we may experience future interruptions and delays in services and availability from time to time. In the event of a catastrophic event with respect to one or more of our systems, we may experience an extended period of system unavailability, which could negatively impact our relationship with clients and members. To operate without interruption, both we and our service providers must guard against: • damage from fire, power loss, natural disasters and other force of nature events outside our control; • communications failures; • software and hardware errors, failures, and crashes; • security breaches, computer viruses, hacking, denial- of- service attacks, and similar disruptive problems; and • other potential interruptions. We also rely on software licensed from third parties in order to offer our services. These licenses are generally commercially available on varying terms. However, it is possible that this software may not continue to be available on commercially reasonable terms, or at all. Any loss of the right to use any of this software could result in delays in the provisioning of our services until equivalent technology is either developed by us, or, if available, is identified, obtained and integrated. Furthermore, our use of additional or alternative third- party software would require us to enter into license agreements with third parties, and integration of our software with new third- party software may require significant work and require substantial investment of our time and resources. Also, any undetected errors or defects in third- party software could prevent the deployment or impair the functionality of our software, delay new updates or enhancements to our platform, result in a failure of our platform, and injure our reputation. Our failure to adequately protect personal information in compliance with evolving legal requirements could harm our business. In the ordinary course of our business, we collect and store sensitive data, including legally protected patient health information and personally identifiable information, **or " PII "**. We collect this kind of information ~~on our customers~~ for purposes of servicing potential warranty claims ~~and~~, for post- marketing safety vigilance ~~, and for other permissible purposes~~. **Data We believe that, because of our current operations and the fact that we do not submit claims to third- party payors for reimbursement, we are not a covered entity or a business associate that acts on behalf of a covered entity under the Health Insurance Portability and Accountability Act (" HIPAA ")**. **Nonetheless, numerous other federal, state, and foreign laws** ~~protection~~ **protect and the confidentiality, privacy -related, availability, integrity and security of health information and other types of PII. These** ~~laws and regulations are evolving and may result in ever- increasing regulatory and public scrutiny and escalating levels of enforcement and sanctions. There are a number of state~~ **subject to change or differing interpretations**, ~~federal and international new laws regarding protecting the privacy, data protection, and information security of~~ **may be enacted in the future. This complex and evolving landscape could expose us — and the Contracted health Telehealth information Groups and personal data their providers — to additional expense, adverse publicity, and liability**. ~~As For example, as~~ part of the American Recovery and Reinvestment Act 2009 (" ARRA "), the U. S. Congress amended the privacy and security provisions of HIPAA. HIPAA imposes limitations on the use and disclosure of an individual' s protected health information by certain health care providers, health care clearinghouses, and health insurance plans, collectively referred to as covered entities, that involve the creation, use, maintenance or disclosure of protected health information. The HIPAA amendments also impose compliance obligations and corresponding penalties for non- compliance on individuals and entities that provide services to health care providers and other covered entities, collectively referred to as business associates. ~~Most~~ **More** recently, on December 10, 2020, HHS issued a Notice of Proposed Rulemaking (the public comment period to which was further extended in March 2021) which, if finalized, would make changes to some of HIPAA' s regulatory requirements, which would impact us, to the extent we are a business associate. ARRA also significantly increased the penalties for improper use or disclosure of an individual' s protected health information under HIPAA and extended enforcement authority to state attorneys general. The amendments also create notification requirements for individuals whose protected health information has been inappropriately accessed or disclosed, notification requirements to federal regulators and in some cases, notification to local and national media. Notification is not required under HIPAA if the health information that is improperly used or disclosed is deemed secured in accordance with encryption or other standards developed by HHS. Most states have laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the protected health information protected by HIPAA. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms to ensure ongoing protection of personal information. ~~In addition, even~~ **Even** when HIPAA does not apply, according to the **Federal Trade Commission (" FTC ")**, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5 (a) of the FTCA, 15 U. S. C § 45 (a). The FTC expects a company' s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. The FTC' s guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule. Many foreign countries and governmental bodies,

including the EU, Canada, Australia and other relevant jurisdictions, have **their own** laws and regulations concerning the collection and use of personal or sensitive data obtained from their residents or by businesses operating within their jurisdiction. For example, the European Commission adopted the General Data Protection Regulation (“GDPR”), effective on May 25, 2018, that supersedes previous EU data protection legislation, imposes more stringent EU data protection requirements and provides for greater penalties for non-compliance. The GDPR applies to any company established in the EU as well as to those outside the EU if they collect and use personal data in connection with the offering goods or services to individuals in the EU or the monitoring of their behavior. In addition, following the United Kingdom’s exit from the EU on January 31, 2020, the GDPR ceased to apply in the United Kingdom at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the United Kingdom’s European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain UK specific amendments) into United Kingdom law (referred to as the UK GDPR). The UK GDPR and the UK Data Protection Act 2018 set out the UK’s data protection regime, which is independent from but aligned to the EU’s data protection regime. **As used herein in this Annual Report on Form 10-K**, “GDPR” refers to both the EU and the UK GDPR, unless specified otherwise. The GDPR enhances data protection obligations for processors and controllers of personal data, including, for example, expanded disclosures about how personal information is to be used, limitations on retention of information, mandatory data breach notification requirements and onerous new obligations on services providers. Non-compliance with the GDPR can trigger steep fines of up to € 20 million (£ 17.5 million) or 4 % of total worldwide annual revenues, whichever is higher. Given the breadth and depth of changes in data protection obligations, meeting the GDPR’s requirements requires time, resources and a review of the technology and systems currently in use against the GDPR’s requirements. EU Member States have adopted national laws to implement the EU GDPR, which may partially deviate from the EU GDPR, and the competent authorities in the EU Member States may interpret GDPR obligations slightly differently from country to country, such that we do not expect to operate in a uniform legal landscape in the EU with respect to data protection laws. In addition, the UK has announced plans to reform the UK data protection regime. The GDPR imposes strict rules on the transfer of personal data out of the European Economic Area (“EEA”), or the United Kingdom to third countries, including the **United States U.S.** On June 4, 2021, the European Commission issued new forms of standard contractual clauses for data transfers from controllers or processors in the EEA, or otherwise subject to the GDPR, to controllers or processors established outside the EEA, and not subject to the GDPR. The new forms of standard contractual clauses have replaced the standard contractual clauses that were adopted previously under the Data Protection Directive. The UK is not subject to the European Commission’s new standard contractual clauses but has published its own transfer mechanism, the International Data Transfer Agreement, which enables transfers from the **UK United Kingdom**. We ~~are will be~~ required to transition to the new forms of standard contractual clauses and doing so ~~will require~~ **requires** significant effort and cost. Although the United Kingdom is regarded as a third country under the EU GDPR, the European Commission has issued a decision recognizing the United Kingdom as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EEA to the United Kingdom remain unrestricted. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the United Kingdom to countries not regarded by the United Kingdom as providing adequate protection. The United Kingdom government has confirmed that personal data transfers from the United Kingdom to the EEA remain free flowing. We may be at risk of enforcement actions taken by certain EU or UK data protection authorities until such point in time that we may be able to ensure that all transfers of personal data to us from the EEA or the United Kingdom are conducted in compliance with all applicable regulatory obligations, the guidance of data protection authorities and evolving best practices. We may find it necessary to establish systems to maintain personal data originating from the EU / UK in the EEA or the United Kingdom (as applicable), which may involve substantial expense and may cause us to need to divert resources from other aspects of our business, all of which may adversely affect our business. Our failure to comply with applicable laws and regulations, or to protect such data, could result in enforcement actions against us, including fines, imprisonment of company officials and public censure, claims for damages by end-customers and other affected individuals, damage to our reputation and loss of goodwill, any of which could harm on our operations, financial performance, and business. Evolving and changing definitions of personal data and personal information, within the European Union, the United Kingdom, the **United States U.S.**, and elsewhere, may limit or inhibit our ability to operate or expand our business, including limiting strategic partnerships that may involve the sharing of data. Moreover, if the relevant laws and regulations change, or are interpreted and applied in a manner that is inconsistent with our data practices or the operation of our products, we may need to expend resources in order to change our business operations, data practices, or the manner in which our products operate. Even the perception of privacy concerns, whether or not valid, may harm our reputation and inhibit adoption of our products. **While we have implemented data privacy and security measures, as well as consent practices, in an effort to comply with applicable laws and regulations relating to data privacy and security, some health information and other PII or confidential information is transmitted to us by third parties, who may not implement adequate security and privacy measures, and it is possible that laws, rules, and regulations relating to privacy, data protection, or information security may be interpreted and applied in a manner that is inconsistent with our practices or those of third parties who transmit health information and other PII or confidential information to us. A finding of noncompliance could result in penalties, orders requiring modification to our data privacy and security practices, or criminal charges, which could adversely affect our business. As noted above, changes in these laws also could result in substantial expenses or require us to materially change our operations in a manner adverse to our business. We maintain a privacy policy available to customers that describes how we handle health information or other PII. Statements in our privacy policy could be subject to claims of deceptive practices by federal or state regulatory authorities or private parties, which could lead to significant legal expenses, divert our management’s attention from our operations, and seriously harm our business and our financial results. Furthermore, the costs of compliance with, and other burdens imposed by, the laws, regulations and policies that are applicable to us may limit**

customers' use and adoption of, and reduce the overall demand for, our platform. Any of the foregoing consequences could have a material adverse impact on our business and our financial results. Finally, ~~There~~ there is the risk that the limits we obtained for our cyber liability insurance may not cover the total loss experienced in the event of a data security incident, including the financial loss, legal costs, and business and reputational harm, particularly if there is an interruption to our systems. Additionally, there is the risk of a data privacy or security incident by an employee, which may expose us to liability. If personal information of our customers or employees is misappropriated, our reputation with our customers and employees may be injured resulting in loss of business and / or morale, and we may incur costs to remediate possible injury to our customers and employees or be required to pay fines or take other action with respect to judicial or regulatory actions arising out of such incidents. **Our business could be affected negatively by increased public scrutiny, regulatory enforcement, or changes in law with respect to online privacy and security. Practices regarding the registration, collection, processing, storage, sharing, disclosure, use and security of personal and other information by companies offering online services like our platform have recently come under increased public scrutiny and regulatory enforcement. The regulatory landscape applicable to internet privacy and security is evolving rapidly and requires careful monitoring to remain in compliance. For example, comprehensive state privacy laws, such as the California Consumer Privacy Act (the "CCPA"), which became effective on January 1, 2020, and which, as of January 1, 2023, was modified significantly by the California Privacy Rights Act require, among other things, that covered companies provide new disclosures to California consumers and afford such consumers new abilities to opt- out of certain sales of personal information. Although there are limited exemptions for clinical trial data under the CCPA, the CCPA and other similar laws could impact our business activities depending on how such laws are interpreted and the types of personal information that we handle. Similar legislation has been proposed or adopted in many other states. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and / or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the United States makes our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. There are also states that are specifically regulating health information. For example, Washington state recently passed a health privacy law that, as of June 30, 2024, regulates the collection and sharing of health information. This law also has a private right of action, which further increases the relevant compliance risk collecting the health information of Washington residents. Connecticut and Nevada have also passed similar laws regulating consumer health data. In addition, other states have proposed and / or passed legislation that regulates the privacy and / or security of certain specific types of information, such as biometric data. These various privacy and security laws may impact our business activities, relationships with business partners and ultimately the marketing and distribution of our products. State laws are changing rapidly and there is discussion in the U. S. Congress of a new comprehensive federal data privacy law to which we may likely become subject, if enacted. Aspects of these new and emerging state privacy laws and regulations, as well as their interpretation and enforcement, are dynamic and evolving. These laws and regulations each require particular assessment for compliance, and we may be required to modify our practices in an effort to comply with them, which may impact demand for our offerings. Although the EU GDPR and the UK GDPR currently impose substantially similar obligations, the UK government has announced plans to reform the data protection legal framework in the UK in its Data Use and Access Bill. This lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations could add legal risk, uncertainty, complexity and cost to our handling of European personal information and our privacy and data security compliance programs and could require us to implement different compliance measures for the UK and the EU. If there is a significant change to applicable laws, regulations, or industry standards or practices regarding the storage, use, or disclosure of data our customers or providers share with us, or regarding the manner in which the express or implied consent of customers or providers for such collection, analysis and disclosure is obtained., we may be required to modify the design of our websites, mobile applications, solutions, features, or our privacy policies, and we may be limited in our ability to develop new offerings, functionalities or features.** If we are not able to satisfy data protection, security, privacy, and other government- and industry- specific requirements, our business could be harmed. There are a number of data protection, security, privacy and other government- and industry- specific requirements, including those that require companies to notify individuals of data security incidents involving certain types of personal data. Security compromises experienced by other companies, by our customers or by us may lead to public disclosures, which could harm our reputation, erode customer confidence in the effectiveness of our security measures, and negatively impact our other products and our ability to attract new customers. As we expand into new regions, we will need to comply with new requirements. If we cannot comply or if we incur a violation in one or more of these requirements, our growth could be adversely impacted, and we could incur significant liability. We have incorporated, and plan to incorporate in the future, artificial intelligence, or AI, into some of our products. This technology is new and developing and may present risks that could affect our business. We have incorporated, and plan to incorporate in the future, AI, including large language models (such as GPT), machine learning, and predictive analytics into our products under a platform which we call Allurion Iris. **Coach Iris is part of the Allurion Iris AI platform, which leverages large learning models to help patients during their weight loss journey by providing 24 / 7 virtual coaching**. AI is a new and emerging technology that is in its early stages of commercial use, particularly within the medical device industry. If any of our products that incorporate AI have perceived or actual negative impacts on the clinicians or patients who use them, we may experience brand or reputational harm, competitive harm or legal liability. The rapid evolution of AI may also require the application of significant resources to develop, test and maintain our products and services that incorporate AI in order to help ensure that it is implemented in a socially responsible

manner, to minimize any real or perceived unintended harmful impacts. In addition, AI is subject to a complex and evolving regulatory landscape, including data protection, privacy, and potentially other laws and different jurisdictions have taken and may take in the future varying approaches to regulating AI. Compliance with these laws and regulations can be complex, costly and time-consuming, and there is a risk of regulatory enforcement actions or litigation if we fail to comply with these requirements. As regulations evolve, we may have to alter our business practices or products in order to comply with regulatory requirements. Risks Related to Our Financial Condition and Capital Requirements We have incurred net operating losses in the past and expect to incur net operating losses for the foreseeable future. We have incurred net operating losses since our inception, and we continue to incur significant research and development, general and administrative, and sales and marketing expenses related to our operations. We do not expect to be profitable in 2024-2025, and, while we instituted cost reduction initiatives in future-recent years and are directing our efforts to become EBITDA positive in 2026, we expect to continue to incur significant sales and marketing and R & D expenses to expand-operate our business and perform clinical research expenses related to, among other things, the AUDACITY trial for effects of the combination of the Allurion Balloon in the U.S. and GLP-1 therapy on muscle mass and long-term GLP-1 adherence. Investment in medical device product development, particularly clinical trials, is highly speculative. It entails substantial upfront capital expenditures and significant risk that any potential planned product will fail to demonstrate adequate safety or effectiveness. We expect to generate significant operating losses for the foreseeable future. As of December 31, 2023-2024 and December 31, 2022-2023, we had an accumulated deficit of \$ 238.9 million and \$ 212.8 million and \$ 132.2 million, respectively. Based on our recurring losses and from operations incurred since inception, the expectations- expectation of continuing operating losses to incur significant expenses and negative cash flow for the foreseeable future, and the potential need to raise additional capital to finance our future operations and debt service payments, and the potential of being unable to remain in compliance with certain financial covenants under the Fortress Term Loan, our independent registered public accounting firm has included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2023 expressing substantial doubt about our ability to continue as a going concern, and we have concluded that there is substantial doubt about our ability to continue as a going concern for a period of one year from the date that the consolidated financial statements for the year ended December 31, 2023-2024 are issued. We expect that our future financial results will depend primarily on our success in launching, selling and supporting the Allurion Balloon and other products that are part of our weight loss platform. This will require us to be successful in a range of activities, including manufacturing, marketing, and selling the Allurion Balloon. We may not succeed in these activities and may never generate revenue that is sufficient to be profitable in the future. Even if we are profitable, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to achieve sustained profitability would depress the value of our company and could impair our ability to raise capital, expand our business, diversify our planned products, market our current and future products, or continue our operations. We have a significant On April 16, 2024, we issued an aggregate principal amount of debt, which may affect our ability to operate our business and secure additional financing in the future. As of December 31, 2023, we had \$ 48.83.1 million in debt and \$ 38.0 of Notes to RTW due April 16, 2031. 0 million. The interest rate is fixed at 6.00 % per annum and is payable quarterly in cash and cash equivalents. Upon consummation of or, at our option, in kind for the first the three years Business Combination, we also entered into a term loan facility (the "Fortress Term Loan") pursuant to a credit agreement and guaranty (the "Fortress Credit Agreement") with Fortress Credit Corp. In addition ("Fortress") to refinance the 2021 Term Loan (as defined below). As of December 31, 2023, the Fortress Term Loan was fully drawn. Upon upon consummation of the Business Combination, we received an investment of \$ 40 million from RTW Investments, L.P., and its affiliates ("RTW") in exchange for future royalty payments pursuant to the Revenue Interest Financing ; we are also required to make royalty payments on an additional \$ 7.5 million under the Additional RIFA (as defined herein). We may also incur additional indebtedness to meet future financing needs. Our ability to make scheduled payments of debt principal and interest on our existing or future indebtedness, or to refinance our indebtedness, and to pay our royalty obligations, depends on our future performance, which is subject to economic, financial, competitive, and other factors beyond our control. Our debt obligations, including the Fortress Term Loan Amended Note Purchase Agreement, contains impose certain financial covenants relating to minimum liquidity and minimum revenue requirements. We have On July 5, 2023, we received from Fortress a waiver-waivers in respect of the minimum liquidity and minimum revenue requirement-requirements under debt arrangements to funding set forth in the past, but there is no guarantee Bridging Agreement we entered into with Fortress because we believed that we will not need to obtain waivers of financial covenants in the future or that, should we require them, we would not have satisfied be able to obtain such condition upon closing of the Business Combination. Subsequently, we received a waiver-waivers from Fortress on terms favorable December 29, 2023, pursuant to which Fortress waived the Company December 31, 2023 testing of our- or at all minimum revenue covenant, and the parties modified certain covenants, including the minimum liquidity covenant. To the extent that we are unable to continue to comply with such ongoing minimum liquidity and revenue requirements as modified, including as a result of any weakness in our business or macroeconomic trends, and are unable to procure additional waivers from Fortress-RTW or other lenders in the future, such lenders may pursue a number of actions, including declaring us in breach of our covenants, requiring conditions to cure such breaches and / or exercising foreclosure remedies. Any or all of these actions may materially impact our working capital, and our business may not continue to generate sufficient cash flows from operations to fund operations, service our debt, and satisfy our royalty payment obligations. If we are unable to generate such cash flows, we may be required to adopt one or more alternatives, such as raising additional capital on terms that may be unfavorable or, selling assets or portions of our business, or ceasing operations. Our ability to refinance our existing or any future indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations. In addition, our investment from indebtedness owed to RTW is and debt with Fortress are collateralized by

substantially all of our assets and subject to customary financial and operating covenants limiting our ability to, among other things, incur additional indebtedness, change the name, location, office or our executive management material line of our business, modify change our business, merge with or our organizational documents acquire other entities, pay dividends or make other distributions to holders of our capital stock, make certain investments, engage in transactions with our affiliates, create liens, sell assets, or prepay other indebtedness pay any subordinated debt and store certain inventory and equipment with third parties. These covenants may make it difficult to operate our business. As of the date of issuance of our December 31, 2022 and December 31, 2023 financial statements, we concluded that there was substantial doubt about our ability to continue as a going concern. Given the risk of being unable to remain in compliance with certain financial covenants with Fortress, there is substantial doubt in our ability to continue as a going concern. Due to the risk of not achieving our covenants, the amounts due under our credit facilities as of December 31, 2022 and December 31, 2023 have been classified as a current liability in the consolidated financial statements. We are also subject to standard event of default provisions under the Revenue Interest Financing Agreement with RTW, Additional RIFA and the Fortress Credit Amended Note Purchase Agreement with Fortress, that, if triggered, would allow the debt to be accelerated, which could significantly deplete our cash resources, cause us to raise additional capital at unfavorable terms, require us to sell portions of our business or result in us becoming insolvent. The existing collateral pledged to RTW and Fortress, and the covenants to which we are bound, may (i) 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, (ii) heighten our vulnerability to downturns in our business, or our industry or the economy in general economy, (iii) limit our ability to adjust to changing market conditions, and (iv) place us at a competitive disadvantage compared to our competitors who have greater capital resources. We may need additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all, which would force us to delay, reduce or suspend our planned development and commercialization efforts. Raising additional capital may subject us to unfavorable terms, cause dilution to our existing stockholders, restrict our operations, or require us to relinquish rights to our products and technologies. Our operations have consumed substantial amounts of cash since our inception, and we expect to incur significant expenses in connection with our planned clinical research, development and product commercialization efforts. If our available cash resources and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements, we may seek to sell equity or convertible debt securities, to obtain another form of third- party funding, or to enter into other debt financing. Any failure to raise the funds necessary to support our operations may force us to delay, reduce or suspend our planned clinical trials, research and development programs, or other commercialization efforts. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your a stockholder's ownership may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your a holder's rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through strategic collaborations or partnerships, or marketing, distribution, royalty or licensing arrangements with third parties, we may be required to do so at an earlier stage than would otherwise be ideal and / or may have to limit valuable rights to our intellectual property, technologies, products, or future revenue streams, or grant licenses or other rights on terms that are not favorable to us. Furthermore, any additional fundraising efforts may divert our management from their day- to- day activities, which may adversely affect our ability to develop and commercialize our products. We receive the majority of our revenue from sales to health care providers and other third- party distributors, and the failure to collect receivables from them could adversely affect our financial position and results of operations. We receive the majority of our revenue from sales to health care providers and other third- party distributors. We extend credit to our customers for a significant portion of our sales and receivables from our customers are not secured by any type of collateral. We are therefore subject to the risk that our customers may not pay for the products they have purchased, pay at a slower rate than we have historically experienced, or may seek extended payment terms, which may, in turn, result in delays in our cash collection and increases in our accounts receivable. Our customers may encounter cash flow or operating difficulties, which may reduce their demand for our products or delay their payments to us, thereby increasing our accounts receivable turnover days, or increasing the risk that they may default on their payment obligations. These risks are heightened during periods of global or industry- specific economic downturn or uncertainty and during periods of rising interest rates. Our liquidity and cash flows from operations may be adversely affected if we are unable to settle our accounts receivable on a timely basis, if our accounts receivable cycles or collection periods lengthen or if we encounter a material increase in defaults of payment of our accounts receivable or repayments of amounts we have extended to our customers on credit. If our estimates or judgments relating to our critical accounting policies prove to be incorrect, our results of operations could be adversely affected. The preparation of our financial statements requires us to make estimates and assumptions affecting the reported amounts of our assets, liabilities, revenues, expenses and earnings. If these estimates or assumptions are incorrect, it could have a material adverse effect on our results of operations or financial condition. We have identified several accounting policies as being critical to the fair presentation of our financial condition and results of operations because they involve major aspects of our business and require us to make judgments about matters that are inherently uncertain. These policies are described under the section entitled “ Management’ s Discussion and Analysis of Financial Condition and Results of Operations ” and should be considered in conjunction with our audited consolidated financial statements and notes thereto included elsewhere in this Annual Report on Form 10- K. The implementation of new accounting requirements or other changes to GAAP could have a material adverse effect on our reported results of operations and financial condition. Our results of operations may be adversely affected if our assumptions change or if actual circumstances differ from those in our assumptions, which could cause our results of operations to fall below our expectations and the expectations of securities analysts and investors, resulting in a decline in the trading price of our common stock. Risks Related to Ownership of Our Securities Our share price may be volatile, and purchasers of our securities could incur substantial losses. Our share price is

likely to be volatile. The securities markets in general, and the market for biotechnology and medical device companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. You may not be able to resell your shares at an attractive price due to a number of factors, including the following:

- our ability to successfully commercialize, and realize revenues from sales of, the Allurion Balloon **and other products and services**;
- the success of competitive products or technologies;
- results of clinical trials of the Allurion Balloon or other current or future products or those of our competitors;
- regulatory or legal developments in the U. S. and other countries, especially changes in laws or regulations applicable to our products;
- introductions and announcements of new products by us, our commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our products, clinical trials, manufacturing processes or sales and marketing terms;
- variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in- license additional products or planned products;
- developments concerning our collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;
- developments concerning our ability to bring our manufacturing processes to scale in a cost- effective manner;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of health care payment systems;
- market conditions in the medical device, pharmaceutical and biotechnology sectors;
- actual or anticipated changes in earnings estimates or changes in securities analyst recommendations regarding our **Common common Stock stock**, other comparable companies or our industry generally;
- trading volume of our **Common common Stock stock**;
- guidance or projections, if any, that we provide to the public, any changes in this guidance or projections or our failure to meet this guidance or projections;
- sales of our **Common common Stock stock** by us or our stockholders;
- general economic and political conditions such as recessions, interest rates, fuel prices, trade wars, pandemics (such as COVID- 19), currency fluctuations, geopolitical conflicts, and acts of war or terrorism;
- the effects of natural disasters, terrorist attacks and the spread and / or abatement of infectious diseases, including with respect to potential operational disruptions, labor disruptions, increased costs, and impacts to demand related thereto; and
- the other risks described in this “ Risk Factors ” section. These broad market and industry factors may harm the market price of our securities, regardless of our operating performance.

Stock markets in general and our stock price in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies and our Company. For example, from January 1, 2024 to December 31, 2024, the closing price per share of our common stock on the NYSE ranged from as low as \$ 7. 00 to as high as \$ 92. 50 and daily trading volume ranged from approximately 156 to 2, 539, 556 shares (in each case, on a post- Reverse Stock Split basis). Investors that purchase our securities may lose their investments if the price of our common stock subsequently declines. In the past, following periods of volatility in the market, securities class- action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management’ s attention and resources, which could adversely affect our business, financial condition, results of operations and growth prospects. We do not intend to pay cash dividends for the foreseeable future. We currently intend to retain our future earnings, if any, to finance the further development and expansion of our business and do not intend to pay cash dividends in the foreseeable future. Any future determination to pay dividends will be at the discretion of our **board Board of directors** and will depend on our financial condition, results of operations, capital requirements, restrictions contained in our current or future credit agreements and financing instruments, business prospects and such other factors as our **board Board of directors** deems relevant. Future sales of our **Common common Stock stock**, or the perception that future sales may occur, may cause the market price of our **Common common Stock stock** to decline, regardless of our operating performance. Sales of a substantial number of shares of our **Common common Stock stock** in the public market, including the resale of shares held by various holders of our securities registered for resale, could occur at any time (after the expiration of any applicable lock- up period). These sales, or the perception in the market that the holders of a large number of shares of our **Common common Stock stock** intend to sell shares, could increase the volatility of the market price of our **Common common Stock stock** or result in a significant decline in the public trading price of our **Common common Stock stock**. In addition, on December 18, 2023, we entered into **the a ChEF- Purchase Agreement (the “ Purchase Agreement ”)** with Chardan Capital Markets (“ Chardan ”) related to a “ ChEF, ” Chardan’ s committed equity facility (the “ Chardan Equity Facility ”). Pursuant to the Purchase Agreement, Chardan shall purchase from us up to \$ 100. 0 million of shares of our **Common common Stock stock**, upon the terms and subject to the conditions and limitations set forth in the Purchase Agreement. As of March **15- 21, 2024- 2025**, we have sold **75, 618 \$ 0. 3 million** of shares of our **Common common Stock stock** **under to Chardan as Purchase Shares (as defined in the Chardan Purchase Agreement) under the Chardan Purchase Agreement**, and for aggregate net cash proceeds to us of approximately **\$ 1. 0 million**. **Additional Additional** shares of our **Common common Stock stock** under the Purchase Agreement may be sold by us to Chardan at our discretion from time to time. Sales of shares of our **Common common Stock stock** under the Purchase Agreement in the future may cause the trading price of shares of our common stock to decrease. The resale, or expected or potential resale, of a substantial number of shares of our **Common common Stock stock** in the public market could adversely affect the market price for our **Common common Stock stock** and make it more difficult for stockholders to sell their holdings at times and prices that they determine are appropriate. Furthermore, we expect that, because there is a large number of shares of our **Common common Stock stock** registered pursuant to various resale registration statements, the selling securityholders thereunder will continue to offer the securities covered thereby for a significant period of time, the precise duration of which cannot be predicted. Accordingly, the adverse market and price pressures resulting from an offering pursuant to the effective resale registration statements may continue for an extended period of time. Sales of a substantial number of such shares in the public market could adversely affect

the market price of our **Common common Stock stock**. Additionally, a significant portion of the shares of our Common Stock registered for resale were purchased by securityholders pursuant to investments in Legacy Allurion that date from 2013 onwards at prices considerably below the current market price of our Common Stock. The sale of such shares would result in the securityholders realizing a significant gain even if other securityholders experience a negative rate of return. For example, holders of Legacy Allurion Common Stock, many of whom purchased their shares pursuant to investments in Legacy Allurion that date from 2013 through the closing of the Business Combination, paid, on average, an effective purchase price of approximately \$ 0. 22 for each share of our Common Stock they received in connection with the Business Combination. Even if our trading price is significantly below \$ 7. 04, the offering price for the units offered in Compute Health's initial public offering (" IPO") after giving effect to the applicable exchange ratio of 1. 420455 pursuant to the Business Combination Agreement (the " CPUH Exchange Ratio"), certain of the securityholders, including such holders of Legacy Allurion Common Stock, may still have an incentive to sell shares of our Common Stock because they purchased the shares at prices lower than the public investors or the current trading price of our Common Stock. For example, based on the closing price of our Common Stock of \$ 2. 66 as of March 15, 2024, such holders of Legacy Allurion Common Stock would experience a potential profit, on average, of up to approximately \$ 2. 44 per share, or approximately \$ 12. 9 million in the aggregate upon the sale of all such shares. Future sales and issuances of our **Common common Stock stock** could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall. Significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell **Common common Stock stock**, convertible securities or other equity securities in one or more transactions at prices and in a manner as determined **by our Board** from time to time. If we sell **Common common Stock stock**, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our **Common common Stock stock**. We will incur increased costs and demands upon management as a result of complying with the laws and regulations affecting public companies, which could adversely affect our business, results of operations, and financial condition. As a public company, we are subject to the reporting requirements of the Exchange Act, the listing standards of the NYSE, and other applicable securities rules and regulations. We expect that the requirements of these rules and regulations will continue to increase our legal, accounting and financial compliance costs, make some activities more difficult, time- consuming and costly, and place significant strain on our personnel, systems and resources. For example, the Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and results of operations. As a result of the complexity involved in complying with the rules and regulations applicable to public companies, our management's attention may be diverted from other business concerns, which could harm our business, results of operations and financial condition. Although we ~~have~~ already hired additional employees to assist us in complying with these requirements, we may need to hire more employees in the future or engage outside consultants, which will increase our operating 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 expect** to invest substantial 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 business operations 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 also expect that being a public company and these new 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 members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers. As a result of disclosure of information in the filings required of a public company, our business and financial condition **is will become** more visible, which may result in an increased risk of threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business and results of operations could be harmed, and even if the claims do not result in litigation or 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, results of operations, and financial condition. Certain parties ~~to our Investor Rights Agreement~~ have the right to nominate directors to our board of directors, and their interests may conflict with ours or yours in the future. Pursuant to our Investor Rights and Lock- up Agreement, dated August 1, 2023, by and among us, Compute Health Sponsor LLC (the "**Sponsor**"), certain Legacy Allurion stockholders and certain other parties (the "**Investors**"), **and such agreement, the " Investor Rights Agreement "**), ~~our board of directors consists of seven directors, a majority of which are required to be " independent "~~ **directors for purposes of NYSE rules, and** the following persons have the following nomination rights with respect to our board of directors: (i) one director and one independent director ~~was required~~ to be nominated by Shantanu Gaur; (ii) one director and one independent director ~~was required~~ to be nominated by Remus Group Management, LLC and its affiliates ("**Remus Capital**"); (iii) one director ~~was required~~ to be nominated by the Sponsor; and (iv) two independent directors ~~to are required~~ to be nominated by Allurion (one of **which whom** shall be designated by RTW until such time as all obligations under the Revenue Interest Financing Agreement or any additional revenue interest financing agreement have been **paid satisfied** by Allurion). **In addition, in September 2024, we appointed Keith Johns to our Board, in satisfaction of certain obligations to RTW set forth in the Amended Note Purchase Agreement, and in January 2025, we entered into the Omnibus Amendment**

pursuant to which RTW has the right to designate an additional director, initially R. Jason Richey, who was appointed to the Board effective as of December 30, 2024. As a result of the foregoing, Shantanu Gaur, Remus Capital, the Sponsor and RTW or their respective nominees to our ~~board~~ **Board collectively of directors** have the ability to control the appointment of our management, the entering into of mergers, sales of substantially all or all of our assets and other extraordinary transactions, and influence amendments to our ~~amended~~ **Amended** and ~~restated~~ **Restated certificate** ~~Certificate~~ of incorporation **Incorporation** ("Charter") and ~~Amended and Restated~~ **Amended and Restated** bylaws ~~Bylaws~~ ("Bylaws"). In any of these matters, the interests of the parties to the Investor Rights Agreement with the right to nominate directors may differ from or conflict with your interests. Moreover, this control over the nomination of directors to our ~~board~~ **Board of directors** may also adversely affect the trading price for our ~~Common~~ **common Stock** ~~stock~~ to the extent investors perceive disadvantages in owning stock of a company with these corporate governance provisions. We are an "emerging growth company" and a "smaller reporting company" within the meaning of the Securities Act, and we intend to take advantage of certain exemptions from disclosure requirements available to emerging growth companies and / or smaller reporting companies, which could make our securities less attractive to investors and may make it more difficult to compare our performance with that of other public companies. We are "emerging growth company," as defined in Section 2 (a) of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"), and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act ("Section 404"), reduced disclosure obligations regarding executive compensation in their periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. Further, Section 102 (b) (1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a registration statement under the Securities Act declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. We have elected not to opt out of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparability of our financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used. Additionally, we are a "smaller reporting company" as defined in Item 10 (f) (1) of Regulation S- K, which allows us to take advantage of certain exemptions from disclosure requirements including exemption from compliance with the auditor attestation requirements of Section 404 and reduced disclosure obligations regarding executive compensation in this Annual Report on Form 10- K and in our periodic reports and proxy statements. We will remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of the shares of our ~~Common~~ **common Stock** ~~stock~~ held by non-affiliates exceeds \$ 250 million as of the prior June 30, and (ii) our annual revenue exceeded \$ 100 million during such completed fiscal year or the market value of the shares of our ~~Common~~ **common Stock** ~~stock~~ held by non-affiliates exceeds \$ 700 million as of the prior June 30. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies difficult or impossible. We could be subject to securities class action litigation. In the past, securities class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Securities litigation brought against us following volatility in the price of our ~~Common~~ **common Stock** ~~stock~~, regardless of the merit or ultimate results of such litigation, could result in substantial costs, which would hurt our financial condition and results of operations and divert management's attention and resources from our business. We have previously identified material weaknesses in our internal control over financial reporting and may identify additional material weaknesses in the future. If we fail to remediate a material weakness or if we otherwise fail to establish and maintain effective control over financial reporting, it may adversely affect our ability to accurately and timely report our financial results, and may adversely affect investor confidence and business operations. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. In connection with the audit of our consolidated financial statements as of and for the years ended December 31, **2024 and** 2023 ~~and 2022~~, we identified material weaknesses in our internal control over financial reporting that we are currently working to remediate, which relate to: (a) insufficient segregation of duties in the financial statement close process; (b) a lack of sufficient levels of staff with public company and technical accounting experience to maintain proper control activities and perform risk assessment and monitoring activities; and (c) insufficient information systems controls, including access and change management controls. We have concluded that these material weaknesses in our internal control over financial reporting occurred because we do not have the necessary business processes, personnel and related internal controls to operate in a manner to satisfy the accounting and financial reporting timeline requirements of a public company. We are focused on designing and implementing effective internal controls measures to improve our evaluation of disclosure controls and procedures, including internal control over financial reporting, and remediating the material weaknesses. We have taken steps to remediate including consulting with experts on technical accounting matters and in the preparation of our financial statements. We have also hired additional senior level experienced staff with public company experience and upgraded our enterprise resource planning system to SAP in August of 2022. However, we cannot assure you that the measures we **have taken and** are taking to remediate the material weaknesses will prevent or avoid potential future material weaknesses. Further, additional weaknesses in our disclosure controls and internal

controls over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls or any difficulties encountered in their implementation or improvement could limit our ability to prevent or detect a misstatement of our accounts or disclosures that could result in a material misstatement of our annual or interim financial statements. In such a case, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to the listing requirements of the NYSE, investors may lose confidence in our financial reporting and our stock price may decline as a result. If we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our ~~Common~~ **common Stock stock** may decrease. We are in the process of designing and implementing our internal controls over financial reporting, which ~~is~~ **will be** time-consuming, costly and complicated. We have identified gaps in our internal control environment in the past and cannot provide assurances that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. If we identify additional material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 in a timely manner, if we are unable to assert that our internal control over financial reporting is effective or, once required, if our independent registered public accounting firm is unable to attest that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our ~~Common~~ **common Stock stock** could decrease. We could also become subject to stockholder or other third-party litigation as well as investigations by the NYSE, the SEC or other regulatory authorities, which could require additional financial and management resources and could result in fines, trading suspensions or other remedies. **We will need to raise additional capital in order to execute our business plan and to respond to changing market conditions, which additional capital may not be available on terms acceptable to us, or at all. We will need to raise additional capital either by issuing equity, debt, or a combination of the two, in order to respond to market timing delays, technological advancements, competition, competitive technologies, customer demands, business opportunities, other challenges, potential acquisitions, unforeseen circumstances, or other reasons. In order to further business relationships with current or potential customers or partners, we may issue equity or equity-linked securities to such customers or partners. Despite the need for additional capital, we may not be able to timely secure additional debt or equity financing on favorable terms, or at all, especially given current market conditions where raising additional capital has proven particularly challenging. If we raise additional capital through the issuance of equity or convertible debt or other equity-linked securities, or if we issue equity or equity-linked securities to current or potential customers to further our business relationships, our existing stockholders would likely experience dilution, which may be significant. Any debt financing obtained by us in the future could involve 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 or to pursue business opportunities, including potential acquisitions. If we are unable to obtain adequate financing on terms satisfactory to us when we require it, our ability to continue to support our business and to respond to business challenges could be significantly limited. Additionally, under current SEC regulations, if our public float is less than \$ 75 million, and for so long as our public float remains less than \$ 75 million, the amount we can raise through primary public offerings of securities in any twelve-month period using shelf registration statements on Form S- 3 is limited to an aggregate of one-third of our public float, which is referred to as the “ baby shelf ” rules. As of a public reporting company, we are subject to filing deadlines for reports that we file pursuant to the date of this Annual Exchange Act, and our failure to timely file such reports may have material adverse consequences on our business. We did not file our Quarterly Report on Form 10- ~~K Q~~ for the quarter ended June 30, 2023 (~~our public float is below \$ 75 million. As such, we will be limited by the “ Second Quarter 2023 10- baby shelf rules until such time as our public float exceeds \$ 75 million, which means we only have the capacity to sell shares up to one - third of Q ”~~) within the timeframe required by the SEC; thus, we have not remained current in our **public float under shelf** reporting requirements with the SEC since we became an SEC reporting company on August 1, 2023. Although we have since regained status as a current filer given that the Second Quarter 2023 10- Q was filed on October 20, 2023, we will not be eligible to use a registration statement **statements** on Form S- 3 **in** that would allow us to continuously incorporate by reference our SEC reports into the registration statement, or to use “ shelf ” registration statements to conduct offerings, until approximately one year from the date we regained (and maintain) status as a current filer. Until such time, if we determine to pursue an **any twelve** offering, we would be required to conduct the offering on an exempt basis, such as in accordance with Rule 144A, or file a registration statement on Form S- 1 **month period** . **If our** Using a Form S- 1 registration statement for a public offering would likely take significantly longer than using a registration statement on **float decreases, the number of securities we may sell under our** Form S- 3 and **shelf registration statement will also increase-decrease** . We will remain constrained by our transaction costs, and could, to the extent **baby shelf rules under our Form S- 3 shelf registration statement until such time as our public float exceeds \$ 75 million, at which time, the number of securities we may sell under a Form S- 3 registration statement will no longer be limited by the baby shelf rules. We are not able to conduct offerings using alternative methods in compliance with the NYSE' s minimum share price requirement or its minimum market capitalization standard and thus are at risk of the NYSE delisting shares of our common stock** , which would have an ~~adversely--~~ **adverse impact** ~~our~~ on the trading volume, liquidity, and market price of shares of our common stock. On August 29, 2024, we received a notice from the NYSE notifying us that as of August 29, 2024, we were not in compliance with the continued listing standard set forth in Section 802. 01B of the NYSE' s Listed Company Manual (the “ Minimum Market Capitalization Standard ”) because our average market capitalization was less than \$ 50. 0 million over the consecutive 30 period ended August 29, 2024 and our last reported stockholders' equity as of August 29, 2024 was less than \$ 50. 0 million. In accordance with applicable NYSE procedures, within 45 days of receipt of the notice, we submitted a plan to the NYSE advising it of outlining measures that would bring us into conformity with the Minimum Market Capitalization Standard within 18 months of**

receipt of the notice (the "Cure Period"). We submitted a business plan to the NYSE demonstrating our ability to raise capital—regain compliance with the NYSE's rules within the Cure Period. The NYSE has accepted the plan and as a result, we are subject to quarterly monitoring or for complete acquisitions in compliance with the business plan and our common stock will continue to trade on the NYSE during the Cure Period, subject to our compliance with other NYSE continued listing requirements. If we fail to comply with the plan or we do not meet the Minimum Market Capitalization Standard at the end of the Cure Period, we will be subject to NYSE's prompt initiation of suspension and delisting procedures. In addition, on August 12, 2024, we received a letter from NYSE notifying us that, as of August 8, 2024, for the preceding 30 consecutive business days, the average closing price of our common stock had closed below \$ 1.00 per share, the minimum average closing bid price required by the continued listing requirements of Rule 802.01C of the NYSE Listed Company Manual (the "Minimum Bid Price Standard"). Pursuant to Rule 802.01C of the NYSE Listed Company Manual, a company will be considered to be below compliance standards if the average closing price of a security fell below \$ 1.00 over a period of 30 consecutive trading days. A company can regain compliance with the Minimum Bid Price Standard at any ~~timely--~~ time manner during the six-month cure period if, on the last trading day of any calendar month during the cure period, the company has (i) a closing share price of at least \$ 1.00 and (ii) an average closing share price of at least \$ 1.00 over the 30 trading-day period ending on the last trading day of that month. In the event that at the expiration of the six-month cure period, both a \$ 1.00 closing share price on the last trading day of the cure period and a \$ 1.00 average closing share price over the 30 trading-day period ending on the last trading day of the cure period are not attained, the NYSE will commence suspension and delisting procedures. On January 3, 2025, we effected a reverse stock split of our common stock at a ratio of 1-for-25 with the primary objective of raising the trading price of our common stock to meet the Minimum Bid Price Standard. On February 3, 2025, we received a letter from NYSE notifying us that we had regained compliance with the Minimum Bid Price Standard. We cannot ~~guarantee assure you~~ that we in the future our reporting will always be timely. If we are ~~unable--~~ able to cure these deficiencies satisfy SEC filing deadlines or otherwise provide disclosures ~~comply with other NYSE continued listing standards. A delisting of shares of~~ material information on a timely basis, stockholders and potential investors in our common stock ~~from the NYSE could negatively~~ may have incomplete information about our business and results of operations, which may impact us as it would likely reduce their ~~the liquidity~~ ability to make an ~~and market~~ informed investment decision, result in a reduction in the trading price of shares, trading volume or analyst coverage of our common stock, reduce the number of investors willing to hold or acquire shares of or our ~~expose us to potential~~ common stock, and negatively impact our ~~liability--~~ ability to access equity markets and obtain financing. An active trading market may not develop or be sustained. The market for our securities may be highly volatile or may decline regardless of our operating performance. An active public market for our securities may not develop or be sustained. We cannot predict the extent to which investor interest in Allurion will lead to the development of an active trading market in our ~~Common common Stock stock~~ or how liquid that market might become. If an active market does not develop or is not sustained, or if we fail to satisfy the continued listing standards of the NYSE for any reason and our securities are delisted, it may be difficult for you to sell your securities at the time you wish to sell them, at a price that is attractive to you, or at all. An inactive trading market may also impair our ability to both raise capital by selling shares of capital stock, attract and motivate employees through equity incentive awards and acquire other companies, products or technologies by using shares of capital stock as consideration. On August 12, 2024, we received a letter from NYSE notifying us that, as of August 8, 2024, we were not in compliance with the Minimum Bid Price Standard because, for the preceding 30 consecutive business days, the average closing price of our common stock had closed below \$ 1.00 per share, the minimum average closing bid price required by the continued listing requirements of Rule 802.01C of the NYSE Listed Company Manual. On February 3, 2025, we received a letter from NYSE notifying us that we had regained compliance with the Minimum Bid Price Standard. On August 29, 2024, we received a notice from the NYSE notifying us that, as of August 29, 2024, we were not in compliance with the Minimum Market Capitalization Standard because our average market capitalization was less than \$ 50.0 million over the consecutive 30 trading-day period ended August 29, 2024 and our last reported stockholders' equity as of August 29, 2024 was less than \$ 50.0 million. Although we have taken steps to regain compliance with the Minimum Market Capitalization Standard listing standards, including the submission of a business plan to the NYSE demonstrating our ability to regain compliance with the Minimum Market Capitalization Standard, which the NYSE accepted, we cannot assure you that we will be able to cure this deficiency or comply with other NYSE continued listing standards, including the Minimum Bid Price Standard. A delisting of shares of our common stock from the NYSE could negatively impact us as it would likely reduce the liquidity and market price of shares of our common stock. If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our ~~Common common Stock stock~~ share price and trading volume could decline. The trading market for our ~~Common common Stock stock~~ will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. If few or no securities or industry analysts cover us, the trading price for our ~~Common common Stock stock~~ would likely be negatively impacted. If one or more of the analysts who cover us downgrade our ~~Common common Stock stock~~ or publish inaccurate or unfavorable research about our business, our share price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our share price would likely decline. If one or more of these analysts cease coverage of Allurion or fail to publish reports on us regularly, demand for our ~~Common common Stock stock~~ could decrease, which ~~might could~~ cause our share price and trading volume to decline. Provisions in our Charter and Bylaws could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our Charter and Bylaws may discourage, delay, or prevent a merger, acquisition, or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that

investors might be willing to pay in the future for our ~~Common~~ **common Stock**, thereby depressing the market price of our ~~Common~~ **common Stock**. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our ~~board~~ **Board of directors** is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. Among others, these provisions include the following: • our ~~board~~ **Board of directors** is divided into three classes with staggered three-year terms, which may delay or prevent a change of our management or a change in control; • our ~~board~~ **Board of directors** has the right to elect directors to fill a vacancy created by the expansion of our board of directors or the resignation, death, or removal of a director, which will prevent stockholders from being able to fill vacancies on our board of directors; • our stockholders are not able to act by written consent, and as a result, a holder, or holders, controlling a majority of our shares are not able to take certain actions other than at annual stockholders' meetings or special stockholders' meetings; • our Charter does not allow cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates; • amendments of our Charter and Bylaws require the approval of stockholders holding 66 2/3 % of our outstanding voting shares (unless amended by our board of directors); • our stockholders are required to provide advance notice and additional disclosures in order to nominate individuals for election to our board of directors or to propose matters that can be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of Allurion; and • our ~~board~~ **Board of directors** is able to issue, without stockholder approval, preferred shares with voting or other rights or preferences that could impede the success of any attempt to acquire us. Sales of shares of our ~~Common~~ **common Stock** may cause the market price of our ~~Common~~ **common Stock** to fall. Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of our common stock intend to sell shares, could increase the volatility of the market price of our common stock or result in a significant decline in the public trading price of our common stock. ~~The While the Sponsor and certain Legacy Allurion stockholders have signed the Investor Rights Agreement which contains lock-up restrictions for a period of either 18 months or 12 months following the consummation of the Business Combination, as applicable, and certain other Legacy Allurion stockholders are subject to similar lock-up restrictions pursuant to our Bylaws, the lock-up restrictions shall not apply to:~~ (a) any shares of our Common Stock purchased pursuant to the PIPE Subscription Agreements (as defined below), (b) 100 shares of our Common Stock held by each Investor (as defined in the Investor Rights Agreement), (c) shares issued to the Sponsor in the Sponsor Loan Equity Issuance (as defined below), (d) certain incremental shares of PIPE Investors who are Legacy Allurion stockholders or holders of convertible unsecured promissory notes issued by Legacy Allurion pursuant to that certain (i) Convertible Note Purchase Agreement, dated December 22, 2021, by and among Legacy Allurion and the investors listed on Exhibit A thereto, (ii) Convertible Note Purchase Agreement, dated February 15, 2023, by and among Legacy Allurion and the investors listed on Exhibit A thereto and (iii) Convertible Note Purchase Agreement, dated June 14, 2023, by and among Legacy Allurion and the investors listed on Exhibit A thereto (collectively, "Legacy Allurion Convertible Notes"), or shares issued upon conversion of the convertible notes issued between February 2023 and August 2023 ("2023 Convertible Notes"); (e) the Backstop Shares or the shares of our Common Stock issued to each of HVL, RTW and Fortress, and such shares of our Common Stock will be freely tradeable subject to federal securities laws and other applicable rules and regulations. In addition, ~~the effective purchase prices at which certain independent directors of Compute Health, certain Legacy Allurion stockholders, the PIPE Investors, RTW, a Fortress affiliate and HVL acquired their shares of our~~ ~~Common~~ **common Stock** are generally substantially less than the IPO price of \$ ~~7-176.04-00~~ per share, after giving effect to the CPUH Exchange Ratio ~~and the Reverse Stock Split~~. Consequently, such stockholders may realize a positive rate of return on the sale of their shares of ~~Common~~ **common Stock** even if the market price per share of our ~~Common~~ **common Stock** is below \$ ~~7-176.04-00~~ per share. While some of our securityholders may experience a positive rate of return based on the current trading price, public securityholders may not experience a similar rate of return on the securities they purchased due to differences in the purchase prices they paid and the trading price at the time of sale and may instead experience a negative rate of return on their investment. On March ~~15-21, 2024-2025~~, the last quoted sale price for our ~~Common~~ **common Stock** as reported on the NYSE was \$ ~~23.66-58~~ per share. Consequently, these securityholders may have an incentive to sell their shares of our ~~Common~~ **common Stock** even if the trading price is below the price paid by investors in Compute Health's IPO, which could cause the market price of our ~~Common~~ **common Stock** to decline. In addition, on December 18, 2023, we entered into the ~~ChEF~~ Purchase Agreement with Chardan related to the Chardan Equity Facility. Pursuant to the ~~ChEF~~ Purchase Agreement, Chardan shall purchase from us up to \$ 100.0 million of shares of our ~~Common~~ **common Stock**, upon the terms and subject to the conditions and limitations set forth in the ~~ChEF~~ Purchase Agreement. The shares of our ~~Common~~ **common Stock** that may be issued under the ~~ChEF~~ Purchase Agreement may be sold by us to Chardan at our discretion from time to time. The purchase price for shares of our ~~Common~~ **common Stock** that we may sell to Chardan under the ~~ChEF~~ Purchase Agreement will fluctuate based on the trading price of shares of our ~~Common~~ **common Stock**. As a result, investors who purchase shares from Chardan at different times will likely pay different prices for those shares, and so may experience different levels of dilution and in some cases substantial dilution and different outcomes in their investment results. Investors may experience a decline in the value of the shares they purchase from Chardan as a result of future sales made by us to Chardan at prices lower than the prices such investors paid for their shares. Depending on market liquidity at the time, sales of shares of our ~~Common~~ **common Stock** may cause the trading price of shares of our ~~Common~~ **common Stock** to decrease. We generally have the right to control the timing and amount of any future sales of shares of our ~~Common~~ **common Stock** to Chardan. Additional sales of shares of our ~~Common~~ **common Stock**, if any, to Chardan will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to

Chardan all, some or none of the additional shares of our ~~Common common Stock stock~~ that may be available for us to sell pursuant to the **ChEF** Purchase Agreement. If and when we do sell shares of our ~~Common common Stock stock~~ to Chardan, after Chardan has acquired shares of our ~~Common common Stock stock~~, Chardan may resell all, some or none of such shares of our ~~Common common Stock stock~~ at any time or from time to time in its discretion. Therefore, sales to Chardan by us could result in substantial dilution to the interests of other holders of shares of our ~~Common common Stock stock~~. In addition, if we sell a substantial number of shares of our ~~Common common Stock stock~~ to Chardan under the **ChEF** Purchase Agreement, or if investors expect that we will do so, the actual sales of shares of our ~~Common common Stock stock~~ or the mere existence of our arrangement with Chardan may make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect such sales. Under applicable NYSE rules, in no event may we issue to Chardan shares of our ~~Common common Stock stock~~ representing more than the lower of the 19.99% voting power threshold and the 19.99% share and share equivalent thresholds referenced in Section 312.03(c) of the NYSE Listed Company Manual, unless we obtain prior stockholder approval or if such approval is not required in accordance with the applicable NYSE rules. In addition, Chardan is not obligated to buy any ~~Common common Stock stock~~ under the **ChEF** Purchase Agreement if such shares, when aggregated with all other ~~Common common Stock stock~~ then beneficially owned by Chardan and its affiliates (as calculated pursuant to Section 13(d) of the Exchange Act and Rule 13d-3 promulgated thereunder), would result in Chardan beneficially owning ~~Common common Stock stock~~ in excess of 4.99% of our outstanding voting power or shares of ~~Common common stock~~. **In April 2024, we entered into the Amended Note Purchase Agreement, pursuant to which we issued and sold \$ 48 million of Notes to the Purchasers. The actual number of shares of our common stock that may be issued upon conversion of the Notes will vary depending on the then-current conversion price of the Notes sold, not to exceed 19,168 shares of common stock, or 1% of the number of shares of the common stock outstanding as of April 14, 2024, unless we obtain approval of our stockholders for such securities issuance (the "First Stockholder Approval"), in accordance with the applicable stock exchange rules. At our 2024 Annual Meeting of Stockholders on December 16, 2024 (the "2024 Annual Meeting"), we obtained the First Stockholder Approval. The holder of the Notes may not exercise the Notes if such holder, together with its affiliates, would beneficially own more than 9.99% of the number of shares of common stock outstanding immediately after giving effect to such conversion. In July 2024, concurrently with the July 2024 Public Offering (as defined herein), we consummated a private placement of an aggregate of 2,260,159 shares of Series A Preferred Stock (as converted to 90,407 shares of common stock on December 19, 2024) and 90,407 private placement warrants to RTW, at a purchase price of \$ 30.00 per share and warrant. At our 2024 Annual Meeting, we obtained the requisite approval of our stockholders, in accordance with the applicable stock exchange rules, of the issuance of common stock that may be issued upon conversion of the Series A Preferred Stock and exercise of the July 2024 Private Placement Warrants (the "Second Stockholder Approval"). Following the date of the Second Stockholder Approval, each share of Series A Preferred Stock automatically converted into one share of common stock. In addition, in connection with the Second Stockholder Approval, the July 2024 Private Placement Warrants became exercisable at an exercise price of \$ 30.00 and will expire five years from the date of issuance, subject to certain limitations. A holder of July 2024 Private Placement Warrants may not exercise the Private Placement Warrant if such holder, together with its affiliates, would beneficially own more than 4.99% (or, upon election by a holder prior to the issuance of the Private Placement Warrants, 9.99%) of the number of shares of common stock outstanding immediately after giving effect to such exercise. In January 2025, we issued and sold 841,751 shares of common stock to RTW for an aggregate purchase price of approximately \$ 2.5 million at a purchase price per share of \$ 2.97 per share. Also in January 2025, we entered into a securities purchase agreement with certain accredited investors pursuant to which we issued and sold 1,240,000 shares of common stock and accompanying common warrants to purchase up to 1,240,000 shares at an offering price of \$ 6.00 per share and accompanying common warrant. Similarly, in February 2025 we entered into a securities purchase agreement with certain accredited investors pursuant to which we issued and sold 900,000 shares of common stock and accompanying common warrants to purchase up to 1,800,000 shares of common stock at an offering price of \$ 5.23 per share and accompanying common warrant. Concurrently, we issued and sold to an accredited investor affiliated with Leavitt Equity Partners LLC ("Leavitt") 267,686 shares of common stock and common warrants to purchase up to 535,372 shares of common stock for an aggregate purchase price of approximately \$ 1.4 million at a purchase price of \$ 5.23 per share and accompanying private placement warrant. The common warrants issued to investors in the January offering, February offering and Leavitt private placement are not be exercisable until we obtain stockholder approval for the issuance of the shares of common stock underlying the common warrants as required by the applicable rules and regulations of the NYSE, and will then be immediately exercisable upon receipt of such stockholder approval. We intend to seek stockholder approval of the issuance of shares of common stock upon exercise of such common warrants at our special meeting of stockholder scheduled for April 4, 2025. In the event stockholder approval is obtained, the common warrants will be immediately exercisable and the underlying shares of common stock acquired upon exercise may be sold by the holders thereof.** Other than as described above, there are no lock-up, beneficial ownership or stock exchange restrictions that would prevent the foregoing stockholders from selling some or all of their ~~Common common Stock stock~~ subject to compliance with applicable rules and regulations. Our warrants are exercisable for ~~Common common Stock stock~~, the exercise of which would increase the number of shares eligible for future resale in the public market and result in dilution to our stockholders. As of ~~December 31, 2023~~ **March 14, 2025**, there ~~are~~ **were outstanding:** (i) 13,206,922-720 Public Warrants to purchase an aggregate of ~~18,750,383~~ **759,838** shares of ~~Common common Stock stock~~ at an exercise price of \$ ~~8-202~~ **10-50** per share ~~outstanding and~~ **347,929** (ii) 14,589 Rollover Warrants to purchase an aggregate of ~~347-14,929~~ **589** shares of ~~Common common Stock stock~~ at exercise prices ranging from \$ ~~0.02-50~~ per share to \$ ~~12-303~~ **14-50** per share ~~outstanding~~, (iii) 662,701 July 2024 Public Warrants to purchase an aggregate of 662,701 shares of common stock at a weighted

average exercise price of \$ 30. 00 per share, (iv) 90, 407 Private Placement Warrants to purchase an aggregate of 90, 407 shares of common stock at an exercise price of \$ 30. 00 per share, (v) 1, 240, 000 January 2025 Warrants to purchase an aggregate of 1, 240, 000 shares of common stock at an exercise price of \$ 6. 00 per share, (vi) 1, 800, 000 February 2025 Warrants to purchase an aggregate of 1, 800, 000 shares of common stock at an exercise price of \$ 5. 23 per share, and (vii) 535, 372 Leavitt Private Placement Warrants to purchase an aggregate of 535, 372 shares of common stock at an exercise price of \$ 5. 23 per share . To the extent such warrants are exercised, additional shares of our ~~Common common Stock stock~~ will be issued, which will result in dilution to the holders of our ~~Common common Stock stock~~ and increase the number of shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market could adversely affect the market price of our ~~Common common Stock stock~~, the impact of which increases as the value of our stock price increases. Our ~~existing~~ warrants may not be exercised at all and we may not receive any cash proceeds from the exercise of the warrants. Due to the significant number of redemptions of Compute Health Class A ~~Common common Stock stock~~ in connection with the Business Combination, there was a significantly lower number of shares of Compute Health Class A ~~Common common Stock stock~~ that converted into shares of our ~~Common common Stock stock~~ in connection with the Business Combination. As a result, the shares of our ~~Common common Stock stock~~ previously registered for resale (a substantial portion of which may not be resold until the expiration of the applicable lock-up period) are anticipated to constitute a considerable percentage of our public float. Additionally, a significant portion of the shares of our ~~Common common Stock stock~~ registered for resale were purchased by securityholders pursuant to investments in Legacy Allurion that date from 2013 through the closing of the Business Combination at prices considerably below the current market price of our ~~Common common Stock stock~~. This discrepancy in purchase prices may have an impact on the market perception of our ~~Common common Stock stock~~'s value and could increase the volatility of the market price of our ~~Common common Stock stock~~ or result in a significant decline in the public trading price of our ~~Common common Stock stock~~. The registration of these shares for resale creates the possibility of a significant increase in the supply of our ~~Common common Stock stock~~ in the market. The increased supply, coupled with the potential disparity in purchase prices, may lead to heightened selling pressure, which could negatively affect the public trading price of our ~~Common common Stock stock~~. The exercise prices of the warrants, in certain circumstances, may be higher than the prevailing market price of our underlying ~~Common common Stock stock~~ and the cash proceeds to us associated with the exercise of ~~such~~ warrants are contingent upon our stock price. The value of our ~~Common common Stock stock~~ may fluctuate and may not exceed the exercise price of the ~~existing~~ warrants at any given time. As of the date of this Annual Report on Form 10- K, all of our Public Warrants, each of which has an exercise price of \$ 8-202. 10-50 per share, our July 2024 Public Warrants, each of which has an exercise price of \$ 30. 00 per share, our January 2025 Warrants, each of which has an exercise price of \$ 6. 00 per share, our February 2025 Warrants, each of which has an exercise price of \$ 5. 23 per share, and our Leavitt Private Placement Warrants, each of which has an exercise price of \$ 5. 23 per share, are "out of the money," meaning the exercise price is higher than the market price of our ~~Common common Stock stock~~. As of March 14, 2025, 893 Rollover Warrants have been exercised . Of the 347-14, 929-589 Rollover Warrants outstanding as of ~~December 31, 2023~~ March 14, 2023-2025, 220-11, 529-655 of such warrants (130-2, 053-231 of which have an exercise price of \$ 6-26, 25-73 and 90, 476-392 of which have an exercise price of \$ 12-28, 14-25, 209 of which have an exercise price of \$ 61. 00, 5, 203 of which have an exercise price of \$ 168. 25, and 3, 620 of which have an exercise price of \$ 303. 50) are "out of the money ." -Holders of such "out of the money " warrants are not likely to exercise such warrants. There can be no assurance that such warrants will be in the money prior to their respective expiration dates, and therefore, we may not receive any cash proceeds from the exercise of such warrants. Certain of our ~~existing Warrants warrants~~ are accounted for as liabilities and the changes in value of such ~~Warrants warrants~~ could have a material effect on, or cause volatility in, our financial results. In connection with the Business Combination, we assumed our Public Warrants to purchase up to 18-750, 383-759, 838 shares of our ~~Common common Stock stock~~ (which were originally issued as warrants to purchase shares of Compute Health Class A common stock in connection with Compute Health's IPO) and Rollover Warrants to purchase up to 403-14, 658-589 shares of our ~~Common common Stock stock~~ (which were originally issued as warrants to purchase shares of Legacy Allurion Common Stock and Legacy Allurion Preferred Stock). **Additionally, in July 2024 we issued the July 2024 Public Warrants to purchase up to 662, 701 shares of our common stock and the Private Placement Warrants to purchase up to 90, 407 shares of our common stock.** We evaluated the accounting treatment of such ~~Warrants warrants~~ and determined to classify certain of such ~~Warrants warrants~~ as liabilities measured at fair value. The fair value of such ~~Warrants warrants~~ is remeasured on a quarterly basis with changes in the estimated fair value recorded in Other (expense) income on the consolidated statement of operations and comprehensive loss. Due to the recurring fair value measurement, we expect that we will recognize non- cash gains or losses on such ~~Warrants warrants~~ each reporting period and that the amount of such gains or losses could materially impact or cause volatility in our financial results. For example, upon consummation of the Business Combination, the total value of the liability associated with the Public Warrants was \$ 13. 8 million measured at fair value based on the Public Warrant quoted price. However, at December 31, 2023-2024, the fair value of the liability associated with the Public Warrants was determined to be \$ 5-0, 9-4 million. Our Earn- Out Shares are accounted for as liabilities and the changes in value of such shares could have a material effect on, or cause volatility in, our financial results. In connection with the Business Combination, holders of Legacy Allurion common stock and Legacy Allurion preferred stock and holders of vested options, warrants and restricted stock units exercisable or convertible into Legacy Allurion capital stock received the contingent right to receive additional shares of our common stock (the "Earn-Out Shares ") upon the achievement of certain ~~earn-out~~ targets. We evaluated the accounting treatment of our ~~Earn-Out Shares~~ and determined to classify such shares as liabilities measured at fair value. The fair value of such shares is remeasured on a quarterly basis over the ~~earn-out~~ period with changes in the estimated fair value recorded in other income (expense) on the consolidated statement of operations and comprehensive loss. Due to the recurring fair value measurement, we expect that we will recognize ~~non-cash~~ gains or losses on

our ~~Earn-Out~~ Shares each reporting period and that the amount of such gains or losses could materially impact or cause volatility in our financial results. For example, upon consummation of the Business Combination, the fair value of the liability associated with the Earn- Out Shares was initially valued and recorded as \$ 53. 0 million. However, at December 31, ~~2023~~ 2024, the fair value of the liability associated with the Earn- Out Shares was determined to be \$ ~~24.1~~ 0.1 million. The provisions of our Bylaws requiring exclusive forum in the Court of Chancery of the State of Delaware and the federal district courts of the United States for certain types of lawsuits may have the effect of discouraging lawsuits against our directors and officers. Our Bylaws provide that, to the fullest extent permitted by law, and unless we consent in writing to the selection of an alternative forum, the Court of Chancery (the “ Chancery Court ”) of the State of Delaware (or, in the event that the Chancery Court does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) and any appellate court thereof will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of, or a claim based on, a breach of a fiduciary duty owed by any of our current or former directors, officers, or other employees or stockholders to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, our Charter or our Bylaws (including the interpretation, validity or enforceability thereof) or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware, or (iv) any action asserting a claim governed by the internal affairs doctrine; provided, however, that the preceding clauses (i) through (iv) will not apply to any causes of action arising under the Securities Act or the Exchange Act, or to any claim for which the federal courts have exclusive jurisdiction. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our Bylaws as described above. Additionally, 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. Accordingly, both state and federal courts have jurisdiction to entertain such Securities Act claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our Bylaws provide that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, the Exchange Act, or the respective rules and regulations promulgated thereunder; however, there is uncertainty as to whether a court would enforce such provision, and investors cannot waive compliance with federal securities laws and the rules and regulations thereunder. These provisions may limit or increase the difficulty in a stockholder’ s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors and officers, or may increase the cost for such stockholder to bring a claim, both of which may have the effect of discouraging lawsuits against our directors and officers. The enforceability of similar choice of forum provisions in other companies’ certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our Bylaws to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provision inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition.