

## Risk Factors Comparison 2024-04-01 to 2023-04-17 Form: 10-K

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The following is a summary of the principal risks and uncertainties that could materially adversely affect our business, results of operations, financial condition, cash flows, prospects and / or the price of our outstanding securities, and make an investment in our securities speculative or risky. You should read this summary together with the more detailed description of each risk factor contained below.

**Risks Related to Our Business and Industry**

- If we are unable to either substantially improve our operating results or obtain additional financing, we may be unable to continue as a going concern.
- **Public health crises. Our current business strategy includes identifying strategic merger and acquisition alternatives. Merger and acquisition transactions are risky and may harm our business, reputation such as COVID-19 pandemic, operating results and financial condition.**
- **We have had, recently undertaken a cost reduction plan and could reorganization, and may do so again** in the future ~~have a negative effect on~~.
- **The assumptions underlying these activities may prove to be inaccurate, our or business we may fail to achieve the expected benefits therefrom.**
- We may be unable to attract and retain management and other personnel we need to succeed.
- The shares of series C convertible preferred stock issued in connection with our acquisition of ReShape Medical have certain rights and preferences senior to our common stock, including a liquidation preference that is senior to our common stock.
- ~~No Obalon directors, officers or employees continued with ReShape which could hinder the ability to transfer the Obalon technology, restart manufacturing operations and maintain FDA regulatory compliance for the Obalon Balloon System and negatively impact our results of operations.~~
- ~~We are a medical device company with a limited history of operations and sales, and we cannot assure you that we will ever generate substantial revenue or be profitable.~~
- Previously, we recorded a non-cash indefinite-lived and definite-lived intangible assets impairment loss, which significantly impacted our results of operations, ~~and we may be exposed to additional impairment losses that could be material.~~
- We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives.
- We have identified material weaknesses in our internal control over financial reporting and any failure to maintain effective internal control over financial reporting, may have a material and adverse effect on our business, operating results, financial condition and prospects.
- ~~We reached a determination to restate certain of our previously issued consolidated financial statements, which resulted in unanticipated costs and may affect investor confidence and raise reputational issues.~~
- ~~The SEC Division of Enforcement has initiated an informal inquiry into our late filing notice related to our quarterly report on Form 10-Q for the fiscal quarter ended June 30, 2022, which could result in an enforcement action that requires us to pay civil penalties and fines and / or sanctions against us or certain of our current and / or former directors and officers.~~
- General economic and political conditions could have a material adverse effect on our business.
- We hold our deposit within the U. S. banking system and may incur a loss of our uninsured deposits if there a closure or other event with our bank.
- We face significant uncertainty in the industry due to government healthcare reform.
- **Public health crises, such as COVID-19 pandemic, have had, and could in the future have a negative effect on our business.**
- We are subject, directly or indirectly, to United States federal and state healthcare fraud and abuse and false claims laws and regulations. Prosecutions under such laws have increased in recent years and we may become subject to such litigation. If we are unable to, or have not fully complied with such laws, we could face substantial penalties.
- Failure to protect our information technology information technology infrastructure against cyber-based attacks, network security breaches, service interruptions or data corruption could materially disrupt our operations and adversely affect our business.
- We operate in a highly competitive industry that is subject to rapid change. If our competitors are able to develop and market products that are safer or more effective than our products, our commercial opportunities will be reduced or eliminated.
- **We face external competition from other technologies such as GLP-1's and alternative medical procedures and we may not be able to compete effectively.**
- Our ability to use net operating losses ("NOL") carryforwards may be limited.
- Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and our financial condition and results of operations.

**Risks Associated with Development and Commercialization of the Lap- Band System, ReShapeCare, ReShape, Lap- Band 2.0 System, Obalon Balloon System, DBSN Device**

- Our efforts to increase revenue from our Lap- Band System, ~~ReShapeCare, ReShape, Lap- Band 2.0 System, Obalon Balloon System, and commercialize our DBSN device~~ and expanded line of bariatric surgical accessories, including ReShape Calibration Tubes, may not succeed or may encounter delays which could significantly harm our ability to generate revenue.
- We may not be able to obtain required regulatory approvals for our DBSN device in a cost-effective manner or at all, which could adversely affect our business and operating results.
- We depend on clinical investigators and clinical sites to enroll patients in our clinical trials, and on other third parties to manage the trials and to perform related data collection and analysis, and, as a result, we may face costs and delays that are outside of our control.
- Modifications to the Lap- Band System and Lap- Band 2.0 may require additional approval from regulatory authorities, which may not be obtained or may delay our commercialization efforts.
- If we or our suppliers fail to comply with ongoing regulatory requirements, or if we experience unanticipated product problems, our Lap- Band system could be subject to restrictions or withdrawal from the market.
- ~~We may be unable to manage our growth effectively.~~
- We face the risk of product liability claims that could be expensive, divert management's attention and harm our reputation and business. We may not be able to obtain adequate product liability insurance.

**Risks Related to Intellectual Property**

- If we are unable to obtain or maintain intellectual property rights relating to our technology and neuroblocking therapy, the commercial value of our technology and any future products will be adversely affected, and our competitive position will be harmed.
- We may lose important patent rights if we do not timely pay required patent fees or annuities.
- Many of our competitors have significant resources and incentives to apply for and obtain

intellectual property rights that could limit or prevent our ability to commercialize our current or future products in the United States or abroad. • If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected. • Intellectual property litigation is a common tactic in the medical device industry to gain competitive advantage. If we become subject to a lawsuit, we may be required to expend significant financial and other resources and our management's attention may be diverted from our business. • ~~We are currently in a lawsuit, and~~ we may in the future become involved in lawsuits, to protect or enforce our intellectual property, which can be expensive and time consuming and could result in the diversion of significant resources. Risks Relating to Ownership of Our Common Stock • The trading price of our common stock has been volatile and is likely to be volatile in the future. • Sales of a substantial number of shares of our common stock in the public market by existing stockholders, or the perception that they may occur, could cause our stock price to decline. • We have a significant number of outstanding warrants, which may cause significant dilution to our stockholders, have a material adverse impact on the market price of our common stock and make it more difficult for us to raise funds through future equity offerings. • If we fail to meet all applicable Nasdaq Capital Market requirements, Nasdaq could delist our common stock, which could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease. • **There are risks associated with effecting the Reverse Stock Split, if approved by the Board.** • You may experience future dilution as a result of future equity offerings. • Our organizational documents and Delaware law make a takeover of our company more difficult, which may prevent certain changes in control and limit the market price of our common stock. • We have not paid dividends in the past and do not expect to pay dividends in the future, and any return on investment may be limited to the value of our common stock. ~~24risk~~ ~~22risk~~

**Risks Related to Our Business and Industry** If we are unable to either substantially improve our operating results or obtain additional financing, we may be unable to continue as a going concern. We currently do not generate revenue sufficient to offset operating costs and anticipate such shortfalls to continue, partially due to the **introduction of GLP-1 pharmaceuticals and the unpredictability of COVID-19**, which has resulted and may continue to result in a slow-down of elective surgeries and restrictions in some locations, and supply chain disruptions. As of December 31, ~~2022~~ **2023**, we had net working capital of approximately \$ ~~2.6~~ **4.5** million, primarily due to cash and cash equivalents and restricted cash of \$ ~~4.0~~ **6** million. Additionally, our anticipated expansion of our product portfolio and future products may not come to fruition. Our principal source of liquidity as of December 31, ~~2022~~ **2023** consisted of approximately \$ ~~4.0~~ **6** million of cash and cash equivalents and restricted cash and \$ ~~2.1~~ **2.7** million of accounts receivable. Based on our available cash resources, we may not have sufficient cash on hand to fund our current operations for more than 12 months from the date of filing this Form 10-K. This condition raises substantial doubt about our ability to continue as a going concern. ~~Public health crises~~ **Our current business strategy includes identifying strategic merger and acquisition alternatives. Merger and acquisition transactions are risky and may harm our business, reputation, operating results and financial condition. We have completed acquisitions and business combinations in the past and may complete merger and acquisition transactions in the future. In December 2023, we announced that we engaged Maxim Group LLC to act as our exclusive financial advisor to identify potential strategic merger and acquisition partnership alternatives. We do not have a defined timeline for such a transaction and cannot provide any assurance whether or when any transaction will be announced or consummated. Our ability to complete merger and acquisition transactions will depend, in part, on the availability of suitable candidates at acceptable prices, terms, and conditions; our ability to compete effectively for merger and acquisition candidates; and the availability of capital and personnel to complete such transactions. Merger and acquisition transactions may involve a number of risks, the occurrence of which could adversely affect our business, reputation, operating results and financial condition, including: • diversion of management's attention; • disruption to our existing operations and plans; • inability to effectively manage our expanded operations; • difficulties or delays in integrating and assimilating information and financial systems, operations, manufacturing processes and products of an acquired business or other business venture or in realizing projected efficiencies, growth prospects, cost savings, and synergies; • inability to successfully integrate or develop a distribution channel for acquired product lines; • potential loss of key employees, customers, agents, distributors, or sales representatives of the acquired businesses or adverse effects on existing business relationships with suppliers, customers, agents, distributors, and sales representatives; • reallocation of amounts of capital from other operating initiatives; • violation of confidentiality, intellectual property and non-compete obligations or agreements by employees of an acquired business or lack of or inadequate formal intellectual property protection mechanisms in place at an acquired business; • inaccurate assessment of additional post-acquisition investments, undisclosed, contingent or other liabilities or problems, unanticipated costs associated with an acquisition, and an inability to recover or manage such liabilities and costs; • incorrect estimates made in the accounting for acquisitions and incurrence of non-recurring charges; and • write-off of significant amounts of goodwill or other assets as a result of deterioration in the performance of an acquired business or product line, adverse market conditions, changes in the competitive landscape, changes in laws or regulations that restrict activities of an acquired business or product line, or as a result of a variety of the other COVID-circumstances.** ~~23~~ We have recently undertaken a cost reduction plan and reorganization, and may do so again in the future. The assumptions underlying these activities may prove to be inaccurate, or we may fail to achieve the expected benefits therefrom. In light of recent macroeconomic conditions and the impact of GLP-1 ~~19 pandemic~~ **prescriptions for weight loss treatment**, we announced a 2024 cost reduction plan and reorganization to promote the long-term sustainability and scalability of the Company. As part of this plan, we ~~have had~~ **significantly reduced our workforce. This reduction in force, and any other future reductions, and the attrition that may occur following them, result in the loss of institutional knowledge and expertise and the reallocation and combination of certain roles and responsibilities across the organization, all of which could in** ~~adversely affect our operations. These actions and the other future~~ **additional measures we might take to reduce costs could strain our workforce, divert management attention, yield**

attrition beyond our intended reduction in force, reduce employee morale, cause us to delay, limit, reduce or eliminate certain development plans or otherwise interfere with our ability to operate and grow our business effectively, each of which could have a negative effect on our business. Pandemics or disease outbreaks, such as the COVID-19 pandemic, have created and an adverse may continue to create significant volatility,..... may continue to have, a negative impact on the sales of our products. The extent to which fear of exposure to or actual effects of COVID-19, new variants, disease outbreak, epidemic or a similar widespread health concern impacts our business will depend, **operating results and financial condition.** **We may not complete the current or any cost reduction plan and reorganization on future developments the anticipated timetable**, which are highly uncertain and cannot be predicted with confidence **even if successfully completed, we may not achieve the anticipated cost savings, operating efficiencies or other benefits of such activities**. We may be unable to attract and retain management and other personnel we need to succeed. Our success depends on the services of our senior management and other key employees. The loss of the services of one or more of our officers or key employees could hinder our sales and marketing efforts, or delay or prevent the commercialization of our Lap- Band System, ReShapeCare, ReShape Marketplace, Lap- Band 2.0, the Obalon Balloon System, and the development of our DBSN device. Our continued growth will require hiring a number of qualified clinical, scientific, commercial and administrative personnel. Accordingly, recruiting and retaining such personnel in the future will be critical to our success. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. If we fail to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our development and commercialization activities. The shares of series C convertible preferred stock issued in connection with our acquisition of ReShape Medical have certain rights and preferences senior to our common stock, including a liquidation preference that is senior to our common stock. There are currently 95,388 shares of our series C convertible preferred stock outstanding, which are convertible into a total of 10 shares of our common stock. We originally issued the shares of our series C convertible preferred stock in connection with our acquisition of ReShape Medical. The series C convertible preferred stock has a liquidation preference of \$ 274.88 per share, or approximately \$ 26.2 million in the aggregate. In general, the series C convertible preferred stock is entitled to receive dividends (on an as-if-converted-to-common stock basis) actually paid on shares of common stock when, as and if such dividends are paid on shares of common stock. No other dividends will be paid on shares of series C convertible preferred stock. Except in connection with the election of directors and limited protective provisions, the series C convertible preferred stock generally does not have voting rights. However, as long as any shares of series C convertible preferred stock remain outstanding, we cannot, without the affirmative vote of holders of a majority of the then-outstanding shares of series C convertible preferred stock, (a) alter or change adversely the powers, ~~25 preferences~~ **preferences** or rights given to the series C convertible preferred stock (including by the designation, authorization, or issuance of any shares of preferred stock that purports to have equal rights with, or be senior in rights or preferences to, the series C convertible preferred stock), (b) alter or amend the series C convertible preferred stock certificate of designation, (c) amend our certificate of incorporation or other charter documents in any manner that adversely affects any rights of the holders of series C convertible preferred stock, (d) increase the number of authorized shares of series C convertible preferred stock, (e) except for stock dividends or distributions for which adjustments are to be made pursuant to the Series C Certificate of Designation, pay dividends on any shares of capital stock of the Company, or (f) enter into any agreement with respect to any of the foregoing. ~~No Obalon directors, officers or employees continued with the Company which could hinder the ability to transfer the Obalon technology, restart manufacturing operations and maintain FDA regulatory compliance for the Obalon Balloon System and negatively impact our results of operations. Following the consummation of the merger, no directors, officers or employees of Obalon continued with ReShape. In order to restart manufacturing of the Obalon Balloon System, ReShape would have to hire and train new personnel to appropriately perform manufacturing operations that meet required performance specifications and maintain quality system and regulatory compliance related to the Obalon Balloon System without the knowledge and expertise of the Obalon management team, including completing a FDA-mandated post-approval study which was halted due to the effects of COVID-19. Obalon's prior suppliers have not supplied Obalon since Obalon halted manufacturing and they may be unwilling or unable to supply ReShape on the prior terms or at all. Obalon had not manufactured or shipped products to customers since March 2020 and customers may not accept a relaunch of the Obalon Balloon System by ReShape. We are a medical device company with a limited history of operations and sales, and we cannot assure you that we will ever generate substantial revenue or be profitable. We are a medical device company with a limited operating history upon which you can evaluate our business.~~ The success of our business will depend on our ability to generate increased sales and control costs, as well as our ability to obtain additional regulatory approvals needed to market new versions of our Lap- Band System, ReShapeCare, ReShape Marketplace, Obalon Balloon System, or regulatory approvals needed to market our DBSN device and any other products we may develop in the future, all of which we may be unable to do. If we are unable to successfully market our Lap- Band System for its **indicated 24 indicated** use, successfully **launch ReShapeCare and ReShape Marketplace**, re-introduce the Obalon Balloon System, or develop and commercialize the DBSN device, we may never become profitable and may have to cease operations as a result. ~~Our lack of a significant operating history also limits your ability to make a comparative evaluation of us, our products and our prospects.~~ Previously, we recorded a non-cash indefinite-lived intangible and definite-lived assets impairment loss, which significantly impacted our results of operations, and we may be exposed to additional impairment losses that could be material. We conduct our annual indefinite-lived intangible assets impairment analysis during the fourth quarter of each year or when circumstances suggest that an indicator for impairment may be present. Previously, we performed a qualitative impairment analysis of the in-process research and development ("IPR & D"). Due to delays in the clinical trials experienced, we revised its expectations of when revenues would commence for the ReShape Vest, thus reducing the projected near-term future net cash flows related to the ReShape Vest. During the quarter ended September 30, 2022, we stopped the clinical trials for the ReShape Vest and closed out the previous trials that occurred, as significant additional clinical work and cost would be required to achieve regulatory approval for the

ReShape Vest. In addition, due to continued market decline and projected cash flows the company recorded an impairment of the developed technology related to the Lap- Band and Obalon Balloon System and our tradenames. As such, we determined the carrying value of the ~~long-lived IPR & D and developed technology assets, and trademarks~~ were impaired and recognized a non-cash impairment charge of approximately \$ ~~18.0~~ **7.8** million on the condensed consolidated balance sheet as of December 31, ~~2022~~ **2023**. In the future, we may have additional impairments requiring us to record an impairment loss related to our remaining finite-lived intangible assets, which could also have a material adverse effect on our results of operations. ~~26~~ **We** incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives. As a public company, we incur significant legal, accounting and other expenses. In addition, the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), as well as rules subsequently implemented by the SEC have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations result in increased legal and financial compliance costs and will make some activities more time-consuming and costly. The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure. In particular, we are required to perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our testing may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. We have incurred and continue to expect to incur significant expense and devote substantial management effort toward ensuring compliance with Section 404. Moreover, if we do not comply with the requirements of Section 404, or if we identify deficiencies in our internal controls that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would entail expenditure of additional financial and management resources. For example, our management assessed the effectiveness of our internal control over financial reporting as of December 31, ~~2022~~ **2023**, and determined that our internal control over financial reporting was not effective at a reasonable assurance level due to material weaknesses in our internal control over financial reporting. We had insufficient internal resources with appropriate accounting and finance knowledge and expertise to design, implement, document and operate effective internal controls around our financial reporting process. ~~The insufficient internal resources resulted in a lack of review over our weighted average share calculation spreadsheet which included a formula error resulting in the inaccurate reporting of our earnings per share.~~ We are currently implementing our remediation plan to address the material weaknesses identified above. Such measures include: ~~hiring additional accounting personnel to ensure timely reporting of significant matters;~~ designing and implementing controls to formalize roles and review responsibilities to align with our team's skills and experience and designing and implementing formalized controls; and designing and implementing formal processes, policies and procedures supporting our financial close process. ~~We~~ **25** ~~We~~ have identified material weaknesses in our internal control over financial reporting and any failure to maintain effective internal control over financial reporting, may have a material and adverse effect on our business, operating results, financial condition and prospects. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, ~~2022~~ **2023**, and determined that our internal control over financial reporting was not effective at a reasonable assurance level due to material weaknesses in our internal control over financial reporting. We had insufficient internal resources with appropriate accounting and finance knowledge and expertise to design, implement, document and operate effective internal controls around our financial reporting process. We are currently implementing our remediation plan to address the material weaknesses identified above. Such measures include: ~~hiring additional accounting personnel to ensure timely reporting of significant matters;~~ designing and implementing controls to formalize roles and review responsibilities to align with our team's skills and experience and designing and implementing formalized controls; and designing and implementing formal processes, policies and procedures supporting our financial close process. ~~We reached a determination to restate certain of our previously issued consolidated financial statements, which resulted in unanticipated costs and may affect investor confidence and raise reputational issues. As discussed in the Explanatory Note, in Note 2, Significant Accounting Policies and Restatement in this Form 10-K, we also reached a determination to restate our consolidated financial statements and related disclosures for the year ended December 31, 2021, and the unaudited consolidated information for the interim periods ended September 30, 2022, June 30, 2022, March 31, 2022, September 30, 2021, and June 30, 2021 following the identification of certain misstatements contained in those financial statements, which resulted in an understatement of impairment of goodwill by approximately \$ 1.9 million. We have determined that it is appropriate to correct the misstatements in our previously issued financial statements. The restatement also included corrections for additional identified out-of-period and uncorrected misstatements in the impacted periods. As a result, we have incurred unanticipated costs for accounting and legal fees in connection with or related to the restatement, and have become subject to a number of additional risks and uncertainties, which may affect investor confidence in the accuracy of our financial disclosures and may raise reputational issues for our business. The SEC Division of Enforcement has initiated an informal inquiry into our late filing notice related to our quarterly report on Form 10-Q for the fiscal quarter ended June 30, 2022, which could result in an enforcement action that requires us to pay civil penalties and fines and/or sanctions against us or certain of our current and/or former directors and officers. We received a letter from the SEC Division of Enforcement, dated January 11, 2023, informing us that it is conducting an informal inquiry regarding our potential violation of certain rules and regulations concerning late filing notifications on Form 12b-25 related to the late filing notice we filed with the SEC for our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2022. As part of the inquiry, the SEC has required that we voluntarily provide certain requested documents and information, which we are in the process of responding to. While the SEC letter specifically notes that it should be not be construed as an indication that any violations of law have occurred, or as an adverse reflection upon any person or security, it is possible that the SEC could conclude that enforcement action is appropriate, in which case we could be~~

~~required to pay substantial civil penalties and fines and the SEC also could impose other sanctions against us or certain of our current and / or former directors and officers. Any of these events could have a material adverse effect on our business, financial condition or results of operations.~~ General economic and political conditions could have a material adverse effect on our business. External factors can affect our financial condition. Such external factors include general domestic and global economic conditions, such as interest rates, tax law including tax rate changes, and factors affecting global economic stability, and the political environment regarding healthcare in general. We cannot predict to what extent the global economic conditions may negatively impact our business. For example, negative conditions in the credit and capital markets could impair our ability to access the financial markets for working capital and could negatively impact our ability to borrow. We face significant uncertainty in the industry due to government healthcare reform. In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. The Patient Protection and Affordable Care Act, as amended, (the “Affordable Care Act”) as well as any future healthcare reform legislation, may have a significant impact on our business. The impact of the Affordable Care Act on the health care industry is extensive and includes, among other things, the federal government assuming a larger role in the health care system, expanding healthcare coverage of United States citizens and mandating basic healthcare benefits. Congress regularly considers legislation to replace or repeal elements or all of the Affordable Care Act. At this time, it is not clear whether the Affordable Care Act will be repealed in whole or in part, and, if it is repealed, whether it will be replaced in whole or in part by another plan and what impact those changes will have on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the Affordable Care Act. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and also indirectly affect the amounts that private payers are willing to pay. In addition, any healthcare reforms enacted in the future may, like the Affordable Care Act, be phased in over a number of years but, if enacted, could reduce our revenue, increase our costs, or require us to revise the ways in which we conduct business or put us at risk for loss of business. In addition, our results of operations, financial position and cash flows could be materially adversely affected by changes under the Affordable Care Act and changes under any federal or state legislation adopted in the future. may continue to create significant volatility, uncertainty and economic disruption in the markets we sell our products into and operate in and may negatively impact business and healthcare activity globally. In response to the COVID- 19 pandemic, governments around the world have imposed measures designed to reduce the transmission of COVID- 19. In particular, elective procedures, such as the Lap- Band procedure, were delayed or cancelled, there was a significant reduction in physician office visits, and hospitals postponed or canceled purchases as well as limited or eliminated services. While elective procedures have increased from the reduced levels during the height of the COVID- 19 pandemic, the reduction in elective procedures has had, and we believe may continue to have, a negative We are subject, directly or indirectly, to United States federal and state healthcare fraud and abuse and false claims laws and regulations. Prosecutions under such laws have increased in recent years and we may become subject to such litigation. If we are unable to, or have not fully complied with such laws, we could face substantial penalties. Our operations are directly, or indirectly through customers, subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti- Kickback Statute and federal False Claims Act. These laws may impact, among other things, our sales, marketing and education programs. 28 The --

**The** federal Anti- Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Anti- Kickback Statute is broad and, despite a series of narrow safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Penalties for violations of the federal Anti- Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Many states have also adopted laws similar to the federal Anti- Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs. The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from the federal government. Suits filed under the False Claims Act, known as “ qui tam ” actions, can be brought by any individual on behalf of the government and such individuals, commonly known as “ whistleblowers, ” may share in any amounts paid by the entity to the government in fines or settlement. The frequency of filing qui tam actions has increased significantly in recent years, causing greater numbers of medical device, pharmaceutical and healthcare companies to have to defend a False Claim Act action. When an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Various states have also enacted laws modeled after the federal False Claims Act. We are unable to predict whether we could be subject to actions under any of these laws, or the impact of such actions. If we are found to be in violation of any of the laws described above or other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare reimbursement programs and the curtailment or restructuring of our operations. Failure to protect our information technology infrastructure against cyber- based attacks, network security breaches, service interruptions or data corruption could materially disrupt our operations and adversely affect our business. The operation of our business depends on our information technology systems. We rely on our information technology systems to, among other things, effectively manage sales and marketing data, accounting and financial functions, inventory management, product development tasks, clinical data, customer service and technical support functions. Our information technology systems are vulnerable to damage or interruption from earthquakes, fires, floods and other natural disasters, terrorist attacks, power losses, computer system or data network failures, security breaches, data

corruption, and cyber- based attacks. Cyber- based attacks can include computer viruses, computer denial- of- service attacks, phishing attacks, worms, and other malicious software programs or other attacks, covert introduction of malware to computers and networks, impersonation of authorized users, and efforts to discover and exploit any design flaws, bugs, security vulnerabilities, or security weaknesses, as well as intentional or unintentional acts by employees or other insiders with access privileges, intentional acts of vandalism by third parties and sabotage. In addition, federal, state, and international laws and regulations, such as the General Data Protection Regulation adopted by the European Union and EEA countries can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties and significant legal liability, if our information technology security efforts fail. In addition, a ~~variety~~ **variety** of our software systems are cloud- based data management applications, hosted by third- party service providers whose security and information technology systems are subject to similar risks. We operate in a highly competitive industry that is subject to rapid change. If our competitors are able to develop and market products that are safer or more effective than our products, our commercial opportunities will be reduced or eliminated. The health care industry is highly competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. The obesity treatment market in which we operate has grown significantly in recent years and is expected to continue to expand as technology continues to evolve and awareness of the need to treat the obesity epidemic grows. Although we are not aware of any competitors in the neuroblocking market, we face potential competition from pharmaceutical and surgical obesity treatments. Many of our competitors in the obesity treatment field have significantly greater financial resources and expertise in research and ~~development~~ **development**, manufacturing, preclinical testing, clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early- stage companies may also prove to be significant competitors, particularly if they pursue competing solutions through collaborative arrangements with large and established companies, such as Allergan, Boston Scientific, LivaNova PLC, Johnson & Johnson, Medtronic or St. Jude Medical. Our competitors may develop and patent processes or products earlier than us, obtain regulatory approvals for competing products more rapidly than we are able to and develop more effective, safer and less expensive products or technologies that would render our products non- competitive or obsolete. **We face external competition from other technologies such as GLP- 1' s, and alternative medical procedures and we may not be able to compete effectively. Companies that may not be deemed competitors in the bariatric surgery space may develop technologies, products or services that may impact the use of our products. For example, certain therapeutic treatments, such as drugs used to treat weight loss such as GLS- 1' s, may enhance patient health. If we do not introduce new products and enhancements in a timely manner, there may be a decrease in the use of certain of our products, in which case our operating results could suffer.** Our ability to use net operating losses (“ NOL ”) carryforwards may be limited. Our ability to use our federal and state NOL carryforwards to offset potential future taxable income is dependent upon our generation of future taxable income before the expiration dates of the NOL carryforwards, and we cannot predict with certainty when, or whether we will generate sufficient taxable income to use all of our NOL carryforwards. As of December 31, ~~2022~~ **2023**, ReShape had U. S. federal net operating loss carryforwards of \$ ~~207~~ **218**. 9 million. Of the total U. S. federal net operating loss carryforwards at December 31, ~~2022~~ **2023**, \$ ~~6.3~~ **6.3** million is subject to a ~~20-year carryover period and began expiring in 2022~~. Losses generated beginning in 2018 will carryover indefinitely. ReShape had state net operating loss carryforwards of \$ ~~329~~ **348**. ~~4~~ **7** million at December 31, ~~2022~~ **2023**, and had foreign net operating loss carryforwards of \$ 0. 2 million at December 31, ~~2022~~ **2023**. Net operating loss carryforwards of ReShape are subject to review and possible adjustment by the taxing authorities. With certain exceptions (e. g. the net operating loss carryforwards), ReShape is no longer subject to U. S. federal, state or local examinations by tax authorities for years prior to 2016. There are no tax examinations currently in progress. ReShape' s ability to utilize its net operating loss carryforwards, tax credits, and built- in items of deduction, including capitalized start- up costs and research and development costs, has been, and may continue to be substantially limited due to ownership changes. These ownership changes limit the amount of net operating loss carryforwards, credits and built- in items of deduction that can be utilized annually to offset future taxable income. In general, an ownership change, as defined in IRC Section 382, results from a transaction or series of transactions over a three- year period resulting in an ownership change of more than 50 % of the outstanding stock of a company by certain stockholders or public groups. Due to the valuation allowance against deferred tax assets at December 31, ~~2022~~ **2023**, the net effect of any further limitation will have no impact on results of operations. Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and our financial condition and results of operations. Substantially all of our cash and cash equivalents were held in accounts with Silicon Valley Bank (SVB) at the time it was closed by state regulators, and the Federal Deposit Insurance Corporation (FDIC) was appointed receiver for ~~SVB~~ **28SVB**, on March 10, 2023. The FDIC created a successor bridge bank for SVB and all deposits of SVB were transferred to the bridge bank under a systemic risk exception approved by the United States Department of the Treasury, the Federal Reserve and the FDIC. If financial institutions in which we hold funds for working capital and operating expenses were to fail, we cannot provide any assurances that such governmental agencies would take action to protect our uninsured deposits in a similar manner. We subsequently moved ~~and hold a portion~~ **and hold a portion** approximately \$ ~~7.0~~ **7.0** million of our cash and cash equivalents ~~to~~ **in accounts with** Bank of America. The balance held in these accounts exceeds the FDIC standard deposit insurance limit of \$ 250, 000. If a financial institution in which we hold such funds fails or is subject to significant adverse conditions in the financial or credit markets, we could be subject to a risk of loss of all or a portion of such uninsured funds or be subject to a delay in accessing all or a portion of such uninsured funds. Any such loss or lack of access to these funds could adversely impact our short- term liquidity and ability to meet our operating expense obligations. In addition, widespread investor concerns regarding the U. S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on 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 ~~30above~~ **above** or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and / or projected business operations and financial condition and results of operations. In addition, a vendor on which we are reliant could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on us, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Any critical vendor bankruptcy or insolvency, or any breach or default by a critical vendor, or the loss of any significant vendor relationships, may have a material adverse impact on our business. Risks Associated with Development and Commercialization of the Lap- Band System, ~~ReShapeCare~~, Lap- Band 2. 0 System, Obalon Balloon System, and the DBSN Device Our efforts to increase revenue from our Lap- Band System, ~~ReShapeCare~~, Lap- Band 2. 0 System, and commercialize our DBSN device and expanded line of bariatric surgical accessories, including ReShape Calibration Tubes, may not succeed or may encounter delays which could significantly harm our ability to generate revenue. Our ability to generate revenue will depend upon the sales of our Lap- Band System, expanded line of bariatric surgical accessories ~~and ReShapeCare~~, and successful commercialization of our DBSN device (if approved for sale). Our efforts to commercialize these products may not succeed for a number of reasons, including: ● we may not be able to obtain the regulatory approvals required for our DBSN device; ● we may not be able to produce the Obalon Balloon System cost- effectively; ● if we are able to produce the Obalon Balloon System, we may not be able to re- introduce the system into the marketplace; ● our products may not be accepted in the marketplace by physicians, patients and third- party payers; ● the price of our products, associated costs of the surgical procedure and treatment and the availability of sufficient third- party reimbursement for the system implantation and follow- up procedures; ● appropriate reimbursement and / or coding options may not exist to enable billing for the system implantation and follow- up procedures for our DBSN device; ● coverage policies for bariatric surgeries and procedures, including Lap- Band and balloons may be restricted in the future; ● we may not be able to sell our products at a price that allows us to meet the revenue targets necessary to generate enough revenue for profitability; ● the frequency and severity of any side effects of our products; ● physicians and potential patients may not be aware of the perceived effectiveness and sustainability of the results of our products; **29** ● we, or the investigators of our products, may not be able to have information on the outcome of the trials published in medical journals; ● the availability and perceived advantages and disadvantages of alternative treatments, including pharmaceutical treatments; ● any rapid technological change may make our products obsolete; ● we may not be able to have our products manufactured in commercial quantities or at an acceptable cost; ● we may not have adequate financial or other resources to complete the development and commercialization of our products or to develop sales and marketing capabilities for our products; and ● we may be sued for infringement of intellectual property rights and could be enjoined from manufacturing or selling our products. Besides requiring physician adoption, market acceptance of our products will depend on successfully communicating the benefits of our products to three additional constituencies involved in deciding whether to treat a particular patient using our products: (1) the potential patients themselves; (2) institutions such as hospitals, where the procedure would be performed and opinion leaders in these institutions; and (3) third- party payers, such as private healthcare insurers and governmental payers, such as Medicare and Medicaid in the United States, which would ultimately bear most of the costs of the various providers and equipment involved in our Lap- Band System, ~~ReShapeCare~~, Obalon Balloon System, and DBSN device (if approved for sale). Marketing to each of these constituencies requires a different marketing approach, and we must convince each of these groups of the efficacy and utility of our products to be successful. ~~31During~~ **During** the year ended December 31, **2023 and** 2022 ~~and 2021~~, there was minimal revenue for ReShapeCare and ReShape Marketplace. There was no revenue or gross profit recorded for the DBSN device for the year ended December 31, **2023 and** 2022 ~~and 2021~~ as this product is still in the research stage of development. There was also no revenue recorded for the Obalon line. If our products, or any other therapy or products that we may develop for other gastrointestinal diseases and disorders that we may develop, do not achieve an adequate level of acceptance by the relevant constituencies, we may not generate significant product revenue and may not become profitable. This estimated timeline could be compressed or extended depending on many factors, including revenue growth from new product introductions, strategic investments not yet foreseen, and other risks and uncertainties due to the general business, economic, regulatory, market and financial conditions. Therefore, the plans cannot be deemed probable of being implemented. As a result, the Company' s plans do not alleviate substantial doubt about our ability to continue as a going concern. We may not be able to obtain required regulatory approvals for our DBSN device in a cost- effective manner or at all, which could adversely affect our business and operating results. The production and marketing of our DBSN device, and our ongoing research and development, preclinical testing and future potential clinical trial activities are subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad. U. S. and foreign regulations applicable to medical devices are wide- ranging and govern, among other things, the development, testing, marketing and premarket review of new medical devices, in addition to regulating manufacturing practices, reporting, advertising, exporting, labeling and record keeping procedures. We are required to obtain regulatory approval before we can market our DBSN device in the United States and certain foreign countries. The regulatory process will require significant time, effort and expenditures to bring products to market, and it is possible that our DBSN device will not be approved for sale. Even if regulatory approval of our DBSN device is granted, it may not be granted within the timeframe that we expect, which could have an adverse effect on our operating results and financial condition. Even after our DBSN device is approved by the FDA, we may have ongoing responsibilities under FDA regulations, non- compliance of which could result in the subsequent withdrawal of such approvals, or such approvals could be withdrawn due to the occurrence of unforeseen problems following initial approval. We also are subject to medical device reporting regulations that require us to report to the FDA if any of our products causes or contributes to a death or serious injury or if a malfunction were it to occur might cause or contribute to a death or serious injury. Any failure

to obtain regulatory approvals on a timely basis or the subsequent withdrawal of such approvals could prevent us from successfully marketing our products, which could adversely affect our business and operating results. ~~We~~<sup>30</sup>~~We~~ depend on clinical investigators and clinical sites to enroll patients in our clinical trials, and on other third parties to manage the trials and to perform related data collection and analysis, and, as a result, we may face costs and delays that are outside of our control. While we currently do not have any active clinical trials enrolling patients, we may in the future need to rely on clinical investigators and clinical sites to enroll patients in our clinical trials and other third parties to manage the trials and to perform related data collection and analysis. However, we may not be able to control the amount and timing of resources that clinical sites may devote to our clinical trials. If these clinical investigators and clinical sites fail to enroll a sufficient number of patients in our clinical trials, ensure compliance by patients with clinical protocols or comply with regulatory requirements, we will be unable to complete these trials, which could prevent us from obtaining or maintaining regulatory approvals for our product. Our agreements with clinical investigators and clinical trial sites for clinical testing place substantial responsibilities on these parties and, if these parties fail to perform as expected, our trials could be delayed or terminated. If these clinical investigators, clinical sites or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, or the clinical data may be rejected by the FDA, adversely affecting our ability to successfully commercialize our product. Modifications to the Lap-Band and Lap- Band 2. 0 system may require additional approval from regulatory authorities, which may not be obtained or may delay our commercialization efforts. The FDA and our European Notified Body require medical device companies to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance; however, some of ~~32~~<sup>32</sup>~~these~~ ~~these~~ regulatory authorities can review a company's decision. Any modifications to an approved device that could significantly affect its safety or efficacy, or that would constitute a major change in its intended use could require additional clinical studies and separate regulatory applications. Product changes or revisions will require all the regulatory steps and associated risks discussed above possibly including testing, regulatory filings and clinical studies. We may not be able to obtain approval of supplemental regulatory approvals for product modifications, new indications for our product or new products. Delays in obtaining future clearances would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our commercialization efforts and future growth. If we or our suppliers fail to comply with ongoing regulatory requirements, or if we experience unanticipated product problems, our Lap- Band system could be subject to restrictions or withdrawal from the market. Any product for which we obtain marketing approval, along with the manufacturing processes, post- approval clinical data and promotional activities for such product, will be subject to continual review and periodic inspections by our European Notified Body and the FDA and other regulatory bodies. In particular we and our manufacturers and suppliers are required to comply with ISO requirements, Good Manufacturing Practices, which for medical devices is called the Quality System Regulation (" QSR "), and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain marketing approval. The FDA enforces the QSR through inspections, which may be unannounced, and the CE system enforces its certification through inspections and audits as well. Our quality system has received certification of compliance to the requirements of ISO 13485: 2016 and will have to continue to successfully complete such inspections to maintain regulatory approvals for sales outside of the United States. Failure by us or one of our manufacturers or suppliers to comply with statutes and regulations administered by the FDA, CE authorities and other regulatory bodies, or failure to adequately respond to any observations, could result in enforcement actions against us or our manufacturers or suppliers, including, restrictions on our product or manufacturing processes, withdrawal of the product from the market, voluntary or mandatory recall, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties. If any of these actions were to occur it would harm our reputation and cause our product sales to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements. If the FDA or any other regulatory body finds their compliance status to be unsatisfactory, our commercialization efforts could be delayed, which would harm our business and our results of operations. ~~Additionally~~<sup>31</sup>~~Additionally~~, if the FDA determines that our promotional materials, training or other activities constitute promotion of an unapproved use, we could be subject to significant liability, the FDA could request that we cease, correct or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. We are subject to medical device reporting regulations that require us to report to the FDA, Competent Authorities or other governmental authorities in other countries if our products cause or contribute to a death or serious injury or malfunction in a way that would be reasonably likely to contribute to death or serious injury if the malfunction were to recur. The FDA and similar governmental authorities in other countries have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacturing. A government mandated, or voluntary, recall by us could occur as a result of component failures, manufacturing errors or design defects, including defects in labeling. Any recall would divert managerial and financial resources and could harm our reputation with customers. There can be no assurance that there will not be product recalls in the future or that such recalls would not have a material adverse effect on our business. Once the product is approved and implanted in a large number of patients, infrequently occurring adverse events may appear that were not observed in the clinical trials. This could cause health authorities in countries where the product is available to take regulatory action, including marketing suspension and recall. For example, on January 18, 2023, we received a letter from the FDA requesting additional information regarding Medical Device Reports submitted in 2021 related adverse events associated with a Lap- Band device and pregnancy. The FDA's letter indicates a concern for an increased risk for Lap- Band



complications in pregnant patients and requests that we provide, among other information, any actions planned or implemented which might reduce the likelihood of ~~such~~ **such** events, which we are in the process of responding to. We believe there is robust peer-reviewed published data that supports our belief that concerns raised by the FDA are anomalies and rare occurrences. For example, a June 2022 consensus statement on laparoscopic adjustable gastric band (LAGB) management, which includes the Lap-Band, by the ASMBS found that (i) a tailored approach to LAGB management during pregnancy allows patients and providers to monitor weight gain, nutritional adequacy, and fetal growth for a healthy pregnancy outcome and (ii) evidence supports LAGB placement as safe and well tolerated during pregnancy with close LAGB monitoring. While improbable, if there are additional, or more serious, adverse events for pregnant Lap-Band patients, or if the FDA issues a warning regarding, or restricts the use of, the Lap-Band with pregnant patients, or patients who may become pregnant, our business could be harmed. One of the goals of our direct-to-consumer marketing campaign is to help people understand that the Lap-Band offers unique benefits for a variety of obese patients, including patients who may become pregnant. If there is a perception that the Lap-Band is not safe for pregnant patients, it could harm our reputation and cause our Lap-Band sales to suffer. We ~~may be unable to manage our growth effectively. Our business strategy entails significant future growth. For example, we will have to expand existing operations in order to increase revenue from our Lap-Band System and ReShapeCare, re-introduce the Obalon Balloon System, and develop our DBSN device, conduct additional clinical trials, increase our contract manufacturing capabilities, hire and train new personnel to handle the marketing and sales of our product, assist patients and healthcare providers in obtaining reimbursement for the use of our product and create and develop new applications for our technology. This growth may place significant strain on our management and financial and operational resources. Successful growth is also dependent upon our ability to implement appropriate financial and management controls, systems and procedures. Our ability to effectively manage growth depends on our success in attracting and retaining highly qualified personnel, for which the competition may be intense. If we fail to manage these challenges effectively, our business could be harmed. We face the risk of product liability claims that could be expensive, divert management's attention and harm our reputation and business. We may not be able to obtain adequate product liability insurance. Our business exposes us to a risk of product liability claims that is inherent in the testing, manufacturing and marketing of medical devices. The medical device industry has historically been subject to extensive litigation over product liability claims. We have previously reported adverse events associated with the Lap-Band system, including as related to pregnant patients, and may be subject to product liability claims if our products cause, or appear to have caused, an injury. Claims may be made by consumers, healthcare providers, third-party strategic collaborators or others selling our products. We have product liability insurance, which covers the use of our products in our clinical trials and any commercial sales, in an amount we believe is appropriate. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, the coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost and on acceptable terms for an adequate coverage amount, or otherwise to protect against potential product liability claims, we could be exposed to significant liabilities, which may harm our business. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations. These liabilities could prevent or interfere with our product commercialization efforts. Defending a suit, regardless of merit, could be costly, could divert management attention and ~~might~~ **might** result in adverse publicity, which could result in the withdrawal of, or inability to recruit, clinical trial volunteers or result in reduced acceptance of our products in the market. We may be subject to product liability claims even if it appears that the claimed injury is due to the actions of others. For example, we rely on the expertise of surgeons and other associated medical personnel to perform the medical procedure to implant and remove our products and to perform the related therapy. If these medical personnel are not properly trained or are negligent, the therapeutic effect of our products may be diminished or the patient may suffer critical injury, which may subject us to liability. In addition, an injury that is caused by the negligence of one of our suppliers in supplying us with a defective component that injures a patient could be the basis for a claim against us. A product liability claim, regardless of its merit or eventual outcome, could result in decreased demand for our products; injury to our reputation; diversion of management's attention; withdrawal of clinical trial participants; significant costs ~~34 of~~ **of** related litigation; substantial monetary awards to patients; product recalls or market withdrawals; loss of revenue; and the inability to commercialize our products under development.~~

**Risks Related to Intellectual Property** If we are unable to obtain or maintain intellectual property rights relating to our technology and neuroblocking therapy, the commercial value of our technology and any future products will be adversely affected and our competitive position will be harmed. Our commercial success depends in part on our ability to obtain protection in the United States and other countries for our Lap-Band System, ~~ReShapeCare~~, Obalon Balloon System, and DBSN device by establishing and maintaining intellectual property rights relating to or incorporated into our technology and products. We own numerous U.S. and foreign patents and have numerous patent applications pending, most of which pertain to treating gastrointestinal disorders and the treatment of obesity. We have also received or applied for additional patents outside the United States. Our pending and future patent applications may not issue as patents or, if issued, may not issue in a form that will provide us any competitive advantage. We expect to incur substantial costs in obtaining patents and, if necessary, defending our proprietary rights. The patent positions of medical device companies, including ours, can be highly uncertain and involve complex and evolving legal and factual questions. We do not know whether we will obtain the patent protection we seek, or that the protection we do obtain will be found valid and enforceable if challenged. If we fail to obtain adequate protection of our intellectual property, or if any protection we obtain is reduced or eliminated, others could use our intellectual property without compensating us, resulting in harm to our business. We may also determine that it is in our best interests to voluntarily challenge a third-party's products or patents in litigation or administrative proceedings, including patent interferences, re-examinations or under more recently promulgated Inter Partes Review proceedings, depending on when the patent application was filed. In the event that we seek to enforce any of our owned or exclusively licensed patents against an infringing party, it is likely that the

party defending the claim will seek to invalidate the patents we assert, which, if successful could result in the loss of the entire patent or the relevant portion of our patent, which would not be limited to any particular party. Any litigation to enforce or defend our patent rights, even if we were to prevail, could be costly and time-consuming and could divert the attention of our management and key personnel from our business operations. Even if we were to prevail in any litigation, we cannot assure you that we can obtain an injunction that prevents our competitors from practicing our patented technology. Our competitors may independently develop similar or alternative technologies or products without infringing any of our patent or other intellectual property rights, or may design around our proprietary technologies. We cannot assure you that we will obtain any patent protection that we seek, that any protection we do obtain will be found valid and enforceable if challenged or that it will confer any significant commercial advantage. U. S. patents and patent applications may also be subject to interference proceedings and U. S. patents may be subject to re-examination proceedings in the U. S. Patent and Trademark Office (“USPTO”), or under more recently promulgated Inter Partes Review proceedings, depending on when the patent application was filed, and foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent offices, which proceedings could result in either loss of the patent or denial of the patent application, or loss or reduction in the scope of one or more of the claims of, the patent or patent application. In addition, such interference, re-examination and opposition proceedings may be costly. Moreover, the U. S. patent laws have recently changed with the adoption of the America Invents Act (“AIA”), possibly making it easier to challenge patents. Some of our technology was, and continues to be, developed in conjunction with third parties, and thus there is a risk that such third parties may claim rights in our intellectual property. Thus, any patents that we own or license from others may provide limited or no protection against competitors. Our pending patent applications, those we may file in the future, or those we may license from third parties, may not result in patents being issued. If issued, they may not provide us with proprietary protection or competitive advantages against competitors with similar technology. We may lose important patents or patent rights if we do not timely pay required patent fees or annuities. We have, from time to time, experienced delays in the payment of required patent fees or annuities. Non-payment or delay in payment of patent fees or annuities, whether intentional or unintentional, may result in loss of patents or patent rights important to our business. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as do the laws of the United States, particularly in the field of medical products and procedures. Many of our competitors have significant resources and incentives to apply for and obtain intellectual property rights that could limit or prevent our ability to commercialize our current or future products in the United States or abroad. Many of our competitors who have significant resources and have made substantial investments in competing technologies may seek to apply for and obtain patents that will prevent, limit or interfere with our ability to make, use or sell our products either in the U. S. or in international markets. Our current or future U. S. or foreign patents may be challenged, circumvented by competitors or others or may be found to be invalid, unenforceable or insufficient. In most cases in the United States patent applications are published 18 months after filing the application, or corresponding applications are published in other countries, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we were the first to make the inventions covered by each of our pending patent applications, or that we were the first to file patent applications for such inventions. If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected. In addition to patented technology, we rely on our unpatented proprietary technology, trade secrets, processes and know-how. We generally seek to protect this information by confidentiality agreements with our employees, consultants, scientific advisors and third parties. These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently developed by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. Intellectual property litigation is a common tactic in the medical device industry to gain competitive advantage. If we become subject to a lawsuit, we may be required to expend significant financial and other resources and our management’s attention may be diverted from our business. There has been a history of frequent and extensive litigation regarding patent and other intellectual property rights in the medical device industry, and companies in the medical device industry have employed intellectual property litigation to gain a competitive advantage. Accordingly, we may become subject to patent infringement claims or litigation in a court of law, or interference proceedings declared by the USPTO to determine the priority of inventions or an opposition to a patent grant in a foreign jurisdiction. We may also become subject to claims or litigation seeking payment of royalties based on sales of our product in connection with licensing or similar joint development arrangements with third parties or in connection with claims of patent infringement. The defense and prosecution of intellectual property suits, USPTO interference proceedings, reexamination proceedings, or under more recently promulgated Inter Partes Review proceedings, depending on when the patent application was filed, or opposition proceedings and related legal and administrative proceedings, are both costly and time consuming and could result in substantial uncertainty to us. Litigation or regulatory proceedings may also be necessary to enforce patent or other intellectual property rights of ours or to determine the scope and validity of other parties’ proprietary rights. Any litigation, opposition or interference proceedings, with or without merit, may result in substantial expense to us, cause significant strain on our financial resources, divert the attention of our technical and management personnel and harm our reputation. We may not have the financial resources to defend our patents from infringement or claims of invalidity. An adverse determination in any litigation could subject us to significant liabilities to third parties, require us to seek licenses from or pay royalties to third parties or prevent us from manufacturing, selling or using our proposed products, any of which could have a material adverse effect on our business and prospects. Our Lap-Band System, ReshapeCare, Obalon

Balloon System or DBSN device may infringe or be claimed to infringe patents that we do not own or license, including patents that may issue in the future based on patent applications of which we are currently aware, as well as applications of which we are unaware. For example, we are aware of other companies that are investigating neurostimulation, including neuroblocking, and of patents and published patent applications held by companies in those fields. While we believe that none of such patents and patent applications are applicable to our products and technologies under development, third parties who own or control these patents and patent applications in the United States and abroad could bring claims against us that would cause us to incur substantial expenses and, if such claims are successfully asserted against us, they could cause us to pay substantial damages, could ~~36~~ result in an injunction preventing us from selling, manufacturing or using our proposed products and would divert management's attention. Because patent applications in many countries such as the United States are maintained under conditions of confidentiality and can take many years to issue, there may be applications now pending of which we are unaware, and which may later result in issued patents that our products infringe. If a patent infringement suit were brought against us, we could be forced to stop our ongoing or planned clinical trials, or delay or abandon commercialization of the product that is subject of the suit. As a result of patent infringement claims, or to avoid potential claims, we may choose or be required to seek a license from a third-party and be required to pay license fees or royalties, or both. A license may not be available at all or on commercially reasonable terms, and we may not be able to redesign our products to avoid infringement. Modification of our products or development of new products could require us to conduct additional clinical trials and to revise our filings with the FDA and other regulatory bodies, which would be time-consuming and expensive. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. This could harm our business significantly. We ~~are currently in a lawsuit, and~~ may in the future become involved in lawsuits, to protect or enforce our intellectual property, which can be expensive and time consuming and could result in the diversion of significant resources. ~~On March 9, 2023, we filed a patent infringement complaint against Allurion Technologies, Inc. in the U. S. District Court for the District of Delaware. The complaint alleges that Allurion is infringing at least two claims of our U. S. Patent No. 10, 463, 520, which is related to our Obalon balloon system, by making the Allurion Gastric Balloon system in the U. S. for exportation and /or sales from the U. S and /or for potential sales in the U. S. relating to Allurion's application to the FDA to sell the Allurion Gastric Balloon in the U. S. The complaint seeks, among other relief, damages for Allurion's alleged infringement of the ' 520 patent, in an amount not less than a reasonable royalty. This matter is in its early stages and we are unable to predict its outcome at this time. We may in the future seek to enforce our patents or other proprietary rights against other potential infringements.~~ Adverse proceedings such as litigation or challenges to the validity of our patents can be expensive, time consuming and may divert the efforts of our technical and managerial personnel, which could in turn harm our business, whether or not we receive a determination favorable to us. In addition, in an infringement or other adverse proceeding, a court may decide that the patent we seek to enforce is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the patent in question does not cover the technology in question. An adverse result in any litigation or proceeding could place one or more of our patents at risk of being invalidated, interpreted narrowly or found unenforceable. Some of our competitors may be able to devote significantly more resources to intellectual property litigation, and may have significantly broader patent portfolios to assert against us, if we assert our rights against them. Risks Relating to Ownership of Our Common Stock The trading price of our common stock has been volatile and is likely to be volatile in the future. The trading price of our common stock has been highly volatile. The market price for our common stock will be affected by a number of factors, including: • the denial or delay of regulatory clearances or approvals of our product or receipt of regulatory approval of competing products; • our ability to accomplish clinical, regulatory and other product development milestones and to do so in accordance with the timing estimates we have publicly announced; • changes in policies affecting third-party coverage and reimbursement in the United States and other countries; • changes in government regulations and standards affecting the medical device industry and our product; • ability of our products to achieve market success; • the performance of third-party contract manufacturers and component suppliers; • our ability to develop sales and marketing capabilities; ~~35~~ • actual or anticipated variations in our results of operations or those of our competitors; ~~37~~ • announcements of new products, technological innovations or product advancements by us or our competitors; • developments with respect to patents and other intellectual property rights; • sales of common stock or other securities by us or our stockholders in the future; • additions or departures of key scientific or management personnel; • disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies; • the trading volume of our common stock; • changes in earnings estimates or recommendations by securities analysts, failure to obtain or maintain analyst coverage of our common stock or our failure to achieve analyst earnings estimates; • public statements by analysts or clinicians regarding their perceptions of our clinical results or the effectiveness of our products; • decreases in market valuations of medical device companies; and • general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors. The stock prices of many companies in the medical device industry have experienced wide fluctuations that have often been unrelated to the operating performance of these companies. Following periods of volatility in the market price of a company's securities, securities class action litigation often has been initiated against a company. If class action litigation is initiated against us, we may incur substantial costs and our management's attention may be diverted from our operations, which could significantly harm our business. Sales of a substantial number of shares of our common stock in the public market by existing stockholders, or the perception that they may occur, could cause our stock price to decline. Sales of substantial amounts of our common stock by us or by our stockholders, announcements of the proposed sales of substantial amounts of our common stock or the perception that substantial sales may be made, could cause the market price of our common stock to decline. We may issue additional shares of our common stock in follow-on offerings to raise additional capital, upon the exercise of options or

warrants, or in connection with acquisitions or corporate alliances. We also plan to issue additional shares to our employees, directors or consultants in connection with their services to us. All of the currently outstanding shares of our common stock are freely tradable under federal and state securities laws, except for shares held by our directors, officers and certain greater than five percent stockholders, which may be subject to holding period, volume and other limitations under Rule 144. Due to these factors, sales of a substantial number of shares of our common stock in the public market could occur at any time and could reduce the market price of our common stock. We have a significant number of outstanding warrants, which may cause significant dilution to our stockholders, have a material adverse impact on the market price of our common stock and make it more difficult for us to raise funds through future equity offerings. As of December 31, 2022-2023, we had outstanding 519-23, 219-457, 047 shares of common stock. In addition, we had outstanding warrants to acquire 193-15, 476-385, 892 shares of common stock. Subsequent to year-end we issued additional warrants in connection with the public offering in February 2023, of which 352, 500 warrants are outstanding, that include an “alternative cashless exercise” pursuant to which the holders would receive an aggregate number of shares of common stock equal to product of (x) the aggregate number of shares of common stock that would be issuable upon a cash exercise and (y) 0.50. The issuance of shares of common stock upon the exercise of warrants would dilute the percentage ownership interest of all stockholders, might dilute the book value per share of our common stock and would increase the number of our publicly traded shares, which could depress the market price of our common stock. In addition to the dilutive effects described above, the perceived risk of dilution as a result of the significant number of outstanding warrants may cause our common stockholders to be more inclined to sell their shares, which would contribute to a downward movement in the price of our common stock. Moreover, the perceived risk of dilution and the resulting downward pressure on our common stock price could encourage investors to engage in short sales of our common stock, which could further contribute to price declines in our common stock. The fact that our stockholders and warrant holders can sell substantial amounts of our common stock in the public market, whether or not sales have occurred or are occurring, could make it more difficult for us to raise additional funds through the sale of equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate, or at all. 381f-361f we fail to meet all applicable Nasdaq Capital Market requirements, Nasdaq could delist our common stock, which could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease. Nasdaq monitors our ongoing compliance with its minimum listing requirements and if we fail to meet those requirements and cannot cure such failure in the prescribed period of time, our common stock could be subject to delisting from the Nasdaq market. In the event that our common stock is delisted from the Nasdaq Capital Market and is not eligible for quotation or listing on another market or exchange, trading of our common stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further. Also, it may be difficult for us to raise additional capital if we are not listed on a major exchange. For example, on July 19-October 10, 2022-2023, we received a written notice from The Nasdaq Stock Market indicating that we were not in compliance with the \$ 1.00 minimum bid price requirement set forth in Nasdaq Listing Rule 5550 (a) (2) for continued listing on The Nasdaq Capital Market. The notice provided that we have until January 16-April 7, 2023-2024 to regain compliance. In order to regain compliance with the bid price requirement, On February 23, we effected-2024, the stockholders of the Company authorized for the Board of Directors, in its discretion but no later than February 23, 2025, to declare a reverse stock split at a ratio in the range of 1-for-50-10 to 1-for-60, such ratio to be determined by the Board (“Reverse Stock Split”). There are risks associated with effecting the Reverse Stock Split, if approved by the Board. Although we expect that the Reverse Stock Split will result in an increase in the market price of our common stock, we cannot assure you that the Reverse Stock Split, if effected, will increase the market price of our common stock in proportion to the reduction in the number of shares of our common stock outstanding or result in a permanent increase in the market price. The effect that the Reverse Stock Split may have upon the market price of our common stock cannot be predicted with any certainty, and the history of similar reverse stock split splits of for companies in similar circumstances to our ours issued is varied. The market price of our common stock is dependent on many factors, including our business and outstanding financial performance, general market conditions, prospects for future growth and other factors detailed from time to time in the reports we file with the SEC. Accordingly, the total market capitalization of our common stock after the proposed Reverse Stock Split may be lower than the total market capitalization before the proposed Reverse Stock Split and, in the future, the market price of our common stock following the Reverse Stock Split may not exceed or remain higher than the market price prior to the proposed Reverse Stock Split. The Reverse Stock Split may result in some stockholders owning “odd lots” of less than 100 shares of common stock on December 23, 2022-a post-split basis. On January 17-These odd lots may be more difficult to sell, 2023-or require greater transaction costs per share to sell. Nasdaq provided us with written confirmation that than we shares in “round lots” of even multiples of 100 shares. Although the Reverse Stock Split will not, by itself, have any immediate regained compliance with Listing Rule 5550 (a) (2) and the matter is now closed. You may experience future dilution-dilutive as a result effect on stockholders, the proportion of shares owned by stockholders relative future equity offerings. In order to raise additional capital-the number of shares authorized for issuance will decrease because general corporate purposes, in the number of authorized future we may offer additional shares of our common stock or other securities convertible into or exchangeable for our would remain unchanged. As a result, additional authorized shares of common stock would become available for issuance at prices-such times and for such purposes as the Board may deem advisable without further action by stockholders, except as required by applicable law or stock exchange rules. To the extent that additional authorized may be lower than the current price per share shares of our common stock. In addition are issued in the future, such investors purchasing shares or other securities in the future could be dilutive have rights superior to

existing stockholders - The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the **Company** price per share paid by investors **decreasing such stockholders' percentage of equity ownership** in prior offerings **the Company**. See **"- Potential Anti- Takeover Effect"** below for more information on potential and bylaws and Section 203 of the Delaware General Corporation Law contain provisions that may have the effect of deterring or delaying attempts by our stockholders to remove or replace management, engage in proxy contests and effect changes in control. These provisions include: • the ability of our board of directors to create and issue preferred stock without stockholder approval, which could be used to implement anti- takeover **effects of** devices; • the authority for **Reverse Stock Split. Although** our board **Board believes that the decrease in** of directors to issue without stockholder approval up to the number of shares of common stock authorized in our certificate **outstanding as a consequence** of incorporation, that, if issued, **the Reverse Stock Split and the anticipated increase in the market price of common stock** would **could encourage interest in** dilute the ownership of our **common stock and possibly promote greater liquidity for** stockholders **, such liquidity could also** ; • the advance notice requirement for director nominations or for proposals that can be **adversely acted affected by the reduced number** upon at stockholder meetings; • a classified and staggered board of **shares** directors, which may make it more difficult for a person who acquires control of a majority of our outstanding **after** voting stock to replace all or a majority of our directors; • the prohibition on actions by written consent of our stockholders; • the limitation on who may call a special meeting of stockholders; • the prohibition on stockholders accumulating their votes for the election of directors; and • the ability of stockholders to amend our bylaws only upon receiving a majority of the votes entitled to be cast by holders of all outstanding shares then **the Reverse Stock Split** entitled to vote generally in the election of directors, voting together as a single class. **37** In addition, as a Delaware corporation, we are subject to Delaware law, including Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder unless certain specific requirements are met as set forth in Section 203. These provisions,