UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **January 26, 2023**

RESHAPE LIFESCIENCES INC.

(Exact name of registrant as specified in its charter)

Delaware	**1-37897**	**26-1828101**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

1001 Calle Amanecer **San Clemente, CA**	**92673**
(Address of principal executive offices)	(Zip Code)

(949) 429-6680
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.001 par value per share	RSLS	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On January 26, 2023, ReShape Lifesciences Inc. (the "Company") filed an Amendment No. 1 to its Registration Statement on Form S-1 (File No. 333-269207) (the "Registration Statement") in connection with a proposed underwritten public offering of its securities. The preliminary prospectus that forms part of the Registration Statement includes certain updates to the description of the Company's business and risk factors, which are attached hereto as Exhibit 99.1 and 99.2, respectively, and are incorporated herein by reference. The information in this Item 8.01 (including Exhibits 99.1 and 99.2) should be read in conjunction with the Company's most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q.

This Current Report on Form 8-K, including the exhibits hereto, shall not constitute an offer to sell or the solicitation of an offer to buy any securities of the Company, which will be made only by means of a written prospectus meeting the requirements of Section 10 of the Securities Act, nor shall there be any sale of the Company's securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of such jurisdiction.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Updated Business Summary
99.2	Updated Risk Factors
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

RESHAPE LIFESCIENCES INC.

By: /s/ Paul F. Hickey
Paul F. Hickey
President and Chief Executive Officer

Date: January 27, 2023

BUSINESS

Our Company

ReShape Lifesciences Inc. is a worldwide premier weight-loss solutions company, offering an integrated portfolio of proven products and services that manage and treat obesity and metabolic disease.

Our current portfolio includes the FDA-approved Lap-Band® system, which provides minimally invasive, long-term treatment of obesity and is a safer surgical alternative to more invasive and extreme surgical stapling procedures such as the gastric bypass or sleeve gastrectomy. The recently launched ReShapeCare™ virtual health coaching program is a novel reimbursed telehealth weight-management program that supports healthy lifestyle changes for all medically managed weight-loss patients, not just the Lap-Band, further expanding our reach and market opportunity. The ReShape Marketplace™, an online store, that provides top of the line products with bariatric patients in mind. Our ReShape Optimize™ supplement options, purchased through the ReShape Marketplace, include multivitamins, probiotics, calcium, vitamin D, protein, and other therapeutic offerings to optimize health. The Obalon® Balloon system, recently acquired in June of 2021, is the first and only swallowable, gas filled, FDA-approved balloon system. The ReShape Vest™ system is an investigational (outside the U.S.) minimally invasive, laparoscopically implanted medical device that wraps around the stomach, emulating the gastric volume reduction effect of conventional weight-loss surgery. It is designed to help enable rapid weight loss in obese and morbidly obese patients without permanently changing patient anatomy. The DBSN device is a technology under development as a new personalized treatment for type 2 diabetes mellitus. ReShape's DBSN device is expected to use bioelectronics to manage blood glucose in treatment of diabetes and individualized 24/7 glucose control. Additional products and accessories from the Company, including calibration tubes, facilitate alternative gastric surgical procedures and ongoing product support for healthcare practitioners and patients (adjustments, etc.).

Our Product Portfolio

Lap-Band System

The Lap-Band System, which we acquired from Apollo Endosurgery, Inc. ("Apollo") in December 2018, is designed to provide minimally invasive long-term treatment of severe obesity and is an alternative to more invasive surgical stapling procedures such as the gastric bypass or sleeve gastrectomy. The Lap-Band System is an adjustable saline-filled silicone band that is laparoscopically placed around the upper part of the stomach through a small incision, creating a small pouch at the top of the stomach, which slows the passage of food and creates a sensation of fullness. The procedure can normally be performed as an outpatient procedure and patients can go home the day of the procedure without the need for an overnight hospital stay.

The Lap-Band System has been in use in Europe since 1993. It was approved in Australia in 1994 by the Therapeutic Goods Administration ("TGA") and received its CE mark in 1997. The FDA approved the Lap-Band System for use in the United States in 2001. The Lap-Band System has been approved in 21 countries, with more than 1,000,000 Lap-Band Systems sold worldwide.

The Lap-Band System has been approved for use in the U.S. for patients with a Body Mass Index ("BMI") greater than or equal to 40 or a BMI greater than or equal to 30 with one or more obesity-related comorbidity conditions.

The Lap-Band System has been subject to more than 400 peer-reviewed publications and extensive real- world experience. Adjustable gastric banding using the Lap-Band System has been reported to be significantly safer than gastric bypass while statistically producing the same weight loss five years after surgery when accompanied by an appropriate post-operative follow-up and adjustment protocol. Studies have reported sustained resolution or improvement in type 2 diabetes, gastroesophageal reflux, obstructive sleep apnea, asthma, arthritis, hypertension and other pre-existing obesity related comorbidities following gastric banding. The gastric banding surgical procedure is generally reimbursed by most payors and insurance programs that cover bariatric surgery.

Benefits. Lap-Band System offers the following benefits:

- **Minimally Invasive.** The Lap-Band System does not change anatomy and is removable or reversible.

- **Lifestyle Enhancing.** The Lap-Band System helps patients lose weight and live a more comfortable life and potentially reduces co-morbidities from excess weight.

- **Durable Weight Loss.** The Lap-Band System offers a sustainable solution that helps patients achieve long-term success.

ReShape Calibration Tubes

The ReShape Calibration tubes are multifunctional devices compared to reusable bougies and disposable gastric tubes. The Calibration tubes are designed to be less traumatic to the patient, as they are intended to fit the lesser curvature of the stomach more easily and quickly reach the pylorus. In August of 2022, we announced FDA clearance of three new sizes — 32, 36, and 40 French — all designed to simplify bariatric procedures such as laparoscopic sleeve gastrectomy, gastric bypass, and adjustable gastric banding. We are ramping up production and moving rapidly towards a full release of this product in early 2023.

ReShapeCare

ReShapeCare is a HIPAA-compliant, virtual coaching program which enhances behavior change through engagement with ReShape's Welcome Specialists and Health Coaches. The program is based on four established dimensions of successful behavior: change sleep, nutrition, exercise and stress. It is designed to provide flexible structure and support from a live certified health coach in a manner that is simple, affordable and practical.

Clinical studies prove that online health coaching leads to higher patient satisfaction, more successful weight loss outcomes, improvements in metabolic health and enhances quality of life. ReShapeCare is appropriate for all weight loss patients, medical weight loss patients, and pre- and post-surgical bariatric patients.

The program is designed to reshape the patient's life through better sleep, nutrition, exercise, and stress management. Patients get paired with a ReShapeCare certified health coach who will be with them every step of the way through their journey, including through daily text messaging or live phone or video calls. The web and mobile app make it easy to increase positive actions and awareness by receiving daily educational content, personalized exercise, and progress reports. This program creates an atmosphere of community with social support from peers and by joining group sessions. When it comes to nutrition, patients can utilize an easy-to-follow, personalized nutrition plan with a recipe library and restaurant guide. Tracking your food is as easy as taking a snapshot from your phone and sending it to your coach. Patients can connect their own devices to automatically track sleep, stress, and weight. This real-time health data can be used to optimize the program to get the best possible results.

ReShape Marketplace

ReShape Marketplace is an online store developed with bariatric patients in mind in order to focus on the four dimensions of successful behavior changes. Within the ReShape Marketplace we have ReShape Optimize, which meets all the nutrient needs to stay healthy. The ReShape Marketplace provides the highest quality products for exercising, that can have immediate and long-term health benefits, sleep which plays a vital role in good health and well-being, and stress to effectively manage stress to make your life happier, healthier and more productive.

ReShape has partnered with ProCare Health® to provide premium supplements to optimize health and well-being. ReShape Optimize is a supplemental option which will include multivitamins, probiotics, calcium, vitamin D, protein, and other therapeutic offerings. Our multivitamins utilize easy to absorb ingredients, meet updated ASMBS guidelines, and are made in the USA.

Obalon Balloon System

The Obalon Balloon System consists of a swallowable capsule that contains an inflatable balloon attached to a microcatheter; the Obalon Navigation System console, which is a combination of hardware

and software used to dynamically track and display the location of the balloon during placement; the Obalon Touch Inflation Dispenser, which is a semi-automated, hand-held inflation device used to inflate the balloon once it is placed; and a disposable canister filled with our proprietary mixture of gas. We continue to explore the compliance requirements, manufacturing viability and quality system controls necessary for re-introducing the Obalon Balloon System.

Placement of the Obalon balloon typically occurs in less than 15 minutes and can be accomplished in an outpatient setting. To place the Obalon balloon, the patient swallows the capsule, which has the Obalon balloon folded inside. No sedation or anesthesia is required. Once swallowed, placement of the capsule is confirmed in the stomach using the Obalon Navigation System. Balloon placement can also be confirmed using x-ray. The microcatheter, which is attached to the Obalon balloon, is then connected to the Obalon Touch Inflation Dispenser. The Touch inflation system provides real-time pressure measurements to confirm that the Obalon balloon is both properly placed and able to be correctly inflated in the stomach. A pre-filled canister of gas is inserted into the inflation system and then the gas is discharged to fill the balloon to a volume of 250cc. Once the inflation of the Obalon balloon is confirmed, the microcatheter is detached from the balloon via hydrostatic pressure and is removed through the patient's mouth. The patient is intended to return two more times over the following 8 to 12 weeks to receive a second and third Obalon balloon, expanding total balloon volume within the stomach to approximately 750cc.

All of the balloons are removed in a single procedure no more than six months after the placement of the initial balloon. The balloons are removed endoscopically under light conscious sedation, using standard commercially available endoscopy tools. The endoscopic procedure to remove the balloons typically requires approximately 15 minutes.

DBSN Device

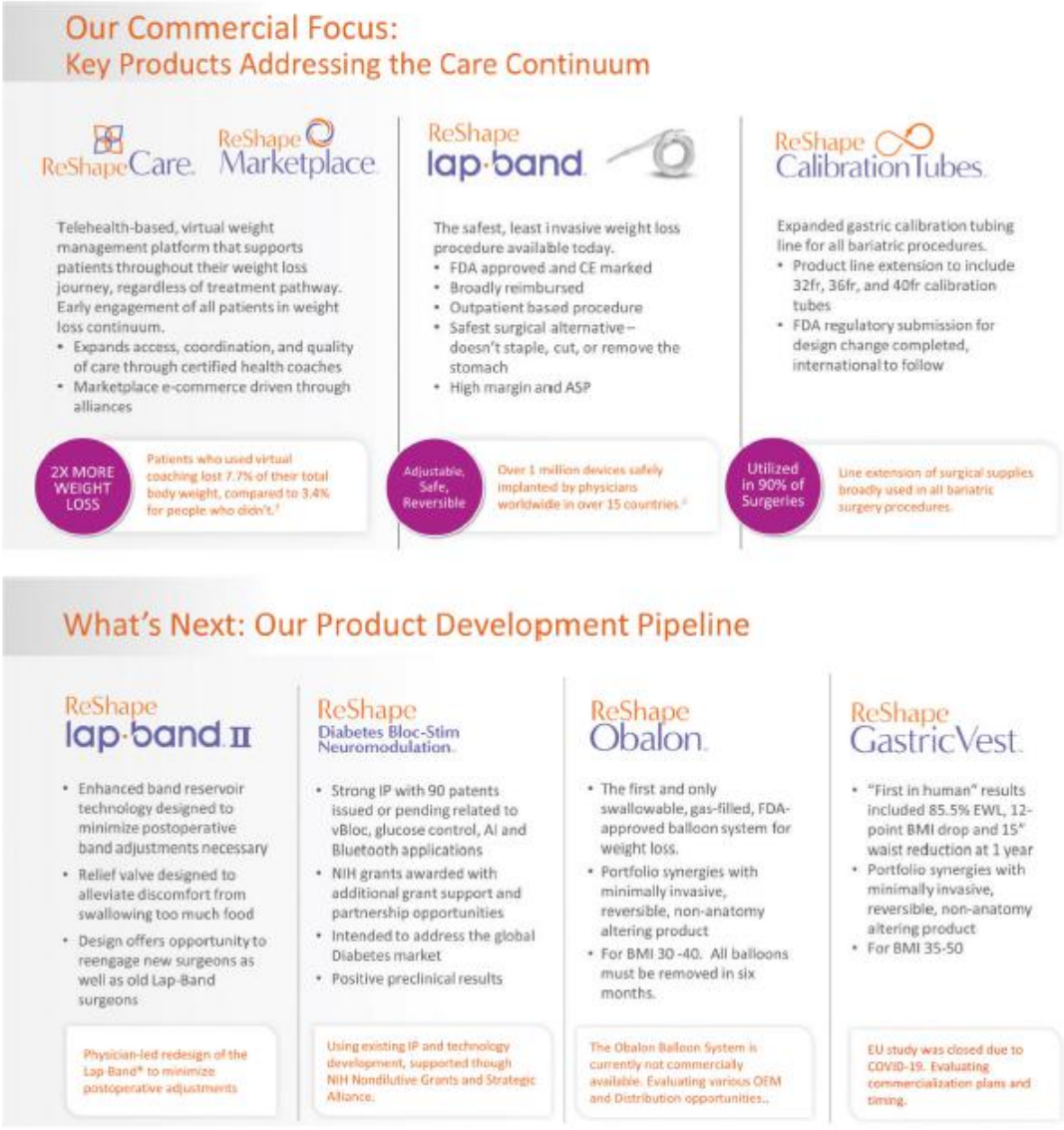
The DBSN device is a technology under development as a new treatment for type 2 diabetes mellitus (T2DM). It combines ReShape Lifesciences' proprietary Vagus Nerve Block (vBloc) technology platform in combination with Vagus nerve stimulation. This new dual Vagus nerve neuromodulation system selectively modulates vagal block and stimulation to the liver and pancreas to manage blood glucose. ReShape's DBSN device is expected to use bioelectronics to manage blood glucose in treatment of diabetes and individualized 24/7 glucose control. The goal is to reduce costs of treatment and complications that arise from poorly controlled blood glucose and non-compliance to T2DM medication.

ReShape's DBSN technology is in preclinical development. It has demonstrated effectiveness and has been well tolerated through experiments in diabetic swine utilizing Phase I funding from an NIH Small Business Innovation Research Grant.

Our Strategic Focus

Develop and Commercialize a Differentiated Portfolio of Products/Therapies

ReShape Lifesciences Inc. is the premier physician-led weight-loss and metabolic health-solutions company, offering an integrated portfolio of proven products and services that manage and treat obesity and metabolic disease. An overarching strategy for our company is to develop and commercialize products, programs and services portfolio that is differentiated from our competition by offering transformative technologies that consists of a selection of patient-friendly, non-anatomy changing, lifestyle enhancing products, programs and services that provide alternatives to more invasive bariatric surgeries, and help patients achieve healthy, durable weight loss. Current offerings include the Lap-Band System and accessories, ReShapeCare virtual coaching program, the recently launched ReShape Marketplace, an online collection of quality wellness products, including ReShape Optimize, a collection of premium supplements to help patients achieve their health goals. The FDA approved Obalon Balloon System, which has been off the market since March 2020 and was acquired in connection with the Obalon merger in June of 2021, and has not yet been re-introduced to the marketplace. If approved for commercial use, we believe the DBSN device will further enhance our multiple compelling and differentiated medical devices offerings. We believe that we are well positioned for the existing market and can serve more of the overweight and obese population with our solutions and thereby help expand the addressable market for obesity.



Drive the Adoption of Our Portfolio through Obesity Therapy Experts and Patient Ambassadors

Our clinical development strategy is to collaborate closely with regulatory bodies, healthcare providers, obesity therapy lifestyle experts and others involved in the obesity management process, patients and their advocates and scientific experts. We have established relationships with physicians, obesity therapy experts, patient advocates, media experts and other market drivers we believe will provide important support towards promoting patient awareness and gaining widespread adoption of the Lap-Band, its accessories, ReShapeCare, ReShape Marketplace, ReShape Optimize and the re-introduction of the Obalon Balloon System. Additionally, with these relationships, if approved, we believe we will be able to expand awareness of the DBSN technology to patients with type 2 diabetes mellitus.

Expand and Protect Our Intellectual Property Position

We believe that our issued patents and our patent applications encompass a broad platform of therapies focused on obesity, diabetes, hypertension and other gastrointestinal disorders. We intend to continue to pursue further intellectual property protection through U.S. and foreign patent applications.

Alternative Weight Loss Solutions

ReShapeCare is an effective, convenient virtual health coaching program that is reimbursed by most insurance companies and works in partnership with physicians to help patients set and achieve their health and wellness goals. Through board certified coaches, it provides a weight-loss solution through behavioral changes, improving the patients' sleep, nutrition, exercise and stress. ReShapeCare is appropriate for all weight loss patients, medical weight loss patients, and pre- and post-surgical bariatric patients.

We believe that we will be able to offer distinct weight loss treatment solutions that may be selected by the physician depending on the severity of the patient's BMI or condition. Together, the Lap-Band, ReShapeCare and potential internal or external pipeline products can provide a minimally invasive continuum of care, independently or in combination, for bariatric surgery or medically managed weight loss patients and their care providers.

Our Market

The Obesity and Metabolic Disease Epidemic

Obesity is a disease that has been increasing at an alarming rate with significant medical repercussions and associated economic costs. The World Health Organization ("WHO") currently estimates that more than 2.5 billion adults, approximately 30% of the global population, are considered overweight or obese. This number has a projected increase to 50% by 2030. The global economic impact of obesity is approximately $2.0 trillion, or approximately 2.8% of global GDP. Healthcare costs for severely or morbidly obese adults are 81% higher than for healthy weight adults and obesity is responsible for 5% of deaths worldwide. We believe our products and programs and product candidates could address a $1.64 billion per year and growing global surgical device market. The Bariatric Surgical Device market is projected to be a $2.8 billion worldwide market ($1.8 billion in the U.S.) by 2025, the Virtual Healthcare Delivery market is projected to be $95 billion worldwide by 2026, and the Global Weight Loss and Obesity Management market is expected to rise to an estimated value of $300 billion with a compound annual growth rate of 6.7% from 2019 to 2026.

We believe that this epidemic will continue to grow worldwide given dietary trends in developed nations that favor highly processed sugars, larger meals and fattier foods, as well as increasingly sedentary lifestyles. Despite the growing obesity rate, increasing public interest in the obesity epidemic and significant medical repercussions and economic costs associated with obesity, there continues to be a significant unmet need for effective treatments.

The United States Market

Obesity has been identified by the U.S. Surgeon General as the fastest growing cause of disease and death in the United States. Currently, it is estimated that approximately 160 million American adults are overweight or obese, 74 million American adults are overweight, 78 million American adults are obese or severely obese, and 24 million American adults are morbidly obese. It is estimated that if obesity rates stay consistent, 51% of the U.S. population will be obese by 2030. According to data from the U.S. Department of Health and Human Services, almost 80% of adults with a BMI above 30 have comorbidity, and almost 40% have two or more of these comorbidities. According to The Obesity Society and the CDC, obesity is associated with many significant weight-related comorbidities including Type 2 diabetes, high blood-pressure, sleep apnea, certain cancers, high cholesterol, coronary artery disease, osteoarthritis and stroke. According to the American Cancer Society, 572,000 Americans die of cancer each year, over one-third of which are linked to excess body weight, poor nutrition and/or physical inactivity. Over 75% of hypertension cases are directly linked to obesity, and more than 90% of the approximately 28 million U.S. adults with Type 2 diabetes are overweight or have obesity.

Currently, medical costs associated with obesity in the U.S. are estimated to be up to $210.0 billion per year and nearly 21% of medical costs in the U.S. can be attributed to obesity. Approximately $1.5 billion was spent in 2015 alone in the U.S. on approximately 200,000 bariatric surgical procedures to treat obesity. By 2025, it is estimated that up to $3.8 billion will be spent in the U.S. on approximately 800,000 bariatric surgical procedures to treat obesity. Researchers estimate that if obesity trends continue, obesity-related

medical costs could rise by another $44-$66 billion each year in the U.S. by 2030. The medical costs paid by third-party payers for people who are obese were $2,741 per year, or 42% higher than those of people who are normal weight and the average cost to employers is $6,627 to $8,067 per year per obese employee (BMI of 35 to 40 and higher).

Current Treatment Options and Their Limitations

We believe existing bariatric surgery and endoscopic procedural options for the treatment of obesity have seen limited adoption to date, with approximately 1% of the bese population qualifying for treatment actually seeking treatment, due to patient concerns and potential side effects including permanently altered anatomy and morbidity.

The principal treatment alternatives available today for obesity include:

- **Behavioral modification.** Behavioral modification, which includes diet and exercise, is an important component in the treatment of obesity; however, most obese patients find it difficult to achieve and maintain significant weight loss with a regimen of diet and exercise alone.

- **Pharmaceutical therapy.** Pharmaceutical therapies often represent a first option in the treatment of obese patients but carry significant safety risks and may present troublesome side effects and compliance issues.

- **Bariatric Surgery and Endoscopic Procedures.** In more severe cases of obesity, patients may pursue more aggressive surgical treatment options such as sleeve gastrectomy and gastric bypass. These procedures promote weight loss by surgically restricting the stomach's capacity and outlet size. While largely effective, these procedures generally result in major lifestyle changes, including dietary restrictions and food intolerances, and they may present substantial side effects and carry short- and long-term safety and side effect risks that have limited their adoption.

Our Research and Development

Current R&D Focus

We have an experienced research and development team, including clinical, regulatory affairs and quality assurance, comprised of scientists and mechanical engineers with significant clinical knowledge and expertise. Our research and development efforts are focused in the following major areas:

- supporting the current Lap-Band System;

- expanding and improving on the Lap-Band portfolio;

- testing and developing the DBSN device; and

- suction and calibration tubing line for gastric and bariatric surgeries.

We have spent a portion of our capital resources on research and development. Our research and development expenses were $2.5 million in 2021 and $3.5 million in 2020.

Our Competition

The market for obesity treatments is competitive, subject to technological change and significantly affected by new product development. Our primary competition in the obesity treatment market is currently from bariatric surgical and endoscopic procedures.

Our Lap-Band System competes, and we expect that our Obalon Balloon System will compete, with surgical and endoscopic obesity procedures, including gastric bypass, gastric balloons, sleeve gastrectomy and the endoscopic sleeve. These current surgical procedures are performed in less than 1% of all eligible obese patients today. Outside of the Obalon Balloon System which we recently acquired, other current manufacturers of gastric balloon and suturing products that are approved in the United States include Apollo (ORBERA Intragastric Balloon System and OverStitch Endoscopic Suturing System) and Spatz Medical.

In June 2016, Aspire Bariatrics, Inc. received FDA approval for the Aspire Assist® System, an endoscopic alternative to weight loss surgery for people with moderate to severe obesity. Due to the financial impact of the COVID-19 pandemic, Aspire Bariatrics shut down operations and withdrew its product from the market in April 2022. We are also aware that GI Dynamics, Inc. has received approvals in various international countries to sell its EndoBarrier Gastrointestinal Liner.

We also compete against the manufacturers of pharmaceuticals that are directed at treating obesity and the 99% of obese patients eligible for surgery that are not willing to pursue a surgical option. We are aware of a number of drugs that are approved for long-term treatment of obesity in the United States: Orlistat, marketed by Roche as Xenical and GlaxoSmithKline as Alli, Belviq marketed by Arena Pharmaceuticals, Inc., Qsymia, marketed by VIVUS, Inc. and Contrave, marketed by Orexigen Therapeutics, Inc. In addition, we are aware of a pivotal trial for GELESIS100 that is being conducted by Gelesis, Inc. While considered a competitive therapy, we expect that some surgeons will use pharmaceuticals to coincide with a Lap-Band placement.

In addition to competition from surgical obesity procedures, we compete with several private early- stage companies developing neurostimulation devices for application to the gastric region and related nerves for the treatment of obesity. Further, we know of two intragastric balloon companies in the U.S., Spatz Medical, which received FDA approval of the Spatz3 Adjustable Balloon in October of 2021, and Allurion Technology's Elipse Balloon, which is in either clinical trials or working toward clinical trials in the U.S. These companies may prove to be significant competitors, particularly through collaborative arrangements with large and established companies. They also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

We believe that the principal competitive factors in our market include:

- acceptance by healthcare professionals, patients and payers;
- published rates of safety and efficacy;
- reliability and high-quality performance;
- effectiveness at controlling and/or resolving comorbidities such as diabetes and hypertension;
- invasiveness and the inherent reversibility of the procedure or device;
- cost and average selling price of products and relative rates of reimbursement;
- effective marketing, training, education, sales and distribution;
- regulatory and reimbursement expertise;
- technological leadership and superiority;
- only surgical device FDA approved for low BMI patients; and
- speed of product innovation and time to market.

Many of our competitors are larger than we are, and they may enjoy several competitive advantages over us, including:

- stronger name recognition;
- existing relations with healthcare professionals, customers and third-party payers;
- established distribution networks;
- significant experience in research and development, manufacturing, preclinical testing, clinical trials, obtaining regulatory approvals, obtaining reimbursement and marketing approved products; and
- greater financial and human resources.

As a result, we cannot assure you that we will be able to compete effectively against these companies or their products.

Market Opportunity

Given the limitations of behavioral modification, pharmaceutical therapy and traditional bariatric surgical approaches, we believe there is a substantial need for patient-friendly, safer, effective and durable solutions that:

- provide proven, long-term weight loss;
- preserve normal anatomy;
- are adjustable in an office setting for individual patient needs and long term efficacy;
- are "non-punitive" in that they support continued ingestion and digestion of foods and micronutrients such as vitamins and minerals found in a typical, healthy diet while allowing the user to modify his or her eating behavior appropriately without inducing punitive physical restrictions that physically force a limitation of food intake;
- diminish undesirable side-effects;
- facilitate outpatient surgical procedures;
- minimize the risks of re-operations, malnutrition and mortality;
- reduce the natural hunger drive of patients; and
- are reversible, if necessary or desired, while preserving anatomy.

Our Intellectual Property

In order to remain competitive, we must develop and maintain protection of the proprietary aspects of our technologies. We rely on a combination of patents, trademarks, trade secret laws and confidentiality and invention assignment agreements to protect our intellectual property rights. Our patent applications may not result in issued patents and our patents may not be sufficiently broad to protect our technology. Any patents issued to us may be challenged by third parties as being invalid or unenforceable, or third parties may independently develop similar or competing technology that does not infringe our patents. The laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of the United States.

Lap-Band

As of December 31, 2022, we had 50 total patents, 28 U.S. and 22 foreign, related to our Lap-Band System. The international patents and patent applications are in regions including Germany, France, Spain, the United Kingdom, Mexico, Canada, Italy, the Netherlands, Portugal, Ireland, Belgium, Poland, Australia, and South Korea. The issued patents expire between the years 2022 and 2031.

We also have 48 total U.S. and international trademarks for the Lap-Band brand name.

ReShape Vest

As of December 31, 2022, we had four granted U.S. patents and four granted foreign patents in China, Israel, Canada and Australia related to our ReShape Vest and 6 pending patents in the U.S. and foreign countries. The patents expire between the years 2028 and 2038.

We also have U.S. and international trademark applications for the ReShape Vest brand name.

Obalon

As of December 31, 2022, we had 43 granted U.S. patents and five granted foreign patents related to our Obalon portfolio. The patents expire between the years 2028 and 2031.

ReShapeCare

As of December 31, 2022, we had eight U.S. trademarks related to the ReShapeCare covering, tradename, logo, electronic pedometers and electronic day planners for tracking food, body weight, pre- recorded nutritional and fitness; as well as nutritional and medical counseling and services. ReShape

Marketplace has one trademark related to the online retail store and ReShape Optimize has one trademark related to the multi-vitamins.

DBSN Device

As of December 31, 2022, we had 14 U.S. patents issued and 54 foreign patents issued. In addition, we have filed a trademark application for Bloc-Stim Neuromodulation. The USPTO Examiner is reviewing the application and provided the Company with a disclaimer being required for "Neuromodulation", as this a standard requirement for words that are in the standard vernacular.

Sales and Distribution

We market directly to patients but sell the Lap-Band program to select qualified surgical centers throughout the U.S. and internationally having patients that would like to treat obesity and its comorbidities. The centers then perform the Lap-Band procedure and are most-commonly reimbursed by leading insurance providers in the U.S. and government health services in many areas outside the U.S. Alternatively, surgical centers can offer the Lap-Band as a cash-pay procedure. Our sales representatives are supported by field based experts who provide training, technical support, and other support services at various medical centers. Our sales representatives help implement consumer marketing programs and provide surgical centers and certified surgeons with educational patient materials.

In order to support our Lap-Band sales efforts, we have five regionally based team members to support the U.S. market. During the fourth quarter of 2021, we launched a national advertising campaign for our flagship product, the Lap-Band. This is the Company's first mainstream mass-market advertising campaign in the U.S. The national television spots are being aired in outlets such as HGTV, TLC, Bravo, Oxygen and more, with print advertisements running in *People Magazine*, *Good Housekeeping*, *Better Homes & Gardens*, *US Weekly* and other select publications nationwide. These coordinated media efforts are intended to reach people struggling with maintaining a healthy weight and to educate them on the advantages and accessibility of the Lap-Band procedure compared to other treatment options, including diets and more aggressive gastric stapling procedures. Another goal of the campaign is to help people understand that the Lap- Band offers unique benefits for a variety of obese patients, including those with lower BMI and women who may become pregnant.

In August of 2022, we began shifting away from national advertising campaign initiatives and focusing on digital marketing channels including search engine ads and social media channels. This shift in marketing is 100% aligned with the Company's focus on expanding Lap-Band use while ensuring a sustainable (profitable) business. The shift to a more targeted and regionalized marketing program allows us to better support interested potential Lap-Band patients while also reducing the overall costs for lead generation programs. This strategy also aligns with our key surgeon Lap-Band programs across the U.S.; surgeons who participate in local marketing and educational initiatives in their communities.

During 2022, our international sales efforts were through a combination of agent and distributor sales channels, with a focus on top Lap-Band customers in Australia, the Middle East, Canada and select countries in Europe. In late 2022, we allocated additional resources to help ensure international sales improves in both volume and profitability.

Our Manufacturers and Suppliers

To date, all of the materials and components for our products, as well as any related outside services, are procured from qualified suppliers and contract manufacturers in accordance with our proprietary specifications. All of our key manufacturers and suppliers have experience working with commercial implantable device systems, are ISO certified and are regularly audited by various regulatory agencies including the FDA. Our key manufacturers and suppliers have a demonstrated record of compliance with international regulatory requirements. In July 2021 we announced that we had completed our Lap-Band manufacturing transition from Apollo Endosurgery, Inc. to a Massachusetts-based contract manufacturer.

Given that we rely on third-party manufacturers and suppliers for the production of our products, our ability to increase production going forward will depend upon the experience, certification levels and large- scale production capabilities of our suppliers and manufacturers. Qualified suppliers and contract

manufacturers have been and will continue to be selected to supply products on a commercial scale according to our proprietary specifications. Our FDA approval process requires us to name and obtain approval for the suppliers of key components of the Lap-Band System.

Many of our parts are custom designed and require custom tooling and, as a result, we may not be able to quickly qualify and establish additional or replacement suppliers for the components of our products. Any new approvals of vendors required by the FDA or other regulatory agencies in other international markets for our products as a result of the need to qualify or obtain alternate vendors for any of our components would delay our ability to sell and market our products and could have a material adverse effect on our business.

We believe that our current manufacturing and supply arrangements will be adequate to continue our ongoing commercial sales and our ongoing and planned clinical trials. In order to produce our products in the quantities we anticipate to meet future market demand, we will need our manufacturers and suppliers to increase, or scale up, manufacturing production and supply arrangements by a significant factor over the current level of production. There are technical challenges to scaling up manufacturing capacity and developing commercial-scale manufacturing facilities that may require the investment of substantial additional funds by our manufacturers and suppliers and hiring and retaining additional management and technical personnel who have the necessary experience. If our manufacturers or suppliers are unable to do so, we may not be able to meet the requirements to expand the launch of the product in the United States or launch the product internationally or to meet future demand, if at all. We may also represent only a small portion of our suppliers' or manufacturers' business and if they become capacity constrained, they may choose to allocate their available resources to other customers that represent a larger portion of their business. If we are unable to obtain a sufficient supply of our product, our revenue, business and financial prospects would be adversely affected.

Government Regulations

Our products and operations are subject to extensive and rigorous regulation by the FDA and other federal, state and local authorities, as well as foreign regulatory authorities. The FDA regulates, among other things, the research, development, testing, design, manufacturing, approval, labeling, storage, recordkeeping, advertising, promotion and marketing, distribution, post approval monitoring and reporting and import and export of medical devices in the United States to assure the safety and effectiveness of medical products for their intended use. The Federal Trade Commission also regulates the advertising of our products in the United States. Further, we are subject to laws directed at preventing fraud and abuse, which subject our sales and marketing, training and other practices to government scrutiny.

Regulatory system for medical devices in the United States

Unless an exemption applies, each new or significantly modified medical device we seek to commercially distribute in the United States will require either a premarket notification to the FDA requesting permission for commercial distribution under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or FFDCA, also referred to as a 510(k) clearance, or approval from the FDA of a PMA application. Both the 510(k) clearance and PMA processes can be resource intensive, expensive, and lengthy, and require payment of significant user fees, unless an exemption is available.

Device Classification

Under the FFDCA, medical devices are classified into one of three classes — Class I, Class II or Class III — depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness.

Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be reasonably assured by adherence to a set of FDA regulations, referred to as the General Controls for Medical Devices, which require compliance with the applicable portions of the Quality System Regulations, or QSR, facility registration and product listing, reporting of adverse events and malfunctions, and appropriate, truthful and non-misleading labeling and promotional materials. Some Class I devices, also

called Class I reserved devices, also require premarket clearance by the FDA through the 510(k) premarket notification process described below. Most Class I products are exempt from the premarket notification requirements.

Class II devices are those that are subject to the General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, patient registries, FDA guidance documents and post-market surveillance. Most Class II devices are subject to premarket review and clearance by the FDA. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process.

Class III devices include devices deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, in addition to those deemed novel and not substantially equivalent following the 510(k) process. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the General Controls and Special Controls described above. Therefore, these devices are subject to the PMA application process, which is generally more costly and time consuming than the 510(k) process. Through the PMA application process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA's satisfaction. Accordingly, a PMA application typically includes, but is not limited to, extensive technical information regarding device design and development, pre-clinical and clinical trial data, manufacturing information, labeling and financial disclosure information for the clinical investigators in device studies. The PMA application must provide valid scientific evidence that demonstrates to the FDA's satisfaction a reasonable assurance of the safety and effectiveness of the device for its intended use.

The Investigational Device Process

In the United States, absent certain limited exceptions, human clinical trials intended to support medical device clearance or approval require an IDE application. Some types of studies considered to present "non-significant risk" are deemed to have an approved IDE once certain requirements are addressed, and IRB approval is obtained. If the device presents a "significant risk" to human health, as defined by the FDA, the sponsor must submit an IDE application to the FDA and obtain IDE approval prior to commencing the human clinical trials. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of subjects. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate institutional review boards at the clinical trial sites. There can be no assurance that submission of an IDE will result in the ability to commence clinical trials, and although the FDA's approval of an IDE allows clinical testing to go forward for a specified number of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and efficacy, even if the trial meets its intended success criteria.

All clinical trials must be conducted in accordance with the FDA's IDE regulations that govern investigational device labeling, prohibit promotion and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with the FDA's good clinical practice regulations for institutional review board approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable, or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant marketing approval or clearance of a product.

The 510(k) Approval Process

Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is "substantially equivalent," as defined in the statute, to a legally marketed predicate device.

A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was previously

found substantially equivalent through the 510(k) process. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence.

After a 510(k) premarket notification is submitted, the FDA determines whether to accept it for substantive review. If it lacks necessary information for substantive review, the FDA will refuse to accept the 510(k) notification. If it is accepted for filing, the FDA begins a substantive review. By statute, the FDA is required to complete its review of a 510(k) notification within 90 days of receiving the 510(k) notification. As a practical matter, clearance often takes longer, and clearance is never assured. Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including clinical data, to make a determination regarding substantial equivalence, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device.

If the FDA determines that the device is not "substantially equivalent" to a predicate device, or if the device is automatically classified into Class III, the device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA approval process, or seek reclassification of the device through the *de novo* process. A manufacturer can also submit a petition for direct *de novo* review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents a moderate or low risk.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, could require a PMA application or *de novo* classification. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. Many minor modifications are accomplished by a letter-to-file in which the manufacture documents the change in an internal letter-to-file. The letter-to-file is in lieu of submitting a new 510(k) to obtain clearance for such change. The FDA can always review these letters to file in an inspection. If the FDA disagrees with a manufacturer's determination regarding whether a new premarket submission is required for the modification of an existing device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA application is obtained. In addition, in these circumstances, the FDA can impose significant regulatory fines or penalties for failure to submit the requisite PMA application(s).

The PMA Approval Process

Following receipt of a PMA application, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If it is, the FDA will accept the application for filing and begin the review. The FDA, by statute and by regulation, has 180 days to review a filed PMA application, although the review of an application more often occurs over a significantly longer period. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies communicated by the FDA. The FDA considers a PMA or PMA supplement to have been voluntarily withdrawn if an applicant fails to respond to an FDA request for information (*e.g.*, major deficiency letter) within a total of 360 days. Before approving or denying a PMA, an FDA advisory committee may review the PMA at a public meeting and provide the FDA with the committee's recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Prior to approval of a PMA, the FDA may conduct inspections of the clinical trial data and clinical trial sites, as well as inspections of the manufacturing facility and processes. Overall, the FDA review of a PMA application generally takes between one and three years, but may take significantly longer. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- device may not be shown safe or effective to the FDA's satisfaction;
- data from pre-clinical studies and/or clinical trials may be found unreliable or insufficient to support approval;
- the manufacturing process or facilities may not meet applicable requirements, and;
- changes in FDA approval policies or adoption of new regulations may require additional data.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter, or an approvable letter, the latter of which usually contains several conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the PMA, or the PMA is withdrawn and resubmitted when the data are available. The PMA process can be expensive, uncertain and lengthy and several devices for which the FDA approval has been sought by other companies have never been approved by the FDA for marketing.

New PMA applications or PMA supplements are required for modification to the manufacturing process, equipment or facility, quality control procedures, sterilization, packaging, expiration date, labeling, device specifications, ingredients, materials or design of a device that has been approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive technical or clinical data or the convening of an advisory panel, depending on the nature of the proposed change.

In approving a PMA application, as a condition of approval, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for several years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional or longer-term safety and effectiveness data for the device. The FDA may also require post-market surveillance for certain devices cleared under a 510(k) notification, such as implants or life-supporting or life-sustaining devices used outside a device user facility. The FDA may also approve a PMA application with other post-approval conditions intended to ensure the safety and effectiveness of the device, such as, among other things, restrictions on labeling, promotion, sale, distribution and use. Our vBloc, Lap-Band System and Intragastric balloons, including the Obalon Balloon System, Obalon Navigation System and Dispenser are considered Class III medical devices. In order to support a PMA application, the FDA required the Company to conduct rigorous and expensive trials, one of which was a double-blinded, randomized, sham-controlled study. We will be required to file new PMA applications or PMA supplement applications for modifications to our PMA-approved Lap-Band System, Obalon Balloon System and Obalon Navigation System and Dispenser or any of their respective components, including modifications to our manufacturing processes, device labeling and device design, based on the findings of post-approval studies.

Pervasive and Continuing FDA Regulation

After the FDA permits a device to enter commercial distribution, numerous regulatory requirements continue to apply. These include:

- The FDA's QSR, which requires manufacturers, including third party manufacturers, to follow stringent design, testing, production, control, supplier/contractor selection, complaint handling, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations, unique device identification requirements and FDA prohibitions against the promotion of products for uncleared, unapproved or off label uses;
- advertising and promotion requirements;

- restrictions on sale, distribution or use of a device;
- PMA annual reporting requirements;
- PMA approval of product modifications;
- PMA approval of product
- Medical device reporting, or MDR, regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- medical device correction and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- recall requirements, including a mandatory recall if there is a reasonable probability that the device would cause serious adverse health consequences or death;
- an order of repair, replacement or refund;
- device tracking requirements; and
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Since February 2017, the FDA has issued three separate letters to healthcare providers warning of serious adverse events, including deaths, which are specific to liquid-filled intragastric balloons. We are aware of the filing of additional reports of serious adverse events, including deaths, associated with liquid- filled balloons since the issuance of the FDA letters to healthcare providers. While the advisory letters were specific to liquid-filled intragastric balloons and not the Obalon gas-filled balloons, these letters could create negative perceptions of the entire gastric balloon category which may cause negative consequences for us including requiring additional warnings, precautions and/or contraindications in the labeling than originally required, delaying or denying approval of our future products, or possible review or withdrawal of our current approval. Since Obalon Therapeutics began selling in United States in January 2017 — before the merger — Obalon Therapeutics has reported adverse events relating to patient injuries associated with use of the Obalon balloon in the FDA's MAUDE database.

The FDA has broad post-market and regulatory enforcement powers. Medical device manufacturers are subject to unannounced inspections by the FDA and other state, local and foreign regulatory authorities to assess compliance with the QSR and other applicable regulations, and these inspections may include the manufacturing facilities of any suppliers.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures, repair, replacement, refunds, recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- the FDA's refusal of our requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products;
- FDA's refusal to issue certificates to foreign governments needed to export products for sale in other countries;
- withdrawing 510(k) clearance or premarket approvals that have already been granted; and
- criminal prosecution.

Regulatory System for Medical Devices in Europe

The European Union ("EU") consists of member states residing in the European Union and has a coordinated system for the authorization of medical devices. As of May 26, 2021, the European Union has

adopted Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009. The Medical Device Regulation 2017/745, or EU MDR repeals Directive 93/42/EEC, which concerns medical devices, and Directive 90/385/EEC, which concerns active implantable medical devices, as of 26 May 2021. The EU allows a transition period from Directive 93/42/EEC and Directive 90/385/EEC to Regulation (EU) 2017/745, that will end 26 May 2024.

The EU MDR aims to ensure the smooth functioning of the internal market as regards medical devices, taking as a base a high level of protection of health for patients and users, and considering the small- and medium-sized enterprises that are active in this sector. At the same time, this Regulation sets high standards of quality and safety for medical devices in order to meet common safety concerns as regards such products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 of the Treaty on the Functioning of the European Union (TFEU), this Regulation harmonises the rules for the placing on the market and putting into service of medical devices and their accessories on the Union market thus allowing them to benefit from the principle of free movement of goods. As regards Article 168(4)(c) TFEU, this Regulation sets high standards of quality and safety for medical devices by ensuring, among other things, that data generated in clinical investigations are reliable and robust and that the safety of the subjects participating in a clinical investigation is protected.

The system of regulating medical devices operates by way of a certification for each medical device. Each certificated device is marked with CE mark which shows that the device has a Certificat de Conformité. There are national bodies known as Competent Authorities in each member state which oversee the implementation of the EUMDR within their jurisdiction. The means for achieving the requirements for CE mark varies according to the nature of the device. Devices are classified in accordance with their perceived risks, similarly to the U.S. system. The class of a product determines the requirements to be fulfilled before CE mark can be placed on a product, known as a conformity assessment. Conformity assessments for our products have carried out as required by the MDD. Each member state can appoint Notified Bodies within its jurisdiction. If a Notified Body of one member state has issued a Certificat de Conformité, the device can be sold throughout the European Union without further conformance tests being required in other member states.

Per MDD 93/42/EEC on Medical Devices, Annex II excluding Section 4, the Lap-Band System is considered a Class IIb device and few of the system's components are considered Class IIa devices. The vBloc, was never commercialized in the EU. The Obalon Balloon System, when delivered with a cellulose- based capsule was considered a Class IIb product under MDD. Prior to the merger, Obalon Therapeutics' management believed the Obalon Navigation System and the Obalon Touch Inflation Dispenser are Class I products not requiring Notified Body approval. Obalon Therapeutics' Medical Device Marketing Authorization under the MDD expired on May 14, 2020. Obalon Therapeutics allowed the Obalon balloon CE-mark to expire and did not renew its agreement with its Notified Body. Prior to the June 16, 2021 merger, Obalon Therapeutics did not apply for a CE-mark for the Obalon Navigation System and Obalon Touch Inflation Dispenser. ReShape Lifesciences will conduct a conformity assessment of the Obalon Balloon System, Obalon Navigation System and Obalon Touch Inflation Dispenser vis-à-vis the EU MDR requirements and determine their classification.

Regulatory frameworks for medical devices in certain countries in Asia Pacific and the Middle East

Australia

As of September 30, 2021, the Australian Register of Therapeutic Goods (ARTG), lists ReShape Lifesciences as the legal manufacturer of the Lap-Band System and accessories in Australia. Previously, Apollo Endosurgery was listed as the legal manufacturer of the Lap-Band System and accessories in Australia.

Middle East

Unlike Europe, while the Gulf Cooperation Council, or GCC, jurisdictions often work together to purchase certain medical products in a coordinated fashion for government hospitals, there is not a

coordinated system for the authorization of medical devices. Most GCC jurisdictions require that the official registered distributor of a product be wholly owned by nationals of that particular GCC jurisdiction.

ReShape distributes the Lap-Band System and accessories in the Middle East through a distributor. Product is shipped to the Kingdom of Saudi Arabia (KSA) and the United Arab Emirates (UAE).

Obalon Therapeutics ceased distribution of the Obalon System, the Obalon Navigation System and the Obalon Touch Inflation Dispenser in the Middle East prior to the June 16, 2021, merger.

Kingdom of Saudi Arabia, or KSA

The most pertinent regulation is the Interim Regulation for Medical Devices, issued by the Saudi Food & Drug Authority, or SFDA, Board of Directors' Decree number 1-8-1429 dated approximately December 27, 2008, and the implementing regulations of the same. The SFDA is an independent regulatory body that is responsible for the authorization of medical devices, and current guidelines are generally based on pre-existing approval in one of the five founding member nations of the Global Harmonization Task Force, or GHTF, which are Australia, Canada, United States, European Union and Japan. There are no overt requirements for the provision of safety and effectiveness data in the form of clinical trials or other studies, but these would likely come as a part of the approvals described above that are used as a basis to support approval within the KSA. The SFDA reserves its rights to require its own independent clinical trials as it deems necessary or appropriate. Regulatory authorization is required for all medical devices, regardless of device class. A potential exception to this requirement is for medical devices that were designed and constructed by local health care facility and staff for internal use. Similar to the United States, the SFDA requires post market surveillance to ensure safety and quality. This program is meant to be conducted by the Authorized Representative. With respect to the use of medical devices, it is the responsibility of the health care institution to inform the manufacturer and the SFDA of any adverse events associated with this use.

As of June 8, 2021, the SFDA has approved the Medical Device Market Authorization, or MDMA application and the listing of ReShape Lifesciences as the legal manufacturer of the Lap-Band System and accessories in KSA. Previously, Apollo Endosurgery was listed as the legal manufacturer of the Lap-Band System and accessories in KSA.

United Arab Emirates, or UAE

The most pertinent regulation is UAE Federal Law No. 4 of 1983 for the Pharmaceutical Profession and Institutions and to Medical Device Regulations. There are many similarities between the SFDA and the Registration and Drug Control Department that is run out of the Ministry of Health & Prevention of the UAE. Applications for registration of medical devices in the UAE are done with the UAE Ministry of Health Registration & Drug Control Department and must include data on effectiveness in addition to safety (a nod to the requirements of the FDA). The UAE body has its own device classification system that is most closely related to that used by the European Union, defined as class 1, low risk; class 2, medium risk but nonimplantable; class 3, medium risk but implantable; and class 4, high risk.

Brexit

The UK Medicines & Healthcare Products Regulatory Agency, or MHRA is responsible for regulating medical devices in Great Britain. The MHRA plans changes to the UK's Medical Devices Regulations 2002 as part of a broader transition away from European Union legal and regulatory systems.

In addition, the Trade Deal between the UK and the EU generally provides for cooperation and exchange of information between the parties in the areas of product safety and compliance, including market surveillance, enforcement activities and measures, standardization related activities, exchanges of officials, and coordinated product recalls. As such, processes for compliance and reporting should reflect requirements from regulatory authorities.

CE Marks issued by EU-recognized notified bodies will continue to be valid in for medical devices placed on the Great Britain market — England, Scotland, and Wales until December 31, 2024. Until that date, MHRA accepts the CE Marking and requires registering active implantable medical devices, Class III medical devices, Class IIb implantable medical devices and IVD List A devices by May 1, 2021. After

December 31, 2024, the UK Conformity Assessment (UKCA) marking will be mandatory. In Northern Island, CE Marking issued by EU-recognized notified bodies will continue to be valid until current CE cert under Medical Device Directive (MDD) expires, after which date, CE marking needs to be approved under EU Medical Device Regulation (EU MDR). ReShape Lifesciences is compliant with the registration requirements and is registered in England, Scotland, Wales, and Northern Ireland. Additionally, the EU no longer recognizes conformity assessment activities performed by UK notified bodies for medical devices placed on the market since January 1, 2021. Notified bodies must be located in a European Union member state, or territory where there is a mutual recognition agreement, or MRA; there is currently no such MRA. The new legislation may create an extra hurdle for manufacturers and thereby limit the availability and/or increase prices of our medical devices in the UK.

Our Products

The ReShape Lifesciences' Lap-Band System, the Obalon Balloon System, Obalon Navigation system and Obalon Touch Inflation Dispenser, and their respective components are medical devices that required a PMA submission form and approval by the FDA for commercial use in the United States. ReShape Lifesciences' vBloc neuromodulation system, which was approved by the FDA for treating obesity is no longer commercialized.

The FDA approved ReShape Lifesciences' vBloc in January of 2015. In September 2018, ReShape Lifesciences made a financial decision to stop the manufacturing and commercialization of the vBloc product line. This business decision was not related to the safety or efficacy of the device. On January 27, 2021, the FDA accepted a PMA amendment to formally withdraw the vBloc PMA. On February 2, 2021, the FDA accepted the PMA amendment for the ReCharge Post Approval Study closure and the study status was marked "Completed" on the FDA Post-Approval Studies webpage. On March 4, 2021, the FDA accepted the PMA amendment for the ReNew Post Approval Study termination and the study status was marked "Terminated" on the FDA Post-Approval Studies webpage. ReShape continues to comply with post-market surveillance requirements of the vBloc such as medical device reporting.

FDA approved the Lap-Band System in 2001. The Lap-Band System was approved for use in the U.S. for patients with a BMI greater than or equal to 40 or a BMI greater than or equal to 30 with one or more obesity-related comorbidity conditions.

The Lap-Band System was CE marked in 1997. The method of assessing conformity with applicable regulatory requirements varies depending on the class of the device, but for our Lap-Band System, the method involved a combination issuance of declaration of conformity by the manufacturer of the safety and performance of the device, and a third-party assessment by a Notified Body of the design of the device and of our quality system. A Notified Body is a private commercial entity that is designated by the national government of a member state as being competent to make independent judgments about whether a product complies with applicable regulatory requirements. The assessment included, among other things, a clinical evaluation of the conformity of the device with applicable regulatory requirements. We use BSI as the Notified Body for our CE marking approval process.

Continued compliance with CE marking requirements is enforced through periodic facility inspections by the Notified Body, which may be unannounced. Because we rely on contract manufacturing sites and service providers, these additional sites may also be subject to these Notified Body inspections.

The Obalon Balloon System was approved in January 2017 and the Obalon Navigation system and Obalon Touch Inflation Dispenser were approved on December 20, 2018. All of the above-listed devices were approved with post-approval conditions intended to ensure the safety and effectiveness of these devices. ReShape Lifesciences assumed and complies with all post market requirements for the Lap-Band System, the Obalon Navigation system, and Obalon Touch Inflation Dispenser.

The ReShape Vest with weight loss indication would be considered a Class III Long Term Implantable product by the FDA requiring the PMA submission. A pivotal trial for the ReShape Vest will likely include a few hundred patients implanted and monitored up to three years. Other implantable devices for the treatment of obesity relied on twelve-month endpoints for the PMA submission with annual follow-up visits up to

five years and we expect the pivotal trial for the ReShape Vest to be similar. A U.S. pivotal trial requires FDA Investigational Device Exemption ("IDE") submission and approval.

Since the beginning of 2020, the COVID-19 pandemic has slowed most of the economy in the European Union. This resulted in many different challenges ranging from notified bodies that were no longer able to perform audits, to manufacturers that were forced to increase their production beyond their existing capabilities or forced to stop their production all together. The original date of application of Regulation (EU) 2017/745 on medical device (MDR) was May 26, 2020. Due to the COVID-19 pandemic, the date of application for MDR was postponed to May 26, 2021. The Company will continue to implement changes across our quality systems to become compliant with the new MDR.

Clinical Trials

Obalon Balloon SMART Pivotal Trial

Obalon published the results of their pivotal SMART trial. The Obalon Balloon System has demonstrated clinically meaningful weight loss with durable results. The Obalon treatment group lost, on average, approximately twice as much body weight as patients in the sham-control group, with an average of 15.1 pounds of weight loss, resulting in an average 6.9% reduction in total body weight and an average 2.4 point decrease in BMI. In the study, 66.7% of patients lost at least 5% of their total body weight and the study showed statistically significant improvements in cardiometabolic risk factors, including fasting glucose, systolic blood pressure, cholesterol and triglycerides. Patients in the treatment group were followed for 48 weeks and showed, on average, that 89.5% of the weight loss achieved during the initial 24-week balloon treatment period was maintained at 48 weeks, or 24 weeks after the balloons were removed.

Obalon Balloon Post-Approval Study (PAS)

The PAS is a prospective, single arm, observational, sequentially enrolling, open label multi-center study. The Obalon PAS is a 1-year study that includes 6-month of Obalon Balloon therapy in conjunction of a weight loss behavior modification, or WLBM program and 6-months of continued WLBM program after balloon removal. The primary study objective is to assess the continued safety and performance of the Obalon Balloon System in commercial settings. FDA has completed their review of the Obalon final PAS Report stating that ReShape has fulfilled our post-approval study requirement.

Post-Approval Study — Obalon Navigation-Touch System (NTS)

To help assure the continued safety and effectiveness of the Obalon Navigation System, the FDA has required a post-approval study as a condition of approval under 21 CFR 814.82(a)(2). As part of PMA approval, Obalon management agreed with the FDA to conduct a post-approval prospective, observational, open-label, multi-center study designed to capture additional safety and effectiveness data of the Obalon balloon administration with NTS, prior to merger with ReShape LifeSciences. The study is a single cohort group that includes patients who commercially purchased the Obalon Balloon System at clinics and hospitals that use NTS and have consented to have their data collected to support this study. All activities related to post-administration management, weight loss and removal of the balloons are conducted in accordance with the commercial Obalon Balloon System device labeling and are not collected in this study; this study focuses on balloon administrations only. The study will evaluate approximately 4,000 balloon administrations in approximately 1,400 subjects at up to 40 clinical sites in the United States.

Patient enrollment for this study began in December 2019. On June 26, 2020, Obalon and the FDA had a call to discuss the impact of COVID-19 on the Company and cessation of commercial distribution of product since March 2020. Therefore, continued enrollment of the post-market study was put on hold and has been on hold since. The study enrolled 32 patients from one site as of March 9, 2020 before it was suspended. The other two participating sites have received IRB approvals but have not enrolled their first patient. ReShape Lifesciences will communicate with the FDA if commercial distribution of product resumes and coordinate resumption of this PAS.

Obalon Balloon System

Obalon Balloon favorable safety profile, In the pivotal SMART trial, only one of 336 (0.3%) patients that received the Obalon balloon experienced a serious adverse device event (SADE) and in data presented at the American Society for Metabolic and Bariatric Surgery Meeting from the first year of commercial experience, only two of 1,343 (0.14%) patients that received our Obalon balloon experienced a SADE. Historically, the reported rate of SADEs reported to Obalon in commercial use is consistent with that experienced in the pivotal SMART trial or the data from their first year of commercial experience.

In addition, data published and presented from Obalon's commercial registry demonstrates greater weight loss in the commercial setting as compared to the pivotal clinical study used to support FDA approval. In May 2019, Obalon updated data from their commercial registry to include 1,411 total patients from 143 treatment sites in the United States. In this data set, for those patients receiving three balloons and at least 20 weeks of therapy, the average weight loss was 21.7 pounds, resulting in a 10.2% reduction in total body weight. Of note, 50.7% of patients lost 10% or more total body weight and 77.9% lost 5% or more total body weight.

Obalon Balloon improved patient tolerability and comfort. The Obalon balloon is inflated with a proprietary mix of gas. This creates a light, buoyant balloon that floats at the top of the stomach instead of sinking to the bottom of the stomach like a traditional liquid-filled intragastric balloon. Further, the Obalon Balloon System consists of three separate 250cc balloons placed individually over a three-month period to progressively add volume. We believe these design elements have the potential to improve patient comfort and tolerability of our Obalon balloon.

Obalon Balloon progressive weight loss with durable results. In the pivotal SMART trial, patients in the Obalon treatment group lost, on average, approximately twice as much body weight as patients in the sham- control group. In addition, patients in the Obalon treatment group showed, on average, progressive weight loss over the balloon treatment period, which we believe is attributable to the individual placement of three separate Obalon balloons over the treatment period. Subsequent data analysis at 12 months also showed that, on average, 89.5% of the weight loss was maintained six months after balloon removal. In May 2019, Obalon analyzed data from their commercial registry on 1,411 total patients from 143 treatment sites in the United States. In this data set, for those patients receiving three balloons and at least 20 weeks of therapy, the average weight loss was 21.7 pounds, resulting in a 10.2% reduction in total body weight.

Obalon Balloon simple and convenient placement. The Obalon balloon is placed without anesthesia or an endoscopy through a swallowable capsule that dissolves in the stomach and releases the balloon. These unique features allow patients the flexibility to receive the Obalon balloon discreetly in an outpatient setting. Placement typically occurs in less than fifteen minutes and can be scheduled in the morning before work, during a lunch break or in the evening. Treated patients can return promptly to their normal daily activities. The balloons are removed endoscopically under light, conscious sedation six months after the first balloon placement. Recently approved new products, the Obalon Navigation System and Obalon Touch Inflation Dispenser, are designed to further improve ease of use and convenience of placement.

Privacy and Security Laws

Medical device companies may be subject to U.S. federal and state and foreign health information privacy, security and data breach notification laws, which may govern the collection, use, disclosure and protection of health-related and other personal information. In the United States, the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and all regulations promulgated thereunder, collectively HIPAA, imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. Although we are not a covered entity, we may provide certain services that require the use or disclosure of PHI on behalf of physicians who are covered entities, and we therefore may be considered to be business associates under HIPAA. HIPAA imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. HIPAA mandates the reporting of certain

breaches of health information to HHS, affected individuals and if the breach is large enough, the media. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information or PHI, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions.

Even when HIPAA does not apply, according to the Federal Trade Commission or the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA security regulations.

In addition, certain state and non-U.S. laws, such as the European Union General Data Protection Regulation, or GDPR, govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Further, "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity, are also subject to certain HIPAA privacy and security standards. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, California recently enacted legislation, the California Consumer Privacy Act or CCPA, which went into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for PHI maintained by a covered entity or business associate, it may regulate or impact our expected processing of personal information depending on the context. In Europe, the GDPR went into effect in May 2018 and introduces strict requirements for processing the personal data of European Union data subjects. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Moreover, the United Kingdom leaving the EU could also lead to further legislative and regulatory changes. It remains unclear how the United Kingdom data protection laws or regulations will develop in the medium to longer term and how data transfer to the United Kingdom from the EU will be regulated, especially following the United Kingdom's departure from the EU on January 31, 2020 without a deal. However, the United Kingdom has transposed the GDPR into domestic law with the Data Protection Act 2018, which remains in force following the United Kingdom's departure from the EU.

Anti-Kickback Statutes

The federal Anti-Kickback Statute prohibits persons from (among other things) knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce the referral of an individual, or the recommending, furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as Medicare or Medicaid.

Courts have interpreted the Anti-Kickback Statute quite broadly, holding that the statute will be violated if even one purpose of a payment — though not its sole or primary purpose — is to induce an act prohibited by the statute with a willful intent to act improperly. The statute prohibits many arrangements and practices that are otherwise lawful in businesses outside of the healthcare industry. Prosecutors may infer intent

from the surrounding circumstances and, because courts have interpreted the statute to be violated if even one purpose of a payment is to induce the purchase of items or services paid for by federal healthcare programs, prosecutors have broad discretion in choosing arrangements to prosecute under the statute. There are statutory exceptions and regulatory "safe harbors" available to protect certain appropriately structured arrangements that otherwise would implicate the Anti-Kickback Statute. Those who structure their business arrangements to satisfy all of the criteria of a safe harbor are protected from liability under the statute.

Penalties for violation of the Anti-Kickback Statute are severe and may include, in addition to the fines and jail time described above, penalties imposed under the Civil Monetary Penalties Law, or the CMP Law, including exclusion from participation in Federal healthcare programs, civil monetary penalties for each improper act, and damages of up to three times the amount of remuneration at issue (regardless of whether some of the remuneration was for a lawful purpose). Because we do not anticipate that the Obalon Balloon System will be reimbursed by any federal healthcare program, we do not believe that we will be subject to the federal Anti-Kickback Statute.

Many states have adopted laws similar to the Anti-Kickback Statute, however, and some of these state prohibitions apply to arrangements involving healthcare items or services reimbursed by any source, and not only by Medicare, Medicaid or another federal healthcare program. These state laws do not always have the same exceptions or safe harbors of the federal Anti-Kickback Statute. The business may be subject to some of these laws.

Government officials have focused recent enforcement efforts on the marketing of healthcare services and products, among other activities, and have brought cases against companies, and certain individual sales, marketing and executive personnel, for allegedly offering unlawful inducements to potential or existing customers in an attempt to procure their business.

False Claims Laws

The federal False Claims Act imposes liability on any individual or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The *qui tam* or "whistleblower" provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has violated the False Claims Act and to share in any monetary recovery. In recent years, the number of lawsuits brought against healthcare industry participants by private individuals has increased dramatically.

When an entity is determined to have violated the 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 instance of false claim. As part of any settlement, the government may ask the entity to enter into a corporate integrity agreement, which imposes certain compliance, certification and reporting obligations. There are many potential bases for liability under the False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The federal government has used the False Claims Act to assert liability on the basis of inadequate care, kickbacks and other improper referrals, and the provision of inaccurate reimbursement coding advice, in addition to the more predictable allegations as to misrepresentations with respect to the services rendered. In addition, companies have been sued under the False Claims Act in connection with the off-label promotion of products.

Various states have also enacted false claims laws that are analogous to the federal False Claims Act. Many of these state laws apply to claims submitted to any third-party payor and are not limited to claims submitted to a federal healthcare program.

Transparency Laws

The federal Physician Payment Sunshine Act, or the Sunshine Act, which was enacted as part of the Patient Protection and Affordable Care Act, or the PPACA, generally requires certain manufacturers of a drug, device, biologic or other medical supply that is covered by Medicare, Medicaid or the Children's Health Insurance Program and applicable group purchasing organizations to report on an annual basis: (i) certain payments and other transfers of value given to physicians (defined to include doctors, dentists, optometrists,

podiatrists and chiropractors), certain other health care professionals beginning in 2022, and teaching hospitals and (ii) any ownership or investment interest that physicians, or their immediate family members, have in their company. The payments required to be reported include the cost of meals provided to a physician, travel reimbursements and other transfers of value, including those provided as part of contracted services such as speaker programs, advisory boards, consultation services and clinical trial services. Under the statute, the federal government makes reported information available to the public. Failure to comply with the reporting requirements can result in significant civil monetary penalties, with additional penalties for the knowing failure to report. Additionally, there are criminal penalties if an entity intentionally makes false statements in the reports.

There has been a recent trend of separate state regulation of payments and transfers of value by manufacturers of medical devices to healthcare professionals and entities, however, and some state transparency laws apply more broadly than does the federal Sunshine Act. Our business may be subject to some of these state laws.

State Corporate Practice of Medicine, Fee-Splitting Prohibitions, and Licensure Requirements

Other regulatory oversight includes, but is not limited to, the corporate practice of medicine, fee- splitting prohibitions, and licensure and scope of practice limitations for physicians and other healthcare professionals. Some states have enacted laws and regulations limiting the extent to which physicians and certain other healthcare professionals may be employed by non-physicians or general business corporations, and the scope and provisions of corporate practice of medicines laws and regulations vary by state. These laws are intended to prevent interference in the medical decision-making process by anyone who is not a licensed physician. Violations may result in civil or criminal penalties. In addition, various state laws also generally prohibit the sharing or splitting professional fees with lay entities or persons. The specific restrictions with respect to enforcement of the corporate practice of medicine and fee-splitting laws varies from state to state. Violations of these laws could require us to restructure our operations and arrangements and may result in penalties or other adverse action.

Moreover, each state defines the scope of practice of physicians and other healthcare professionals through legislation and through their respective licensing boards, and we will need to comply with laws related to the physician supervision of services and scope of practice requirements. Activities that qualify as professional misconduct under state law may subject our personnel to sanctions or may even result in loss of their license and could, possibly, subject us to sanctions as well. Some state boards of medicine impose reciprocal discipline, that is, if a physician is disciplined for having committed professional misconduct in one state where he or she is licensed, another state where he or she is also licensed may impose the same discipline even though the conduct occurred in another state.

Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits U.S. businesses and their representatives from offering to pay, paying, promising to pay or authorizing the payment of money or anything of value to a foreign official in order to influence any act or decision of the foreign official in his or her official capacity or to secure any other improper advantage in order to obtain or retain business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records, which in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the corporation, including international subsidiaries, if any, and to devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances regarding the reliability of financial reporting and the preparation of financial statements. The scope of the FCPA includes interactions with certain healthcare professionals in many countries.

International Laws

In Europe, and throughout the world, other countries have enacted anti-bribery laws and/or regulations similar to the FCPA. Violations of any of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation.

There are also international privacy laws that impose restrictions on the access, use, and disclosure of health information. All of these laws may impact our business. Our failure to comply with these privacy laws or significant changes in the laws restricting our ability to obtain required patient information could significantly impact our business and our future business plans.

U.S. Healthcare Reform

Changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our products. By way of example, ACA substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the medical device industry.

There will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge and/or patients' willingness to pay for our products. While in general it is too early to predict what effect, if any, ACA and its implementation, or any future healthcare reform legislation or policies will have on our business, current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition.

Employees

As of December 31, 2022, we had 47 employees, all of which were full-time. All of these employees are located in the U.S.

From time to time we also employ independent contractors, consultants and temporary employees to support our operations. None of our employees are subject to collective bargaining agreements. We have never experienced a work stoppage and believe that our relations with our employees are good.

Legal Proceedings

On August 6, 2021, Cowen and Company, LLC ("Cowen") filed a complaint against ReShape, as successor in interest to Obalon Therapeutics, in the Supreme Court of the State of New York based on an alleged breach of contract arising out of Cowen's prior engagement as Obalon's financial advisor. The complaint alleged that Cowen is entitled to be paid a $1.35 million fee in connection with ReShape's merger with Obalon under the terms of Cowen's engagement agreement with Obalon. The complaint also sought reimbursement of Cowen's attorneys' fees and interest in connection with its claim. On December 6, 2022, the Court granted Cowen's motion for summary judgment and directed ReShape to pay Cowen the principal amount of $1.35 million, plus interest at the statutory rate of 9% per annum from June 16, 2021, and to reimburse Cowen's attorneys' fees.

RISK FACTORS

An investment in our securities is speculative and involves a high degree of risk and uncertainty. You should carefully consider the risks described below, together with the other information contained in this registration statement, including the consolidated financial statements and notes thereto, before deciding to invest in our securities. The occurrence of any of the events described below could have a material adverse effect on our business, financial condition, results of operations, cash flows, prospects or the value of our common stock. These risks are not the only ones that we face. Additional risks not currently known to us or that we currently deem immaterial also may impair our business.

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 unpredictability of new variants of COVID-19, which has resulted and may continue to result in a slow-down of elective surgeries and restrictions in some locations. As of September 30, 2022, we had net working capital of approximately $6.1 million, primarily due to cash and cash equivalents and restricted cash of $6.2 million. Additionally, our anticipated expansion of our product portfolio and future products may not come to fruition. Our principal source of liquidity as of September 30, 2022 consisted of approximately $6.2 million of cash and cash equivalents and restricted cash and $2.2 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 prospectus. This condition raises substantial doubt about our ability to continue as a going concern.

Public health crises, such as the COVID-19 pandemic, have had, and could in the future have, a negative effect on our business.

Pandemics or disease outbreaks, such as the COVID-19 pandemic, have created and 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 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 on future developments, which are highly uncertain and cannot be predicted with confidence.

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 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, 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 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.

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 has 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 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 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. As such, we determined the carrying value of the IPR&D asset was impaired and recognized a non-cash impairment charge of approximately $6.9 million on the condensed consolidated balance sheet as of September 30, 2022, which reduced the value of this asset to zero. In the future, we may have additional impairments requiring us to record an impairment loss related to our remaining indefinite-lived and finite-lived intangible assets, which could also have a material adverse effect on our results of operations.

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 September 30, 2022, and determined that our internal control over financial reporting was not effective at a reasonable assurance level due to a 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.

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 a restatement of prior period financial statements or 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. In our Form 10-Q for the fiscal quarter ended June 30, 2022, and as set forth in note 1 to the financial statements for the period ended September 30, 2022 included in this prospectus, we revised the statement of operations for the periods ended December 31, 2020, March 31, 2021, June 30, 2021, September 30, 2021, December 31, 2021, and

March 31, 2022, to reflect the correction of an immaterial error in the computation of the weighted average shares used to compute basic and diluted net loss per share. As part of the inquiry, the SEC has requested that we voluntarily provide certain 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 require that we restate prior period financial statements and/or 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.

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.

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 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, 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.

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 September 30, 2022, ReShape had U.S. federal net operating loss carryforwards of $178.2 million. Of the total U.S. federal net operating loss carryforwards at September 30, 2022, $1.2 million is subject to a 20 year carryover period and began expiring in 2021. Losses generated beginning in 2018 will carryover indefinitely. ReShape had state net operating loss carryforwards of $280.9 million at September 30, 2022, and had foreign net operating loss carryforwards of $0.2 million at September 30, 2022. 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 September 30, 2022, the net effect of any further limitation will have no impact on results of operations.

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, Obalon Balloon System, and commercialize 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, the successful relaunch and commercialization of the Obalon Balloon System, 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;
- 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.

During the three and nine months ended September 30, 2022 and 2021, there was minimal revenue for ReShapeCare. There was no revenue or gross profit recorded for the ReShape Vest or DBSN device for the three months and nine months ended September 30, 2022 and 2021 as these two products are still in the development stage. There was also no revenue recorded for the Obalon line.

If our products, or any other therapy or products 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. If we complete the offering contemplated by this prospectus, we believe we will have sufficient cash on hand to execute on our goal of becoming profitable within the next 18 months. 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. The company could achieve its goal of becoming profitable within the next 18 months by becoming cash flow positive, achieving positive EBITDA, or positive net income.

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 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 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, 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 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 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 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, ReShape Vest 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 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.

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;
- actual or anticipated variations in our results of operations or those of our competitors;
- 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 27, 2022, we had outstanding 519,198 shares of common stock. In addition, as of that date we had outstanding warrants to acquire 206,819 shares of common stock. 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.

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.

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, 2022, 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, 2023 to regain compliance. If at any time during this period the closing bid price of our common stock is at least $1.00 per share for a minimum of 10 consecutive business days, Nasdaq will provide us with a written confirmation of compliance and the matter will be closed. In order to regain compliance with the bid price requirement, we effected a 1-for-50 reverse stock split of our issued and outstanding common stock on December 23, 2022. On January 17, 2023, Nasdaq provided us with written confirmation that we have regained compliance with Listing Rule 5550(a)(2) and the matter is now closed.

You may experience future dilution as a result of future equity offerings.

In order to raise additional capital for general corporate purposes, in the future we may offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may be lower than the current price per share of our common stock. In addition, investors purchasing shares or other securities in the future could 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 price per share paid by investors in prior 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.

Our certificate of incorporation 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 devices;
- the authority for our board of directors to issue without stockholder approval up to the number of shares of common stock authorized in our certificate of incorporation, that, if issued, would dilute the ownership of our stockholders;
- the advance notice requirement for director nominations or for proposals that can be acted upon at stockholder meetings;
- a classified and staggered board of directors, which may make it more difficult for a person who acquires control of a majority of our outstanding 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 entitled to vote generally in the election of directors, voting together as a single class.

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, alone or together, could have the effect of deterring or delaying changes in incumbent management, proxy contests or changes in control.

These provisions also could discourage proxy contests and make it more difficult for you and other stockholders to elect directors and take other corporate actions. The existence of these provisions could

limit the price that investors might be willing to pay in the future for shares of our common stock. Some provisions in our certificate of incorporation and bylaws may deter third parties from acquiring us, which may 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.

We have never paid dividends on our common stock and do not anticipate paying dividends on our common stock in the foreseeable future. The payment of dividends on our common stock will depend on our earnings, financial condition and other business and economic factors affecting us at such time as our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if our stock price appreciates.