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

**Form 10-K**

(Mark one)

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2018

or

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

**Commission file number: 1-33818**

**RESHAPE LIFESCIENCES INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation)

**48-1293684**

(IRS Employer Identification No.)

**1001 Calle Amanecer, San Clemente, California 92673**

(Address of principal executive offices, including zip code)

**(949) 429-6680**

(Registrant's telephone number, including area code)

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

Title of Class	Trading Symbol	Name of Exchange on which Registered
Common stock, \$0.01 par value per share	RSLS	OTCQB Market

**Securities registered pursuant to Section 12(g) of the Act: None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

At June 30, 2018, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant, based upon the closing price of a share of the registrant's common stock as reported by the NASDAQ Capital Market on that date was \$7,608,535.

As of April 22, 2019, 8,895,233 shares of the registrant's Common Stock were outstanding.

**Documents Incorporated by Reference**

Portions of the registrant's proxy statement for the 2019 Annual Meeting of Stockholders (to be filed within 120 days of December 31, 2018) are incorporated by reference into Part III, as indicated herein.

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**Registered Trademarks and Trademark Applications:** In the United States we have registered trademarks for LAP-BAND®, LAP-BAND AP®, LAP BAND SYSTEM®, RAPIDPORT®, RESHAPE® and RESHAPE MEDICAL®, each registered with the United States Patent and Trademark Office, and trademark applications for RESHAPE VEST, and RESHAPE LIFESCIENCES. In addition, some or all of the marks LAP-BAND, LAP-BAND AP, LAP BAND SYSTEM, RAPIDPORT, RESHAPE, RESHAPE MEDICAL, RESHAPE VEST, and RESHAPE LIFESCIENCES are the subject of either a trademark registration or an application for registration in Australia, Canada, the European Community, Mexico, Saudi Arabia, South Korea, and the United Arab Emirates. We believe that we have common law trademark rights to RESHAPE VEST. This Annual Report on Form 10-K contains other trade names and trademarks and service marks of ReShape Lifesciences and of other companies.

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## ITEM 1. BUSINESS

### Our Company

The Company is a developer of minimally invasive medical devices that advance bariatric surgery to treat obesity and metabolic diseases. The Company's current portfolio includes the LAP-BAND® Adjustable Gastric Banding System and the ReShape Vest™, an investigational device, to help treat more patients with obesity. Our vision is to be recognized as a leading medical technology company focused on the design, development and commercialization of transformative technology to treat obesity and metabolic diseases.

### 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, where the patient is able to 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 and received the CE mark in 1997. FDA approval for the Lap-Band System in the U.S. was obtained in 2001 and the Lap-Band System has been approved in many countries around the world. More than 860,000 Lap-Band Systems have been distributed worldwide.

The Lap-Band System was approved for use in the U.S. for patients with Body Mass Index ("BMI") greater than or equal to 40 or a BMI greater than or equal to 35 with one or more severe comorbid conditions. In 2011, the U.S. FDA granted approval for an expanded indication for the Lap-Band System to include patients with a BMI in the range of 30 to 35 and with one or more comorbid 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 Vest

The ReShape Vest is an investigational, minimally invasive, laparoscopically implanted medical device being studied for weight loss in morbidly obese adults with a BMI of at least 35. The device wraps around the stomach, emulating the effect of conventional weight loss surgery, and is intended to enable gastric volume reduction. This device is designed to restrict the intake of food and provide the feeling of fullness without cutting or permanently removing portions of the stomach, or bypassing, any portion of the gastrointestinal tract. The implantation of the device mimics a traditional weight-loss surgery without permanently altering the anatomy and may not require vitamin supplementation.

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In a small pilot study conducted outside the United States, at 12 months, ReShape Vest patients demonstrated a mean percent excess weight loss (“%EWL”) of 85% and a mean percent total body weight loss of 30.2%, an average drop in HbA1c (Hemoglobin A1c) of 2.1 points, an average decrease of systolic blood pressure of 13mmHg, an average waist circumference reduction of 38 centimeters, or approximately 15 inches, and an average increase in HDL “good cholesterol” of 29 mg/dl.

**Benefits.** The ReShape Vest, if approved for sale, would allow us to offer an additional weight loss solution that emulates the effect of conventional weight loss surgery through a procedure that is minimally invasive. The ReShape Vest potentially offers the following benefits:

- **Minimizes Changes to Normal Anatomy.** The ReShape Vest emulates the effects of conventional weight-loss surgery without stapling, cutting or removing any portion of the stomach.
- **Minimally Invasive Procedure.** Unlike conventional weight loss surgery, which typically is performed in a hospital setting under general anesthesia and requires a hospital stay of up to four days, the ReShape Vest may result in shorter hospital stays.
- **Removable/Reversible.** The ReShape Vest is designed to be removed laparoscopically, permitting the removal of the device at a later time, if that is desired.
- **Allows Continued Ingestion and Digestion of Foods Found in a Typical, Healthy Diet.** Because the ReShape Vest also leaves the digestive anatomy largely unaltered, patients are able to maintain a more consistent nutritional balance compared to conventional surgical approaches, thus allowing them to effect positive changes in their eating behavior in a non-forced and potentially more consistent way.

The ReShape Vest will continue to be studied in upcoming trials in the US and internationally. In the U.S., we are currently planning a non-randomized trial enrolling approximately 250 patients at approximately 15-20 investigational sites with a 12-month primary endpoint (weight loss and safety) and 24 to 36-month follow-up. We intend to initiate that study in 2020 and our goal is to have FDA premarket approval (“PMA”) in the second half of 2022. Internationally, we initiated a non-randomized trial enrolling up to 95 patients at investigational sites in five countries (Germany, Netherlands, Belgium, Spain and Czech Republic) with a 12-month primary endpoint (weight loss and safety) and 24-month follow-up. We expect to obtain the CE mark by the third quarter of 2021.

### **ReShape vBloc**

ReShape vBloc uses vBloc Therapy to block the gastrointestinal effects of the vagus nerve using high-frequency, low-energy electrical impulses to intermittently interrupt naturally occurring neural impulses on the vagus nerve between the brain and the digestive system. We are not currently actively marketing ReShape vBloc, although we continue to support existing patients and their physicians. We are also currently investigating a proprietary technique that would utilize our vBloc technology to stimulate nerves feeding into the pancreas while simultaneously blocking nerves feeding into the liver. The goal of the procedure is to increase release of the body’s natural insulin and to prevent glucose release from the liver into the blood stream.

### **Our Strategic Focus**

#### **Develop and Commercialize a Differentiated Portfolio of Products/Therapies**

An overarching strategy for our company is to develop and commercialize a product portfolio that is differentiated from our competition by offering transformative technologies to bariatric surgeons that consists of a selection of patient friendly, non-anatomy changing, lifestyle enhancing alternatives to traditional bariatric surgery that help patients achieve durable weight loss. With the Lap-Band System and the ReShape Vest (if approved for commercial use), we believe we have two compelling and differentiated medical devices. 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 experts and others involved in the obesity management process, patients and their advocates and scientific experts. We have established relationships with obesity therapy experts and healthcare providers, including physicians and hospitals, and have identified Lap-Band patient ambassadors and we believe these individuals will be important in promoting patient awareness and gaining widespread adoption of the Lap-Band and the ReShape Vest.

**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.

**Leverage our vBloc Technology for Other Disease States**

We intend to continue to conduct research and development for other potential applications for our vBloc Therapy and believe we have a broad technology platform that will support the development of additional clinical applications and therapies for other metabolic and gastrointestinal disorders in addition to obesity.

**Alternative Weight Loss Solutions**

If we are able to commercialize the ReShape Vest, we believe that we will be able to offer two 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 and ReShape Vest provide a minimally-invasive continuum of care for bariatric 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 2.1 billion adults, approximately 30% of the global population, are overweight. The global economic impact of obesity is approximately \$2 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 product candidates could address a \$1.64 billion per year global surgical device market.

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, and according to a 2014 McKinsey Report is the leading cause of preventable death in the U.S. 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 billion per year and nearly 21% of medical costs in the U.S. can be attributed to obesity. An estimated 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 obese 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;
- testing and developing the ReShape Vest; and
- investigating ReShape vBloc for the treatment of type 2 diabetes, which, if marketed, would require additional FDA approval through the PMA process.

We have spent a significant portion of our capital resources on research and development. Our research and development expenses from continuing operations were \$5.7 million in 2018 and \$5.4 million in 2017.

### **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 procedures and from endoscopic procedures.

Our Lap-Band System competes, and we expect that our ReShape Vest System will compete, with surgical 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. 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 Obalon Therapeutics, Inc. (Obalon Balloon System).

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. 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.

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 either in clinical trials or working toward clinical trials in the US: Spatz3 Adjustable Balloon and Allurion Technology's Eclipse Balloon. 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.

In addition, there are many larger potential competitors experimenting in the field of neurostimulation to treat various diseases and disorders. For example, Medtronic plc, which develops deep brain stimulators and spinal cord



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stimulators, acquired TransNeuronix, which sought to treat obesity by stimulating the smooth muscle of the stomach wall and nearby tissue. St. Jude Medical, Inc., through its acquisition of Advanced Neuromodulation Systems, is developing spinal cord stimulators. LivaNova PLC is developing vagus nerve stimulators to modulate epileptic seizures and other neurological disorders. Boston Scientific Corporation, through its Advanced Bionics division, is developing neurostimulation devices such as spinal cord stimulators and cochlear implants. Ethicon-Endo Surgery acquired LivaNova PLC's patents and patent applications pertaining to vagus nerve stimulation for the treatment of obesity and two related comorbidities, diabetes and hypertension, in overweight patients.

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 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, education, sales and distribution;
- regulatory and reimbursement expertise;
- technological leadership and superiority; and
- speed of product innovation and time to market.

Many of our competitors are larger than we are and are either publicly-traded or are divisions of publicly-traded companies, and they enjoy several competitive advantages over us, including:

- significantly greater name recognition;
- established relations with healthcare professionals, customers and third-party payers;
- established distribution networks;
- greater 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:

- preserves normal anatomy;
- 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

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behavior appropriately without inducing punitive physical restrictions that physically force a limitation of food intake;

- minimize undesirable side-effects;
- minimize the risks of re-operations, malnutrition and mortality; and
- reduce the natural hunger drive of patients.

### **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, 2018, we had 101 total U.S. and foreign patents and patent applications related to our Lap-Band System. The international patents and patent applications are in regions including the United States, Germany, France, Spain, the UK, Mexico, Canada, Italy, the Netherlands, Portugal, Ireland, Belgium, Poland, Australia, and South Korea. The issued patents expire between the years 2020 and 2031.

We also have 226 total U.S. and international trademarks for the LAP-BAND brand name.

#### **ReShape Vest**

As of December 31, 2018, we had four granted U.S. patents and four granted foreign patents in China, Israel, Canada and Australia related to our ReShape Vest. The patents expire between the years 2029 and 2032.

We also have U.S. and international trademark applications for the RESHAPE VEST brand name.

### **Sales and Distribution**

We market directly to patients but sell the Lap-Band System to select surgical centers throughout the United States and internationally that have patients that would like to treat obesity and its comorbidities. The surgical centers then sell our product to the patients and implant. Our sales representatives are supported by field clinical experts who are responsible for training, technical support, and other support services at various implant centers. Our sales representatives implement consumer marketing programs and provide surgical centers and implanting surgeons with educational patient materials.

In connection with our acquisition of the Lap-Band System in December 2018, we entered into a transition services agreement, supply agreement and distribution agreement with Apollo pursuant to which, among other things, Apollo will manufacture the Lap-Band product for us for up to two years and Apollo will serve as our distributor of the Lap-Band product outside of the United States for up to one year.

In order to support our Lap-Band sales efforts, we have increased the size of our dedicated U.S. sales team from two to six. We have also launched co-op marketing campaigns that allow us to partner with clinics in marketing efforts and use digital marketing to drive qualified leads to physicians. During the first half of 2019, our international sales efforts will be through a combination of distributor and direct sales channels, with a focus on top Lap-Band customers in Australia and Europe.

On July 25, 2017, we entered into a Collaboration Agreement with Galvani Bioelectronics Limited (“Galvani”). Under the Collaboration Agreement, we agreed to modify our ReShape vBloc for use in pre-clinical research by Galvani

in exchange for payment for our development work and supply under this agreement. We retained all rights, title, and ownership in the intellectual property for the new device. Galvani was granted a right of first negotiation for the potential exclusive or non-exclusive supply by us of the developed device, exercisable at Galvani's election. We have not collaborated with Galvani since late in 2017 and we do not have any further plans to re-engage any further research activities with them at this time.

### **Our Manufacturers and Suppliers**

We are party to a supply agreement with Apollo pursuant to which, among other things, Apollo will manufacture the Lap-Band product for us for up two years after our acquisition of the Lap-Band product, which was completed in December 2018.

To date, all of the materials and components of 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.

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 required 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**

#### **Device Classification and Regulations**

##### **United States**

Our products and products under development are regulated by the FDA as medical devices under the Federal Food, Drug, and Cosmetic Act ("FFDCA") and the regulations promulgated under the FFDCA. Pursuant to the FFDCA, the FDA regulates the research, design, testing, manufacture, safety, labeling, storage, record keeping, advertising, sales and distribution, post-market adverse event reporting, production and advertising and promotion of medical devices in the United States. Noncompliance with applicable requirements can result in warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the government to grant premarket approval for devices and criminal prosecution.

Medical devices in the United States are classified into one of three classes, Class I, II or III, on the basis of the amount of risk and the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I, low risk, devices are subject to general controls (e.g., labeling and adherence to good manufacturing practices). Class II, intermediate risk, devices are subject to general controls and to special controls (e.g., performance standards, and premarket notification). Generally, Class III devices are those which must receive premarket approval by the FDA to ensure their safety and effectiveness (e.g., life-sustaining, life-supporting and implantable devices, or new devices which have not been found substantially equivalent to legally marketed devices), and require clinical testing to ensure safety and effectiveness and FDA approval prior to marketing and distribution. The FDA also has the authority to require clinical testing of Class II devices. In both the United States and certain international markets, there have been a number of legislative and regulatory initiatives and changes, such as the Modernization Act and the EU-Medical Device Regulations, which could and have altered the healthcare system in ways that could impact our ability to sell our medical devices profitably.

The FDCA provides two basic review procedures for medical devices. Certain products may qualify for a submission authorized by Section 510(k) of the FDCA, where the manufacturer submits to the FDA a premarket notification of the manufacturer's intention to commence marketing the product. The manufacturer must, among other things, establish that the product to be marketed is substantially equivalent to another legally marketed product. Marketing may commence when the FDA issues a letter finding substantial equivalence. If a medical device does not qualify for the 510(k) procedure, the manufacturer must file a PMA application with the FDA. This procedure requires more extensive pre-filing clinical and preclinical testing than the 510(k) procedure and involves a significantly longer FDA review process. A PMA is required to establish the safety and effectiveness of the device and a key component of a PMA submission is the pivotal clinical trial data, as discussed in more detail below.

#### **Premarket Approval**

Our ReShape vBloc and our Lap-Band System are medical devices that required PMAs from the FDA to market in the United States. The FDA approved ReShape vBloc in January of 2015 and the Lap-Band System in 2001 with post-approval conditions intended to ensure the safety and effectiveness of the devices. Failure to comply with the conditions of approval can result in material adverse enforcement action, including the loss or withdrawal of the approvals. Even after approval of the PMAs, new PMAs or supplemental PMAs will be required for significant modifications to the manufacturing process, labeling, use and design of a device that is approved through the premarket approval process. Premarket approval supplements often require submission of the same type of information as a PMA except that the supplement is limited to information needed to support any changes from the device covered by the original PMA. In addition, holders of an approved PMA are required to submit annual reports to the FDA that include relevant information on the continued use of the device.

The ReShape Vest will be considered a Class III Long Term Implantable ("LTI") product by the FDA requiring the PMA path. A pivotal trial for the ReShape Vest will likely include approximately 250 implanted patients 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 US pivotal trial requires FDA Investigational Device Exemption ("IDE") submission and approval.

#### **Clinical Trials**

A clinical trial is almost always required to support a PMA. Clinical trials for a "significant risk" device such as ours require submission to the FDA of an application for an IDE for clinical studies to be conducted within the United States. 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. Clinical trials for a significant risk device in the United States may begin once the IDE application is approved by the FDA and by the Institutional Review Boards ("IRBs") overseeing the clinical trial at the various investigational sites.

Clinical trials require extensive recordkeeping and detailed reporting requirements. Our clinical trials must be conducted under the oversight of an IRB for each participating clinical trial site and in accordance with applicable regulations and policies including, but not limited to, the FDA's good clinical practice IDE requirements. We, the trial Data Safety Monitoring Board, the FDA or the IRB for each site at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

***Pervasive and Continuing U.S. Regulation***

Numerous regulatory requirements apply. These include:

- Quality System Regulation, which requires manufacturers to follow design, testing, control, documentation, complaint handling and other quality assurance procedures during the design and manufacturing processes;
- regulations which govern product labels and labeling, prohibit the promotion of products for unapproved or “off-label” uses and impose other restrictions on labeling and promotional activities;
- medical device reporting 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 it were to recur;
- notices of correction or removal and recall regulations;
- periodic reporting of progress related to clinical trials, post approval studies required as conditions of PMA approval and relevant changes to information contained within the PMA approval; and
- reporting of transfers of value and payments to physicians and teaching hospitals.

Advertising and promotion of medical devices are also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. Recently, some promotional activities for FDA-regulated products have resulted in enforcement actions brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act, competitors and others can initiate litigation relating to advertising claims.

Compliance with regulatory requirements is enforced through periodic facility inspections by the FDA, which may be unannounced. Because we rely on contract manufacturing sites and service providers, these additional sites are also subject to these FDA inspections. Failure to comply with applicable regulatory requirements can result in enforcement action, which may include any of the following sanctions:

- warning letters or untitled letters;
- fines, injunction and civil penalties;
- recall or seizure of our products;
- customer notification, or orders for repair, replacement or refund;
- operating restrictions, partial suspension or total shutdown of production or clinical trials;
- refusing our request for premarket approval of new products;
- withdrawing premarket approvals that are already granted; and
- criminal prosecution.

***International Regulations***

International sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ. The primary regulatory environment in Europe is that of the European Economic Community (“EEC”), which consists of 28 European Union (“EU”) member states encompassing nearly all the major countries in Europe. Additional countries that are not part of the EU, but are part of the European Economic Area (“EEA”), and other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the EEC with respect to medical devices. The EEC has adopted Directive 90/385/EEC as amended by

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2007/47/EC for active implantable medical devices and numerous standards that govern and harmonize the national laws and standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices that are marketed in member states. Medical devices that comply with the requirements of the national law of the member state in which their Notified Body is located will be entitled to bear CE marking, indicating that the device conforms to applicable regulatory requirements, and, accordingly, can be commercially marketed within the EEA and other countries that recognize this mark for regulatory purposes.

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 of self-assessment and 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.

**Patient Privacy Laws**

United States and various international laws have been evolving to protect the confidentiality of certain patient health information, including patient medical records. These laws restrict the use and disclosure of certain patient health information. Enforcement actions, including financial penalties, related to patient privacy issues are globally increasing. The management of patient data may have an impact on certain clinical research activities and product design considerations.

**Employees**

As of December 31, 2018, we had 43 employees. All of these employees are located in the United States.

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.

**Executive Officers**

The following table sets forth information regarding our executive officers as of April 1, 2019:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Barton P. Bandy	58	President and Chief Executive Officer
Scott P. Youngstrom	59	Chief Financial Officer and Senior Vice President, Finance

*Barton P. Bandy* has served as our President and Chief Executive Officer since April 1, 2019. Mr. Bandy has extensive leadership experience in health care and specifically in the obesity and bariatric space. Most recently, Mr. Bandy was President and Chief Executive Officer of BroadSpot Imaging Corporation, a developer of medical devices for eye care, since April 2017. From April 2013 to August 2016, Mr. Bandy was President of Wellness at Alphaeon Corporation, where he was responsible for business development, commercial activities, strategy and acquisition integration. He previously spent 10 years at Inamed, including during its acquisition by Allergan.

*Scott P. Youngstrom* is our Senior Vice President, Finance and has served as our Chief Financial Officer since October 3, 2016. Mr. Youngstrom has over 25 years of strategic financial and operational experience in a variety of medical device companies, most recently having served as Chief Financial Officer and Vice President, Finance at Galil Medical, a leading developer of cryotherapy technology. Prior to Galil Medical, from 2009-2014, Mr. Youngstrom served as Vice President, Chief Operating Officer, and Chief Financial Officer at DGIMED Ortho, Inc., a developer of

orthopedic medical devices. Mr. Youngstrom has previously served as Chief Financial Officer and Vice President, Finance with Anulex Technologies, Enpath Medical, Compex Technologies, Acist Medical Systems, and Cardiometrics.

## **Our Corporate Information**

We were incorporated in Minnesota in December 2002 and then reincorporated in the state of Delaware in July 2004. On October 23, 2017 we changed the company name from EnteroMedics Inc. to ReShape Lifesciences Inc. Our shares of common stock were traded on the Nasdaq Capital Market under the symbol RSL5 until December 31, 2018. Effective as of December 31, 2018, our shares were delisted from the Nasdaq Capital Market and now trade on the OTCQB Market under the symbol RSL5.

We file reports and other information with the Securities and Exchange Commission (“SEC”) including annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and proxy or information statements. Those reports and statements as well as all amendments to those documents filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (1) are available at the SEC’s Public Reference Room at 100 F Street, N.E., Washington, DC 20549, (2) may be obtained by sending an electronic message to the SEC at [publicinfo@sec.gov](mailto:publicinfo@sec.gov) or by sending a fax to the SEC at 1-202-777-1027, (3) are available at the SEC’s internet site (<http://www.sec.gov>), which contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC and (4) are available free of charge through our website as soon as reasonably practicable after electronic filing with, or furnishing to, the SEC. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330.

Our principal executive offices are located at 1001 Calle Amanecer, San Clemente, California 92673, and our telephone number is (949) 429-6680. Our website address is [www.reshapelifesciences.com](http://www.reshapelifesciences.com). The information on, or that may be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K and should not be considered a part of this Annual Report on Form 10-K.

## **ITEM 1A. RISK FACTORS**

### **RISK FACTORS**

#### **Risks Related to Our Business and Industry**

***Our acquisition of the assets related to the Lap-Band System from Apollo Endosurgery, Inc. in December 2018 could adversely affect our operations, financial results and financial condition.***

In December 2018, we acquired substantially all of the assets exclusively related to Apollo Endosurgery, Inc.’s Lap-Band product line and Apollo acquired from us substantially all of the assets exclusively related to our ReShape Balloon product line. In addition, we agreed to pay Apollo \$17 million in cash, of which \$10 million was paid at the closing of the transaction, \$2 million is payable on the first anniversary of the closing date, \$2 million is payable on the second anniversary of the closing date, and \$3 million is payable on the third anniversary of the closing date.

A successful acquisition depends on our ability to identify, negotiate, complete and integrate such acquisition and to obtain any necessary financing. With respect to our acquisition of the Lap-Band product line and any future acquisitions, we may experience:

- difficulties in integrating the acquired businesses and their respective personnel and products into our existing business;
- difficulties in integrating commercial organizations;
- delays in transferring regulatory approvals from Apollo to ReShape Lifesciences
- difficulties or delays in realizing the anticipated benefits of the acquisition;
- diversion of our management’s time and attention from other business concerns;

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- challenges due to limited or no direct prior experience in new markets or countries we may enter;
- inability to successfully develop new products and services on a timely basis that address our new market opportunities post-acquisition;
- inability to compete effectively against companies already serving the broader market opportunities expected to be available to us post-acquisition;
- unanticipated costs and other contingent liabilities; and
- any unforeseen compliance risks and accompanying financial and reputational exposure or loss not uncovered in the due diligence process and which are imputed to our company, such as compliance with federal laws and regulations, the advertising and promotion regulations under the federal Food, Drug and Cosmetic Act, the Anti-kickback Statute, the False Claims Act, the Physician Sunshine Payments Act and other applicable laws.

We have invested, and expect to continue to invest, significant cash and other resources in connection with our acquisition of the Lap-Band product line, including our obligation to pay the remaining \$7 million of the purchase price. Our efforts to successfully integrate and continue the commercialization of the Lap-Band product line will require significant cash expenditures. There can be no assurance that we will be successful in our efforts. Should we be unable to obtain adequate financing or generate sufficient revenue in the future, our business, results of operations, liquidity and financial condition could be materially and adversely harmed.

***We face a risk of default under our security agreement with Apollo that we entered into in connection with our acquisition of the Lap-Band product line and under our subordinated secured debentures that we issued in March 2019.***

In connection with our acquisition of the Lap-Band product line, we entered into a security agreement with Apollo pursuant to which we granted to Apollo a security interest in substantially all of our assets as security for our obligations under the asset purchase agreement entered into in connection with the transaction, including our obligation to pay the cash purchase price. The security interest will be terminated upon the earlier of the date we pay the cash purchase price to Apollo in full or complete an equity financing raising gross proceeds of at least \$15 million. In March 2019, we issued \$2.2 million in aggregate principal amount subordinated secured debentures and a related security agreement to secure our payment obligations under the debentures, which obligations and security interest are subordinated to our obligations to and security interest of Apollo. If we default on our payment obligations, Apollo and our other secured lenders have the right to enforce their rights under the security agreements, including by enforcing their security interest and taking control of substantially all of our assets and declaring the entire remaining portion of our outstanding obligations to be immediately due and payable. In addition, the security agreements contain certain restrictions that may adversely affect our ability to engage in certain business activities or finance our future operations or capital needs. Transactions that we may view as important opportunities, such as acquisitions, may be subject to the consent of Apollo or our other secured lenders, which consent may be withheld or granted subject to conditions specified at the time that may affect the attractiveness or viability of the transaction.

***If we do not achieve the contemplated benefits of our acquisition of the Lap-Band product line, our business and financial condition may be materially impaired.***

We may not achieve the desired benefits from our acquisition of the Lap-Band product line. For any of the reasons described above and elsewhere in this report and even if we are able to successfully integrate the Lap-Band product line within our company, we may not be able to realize the revenue and other growth that we anticipate from the acquisition in the time frame that we currently expect, and the costs of achieving these benefits may be higher than what we currently expect, because of a number of risks, including, but not limited to:

- the possibility that the acquisition may not further our business strategy as we expected; and
- the possibility that the revenue from the Lap-Band product line may be lower than we expected.

As a result of these risks, we may not achieve the anticipated strategic and financial benefits of the Lap-Band acquisition.



***If we are unable to either substantially improve our operating results or obtain additional financing in the future, we will be unable to continue as a going concern.***

Our independent registered public accounting firm's report on our December 31, 2018 audited financial statements includes an explanatory paragraph referring to our ability to continue as a going concern. The proceeds from any future financings that we may be able to obtain, if any, together with our other available cash, may not be sufficient to fund our operating expenses, capital expenditures and other cash requirements. Should we be unable to obtain adequate financing or generate sufficient revenue in the future, our business, result of operations, liquidity and financial condition would be materially and adversely harmed, and we would be unable to continue as a going concern. These events and circumstances could have a material adverse effect on our ability to raise additional capital and on the market value of our common stock and the warrants offered hereby. Moreover, should we experience a cash shortage that requires us to curtail or cease our operations, or should we be unable to continue as a going concern, you could lose all or part of your investments in our securities.

We currently are not generating revenue from operations that is significant relative to our level of operating expenses, and we do not anticipate generating revenue sufficient to offset operating costs in the short-term to mid-term. We have financed our operations to date principally through the sale of equity securities. Our history of operating losses, limited cash resources and lack of certainty regarding obtaining significant third-party reimbursement for our products or timing thereof, raise substantial doubt about our ability to continue as a going concern. As of December 31, 2018, we had \$5.5 million of cash and cash equivalents. We expect our current cash and cash equivalents to fund our operations through early 2019.

Our anticipated operations include plans to (i) integrate the sales and operations of the Lap-Band product line as well as to obtain cost savings synergies (ii) continue development of the ReShape Vest, (iii) seek opportunities to leverage our intellectual property portfolio and custom development services to provide third party sales and licensing opportunities, and (iv) explore and capitalize on synergistic opportunities to expand our portfolio and offer future minimally invasive treatments and therapies in the obesity continuum of care. We believe that we have the flexibility to manage the growth of our expenditures and operations depending on the amount of available cash flows, which could include reducing expenditures for marketing, clinical and product development activities. However, we will ultimately need to achieve sufficient revenues from product sales and obtain additional debt or equity financing in addition to the proceeds from this offering to support our operations.

***Our ReShape Vest product is in the early stages of clinical evaluation. If the clinical trial is not successfully completed or any required regulatory approvals are not obtained, the ReShape Vest may not be commercialized and our business prospects may suffer.***

Our ReShape Vest product is in the early stages of development and is currently in the early stages of clinical evaluation. Our ability to market the ReShape Vest in the United States and abroad depends upon our ability to demonstrate the safety and effectiveness of the product with clinical data to support our requests for regulatory approval. The ReShape Vest may not be found to be safe and, where required, effective in clinical trials and may not ultimately be approved for marketing by U.S. or foreign regulatory authorities, which would have a negative impact on our net sales.

There is no assurance that we will be successful in achieving the desired results in our anticipated clinical trials for the ReShape Vest or, if we do, that the FDA or other regulatory agencies will approve the product for sale without the need for additional clinical trial data to demonstrate safety and efficacy. We continually evaluate the potential financial benefits and costs of clinical trials and the products being evaluated in them. If we determine that the costs associated with obtaining regulatory approval of a product exceed the potential financial benefits of that product or if the projected development timeline is inconsistent with our investment horizon, we may choose to stop a clinical trial and/or the development of a product.

***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 4,543 shares of our common stock. We 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

\$274.8774 per share, or \$5,772.4254 per underlying share of common stock, or approximately \$26.2 million in the aggregate. Holders of the series C convertible preferred stock have the right to convert their shares into shares of common stock instead of receiving the liquidation preference. 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. While the series C convertible preferred stock generally does not have voting rights, 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 or (e) enter into any agreement with respect to any of the foregoing.

***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. We have been engaged in research and development and clinical trials since our inception in 2002 and have invested substantially all of our time and resources in developing our products and product candidates. The success of our business will depend on our ability to establish a sales force, make sales and control costs, as well as our ability to obtain additional regulatory approvals needed to market new versions of our Lap-Band system or regulatory approvals needed to market our ReShape Vest 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 or develop and commercialize the ReShape Vest, 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.

***We have incurred losses since inception and we anticipate that we will continue to incur losses for the foreseeable future.***

We have incurred losses in each year since our formation in 2002. For the years ended December 31, 2018 and 2017, our loss from continuing operations was \$35.3 million and \$30.5 million, respectively, and our net loss attributable to common stockholders was \$84.2 million and \$33.8 million, respectively. We have funded our operations to date principally from the sale of securities and the issuance of indebtedness. Development of a new medical device, including conducting clinical trials and seeking regulatory approvals, is a long, expensive and uncertain process. We expect to incur significant sales and marketing expenses prior to recording sufficient revenue to offset these expenses. We expect our general and administrative expenses to increase as we continue to add the infrastructure necessary to support our initial commercial sales, market the Lap-Band system, develop the ReShape Vest, operate as a public company and develop our intellectual property portfolio. For these reasons, we expect to continue to incur significant operating losses for the next several years. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and working capital. Because of the numerous risks and uncertainties associated with developing new medical devices, we are unable to predict the extent of any future losses or when we will become profitable, if ever.

***During the second quarter of 2018 we were required to record a non-cash goodwill 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 goodwill impairment analysis for our businesses during the fourth quarter of each year or when circumstances suggest that an indicator for impairment may be present. Subsequent to our registered direct securities offering on April 3, 2018, the price of our common stock declined significantly and, given the decline which indicated a potential impairment of some or all of our goodwill, requiring us to perform an impairment analysis that included valuing all the tangible and intangible assets of the business. We performed an impairment analysis during the second quarter of 2018 resulting in a write-off of goodwill from continuing operations of \$14.0 million and a write-off of goodwill from discontinued operations of \$13.2 million. These goodwill write-offs had a material adverse effect on our results of operations. In the future, we may have additional indicators of potential impairment 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 will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or liquidate some or all of our assets.***

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts on the development and commercialization of our products and on research and development, including conducting current and future clinical trials for our Lap-Band system, ReShape Vest (if approved for sale) and subsequent versions of our products. For the years ended December 31, 2018 and 2017, net cash used in operating activities from continuing operations was \$20.1 million and \$22.1 million, respectively, and net cash used in operating activities (including discontinued operations) was \$27.5 million and \$24.6 million, respectively. We expect that our cash used in operations will continue to be significant in the upcoming years, and that we will need to raise additional capital to commercialize our Lap-Band system, to develop the ReShape Vest, to continue our research and development programs, and to fund our ongoing operations.

Our future funding requirements will depend on many factors, including:

- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our Lap-Band system, ReShape Vest and any products that we may develop; the rate of market acceptance of our Lap-Band system, ReShape Vest and any other product candidates;
- the rate of market acceptance of our Lap-Band system, ReShape Vest and any other product candidates;
- the cost of filing and prosecuting patent applications and defending and enforcing our patent and other intellectual property rights;
- the cost of defending, in litigation or otherwise, any claims that we infringe third-party patent or other intellectual property rights;
- the effect of competing products and market developments;
- the cost of explanting clinical devices;
- the terms and timing of any collaborative, licensing or other arrangements that we may establish;
- any revenue generated by sales of our Lap-Band system, ReShape Vest or our future products;
- the scope, rate of progress, results and cost of any clinical trials and other research and development activities;
- the cost and timing of obtaining any further required regulatory approvals; and
- the extent to which we invest in products and technologies, although we currently have no commitments or agreements relating to these types of transactions.

Until the time, if ever, when we can generate a sufficient amount of product revenue, we expect to finance our future cash needs through public or private equity offerings, debt financings or corporate collaboration, licensing arrangements and grants, as well as through interest income earned on cash balances.

Additional capital may not be available on terms favorable to us, or at all. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve restrictive covenants or additional security interests in our assets. Any additional debt or equity financing that we complete may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or products, or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may have to delay, reduce the scope of, or eliminate some or all of, our development programs or liquidate some or all of our assets.

***We may be subject to fines, restrictions or prohibitions on sales, or other penalties for failure to maintain licenses in certain states.***

Certain of our licenses in states in which we currently conduct our business are expired, and we may not maintain required licenses in every state in which we conduct business. As a result, we could be subject to fines, restrictions or prohibitions on its sales, or other penalties under applicable state laws, which could adversely affect our business and 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. There have been material weaknesses identified in the past and we have identified a material weakness as of December 31, 2018 related to our ability to maintain adequate accounting resources with a sufficient understanding of accounting principles generally accepted in the United States of America (“GAAP”) to allow the Company to identify and properly account for new complex transactions. Specifically, we did not design and implement internal controls around research and development expenses paid to a CRO. This material weakness resulted in our not identifying that certain research and development expenses paid to the CRO in connection with the clinical trial of the ReShape Vest are required to be capitalized under GAAP, and recognized into expense as the value of the capitalized asset is realized.

We have incurred and continue to expect to incur significant expense and devote substantial management effort toward ensuring compliance with Section 404 and remediating material weaknesses in our internal controls over financial reporting. Moreover, if we do not comply with the requirements of Section 404, or if we identify additional 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.

***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. The Affordable Care Act contains many provisions designed to generate the revenues necessary to fund the coverage expansions and to reduce costs of Medicare and Medicaid, including imposing a 2.3% excise tax on domestic sales of many medical devices by manufacturers that began in 2013. Although a moratorium was placed on the medical device excise tax through 2019, if Congress does not pass legislation further extending or otherwise eliminating the excise tax, our sales and selling, general and administrative expenses may be adversely affected in the future.

Congress is considering legislation to replace or repeal elements or all of the Affordable Care Act. In addition, there have been recent public announcements by members of Congress and the current presidential administration regarding their plans to repeal and replace the Affordable Care Act. Further, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or

medical devices. 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.

***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, Apollo Endosurgery, 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.

***Failure to protect our information technology infrastructure against cyber-based attacks, network security breaches, service interruptions, or data corruption could significantly disrupt our operations and adversely affect our business and operating results.***

We currently rely on information technology and telephone networks and systems, including the Internet, to process and transmit sensitive electronic information and will rely on such systems to manage or support a variety of business processes and activities, including sales, billing, customer service, procurement and supply chain, manufacturing, and distribution. We use enterprise information technology systems to record, process, and summarize financial information and results of operations for internal reporting purposes and to comply with regulatory financial reporting, legal, and tax requirements.

Our information technology systems, some of which are managed by third-parties, may be susceptible to damage, disruptions or shutdowns due to computer viruses, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures, user errors or catastrophic events. We are not aware of any breaches of our information technology infrastructure. Despite the precautionary measures we have taken to prevent breakdowns in our information technology and telephone systems, if our systems suffer severe damage, disruption or shutdown and we are unable to effectively resolve the issues in a timely manner, our business and operating results may suffer.

#### **Risks Associated with Development and Commercialization of the Lap-Band system and ReShape Vest**

***Our efforts to increase revenue from our Lap-Band system and commercialize the ReShape Vest 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 and successful commercialization of our ReShape Vest (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 ReShape Vest;
- 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 ReShape Vest;
- coverage policies for bariatric surgeries, including Lap-Band 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;

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- the availability and perceived advantages and disadvantages of alternative 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 and ReShape Vest (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.

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.

***We may not be able to obtain required regulatory approvals for our ReShape Vest in a cost-effective manner or at all, which could adversely affect our business and operating results.***

The production and marketing of our ReShape Vest and our ongoing research and development, preclinical testing and 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 ReShape Vest 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 ReShape Vest will not be approved for sale. Even if regulatory approval of our ReShape Vest 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 ReShape Vest 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.***

We 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 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 study. 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.

***If we are unable to establish sales and marketing capabilities or enter into and maintain arrangements with third parties to market and sell our Lap-Band product, our business may be harmed.***

We have limited experience as a company in sales, marketing and distribution of our products. We market our products in the United States through a direct sales force supported by field technical managers who provide training, technical and other support services to our customers. Apollo Endosurgery will serve as our exclusive distributor of the Lap-Band system outside of the United States and Canada for up to two years following our acquisition of the Lap-Band system. Developing a sales force is expensive and time consuming and we may be unable to develop an effective sales and marketing organization on a timely basis, if at all, or maintain our current sales and marketing capabilities, either of which would delay or prevent us from generating enough revenue to become profitable. Our sales force will be competing with the experienced and well-funded marketing and sales organizations of our more established competitors. If we are unable to establish and maintain our own sales and marketing capabilities, we will need to contract with third parties to market and sell our product. In this event, our profit margins would likely be lower than if we performed these functions ourselves. In addition, we would necessarily be relying on the skills and efforts of others for the successful marketing of our product. If we are unable to establish and maintain effective sales and marketing capabilities, independently or with others, we may not be able to generate product revenue and may not become profitable.

***The commercialization of our products in countries outside the United States will expose our business to certain risks associated with international operations.***

We currently sell our Lap-Band system in the United States, Canada and Australia. Conducting international operations subjects us to unique risks, including:

- unfamiliar legal requirements with which we would need to comply;
- fluctuations in currency exchange rates;
- potentially adverse tax consequences, including the complexities of foreign value added tax systems and restrictions on the repatriation of earnings;
- increased financial accounting and reporting burdens and complexities; and
- reduced or varied protection for intellectual property rights in some countries.

The occurrence of any one of these risks could negatively affect our business and results of operations generally. Additionally, operating in international markets requires significant management attention. We cannot be certain that investments required to establish operations in other countries will produce desired levels of revenues or profitability.

***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 successful completion of our clinical trials and the commercialization of our Lap-Band system and the development of our ReShape Vest. 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.

***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 develop our ReShape Vest, 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 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 and ReShape Vest 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.

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 United States 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.

Specifically, on April 20, 2017, Fulfillium, Inc. filed a complaint in the United States District Court for the District of Delaware accusing ReShape Medical, our wholly owned subsidiary, of trade secret misappropriation and patent infringement of U.S. Patent Nos. 9,445,930 and 9,456,915, which we are currently in the process of defending. 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 or ReShape Vest 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**

***Our common stock has been delisted from the Nasdaq Stock Market and our shares currently trade on an over-the-counter market.***

On December 27, 2018, we received a written notice from the Office of General Counsel of The Nasdaq Stock Market notifying us that the Nasdaq Hearings Panel (the “Panel”) had determined to delist our securities pursuant to Nasdaq’s discretionary authority under Listing Rule 5101. The Panel also cited in its decision our failure to maintain compliance with the minimum bid price requirement under Listing Rule 5550(a)(2) and our failure to comply with Listing Rule 5250(e), which requires a company to file a Notification Form Listing of Additional Shares at least 15 days prior to the issuance or potential issuance of common stock greater than 10% of the total shares outstanding. As a result of the Panel’s decision, Nasdaq suspended trading in our common stock effective with the open of business on December 31, 2018 and our common stock has now been delisted from Nasdaq.

Our common stock currently trades on the OTCQB market and therefore may have less liquidity and may experience potentially more price volatility than experienced on Nasdaq. Stockholders may not be able to sell their shares of common stock on the OTCQB market in the quantities, at the times, or at the prices that could potentially be available on a more liquid trading market. The delisting of our common stock from Nasdaq could also adversely affect our ability to obtain financing for our operations and/or result in a loss of confidence by investors or employees.

***Our common stock may be deemed to be a “penny stock” and broker-dealers who make a market in our stock may be subject to additional compliance requirements.***

If our common stock is deemed to be a “penny stock” as defined in the Securities Exchange Act of 1934, broker-dealers who make a market in our stock will be subject to additional sales practice requirements for selling our common stock to persons other than established customers and accredited investors. For instance, the broker-dealer must make a special suitability determination for the purchaser and receive the purchaser’s written agreement to the transaction prior to the sale. Consequently, the penny stock rules, if they were to become applicable, would affect the ability or willingness of broker-dealers to sell our securities, and accordingly would affect the ability of stockholders to sell their securities in the public market. These additional procedures could also limit our ability to raise additional capital in the future.

***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 and may be more volatile now that it trades on the OTCQB Market and not the Nasdaq Capital Market. 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;

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- 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, options and shares of convertible preferred stock, some of which contain full-ratchet anti-dilution protection, which may cause significant dilution to our stockholders, have a material adverse impact on the market price of our common stock and make it more difficult for us to raise funds through future equity offerings.***

As of December 31, 2018, we had outstanding 8,770,433 shares of common stock. In addition, as of that date we had outstanding warrants to acquire 15,304,722 shares of common stock, options to acquire 4,225 shares of common stock and shares of convertible preferred stock convertible into an aggregate of 131,743 shares of common stock. The issuance of shares of common stock upon the exercise of warrants or options or conversion of preferred stock would dilute the percentage ownership interest of all stockholders, might dilute the book value per share of our common stock and would increase the number of our publicly traded shares, which could depress the market price of our common stock.

In addition, a substantial number of our outstanding warrants and shares of convertible preferred stock contain so-called full-ratchet anti-dilution provisions which, subject to limited exceptions, would reduce the exercise price of the warrants (but not increase the number of shares issuable) and reduce the conversion price of the convertible preferred stock (and increase the number of shares issuable) in the event that we in the future issue common stock, or securities

convertible into or exercisable to purchase common stock, at a lower price per share, to such lower price. Of our outstanding warrants as of December 31, 2018, warrants exercisable to purchase 41,963 shares of common stock with an exercise price of \$1.25 per share contained a full-ratchet anti-dilution provision, and shares of convertible preferred stock convertible into 127,200 shares of common stock at a conversion price of \$1.25 per share contained a full-ratchet anti-dilution provision. These full ratchet anti-dilution provisions would be triggered by the future issuances by us of shares of our common stock or common stock equivalents at a price per share below the then-exercise price of the warrants and the then-conversion price of the convertible preferred stock, subject to limited exceptions. In the event of a liquidation, the holders of shares of series C convertible preferred stock are entitled to be paid, before any payments are to be made to the holders of common stock or any other series of preferred stock, an amount per share equal to the greater of (i) \$5,772.4254 per share (on an as-converted-to-common stock basis), or an aggregate of approximately \$26.2 million, plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had all shares of series C convertible preferred stock been converted to common stock immediately prior to such liquidation.

In addition to the dilutive effects described above, the perceived risk of dilution as a result of the significant number of outstanding warrants, options and shares of convertible preferred stock 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, warrant holders and option holders can sell substantial amounts of our common stock in the public market, whether or not sales have occurred or are occurring, as well as the existence of full-ratchet anti-dilution provisions in a substantial number of our outstanding warrants and shares of convertible preferred stock, 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.

***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.

***Since our securities are currently quoted on the OTCQB market, our stockholders may face significant restrictions on the resale of our securities due to state “blue sky” laws.***

Each state has its own securities laws, often called “blue sky” laws, which (i) limit sales of securities to a state’s residents unless the securities are registered in that state or qualify for an exemption from registration, and (ii) govern the reporting requirements for broker-dealers doing business directly or indirectly in the state. Before a security is sold in a state, there must be a registration in place to cover the transaction, or the transaction must be exempt from registration. The applicable broker must be registered in that state. We do not know whether our common stock will be registered or exempt from registration under the laws of any state. Since our common stock is currently quoted on the OTCQB, a determination regarding registration will be made by those broker-dealers, if any, who agree to serve as the market-makers for our common stock. There may be significant state blue sky law restrictions on the ability of investors to sell, and on purchasers to buy, our common stock. Investors should therefore consider the resale market for our common stock to be limited, as they may be unable to resell your common stock without the significant expense of state registration or qualification.

***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;

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- 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.

### **ITEM 1B. UNRESOLVED STAFF COMMENTS**

Not applicable.

### **ITEM 2. PROPERTIES**

We lease (i) approximately 14,479 square feet of office/warehouse space in San Clemente, California under an operating lease that expires June 30, 2022 and (ii) approximately 8,000 square feet of office and manufacturing space in San Clemente, California under an operating lease that expires October 31, 2019.

### **ITEM 3. LEGAL PROCEEDINGS**

*Du.* On February 28, 2017, the Company received a class action and derivative complaint filed on February 24, 2017 in U. S. District Court for the District of Delaware by Vinh Du, one of the Company's shareholders. The complaint named as defendants ReShape Lifesciences, the board of directors and four members of our senior management, namely, Scott Youngstrom, Nick Ansari, Peter DeLange and Paul Hickey, and contained a purported class action claim for breach of fiduciary duty against the board of directors and derivative claims for breach of fiduciary duty against the board of directors and unjust enrichment against our senior management. The allegations in the complaint related to the



increase in the number of shares authorized for grant under our Second Amended and Restated 2003 Stock Incentive Plan (the “Plan”), which was approved by our shareholders at the Special Meeting of Shareholders held on December 12, 2016 (the “Special Meeting”), and to our subsequent grant of stock options on February 8, 2017, to the Company’s Directors and senior management to purchase an aggregate of 521 shares of our common stock (the “Option Grants”). In the complaint, the plaintiff contended that (i) the number of shares authorized for grant under the Plan, as adjusted by the board of directors after the Special Meeting for the subsequent recapitalization of the Company, resulted from an alleged breach of fiduciary duties by the board of directors, and (ii) our senior management was allegedly unjustly enriched by the subsequent Option Grants. The plaintiff sought relief in the form of an order rescinding the Plan as approved by the shareholders at the Special Meeting, an order cancelling the Option Grants, and an award to plaintiff for his costs, including fees and disbursements of attorneys, experts and accountants. The parties settled the matter on December 17, 2018. The terms of the settlement require us to (i) rescind and cancel the Option Grants, with the exception of options that were already rescinded when certain individuals left the company in the last fiscal quarter of 2017, (ii) amend the Plan to add a provision establishing the maximum total annual equity compensation for non-employee directors and to seek stockholder approval of this amendment at the Company’s next annual meeting of stockholders, and (iii) proportionally adjust all share reserves and limitations in the Plan (and any other equity compensation plan for the company) in connection with any future split of the company’s stock during the next five years unless otherwise brought to and approved by stockholder vote. The Company is required to pay \$197,000 and this was fully accrued for in 2018.

*Fulfillium.* On April 20, 2017, Fulfillium, Inc. filed a complaint against ReShape Medical, Inc. (which the Company acquired in October 2017 and which is now a wholly owned subsidiary of the Company) in the U.S. District Court for the District of Delaware, which alleged misappropriation of trade secrets and infringement of two U.S. Patents (“Fulfillium I”). On July 28, 2017, ReShape Medical moved to dismiss both the trade secret claim and certain aspects of the patent infringement claim, and to transfer the litigation to the U.S. District Court for the Central District of California. On October 16, 2017, the Court granted ReShape Medical’s motion to dismiss the trade secret and willful infringement claims, and ordered the case transferred to the U.S. District Court for the Central District of California. Fulfillium twice amended its complaint, narrowing its original trade secret claim and adding further patent infringement claims and additional parties. On June 4, 2018, ReShape Medical filed a motion to dismiss the patent infringement claims for lack of standing, which the Court granted on July 5, 2018. On August 10, 2018, the Court dismissed without prejudice the trade secret claim for lack of subject matter jurisdiction and terminated the case. Fulfillium has appealed these dismissals and ReShape Medical has appealed the grant and denial of certain attorney fee awards. On July 20, 2018, Fulfillium filed a new complaint against ReShape Lifesciences, Inc. (and its wholly owned subsidiary ReShape Medical LLC) in the U.S. District Court for the Central District of California (“Fulfillium II”) reasserting the patent infringement claims asserted in Fulfillium I. On August 15, 2018, Fulfillium amended its complaint in Fulfillium II to reassert the trade secret misappropriation claim asserted in Fulfillium I against ReShape Medical LLC and others. On September 7, 2018, Fulfillium filed a complaint in California state court alleging the same trade secret misappropriation claim asserted in both Fulfillium I and Fulfillium II. On November 7, 2018, the Court dismissed the non-Company parties from Fulfillium II. On April 20, 2018, ReShape Medical filed Inter Partes Review (“IPR”) petitions with the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office (the “PTAB”) to have all claims of both of the originally asserted Fulfillium patents canceled as unpatentable over various combinations of prior art. On November 6, 2018, the PTAB denied those petitions. The parties held a mediation on April 9, 2019, but were unable to resolve the matter. The Company intends to continue to vigorously defend itself against Fulfillium’s claims. We currently are unable to estimate the losses or range of losses for these two matters where there is a reasonable possibility of a loss or it is probable that a loss may have been incurred.

On July 12, 2018, Alpha Capital Anstalt (“Alpha”) filed a complaint against the Company in the U.S. District Court for the Southern District of New York. In August 2017, Alpha acquired shares of the Company’s series B convertible preferred stock and warrants to purchase shares of the Company’s common stock in an underwritten public offering. Pursuant to the terms of the series B convertible preferred stock and warrants, the conversion price of the series B convertible preferred stock and exercise price of the warrants was subject to adjustment in the case of, among other things, dilutive issuances of securities by the Company. The complaint alleges breach of contract, claiming that the Company should have adjusted the conversion price of the series B convertible preferred stock and exercise price of the warrants to not less than \$420.00 per share, rather than the \$1,575.00 per share to which the Company actually adjusted such conversion price and exercise price, in connection with its registered direct offering of series D convertible preferred stock and warrants to purchase common stock that it completed and announced in April 2018. Alpha seeks declaratory relief, damages of not less than approximately \$3.6 million (less the proceeds of actual sales of the Company’s common stock made by Alpha) and attorneys’ fees. The Company believes the claims alleged are without merit and intends to vigorously protect and defend itself. However, we are currently unable to estimate a loss or range of loss for this matter.

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On July 26, 2018, Iroquois Capital Investment Group, LLC and Iroquois Master Fund, Ltd. filed a complaint against the Company in the U.S. District Court for the Southern District of New York, with substantially the same claims and seeking substantially the same relief as Alpha's complaint described above, except that Iroquois claims that the conversion price of the series D convertible preferred stock and exercise price of the warrants should have been adjusted to \$189.00 per share, and Iroquois is claiming damages estimated to exceed \$5 million. The Company believes the claims alleged are without merit and intends to vigorously protect and defend itself. However, we are currently unable to estimate a loss or range of loss for this matter

Except as disclosed in the foregoing paragraphs, the Company is not currently a party to any litigation and the Company is not aware of any pending or threatened litigation against it that could have a material adverse effect on the Company's business, operating results or financial condition. The medical device industry in which the Company operates is characterized by frequent claims and litigation, including claims regarding patent and other intellectual property rights as well as improper hiring practices. As a result, the Company may be involved in various legal proceedings from time to time.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**PART II.**

**ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

**Market for Our Common Stock**

Our common stock is traded on the OTCQB Market under the symbol RSL5. As of March 31, 2019, there were approximately 19 holders of record of our common stock.

The following table sets forth the high and low sales prices of our common stock as quoted on the NASDAQ Stock Market and OTC Markets for the periods indicated.

**Price Range of Common Stock**

	Price Range	
	High	Low
<b>Year Ended December 31, 2018</b>		
First Quarter	\$ 3,759.00	\$ 2,772.00
Second Quarter	\$ 1,512.00	\$ 288.40
Third Quarter	\$ 448.00	\$ 5.60
Fourth Quarter	\$ 8.40	\$ 0.17
<b>Year Ended December 31, 2017</b>		
First Quarter	\$ 63,861.00	\$ 3,675.00
Second Quarter	\$ 13,608.00	\$ 8,400.00
Third Quarter	\$ 10,920.00	\$ 3,360.00
Fourth Quarter	\$ 5,460.00	\$ 2,583.00

The closing price for our common stock as reported by the OTCQB Market on March 31, 2019 was \$0.24 per share.

**Securities Authorized for Issuance Under Equity Compensation Plans**

The information required by this Item regarding equity compensation plans is incorporated by reference to the information set forth in Part III, Item 12 of this Annual Report on Form 10-K.

**Unregistered Sales of Equity Securities**

During the period covered by this report, we did not sell any securities which were not registered under the Securities Act of 1933, as amended.

**Uses of Proceeds from Sale of Registered Securities**

None.

**Dividend Policy**

We have never paid cash dividends on our common stock. The board of directors presently intends to retain all earnings for use in our business and does not anticipate paying cash dividends in the foreseeable future. We do not have a dividend reinvestment plan or a direct stock purchase plan.

**Issuer Purchases of Equity Securities**

None.

**ITEM 6. SELECTED FINANCIAL DATA**

Not applicable.

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*Except for the historical information contained herein, the matters discussed in this "Management's Discussion and Analysis of Financial Condition and Results of Operations," and elsewhere in this Form 10-K are forward-looking statements that involve risks and uncertainties. The factors listed in Item 1A "Risk Factors," as well as any cautionary language in this Form 10-K, provide examples of risks, uncertainties and events that may cause our actual results to differ materially from those projected. Except as may be required by law, we undertake no obligation to update any forward-looking statement to reflect events after the date of this report.*

### Overview

We are a developer of minimally invasive medical devices that advance bariatric surgery to treat obesity and metabolic diseases. Our current portfolio includes the LAP-BAND® Adjustable Gastric Banding System and the ReShape Vest™, an investigational device, to help treat more patients with obesity.

In December 2018, we acquired from Apollo Endosurgery, Inc. ("Apollo") substantially all of the assets exclusively related to Apollo's Lap-Band product line and Apollo acquired from us substantially all of the assets exclusively related to the our ReShape Balloon product line ("Asset Purchase Agreement"). The assets and operating results of the ReShape Balloon product line prior to disposal have been reflected as discontinued operations in the Consolidated Financial Statements. As a result of our acquisition of the Lap-Band product line, we will no longer be actively marketing our ReShape vBloc product.

### Financial Overview

#### Results of Operations – Continuing Operations

*Revenue.* Revenue from continuing operations totaled \$0.6 million in both of the years ended December 31, 2018 and 2017. In 2018, revenue included sales of our recently acquired Lap-Band product of \$0.4 million and sales of our ReShape vBloc product of \$0.2 million. In 2017, revenue was comprised of \$0.3 million in sales of our ReShape vBloc product and \$0.3 million in other revenue related to custom development services based on our intellectual property portfolio that had been requested and contracted for by a third party.

*Cost of revenue.* Cost of revenue from continuing operations was \$0.2 million for the year ended December 31, 2018 compared to \$0.3 million for the year ended December 31, 2017. For 2018, cost of revenue was comprised of \$0.1 million related to Lap-Band product sales, and \$0.1 million related to sales of our ReShape vBloc product. In 2017, cost of revenue was comprised of \$0.2 million related to sales of our ReShape vBloc product and \$0.1 million related to cost of services in connection with the custom development.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses from continuing operations were \$19.3 million for the year ended December 31, 2018, compared to \$22.8 million for the year ended December 31, 2017. The reduction was primarily due to reduced headcount in 2018 in connection with a strategic realignment of our operations.

*Research and Development Expenses.* Research and development expenses from continuing operations were \$5.7 million for the year ended December 31, 2018 compared with \$5.4 million for the year ended December 31, 2017. The increase was primarily attributable to a full year of research and development activities associated with of our ReShape Vest, acquired with our acquisition of BarioSurg in May 2018. Our ReShape Vest product is in the early stages of development and is currently in an initial clinical trial stage.

*Goodwill Impairment.* The goodwill impairment of \$14.0 million for the year ended December 31, 2018 reflects the full write-down of the goodwill recorded in connection with our acquisition of BarioSurg, Inc. As discussed further in Note 8 to the Consolidated Financial Statements, we performed an impairment analysis due to the significant decline in our stock price following our registered direct securities offering in April 2018, which resulted in the impairment of goodwill.

*Warrants Expense.* Warrant expense of \$0.1 million for the year ended December 31, 2018 is primarily related to the change in fair value of certain warrants held by an institutional investor for which the exercise price was reduced as an inducement for the investor to exercise the warrants. For the year ended December 31, 2017 in connection with our public offering of series B convertible preferred stock in August 2017, we recorded \$4.4 million for the value of warrants issued to former investors as consideration for the waiver by each investor of their right to participate in future securities offerings by the Company.

*Net Interest Expense.* Interest expense was \$12,000 for the year ended December 31, 2018 compared with \$3,000 for the year ended December 31, 2017. In 2018, we recorded \$14,000 of accretion of interest expense on the net present value of the asset purchase consideration payable for our acquisition of the Lap-Band product line. Interest expense in both 2018 and 2017 was recorded net of an insignificant amount of interest income. We do not hold any investment securities in 2018 or 2017.

*Income tax benefit.* Income tax benefit from continuing operation was \$3.4 million and \$2.3 million for the years ended December 31, 2018 and 2017, respectively. The tax benefit recorded in 2018 is attributable to the losses for U.S. federal income tax purposes, which, effective with the enactment of the 2017 Tax Cuts and Jobs Act, have an unlimited carryforward period. The tax benefit in 2017 was primarily the result of the revaluation of our deferred income taxes upon enactment of the 2017 Tax Cuts and Jobs Act.

### **Results of Operations – Discontinued Operations**

Results of operations from discontinued operations reflect the activities of our Reshape Balloon product line, which we acquired as part of our acquisition of ReShape Medical, Inc. in October 2017 and sold in December 2018 in connection with our acquisition of the Lap-Band product line assets. Loss from discontinued operations was \$45.9 million and \$3.4 million for the years ended December 31, 2018 and 2017, respectively. The loss in 2018 includes an impairment charge of \$13.2 million for the full write-down of the goodwill recorded in connection with our acquisition of ReShape Medical. In addition, in connection with the determination of the fair value of the Lap-Band assets acquired, no value was assigned to the ReShape Balloon product line assets sold as projections updated during the fourth quarter of 2018 indicated negative cash flows. Accordingly, the loss from discontinued operations for the year ended December 31, 2018 includes an impairment charge of \$22.6 million for the full write-down of the ReShape Balloon product line assets disposed of. There was no income tax expense or benefit for discontinued operations.

### **Liquidity and Capital Resources**

We have financed our operations to date principally through the sale of equity securities and debt financing. During the years ended December 31, 2018 and 2017, we received aggregate net proceeds of \$33.2 million and \$34.5 million, respectively, from equity offerings and \$0.5 million and \$3.3 million, respectively, from the exercise of warrants to purchase common stock. As of December 31, 2018, we had \$5.5 million of cash and cash equivalents to fund operations into early 2019.

Our anticipated operations include plans to (i) integrate the sales and operations of the Company with the newly acquired Lap-Band product line in order to expand sales domestically and internationally as well as to obtain cost savings synergies, (ii) continue development of the ReShape Vest, (iii) seek opportunities to leverage our intellectual property portfolio and custom development services to provide third party sales and licensing opportunities, and (iv) explore and capitalize on synergistic opportunities to expand our portfolio and offer future minimally invasive treatments and therapies in the obesity continuum of care. The Company believes that it has the flexibility to manage the growth of its expenditures and operations depending on the amount of available cash flows, which could include reducing expenditures for marketing, clinical and product development activities. However, the Company will ultimately need to achieve sufficient revenues from product sales and obtain additional debt or equity financing to support its operations.

Management is currently pursuing various funding options, including seeking additional equity or debt financing as well as a strategic merger or other transaction to obtain additional funding to support the expansion of Lap-Band product sales and to continue the development of, and to successfully commercialize, the ReShape Vest. While the acquisition of Lap-Band product line does provide incremental revenues to the Company, the cost to support the European clinical trial of the ReShape Vest is expected to exceed revenues for the foreseeable future. While there can be no assurance that the Company will be successful in its efforts, the Company has a long history of raising equity financing to fund its development activities. Should the Company be unable to obtain adequate financing in the near

term, the Company's business, result of operations, liquidity and financial condition would be materially and negatively affected, and the Company would be unable to continue as a going concern. Additionally, there can be no assurance that, assuming the Company is able to strengthen its cash position, it will achieve sufficient revenue or profitable operations to continue as a going concern.

***Net Cash Used in Operating Activities - Continuing Operations***

Net cash used in operating activities from continuing operations was \$20.1 million and \$22.1 million for the years ended December 31, 2018 and 2017, respectively. Net cash used in operating activities from continuing operations was primarily the result of the loss from continuing operations in each year net of noncash items and changes in operating assets and liabilities.

***Net Cash Used in Investing Activities - Continuing Operations***

Net cash used in investing activities from continuing operations was \$10.3 million for the year ended December 31, 2018, as compared with \$2.0 million for the year ended December 31, 2017. Investing activities in 2018 reflect our acquisition of the Lap-Band product line, which included asset purchase consideration paid of \$10 million and transaction costs paid of \$0.3 million. Of the remaining \$7 million of asset purchase consideration, \$2 million is payable on the first anniversary of the closing date, \$2 million is payable on the second anniversary of the closing date and \$3 million is payable on the third anniversary of the closing date. In 2017, \$1.8 million of cash, net of cash acquired, was used as part of the consideration paid to acquire BarioSurg. Cash used for purchases of property and equipment was \$50,000 and \$0.1 million in 2018 and 2017, respectively.

***Net Cash Provided by Financing Activities from Continuing Operations***

Net cash provided by financing activities from continuing operations was \$33.2 million and \$37.8 million for the years ended December 31, 2018 and 2017, respectively. During the years ended December 31, 2018 and 2017, we received aggregate net proceeds of \$33.2 million and \$34.5 million, respectively, from equity offerings and \$0.5 million and \$3.3 million, respectively, from the exercise of warrants to purchase common stock. In connection with these equity transactions, we paid an aggregate of \$4.6 million and \$4.5 million of related transaction costs in 2018 and 2017, respectively. In 2018, we used cash of \$0.5 million to redeem 500 shares of our series D convertible preferred stock.

On March 29, 2019, we completed a private placement with two healthcare focused institutional investors for the sale of secured subordinated original issue discount convertible debentures for a purchase price of \$2 million. The debentures are due June 28, 2019 and have a face amount of \$2.2 million, reflecting a 10% original issue discount. At any time after June 28, 2019, if the debentures have not been repaid, subject to certain investor ownership limitations, the debentures will be convertible into shares of common stock at a conversion price equal to the lesser of \$0.33 and 80% of the average of the lowest two volume weighted average prices of the Company's common stock during the 20 trading days prior to conversion. As collateral for the Company's obligations under the debentures, the Company has granted the debenture holders a subordinated security interest in all of the assets of the Company and its subsidiary.

***Discontinued Operations***

Net cash used in operating activities of discontinued operations of \$7.4 million for the year ended December 31, 2018, reflects activities of the ReShape Balloon product line until its disposal on December 17, 2019. For the year ended December 31, 2017, net cash used in operating activities of \$2.4 million reflects activities since the October 2, 2017 acquisition of ReShape Medical, Inc. There were no investing or financing activities related to discontinued operations for the year ended December 31, 2018. For the year ended December 31, 2017, net cash used in investing activities for discontinued operations related to the cash portion of the purchase price for ReShape Medical, Inc. of \$5.0 million, net of \$0.6 million of cash acquired.

***Operating Capital and Capital Expenditure Requirements***

Our anticipated operations include plans to (i) integrate the sales and operations of the Company with the newly acquired Lap-Band product line; (ii) continue development of the ReShape Vest, (iii) seek opportunities to leverage the Company's intellectual property portfolio and custom development services to provide third party sales and licensing opportunities, and (iv) explore and capitalize on synergistic opportunities to expand our portfolio and offer future

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minimally invasive treatments and therapies in the obesity continuum of care. The Company believes that it has the flexibility to manage the growth of its expenditures and operations depending on the amount of available cash flows, which could include reducing expenditures for marketing, clinical and product development activities. However, the Company will ultimately need to achieve sufficient revenues from product sales and obtain additional equity or debt financing to support its operations.

Obtaining funds through the sale of additional equity and debt securities or the warrant holders' exercise of outstanding common stock warrants may result in dilution to our stockholders. If we raise additional funds through the issuance of debt securities, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. The sale of additional equity may require us to obtain approval from our stockholders to increase the number of shares of common stock we have authorized under our certificate of incorporation. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. If we are unable to obtain additional financing, we may be required to reduce the scope of, delay, or eliminate some or all of, our planned research, development and commercialization activities, which could materially harm our business. In addition, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to products or proprietary technologies, or grant licenses on terms that are not favorable.

Our forecast of the period of time through which our financial resources will be adequate to support our operations, the costs to complete development of products and the cost to commercialize our products are forward-looking statements and involve risks and uncertainties, and actual results could vary materially and negatively as a result of a number of factors, including the factors discussed in Part I, Item 1A, *Risk Factors*, of our Annual Report on Form 10-K. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

The Company's acquisition of the Lap-Band product line provides incremental revenues and does not require further product development. In order to continue the development of, and to successfully commercialize the Lap-Band and provide clinical support for the ReShape Vest, the Company's management is currently pursuing various funding options, including seeking additional equity or debt financing as well as a strategic merger or other transaction to obtain additional funding. The Company has a long history of raising equity financing to fund its development activities; however, there can be no assurance that the Company will continue to be successful in its efforts. Should the Company be unable to obtain adequate financing in the near term, the Company's business, result of operations, liquidity and financial condition would be materially and negatively affected, and the Company would be unable to continue as a going concern. Additionally, there can be no assurance that, assuming the Company is able to strengthen its cash position, it will achieve sufficient revenue or profitable operations to continue as a going concern. The consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

Because of the numerous risks and uncertainties associated with the development of medical devices, such as our ReShape Vest, we are unable to estimate the exact amounts of capital outlays and operating expenditures necessary to complete the development of the ReShape Vest or other additional products and successfully deliver a commercial product to the market. Our future capital requirements will depend on many factors, including, but not limited to, the following:

- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our ReShape Vest and any products that we may develop;
- the rate of market acceptance of our ReShape Vest and any other product candidates;
- the cost of filing and prosecuting patent applications and defending and enforcing our patent and other intellectual property rights;
- the cost of defending, in litigation or otherwise, any claims that we infringe third-party patent or other intellectual property rights;

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- the effect of competing products and market developments;
- the cost of explanting clinical devices;
- the terms and timing of any collaborative, licensing or other arrangements that we may establish;
- any revenue generated by sales of our Lap-Band, ReShape Vest or our future products;
- the scope, rate of progress, results and cost of our clinical trials and other research and development activities;
- the cost and timing of obtaining any further required regulatory approvals; and
- the extent to which we invest in products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

### **Off-balance-sheet Arrangements**

Since our inception, we have not engaged in any off-balance-sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities as defined by rules enacted by the SEC and FASB, and accordingly, no such arrangements are likely to have a current or future effect on our financial position, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

### **Critical Accounting Policies and Significant Judgments and Estimates**

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. Actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements included in Item 8 of this Annual Report on Form 10-K, we believe that the following accounting policies and estimates are most critical to a full understanding and evaluation of our reported financial results.

#### ***Revenue Recognition***

When we recognize revenue from the sale of our products, the amount of consideration we ultimately receive may vary depending upon the return terms and any sales rebates that we may offer, which are accounted for as variable consideration when estimating the amount of revenue to recognize. As discussed in Note 14 to the Consolidated Financial Statements, such variable consideration to date has not been material.

#### ***Goodwill and Long-Lived Assets***

We evaluate long-lived assets, including finite-lived intangible assets, for impairment by comparison of the carrying amounts to future net undiscounted cash flows expected to be generated by such assets when events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Should an impairment exist, the impairment loss would be measured based on the excess carrying value of the asset over the asset's fair value or estimates of future discounted cash flows.

For goodwill and indefinite-lived intangible assets, in-process research and development, we review for impairment annually and upon the occurrence of certain events as required by Accounting Standards Codification ("ASC") Topic 350, "Intangibles — Goodwill and Other." Goodwill and indefinite-lived intangible assets are tested at least annually for impairment and more frequently if events or changes in circumstances indicate that the asset might be impaired. We review goodwill for impairment by first assessing qualitative factors to determine whether it is more likely



than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test. If we are able to determine that it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, we would conclude that goodwill is not impaired. If the carrying amount of a reporting unit is zero or negative, the second step of the impairment test is performed to measure the amount of impairment loss, if any, when it is more likely than not that a goodwill impairment exists. In 2018, the Company recorded goodwill impairment of \$14.0 million included in continuing operations and \$13.2 million included in discontinued operations. There was no goodwill impairment recorded in 2017. In connection the Company's sale and disposal of its ReShape Balloon product line, the Company recorded an impairment charge of \$22.6 million for the full write-down of the ReShape Balloon product line assets. The Company did not identify any other impairments of indefinite-lived or finite-lived intangible assets in 2018 or 2017.

#### ***Research and Development Expenses***

We record the estimated costs of research and development activities performed by third party service providers based upon the estimated services provided but not yet invoiced and includes these costs in accrued expenses and other payables in the Consolidated Balance Sheets and within research and development expense in the consolidated statements of operations. We accrue for these costs based on factors such as estimates of the work completed and in accordance with agreements established with its third party service providers. As actual costs become known, the Company adjusts its accrued liabilities.

The Company's CRO arrangement generally requires payments in advance of services. Upon making a payment, the Company makes a determination as to the amount to record as a deferred charge and the amount of research and development expense. The amount of CRO related costs included in research and development expense each period is based upon the Company's estimate of the time period over which services will be performed, enrollment of patients, number of sites activated and level of effort to be expended. Any amount of advances paid in excess of expense recognized is included in Prepaid expenses and other current assets on the Consolidated Balance Sheets. If the actual timing of the CRO's performance of services or the level of effort varies from the Company's estimate, the amount of prepaid CRO expense is adjusted accordingly.

We make significant judgments and estimates in determining the accrued balance and any deferred charges in each reporting period. Our understanding of factors such as the status and timing of services performed, the number of patients enrolled and the rate of patient enrollment may vary from our estimates and could result in us reporting amounts that are too high or too low in any particular period.

#### ***Income Taxes***

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry-forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance for deferred income tax assets is recorded when it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The Company's policy is to classify interest and penalties related to income taxes as income tax expense in the consolidated statements of operations.

#### **Recent Accounting Pronouncements**

See Note 2 to our financial statements for a discussion of new accounting standards that have been adopted and those not yet adopted.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the shareholders and the Board of Directors of ReShape Lifesciences Inc.

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of ReShape Lifesciences Inc. and subsidiaries (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations, stockholders' equity, and cash flows, for each of the two years in the period ended December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

**Going Concern**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3 to the financial statements the Company is experiencing difficulty in generating sufficient revenues and cash flow to meet its obligations and sustain its operations, which raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are described in Note 3. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ DELOITTE & TOUCHE LLP

Minneapolis, Minnesota

May 16, 2019

We have served as the Company's auditor since 2006.

**RESHAPE LIFESCIENCES INC.**

**Consolidated Balance Sheets**

	<b>December 31,</b>	
	<b>2018</b>	<b>2017</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 5,547,745	\$ 10,163,208
Accounts receivable (net of allowance for bad debts of \$235,567 and \$155,872 at December 31, 2018 and December 31, 2017)	916,813	488,613
Inventory	984,735	1,968,546
Prepaid expenses and other current assets	1,269,741	467,783
Current assets of discontinued operations	—	848,566
Total current assets	8,719,034	13,936,716
Property and equipment, net	63,548	341,976
Goodwill	—	14,004,573
Other intangible assets, net	36,927,221	21,808,827
Other assets	562,863	990,015
Noncurrent assets of discontinued operations	—	37,622,442
Total assets	<u>\$ 46,272,666</u>	<u>\$ 88,704,549</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,626,545	\$ 1,088,271
Accrued and other liabilities	4,829,176	5,955,518
Asset purchase consideration payable, current	1,906,821	—
Total current liabilities	8,362,542	7,043,789
Asset purchase consideration payable, noncurrent	4,403,389	—
Deferred income taxes	1,844,297	5,292,291
Common stock warrant liability	—	1,600
Total liabilities	<u>14,610,228</u>	<u>12,337,680</u>
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, 5,000,000 shares authorized:		
Series B convertible preferred stock, \$0.01 par value; 159 and 6,055 shares issued and outstanding at December 31, 2018 and 2017, respectively	2	61
Series C convertible preferred stock, \$0.01 par value; 95,388 shares issued and outstanding at December 31, 2018 and 2017	954	954
Common stock, \$0.01 par value; 275,000,000 shares authorized at December 31, 2018 and 2017; 8,770,433 and 14,742 shares issued and outstanding at December 31, 2018 and 2017, respectively	87,704	147
Additional paid-in capital	450,563,689	411,125,061
Accumulated deficit	<u>(418,989,911)</u>	<u>(334,759,354)</u>
Total stockholders' equity	31,662,438	76,366,869
Total liabilities and stockholders' equity	<u>\$ 46,272,666</u>	<u>\$ 88,704,549</u>

See accompanying notes to consolidated financial statements.

**RESHAPE LIFESCIENCES INC.**  
**Consolidated Statements of Operations**

	Year Ended December 31,	
	2018	2017
<b>Revenue:</b>		
Product sales	\$ 606,710	\$ 319,160
Service and other revenue	—	250,000
Total revenue	<u>606,710</u>	<u>569,160</u>
<b>Cost of revenue:</b>		
Cost of goods sold	164,299	173,745
Cost of service and other revenue	—	159,531
Total cost of revenue	<u>164,299</u>	<u>333,276</u>
Gross profit	<u>442,411</u>	<u>235,884</u>
<b>Operating expenses:</b>		
Selling, general and administrative	19,261,680	22,848,922
Research and development	5,722,117	5,441,189
Goodwill impairment	14,004,573	—
Total operating expenses	<u>38,988,370</u>	<u>28,290,111</u>
Operating loss	<u>(38,545,959)</u>	<u>(28,054,227)</u>
<b>Other expense (income), net</b>		
Interest expense, net	12,378	2,808
Warrant expense	144,751	4,721,246
Other, net	10,643	652
Loss from continuing operations before income taxes	<u>(38,713,731)</u>	<u>(32,778,933)</u>
Income tax benefit	<u>3,446,708</u>	<u>2,314,611</u>
Loss from continuing operations	<u>(35,267,023)</u>	<u>(30,464,322)</u>
Loss from discontinued operations, net of tax	<u>(45,884,552)</u>	<u>(3,353,650)</u>
Net loss	<u>(81,151,575)</u>	<u>(33,817,972)</u>
Less: Down round adjustments for convertible preferred stock and warrants	<u>(3,078,982)</u>	<u>—</u>
Net loss attributable to common shareholders	<u>\$ (84,230,557)</u>	<u>\$ (33,817,972)</u>
<b>Net loss per share - basic and diluted:</b>		
Continuing operations	\$ (34.28)	\$ (5,803.84)
Discontinued operations	(41.03)	(638.91)
Net loss per share - basic and diluted	<u>\$ (75.31)</u>	<u>\$ (6,442.75)</u>
Shares used to compute basic and diluted net loss per share	<u>1,118,439</u>	<u>5,249</u>

See accompanying notes to consolidated financial statements.

**RESHAPE LIFESCIENCES INC.**
**Consolidated Statements of Stockholders' Equity**

	Series A Convertible Preferred Stock		Conditional Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series D Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
<b>Balance December 31, 2016</b>	—	\$ —	—	\$ —	—	\$ —	—	\$ —	—	\$ —	1,304	\$ 13	\$303,879,935	\$(300,941,382)	\$ 2,938,566
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(33,817,972)	(33,817,972)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	4,436,797	—	4,436,797
Issuance of convertible preferred stock, common stock and warrants in January 2017 public offering, net of issuance costs (Note 12)	12,531	125	—	—	—	—	—	—	—	—	581	6	16,493,773	—	16,493,904
Issuance of convertible preferred stock and common stock related to BarioSurg, Inc. acquisition (Note 3)	—	—	1,000,181	10,002	—	—	—	—	—	—	658	6	26,248,955	—	26,258,963
Issuance of convertible preferred stock and warrants in August 2017 public offering, net of issuance costs (Note 12)	—	—	—	—	20,000	200	—	—	—	—	—	—	17,980,039	—	17,980,239
Issuance of warrants to certain investors as consideration for their waiver of future securities offering participation rights (Note 13)	—	—	—	—	—	—	—	—	—	—	—	—	4,438,149	—	4,438,149
Issuance of convertible preferred stock and common stock related to ReShape Medical, Inc. acquisition (Note 12)	—	—	—	—	—	—	187,772	1,878	—	—	1,123	11	33,981,468	—	33,983,357
Conversions of convertible preferred stock into common stock	(12,531)	(125)	(1,000,181)	(10,002)	(13,945)	(139)	(92,384)	(924)	—	—	10,790	108	11,082	—	—
Issuance of common stock upon exercise of warrants	—	—	—	—	—	—	—	—	—	—	286	3	3,654,863	—	3,654,866
<b>Balance December 31, 2017</b>	—	—	—	—	6,055	61	95,388	954	—	—	14,742	147	411,125,061	(334,759,354)	76,366,869
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(81,151,575)	(81,151,575)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	3,097,806	—	3,097,806
Down round adjustments for convertible preferred stock and warrants	—	—	—	—	—	—	—	—	—	—	—	—	3,078,982	(3,078,982)	—
Institutional sale of convertible preferred stock and warrants in April 2018, net of issuance costs (Note 12)	—	—	—	—	—	—	—	—	6,000	60	—	—	5,081,128	—	5,081,188
Institutional sales of common stock and warrants in June, July, August and November 2018, net of issuance costs (Note 12)	—	—	—	—	—	—	—	—	—	—	692,041	6,920	14,309,416	—	14,316,336
Issuance of common stock and warrants in September 2018 public offering (Note 12)	—	—	—	—	—	—	—	—	—	—	83,493	835	445,825	—	446,660
Issuance of common stock and warrants in an at-the-market public offering, net of issuance costs (Note 12)	—	—	—	—	—	—	—	—	—	—	6,263,576	62,636	13,322,197	—	13,384,833
Redemption of convertible preferred stock	—	—	—	—	—	—	—	—	(500)	(5)	—	—	(499,995)	—	(500,000)
Conversions of convertible preferred stock into common stock	—	—	—	—	(5,896)	(59)	—	—	(5,500)	(55)	584,699	5,847	(5,733)	—	—
Issuance of common stock upon exercise of warrants, net of transaction costs	—	—	—	—	—	—	—	—	—	—	1,131,892	11,319	609,002	—	620,321
<b>Balance December 31, 2018</b>	—	\$ —	—	\$ —	159	\$ 2	95,388	\$ 954	—	\$ —	8,770,443	\$87,704	\$450,563,689	\$(418,989,911)	\$ 31,662,438

See accompanying notes to consolidated financial statements.

**RESHAPE LIFESCIENCES INC.**  
**Consolidated Statements of Cash Flows**

	<b>Year Ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (81,151,575)	\$ (33,817,972)
Loss from discontinued operations, net of tax	45,884,552	3,353,650
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	242,410	189,796
Provision for doubtful accounts	79,695	12,666
Deferred income taxes	(3,447,994)	(2,314,611)
Accretion of interest on asset purchase consideration payable	13,792	—
Stock-based compensation	3,097,806	4,436,797
Warrant expense	144,751	4,721,246
Goodwill impairment	14,004,573	—
Amortization of intangible assets	198,147	78,359
Change in operating assets and liabilities:		
Accounts receivable	(507,895)	28,103
Inventory	1,977,651	(178,968)
Prepaid expenses and other current assets	(801,958)	182,584
Other assets	998,679	212,274
Accounts payable	317,081	(223,435)
Accrued and other liabilities	(1,126,342)	1,180,236
<b>Net cash used in operating activities - continuing operations</b>	<b>(20,076,627)</b>	<b>(22,139,275)</b>
<b>Net cash used in operating activities - discontinued operations</b>	<b>(7,413,543)</b>	<b>(2,448,933)</b>
<b>Net cash used in operating activities</b>	<b>(27,490,170)</b>	<b>(24,588,208)</b>
<b>Cash flows from investing activities:</b>		
Acquisition of Lap-Band product line assets, including transaction costs	(10,278,807)	—
Acquisition of BarioSurg, Inc., net of cash acquired, excluding transaction costs	—	(1,848,720)
Purchases of property and equipment	(49,579)	(137,123)
<b>Net cash used in investing activities - continuing operations</b>	<b>(10,328,386)</b>	<b>(1,985,843)</b>
<b>Net cash used in investing activities - discontinued operations</b>	<b>—</b>	<b>(4,381,847)</b>
<b>Net cash used in investing activities</b>	<b>(10,328,386)</b>	<b>(6,367,690)</b>
<b>Cash flows from financing activities:</b>		
Proceeds from warrants exercised	513,136	3,334,176
Proceeds from sale and issuance of equity securities	37,745,233	38,999,148
Payments of equity issuance costs	(4,555,276)	(4,525,005)
Preferred stock redemption	(500,000)	—
<b>Net cash provided by financing activities - continuing operations</b>	<b>33,203,093</b>	<b>37,808,319</b>
<b>Net cash provided by financing activities - discontinued operations</b>	<b>—</b>	<b>—</b>
<b>Net cash provided by financing activities</b>	<b>33,203,093</b>	<b>37,808,319</b>
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>(4,615,463)</b>	<b>6,852,421</b>
<b>Cash and cash equivalents at beginning of year</b>	<b>10,163,208</b>	<b>3,310,787</b>
<b>Cash and cash equivalents at end of year</b>	<b>\$ 5,547,745</b>	<b>\$ 10,163,208</b>
<b>Noncash investing and financing activities:</b>		
Acquisition of Lap-Band product line assets, asset purchase consideration payable	\$ 6,296,418	\$ —
Down round adjustment for convertible preferred stock and warrants	3,078,982	—
Conversion of convertible preferred shares to common stock	114	11,190
Issuance of convertible preferred shares and common shares for acquisitions - continuing operations	—	26,258,963
Issuance of convertible preferred shares and common shares for acquisitions - discontinued operations	—	33,983,357

See accompanying notes to consolidated financial statements.



**ReShape Lifesciences Inc.**

**Notes to Consolidated Financial Statements**

**(1) Description of the Business and Risks and Uncertainties**

*Description of Business*

ReShape Lifesciences Inc. (the “Company”) was originally incorporated in the state of Minnesota in December 2002 and reincorporated in the state of Delaware in July 2004. The Company is headquartered in San Clemente, California. The Company is a developer of minimally invasive medical devices that advance bariatric surgery to treat obesity and metabolic diseases. The Company’s current portfolio includes the LAP-BAND® Adjustable Gastric Banding System and the ReShape Vest™, an investigational device, to help treat more patients with obesity.

EnteroMedics Europe Sàrl (“EnteroMedics Europe”), a wholly owned subsidiary of the Company, was formed in Switzerland in January 2006. EnteroMedics Europe was established as a means to conduct clinical trials in Switzerland. The functional currency of EnteroMedics Europe is the U.S. Dollar.

*Risks and Uncertainties*

The Company continues to devote significant resources to developing its product technology, commercialization activities and raising capital. These activities are subject to significant risks and uncertainties, including the ability to obtain additional financing, and there can be no assurance that the Company will be successful in obtaining additional financing on favorable terms, or at all. If adequate funds are not available, the Company may have to further reduce its cost structure until financing is obtained and/or delay development or commercialization of products or license to third parties the rights to commercialize products or technologies that the Company would otherwise seek to commercialize. Refer to Note 3 for additional information about the Company’s liquidity and management’s plans.

The medical device industry is characterized by frequent and extensive litigation and administrative proceedings over patent and other intellectual property rights. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often difficult to predict, and the outcome may be uncertain until the court has entered final judgment and all appeals are exhausted. The Company’s competitors may assert that its products or the use of the Company’s products are covered by U.S. or foreign patents held by them. Refer to Note 11 for additional information about contingencies and litigation matters.

**(2) Summary of Significant Accounting Policies**

*Basis of Presentation*

The Company has prepared the accompanying consolidated financial statements in conformity with accounting principles generally accepted in the United States of America (“GAAP”).

Certain reclassifications have been made to previously reported amounts to conform to the current presentation of interest expense, which is net of immaterial amounts of interest income, and warrant expense, which includes immaterial amounts of change in fair value of warrant liability.

*Reverse Stock Splits*

During 2018, the Company’s board of directors and stockholders approved the following reverse stock splits:

- 1-for-15 reverse split of the Company’s outstanding common stock that became effective after the close of market on June 1, 2018.
- 1-for-140 reverse split of the Company’s outstanding common stock that became effective after the close of market on November 7, 2018.

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In connection with the reverse stock splits, proportional adjustments were made to the number of shares of common stock issuable upon exercise or conversion, and the per share exercise or conversion price, of the Company's outstanding warrants, stock options and convertible preferred stock, in each case in accordance with their terms. Neither of the reverse stock splits altered the par value of the Company's common stock or preferred stock or reduced the number of common or preferred shares authorized by the Company's certificate of incorporation. All share and per-share amounts have been retroactively adjusted to reflect the reverse stock splits for all periods presented.

### ***Principles of Consolidation***

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany transactions and accounts have been eliminated in consolidation.

### ***Use of Estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

### ***Discontinued Operations***

The assets and operating results of the ReShape Balloon product line prior to disposal have been reflected as discontinued operations in the Consolidated Financial Statements (see Note 5). In addition, the cash flows associated with discontinued operations are presented separately in the accompanying Consolidated Statements of Cash Flows. Unless otherwise noted, amounts in these Notes to the Consolidated Financial Statements exclude amounts attributable to discontinued operations.

### ***Cash and Cash Equivalents***

The Company considers highly liquid investments generally with maturities of 90 days or less when purchased to be cash equivalents. Cash equivalents are stated at cost, which approximates market value. The Company's cash equivalents are primarily in money market funds and certificates of deposit. The Company deposits its cash and cash equivalents in high-quality credit institutions.

### ***Inventory***

The Company accounts for inventory at the lower of cost or market and records any noncurrent inventory within other assets in the Consolidated Balance Sheets. The Company establishes inventory reserves for obsolescence based upon projected sales and for defect based upon specific identification of defective or unsalable units.

### ***Property and Equipment, Net***

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation of property and equipment is computed using the straight-line method over their estimated useful lives of five to seven years for furniture and equipment and three to five years for computer hardware and software. Leasehold improvements are amortized on a straight-line basis over the lesser of their useful life or the term of the lease. Upon retirement or sale, the cost and related accumulated depreciation or amortization are removed from the Consolidated Balance Sheets and the resulting gain or loss is reflected in the Consolidated Statements of Operations. Repairs and maintenance are expensed as incurred.

### ***Goodwill and Other Intangible Assets***

Goodwill represents the excess of the cost of an acquired business over the fair value of the identifiable tangible and intangible assets acquired and liabilities assumed in a business combination.

Indefinite-lived intangible assets relate to in-process research and development ("IPR&D") acquired in business combinations. The estimated fair values of IPR&D projects acquired in a business combination which have not reached technological feasibility are capitalized and accounted for as indefinite-lived intangible assets until completion or

abandonment of the projects. In accordance with guidance within Financial Accounting Standards Board (FASB) Accounting Standards Codification (“ASC”) 350 “Intangibles - Goodwill and Other,” goodwill and identifiable intangible assets with indefinite lives are not subject to amortization but must be evaluated for impairment.

#### ***Impairment of Goodwill and Long-Lived Assets***

Goodwill and indefinite-lived intangible assets are reviewed for impairment annually in the fourth quarter of each fiscal year or whenever an event occurs or circumstances change that would indicate that the carrying amount may be impaired. For purposes of impairment testing, the Company has identified one reporting unit as defined within ASC 350 “Intangibles – Goodwill and Other.” The Company compares the estimated fair value of the reporting unit to the carrying amount, including existing goodwill. If the carrying value of the reporting unit exceeds its estimated fair value, then the Company measures the amount of the impairment loss by comparing the implied fair value of goodwill to its carrying value. See Note 8 for additional information.

The Company evaluates long-lived assets under the provisions of ASC 360 “Property, Plant, and Equipment” which addresses financial accounting and reporting for the impairment of long-lived assets and for long-lived assets to be disposed of. For purposes of assessing the recoverability of long-lived assets, the Company has one asset group which includes all assets of the Company. For assets to be held and used, the Company compares the carrying amounts to future net undiscounted cash flows expected to be generated by such assets when events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Should an impairment exist, the impairment loss would be measured based on the excess carrying value of the assets over the assets’ fair value or estimates of future discounted cash flows.

#### ***Income Taxes***

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry-forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance for deferred income tax assets is recorded when it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The Company’s policy is to classify interest and penalties related to income taxes as income tax expense in the consolidated statements of operations.

#### ***Comprehensive Loss***

Comprehensive loss is defined as the change in equity of a company during a period from transactions and other events and circumstances excluding transactions resulting from distributions to owners. As there was no other comprehensive income or loss for the years ended December 31, 2018 and 2017, reported net loss and comprehensive loss were the same.

#### ***Equity***

Certain issuances of the Company’s convertible preferred stock and warrants classified within equity contain non-standard down round features that result in the strike price being reduced on the basis of the pricing of future equity offerings. The value of the effect of the down round feature when it is triggered is recorded similar to a dividend and as a numerator adjustment in the basic earnings per share calculation.

#### ***Revenue Recognition***

The Company recognizes revenue when it satisfies a performance obligation by transferring control of the promised goods or services to its customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services. Product sales consist of a single performance obligation that the Company satisfies at a point in time. The Company recognizes product revenue when the following events have occurred: (a) the Company has transferred physical possession of the products, (b) the Company has a present right to

payment, (c) the customer has legal title to the products, and (d) the customer bears significant risks and rewards of ownership of the products.

For the Company's Lap-Band product, these criteria are met under the agreements with most customers upon product shipment. This includes sales to distributors, who sell the products to their customers, take title to the products and assume all risks of ownership at the time of shipment. Distributors are obligated to pay within specified terms regardless of when, if ever, they sell the products. For the Company's ReShape vBloc product, these criteria were met when the product was implanted in the patient. Refer to Note 14 for additional information about the Company's products and contractual arrangements.

Taxes collected from customers and remitted to governmental authorities are accounted for on a net basis. Accordingly, such amounts are excluded from revenues. Amounts billed to customers related to shipping and handling are included in revenues. Shipping and handling costs related to revenue producing activities are included in cost of sales.

#### ***Research and Development Expenses***

Research and development expenses consist of costs incurred to further the Company's research and development activities, including product development, clinical trial expenses, quality assurance, regulatory expenses, payroll and other personnel expenses, materials and consulting costs. Certain of these activities, such as pre-clinical studies and clinical trials, may be conducted by third party service providers at the direction of the Company. In addition, during 2018, the Company entered into an arrangement with a Contract Research Organization ("CRO") under which the CRO performs and manages research and development activities on the Company's behalf.

The Company records the estimated costs of research and development activities performed by third party service providers based upon the estimated services provided but not yet invoiced and includes these costs in accrued expenses and other payables in the Consolidated Balance Sheets and within Research and Development expense in the Consolidated Statements of Operations. The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with agreements established with its third party service providers. As actual costs become known, the Company adjusts its accrued liabilities.

The Company's CRO arrangement generally requires payments in advance of services. Upon making a payment, the Company makes a determination as to the amount to record as a deferred charge and the amount of research and development expense. The amount of CRO related costs included in research and development expense each period is based upon the Company's estimate of the time period over which services will be performed, enrollment of patients, number of sites activated and level of effort to be expended. Any amount of advances paid in excess of expense recognized is included in Prepaid expenses and other current assets on the Consolidated Balance Sheets. If the actual timing of the CRO's performance of services or the level of effort varies from the Company's estimate, the amount of prepaid CRO expense is adjusted accordingly.

#### ***Patent Costs***

Costs associated with the submission of a patent application are expensed as incurred given the uncertainty of the patents resulting in probable future economic benefits to the Company. Patent-related legal expenses included in selling, general and administrative costs were \$257,000 and \$305,000 for the years ended December 31, 2018 and 2017, respectively.

#### ***Stock-Based Compensation***

The Company applies ASC 718 Compensation — Stock Compensation and accordingly records compensation expense for stock options over the vesting or service period using the fair value on the date of grant, as calculated by the Company using the Black-Scholes model. The Company's stock-based compensation plans are more fully described in Note 16.

### ***Net Loss Per Share***

Basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is based on the weighted-average common shares outstanding during the period plus dilutive potential common shares calculated using the treasury stock method. Such potentially dilutive shares are excluded when the effect would be to reduce a net loss per share. For purposes of basic and diluted per share computations, loss from continuing operations and net loss are reduced by the down round adjustments for convertible preferred stock and warrants.

The following table sets forth the potential shares of common stock that are not included in the calculation of diluted net loss per share because to do so would be anti-dilutive as of the end of each period presented:

	December 31,	
	2018	2017
Stock options outstanding	4,225	1,826
Common shares underlying convertible preferred stock	131,743	5,797
Warrants to purchase common stock	15,304,722	6,814

### ***Concentration of Credit Risk***

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. Cash and cash equivalents are primarily deposited in demand and money market accounts. At times, such deposits may be in excess of insured limits. Investments in money market funds are not considered to be bank deposits and are not insured or guaranteed by the federal deposit insurance company or other government agency. These money market funds seek to preserve the value of the investment at \$1.00 per share; however, it is possible to lose money investing in these funds. The Company has not experienced any losses on its deposits of cash and cash equivalents.

### ***Fair Value of Financial Instruments***

The carrying amounts of the Company's financial instruments, including cash equivalents, accounts receivable, accounts payable and certain accrued and other liabilities approximate fair value due to their short-term maturities. For additional information, see Note 4 regarding the asset purchase consideration payable as of December 31, 2018 and Note 13 regarding the common stock warrant liability as of December 31, 2017.

### ***Segment Reporting***

Operating segments are defined as components of an enterprise for which discrete financial information is available that is evaluated regularly by the chief operating decision maker ("CODM") in deciding how to allocate resources and in assessing performance. The Company's CODM is the Chief Executive Officer.

Under the provisions of ASC 280, "Segment Reporting," the Company has determined that it has three operating segments: the Lap-Band segment, the ReShape Vest segment, and the ReShape vBloc Segment. The Lap-Band is an FDA approved minimally invasive treatment designed to treat severe obesity. The ReShape Vest is an investigational, minimally invasive, laparoscopically implanted medical device being studied for weight loss in morbidly obese adults with a BMI of at least 35. ReShape vBloc uses vBloc Therapy to block the gastrointestinal effects of the vagus nerve using high-frequency, low-energy electrical impulses to intermittently interrupt naturally occurring neural impulses on the vagus nerve between the brain and the digestive system. The Company is not currently actively marketing ReShape vBloc.

The Company's CODM evaluates segment performance based on gross margin. Gross profit for the Lap-Band segment was \$373,008 and \$0 for years ended December 31, 2018 and 2017, respectively. Gross profit for the ReShape vBloc product was \$69,403 and \$145,415 for years ended December 31, 2018 and 2017, respectively. In addition, there was \$90,469 of non-segment gross profit from other revenue for the year ended December 31, 2017. There were no revenues or gross profit recorded for the ReShape Vest operating segment in 2018 or 2017 because the ReShape Vest is still in the development stage. Operating segment revenues for Lap-Band and ReShape vBloc are reported in Note 14.

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The Company's CODM does not use operating segment assets information to allocate resources or to assess performance of the operating segments and thus total segment assets have not been disclosed.

### ***Recent Accounting Pronouncements***

New accounting standards adopted by the Company in 2018 are discussed below or in the related notes, where appropriate.

In May 2014, the FASB issued Accounting Standards Update, or ASU, 2014-09, Revenue from Contracts with Customers ("ASC Topic 606"), which amends the guidance for accounting for revenue from contracts with customers. This ASU supersedes the revenue recognition requirements in ASC Topic 605, Revenue Recognition, and creates a new ASC Topic 606, Revenue from Contracts with Customers. In 2015, 2016 and 2017, the FASB issued additional ASUs related to ASC Topic 606, including ASUs 2015-14, 2016-08, 2016-10, 2016-12, 2016-20, 2017-13, 2017-14, that delayed the effective date of and clarified various aspects of the new guidance, including principal versus agent considerations, identifying performance obligations, and licensing. The Company adopted the standard on January 1, 2018 using the modified retrospective method applied to those contracts which were not completed as of December 31, 2017. Results for reporting periods beginning after January 1, 2018 are presented under Topic 606, while prior-period amounts have not been retrospectively adjusted and continue to be reported in accordance with Topic 605, Revenue Recognition. Based upon the Company's contracts which were not completed as of December 31, 2017, the Company was not required to make an adjustment to the opening balance of retained earnings as of January 1, 2018. See Note 14 for further discussion.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments, which clarifies the classification of certain cash receipts and cash payments in the statements of cash flow to eliminate the diversity in practice related to eight specific cash flow issues. This guidance is effective for fiscal years and interim periods within those years beginning after December 15, 2017, with early adoption permitted. The Company adopted this guidance effective January 1, 2018. The adoption of this guidance had no effect on the Company's consolidated financial statements and disclosures.

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash, which requires the presentation of changes in restricted cash or restricted cash equivalents on the statement of cash flows. This guidance was effective for the fiscal years and interim periods within those years beginning after December 15, 2017, with early adoption permitted. The adoption of this guidance had no effect on the Company's Consolidated Statements of Cash Flows.

In January 2017 FASB issued ASU No. 2017-04 Intangibles-Goodwill and Other (Topic 350) Simplifying the Test for Goodwill Impairment. The guidance removes step two of the goodwill impairment test, which requires a hypothetical purchase price allocation. A goodwill impairment will now be the amount by which a reporting unit's carrying value exceeds its fair value, not to exceed the carrying amount of goodwill. Entities will continue to have the option to perform a qualitative assessment to determine if a quantitative impairment test is necessary. The amendments in this update are required for public business entities in fiscal years beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company adopted the standard during the second quarter of 2018. Please refer to Note 8 for further discussion.

In May 2017, the FASB issued ASU No. 2017-09, Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting, which provides guidance on the types of changes to the terms and conditions of share-based payment awards to which an entity would be required to apply modification accounting. Specifically, an entity would not apply modification accounting if the fair value, vesting conditions and classification of the awards are the same immediately before and after the modification. This guidance is effective for fiscal years and interim periods within those years beginning after December 15, 2017, with early adoption permitted. The Company adopted this guidance effective January 1, 2018. The adoption of this guidance had no effect on the Company's consolidated financial statements and disclosures.

In January 2017, the FASB issued ASU 2017-01, Business Combinations: Clarifying the Definition of a Business. The amendment clarifies the definition of a business and provides a screen to determine when an integrated set of assets and activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is

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not a business. The guidance was effective for annual periods beginning after December 15, 2017, including interim periods within those periods.

In March 2018, FASB issued ASU No. 2018-05, Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118. The ASU updates the income tax accounting in U.S. GAAP to reflect the SEC interpretive guidance released on December 22, 2017, when the legislation referred to as the Tax Cuts and Jobs Act (the "2017 Tax Act") was signed into law. We have adopted this ASU, as further discussed in Note 15 – Income Taxes.

New accounting standards not yet adopted are discussed below.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842) in order to increase transparency and comparability among organizations by, and among other provisions, recognizing lease assets and lease liabilities on the balance sheet for those leases classified as operating leases under previous GAAP. For public companies, ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 (including interim periods within those periods) using a modified retrospective approach and early adoption is permitted. In transition, entities may also elect a package of practical expedients that must be applied in its entirety to all leases commencing before the adoption date, unless the lease is modified, and permits entities to not reassess (a) the existence of a lease, (b) lease classification or (c) determination of initial direct costs, as of the adoption date, which effectively allows entities to carryforward accounting conclusions under previous GAAP. In July 2018, the FASB issued ASU 2018-11, Leases (Topic 842): Targeted Improvements, which provides entities an optional transition method to apply the guidance under Topic 842 as of the adoption date, rather than as of the earliest period presented. The Company adopted Topic 842 on January 1, 2019, using the optional transition method to apply the new guidance as of January 1, 2019, rather than as of the earliest period presented, and elected the package of practical expedients described above. On the date of adoption, the Company recorded a right-of-use asset and corresponding lease liability of approximately \$1 million on its balance sheet primarily related to the operating lease agreement for its corporate headquarters.

In June 2018, the FASB issued ASU No. 2018-07, Compensation – Stock Compensation (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting, which is intended to simplify the accounting for nonemployee share-based payment transactions by expanding the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The guidance is effective for fiscal years and interim periods within those years beginning after December 15, 2018, with early adoption permitted. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements as there were no share-based payment transactions with nonemployees in 2018 and such transactions in prior years, all of which had an established measurement date, were not material.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820) – Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement, which modifies the disclosure requirements on fair value measurements and is intended to improve the effectiveness of disclosures, including the consideration of costs and benefits. The guidance is effective for the fiscal years and interim periods within those years beginning after January 1, 2020. Early adoption is permitted, and an entity is permitted to early adopt any removed or modified disclosures and delay adoption of additional disclosures until their effective date. The Company is evaluating the effects of ASU 2018-13 on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-15 Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40), Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract. The amendments in this update align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). The ASU is effective for the Company on January 1, 2020. Early adoption of the ASU is permitted. The Company is evaluating the effects of ASU 2018-15 on its consolidated financial statements.

Various other accounting standards and interpretations have been issued with 2019 effective dates and effective dates subsequent to December 31, 2018. The Company has evaluated the recently issued accounting pronouncements that are currently effective or will be effective in 2019 and believe that none of them have had or will have a material effect on the Company's financial position, results of operations or cash flows.

### **(3) Liquidity and Management's Plans**

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. The Company currently is not generating revenue from operations that is significant relative to its level of operating expenses, and does not anticipate generating revenue sufficient to offset operating costs in the short-term to mid-term. The Company's history of operating losses, limited cash resources and lack of certainty regarding obtaining significant third-party reimbursement for its products, raise substantial doubt about its ability to continue as a going concern. During the years ended December 31, 2018 and 2017, the Company received aggregate net proceeds of \$33.2 million and \$34.5 million, respectively, from equity offerings and \$0.5 million and \$3.3 million, respectively, from the exercise of warrants to purchase common stock. Refer to Note 12 for detailed information about equity offerings and warrants. As of December 31, 2018, the Company had \$5.5 million of cash and cash equivalents to fund its operations into early 2019.

The Company's anticipated operations include plans to (i) integrate the sales and operations of the Company with the newly acquired Lap-Band product line; (ii) continue development of the ReShape Vest, (iii) seek opportunities to leverage the Company's intellectual property portfolio and custom development services to provide third party sales and licensing opportunities, and (iv) explore and capitalize on synergistic opportunities to expand our portfolio and offer future minimally invasive treatments and therapies in the obesity continuum of care. The Company believes that it has the flexibility to manage the growth of its expenditures and operations depending on the amount of available cash flows, which could include reducing expenditures for marketing, clinical and product development activities. However, the Company will ultimately need to achieve sufficient revenues from product sales and obtain additional equity or debt financing to support its operations.

Management is currently pursuing various funding options, including seeking additional equity or debt financing as well as a strategic merger or other transaction to obtain additional funding to support the expansion of Lap-Band product sales and to continue the development of, and to successfully commercialize, the ReShape Vest. While the acquisition of Lap-Band product line does provide incremental revenues to the Company, the cost to support the European clinical trial of the ReShape Vest is expected to exceed revenues for the foreseeable future. While there can be no assurance that the Company will be successful in its efforts, the Company has a long history of raising equity financing to fund its development activities. Should the Company be unable to obtain adequate financing in the near term, the Company's business, result of operations, liquidity and financial condition would be materially and negatively affected, and the Company would be unable to continue as a going concern. Additionally, there can be no assurance that, assuming the Company is able to strengthen its cash position, it will achieve sufficient revenue or profitable operations to continue as a going concern.

### **(4) Acquisitions**

#### ***Lap-Band Product Line Assets***

On December 17, 2018, the Company acquired from Apollo Endosurgery, Inc. ("Apollo") substantially all of the assets exclusively related to Apollo's Lap-Band product line and Apollo acquired from the Company substantially all of the assets exclusively related to the Company's ReShape Balloon product line ("Asset Purchase Agreement"). In addition to the transfer to Apollo of the ReShape Balloon product line assets, the Company is required to pay Apollo cash consideration of \$17 million, of which \$10 million was paid at the closing of the transaction, \$2 million is payable on the first anniversary of the closing date, \$2 million is payable on the second anniversary of the closing date and \$3 million is payable on the third anniversary of the closing date. Pursuant to a transition services agreement, supply agreement and distribution agreement, Apollo will manufacture the Lap-Band product for the Company for up to two years, serve as the Company's distributor of the Lap-Band product outside of the United States for up to one year and provide other specified services.

The Company evaluated the Lap-Band product line asset acquisition under the guidance of ASU 2017-01, "Clarifying the Definition of a Business" and concluded that the group of assets acquired did not meet the definition of a business. Accordingly, the Lap-Band product line asset purchase was accounted for as an asset acquisition and the assets acquired were recorded at their relative fair values during the fourth quarter of 2018. The disposal of the Reshape Balloon product line assets has been accounted for as a discontinued operation.



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The total transaction cost for the assets acquired was comprised of the net present value of the consideration transferred plus the transaction costs. The Company determined that the ReShape Balloon product line assets transferred as part of the Lap-Band product line purchase transaction had no value, as management's projections of the ReShape Balloon product line as of the transaction date indicated negative cash flows. See Note 5 for additional information regarding the sale to Apollo of the Reshape Balloon product line.

Asset purchase consideration paid at closing	\$ 10,000,000
Aggregate asset purchase consideration payable	7,000,000
Adjustment to net present value of asset purchase consideration payable	(703,582)
Present value of asset purchase consideration	16,296,418
Asset purchase transaction costs	500,000
Fair value of ReShape Balloon product line assets transferred	—
Total transaction cost	<u>\$ 16,796,418</u>

The Company has granted Apollo a security interest in substantially all of the Company's assets as security for the payment and performance when due of all of its obligations under the Asset Purchase Agreement, including the remaining asset purchase consideration. The security interest will be terminated upon the earlier of the date the Company pays the asset purchase consideration to Apollo in full or completes an equity financing raising gross proceeds of at least \$15 million. The net present value of the secured asset purchase consideration payable was determined using a discount rate of 5.1%. At December 31, 2018, the aggregate carrying value of the current and noncurrent asset purchase consideration payable of \$6,310,210, as adjusted for accretion of interest of \$13,792, approximates fair value.

Under the asset acquisition method of accounting, the total transaction cost is allocated to the relative fair values of the assets acquired. The table below represents the allocation of the relative fair values of the Lap-Band product line tangible and intangible assets acquired as of the December 17, 2018 acquisition date.

Developed technology/know-how	\$ 14,361,732
Trademarks	954,809
Inventory	993,840
Fixed assets	486,037
Total transaction cost	<u>\$ 16,796,418</u>

Apollo retained all other working capital associated with the Lap-Band product line, including accounts receivable, accounts payable and certain accrued and other liabilities arising from operations before the closing of the Apollo transaction, and there was no transfer of workforce. The Lap-Band related fixed assets have been included in Other assets in the Consolidated Balance Sheet as the Company will not take possession of the fixed assets until the expiration of the transition services and supply agreements.

The Company used the income approach valuation technique to measure the fair value of the intangible assets, based on the present value of their future economic benefits reflecting current market expectations. Specifically, the developed technology/know-how was valued using a multi-period excess earnings method and the relief from royalty method was used to value the trademark. The assumptions used in these fair value measurements are not observable in active markets and thus represent Level 3 fair value measurements.

***BarioSurg, Inc.***

On May 22, 2017, the Company acquired all of the ownership interests of BarioSurg, Inc. ("BarioSurg"), a company developing the Gastric Vest System (rebranded "ReShape Vest" subsequent to the acquisition), an investigational, minimally invasive, laparoscopically implanted medical device being studied for weight loss in obese and morbidly obese patients. The consideration paid by the Company of \$28.3 million Surg consisted of: (i) \$2.0 million in cash; (ii) 658 shares of the Company's common stock; and (iii) 1,000,181 shares of newly created conditional convertible preferred stock, par value \$0.01 per share ("Conditional Preferred Stock"). The aggregate of the equity consideration was valued \$26.3 million. The valuation of the equity consideration took into account (i) the conversion ratio of the conditional convertible preferred stock, (ii) the closing prices of the Company's common stock on the NASDAQ Stock Market on the date the transaction was announced, and (iii) a 19% discount for lack of marketability related to the shares issued in the transaction. Transaction related expenses, excluded from the acquisition cost, were

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\$454,000 and were expensed as incurred. Refer to Note 12 for additional information regarding the equity securities issued in connection with the BarioSurg acquisition.

The acquisition was accounted for as a business combination. Tangible and intangible assets acquired were recorded based on their estimated fair values at the acquisition date. The excess of the purchase price over the fair value of net assets acquired was recorded to goodwill. The final determination of fair values was completed during the second quarter of 2018 and did not result in any adjustments. The following table summarizes the fair values of the assets acquired and liabilities assumed:

Cash	\$	151,280
Property and equipment		3,000
Goodwill		14,004,573
In Process Research & Development		20,720,939
Trademarks/tradenames		1,090,363
Covenant not to compete		75,884
Other assets		5,826
Current liabilities assumed		(186,000)
Deferred income tax liability		(7,606,902)
Net assets acquired	\$	<u>28,258,963</u>

In-process research and development (“IPR&D”) consists of the ReShape Vest, which has not yet been clinically tested in the United States and has not yet been approved by the FDA. Acquired IPR&D assets are initially recognized at fair value and are classified as indefinite-lived assets until the successful completion or abandonment of the associated research and development efforts. The value assigned to IPR&D was determined by estimating the net cash flows from the ReShape Vest development project and discounting the net cash flows to their present value. During the development period, this asset will not be amortized as charges to earnings; instead, this asset will be subject to periodic impairment testing. Upon successful completion of the development process for the acquired IPR&D, the asset would then be considered a finite-lived intangible asset and amortization will commence. Trademarks/tradenames were valued using the relief from royalty method. The covenant not to compete was valued using the comparative business valuation method-income approach. See Note 9 for additional information regarding other intangible assets and amortization periods.

The amount of goodwill relative to identifiable intangible assets at the acquisition date related to several factors, including (i) potential synergies related to market opportunities for multiple product offerings; (ii) future technology; and (iii) initial relationships and awareness of the gastric vest. During the second quarter of 2018, the Company recorded an impairment charge of \$14.0 million for the full write-down of the goodwill recorded in connection with the BarioSurg acquisition. Refer to Note 8 for additional information regarding evaluation of goodwill for impairment.

The result of operations of BarioSurg have been included in the accompanying consolidated financial statements from the date of acquisition. For the period from May 22, 2017 through December 31, 2017, BarioSurg had revenues of zero and a loss of \$832,000. Pro forma results have not been presented as the effect of pro forma adjustments in 2017, primarily related to a full year of intangible asset amortization, are not material in relation to the consolidated financial statements of the Company. In addition, the full year effect in 2017 of the common and common equivalent shares issued in connection with the BarioSurg acquisition is anti-dilutive.

### **(5) Discontinued Operations**

Effective December 17, 2018, the Company sold substantially all of the assets exclusively related to its ReShape Balloon product line to Apollo in connection with the Company’s acquisition of substantially all of the assets exclusively related to Apollo’s Lap-Band product line. The ReShape Balloon product line assets sold to Apollo consisted of inventory, property and equipment and the related intellectual property underlying the intangible assets. In connection with the Apollo transaction, the Company retained all other working capital associated with the ReShape Balloon product line, including accounts receivable, accounts payable and certain accrued and other liabilities arising from operations before the closing of the Apollo transaction, and there was no transfer of workforce. The ReShape Balloon product line was the primary operating activity of ReShape Medical, Inc. (“ReShape Medical”), a business the Company acquired in October 2017 and accounted for as a business combination. The purchase accounting was finalized during

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the fourth quarter of 2018 and did not result in any changes to the purchase price allocation. The assets and operations of the ReShape Balloon product line are shown as discontinued operations in the accompanying Consolidated Financial Statements. See Note 4 for more information regarding the Lap-Band product line acquisition.

In the second quarter of 2018, the Company recorded an impairment charge of \$13.2 million for the full write-down of the goodwill recorded in connection with its acquisition of ReShape Medical. Refer to Note 8 for additional information regarding evaluation of goodwill for impairment. In connection with the determination of the fair value of the Lap-Band assets acquired, no value was assigned to the ReShape Balloon product line assets sold as projections updated during the fourth quarter of 2018 indicated negative cash flows. Accordingly, the loss on disposal of discontinued operations consists of an impairment charge of \$22.6 million for the full write-down of the ReShape Balloon product line assets disposed of, which had the following carrying values as of December 17, 2018 prior to the write-down:

Inventory	\$ 670,011
Property and equipment, net	42,163
Other intangible assets, net	<u>21,884,317</u>
	<u>\$ 22,596,491</u>

The components of loss from discontinued operations for the years ended December 31, 2018 and 2017 (period from the October 2, 2017 acquisition date through December 31, 2017) consisted of the following:

	Year Ended December 31,	
	2018	2017
Total revenue	<u>\$ 2,285,115</u>	<u>\$ 717,994</u>
Loss from operations and disposal/impairment of discontinued operations before income taxes	<u>(45,884,552)</u>	<u>(3,353,650)</u>
Income tax benefit	<u>—</u>	<u>—</u>
Loss from discontinued operations, net of tax	<u>\$ (45,884,552)</u>	<u>\$ (3,353,650)</u>

There were no assets associated with the ReShape Balloon product line at December 31, 2018. The assets associated with discontinued operations included in the Company's Consolidated Balance Sheet as of December 31, 2017 consisted of the following:

<b>ASSETS:</b>	
Current assets:	
Inventory	<u>\$ 848,566</u>
Current assets of discontinued operations	<u>848,566</u>
Noncurrent assets:	
Property and equipment, net	96,645
Goodwill	<u>13,182,047</u>
Other intangible assets, net	<u>24,343,750</u>
Noncurrent assets of discontinued operations	<u>37,622,442</u>
Total assets of discontinued operations	<u>\$ 38,471,008</u>

**(6) Inventory**

Current inventory consists of the following:

	December 31,	
	2018	2017
Raw materials	\$ —	\$ 496,156
Work-in-process	—	1,353,877
Finished goods	984,735	118,513
Inventory	<u>\$ 984,735</u>	<u>\$ 1,968,546</u>

There was no noncurrent inventory as of December 31, 2018 and approximately \$1.0 million of noncurrent inventory as of December 31, 2017, primarily consisting of raw materials.

During the year ended December 31, 2018, the Company recorded a \$2.9 million write-down of the carrying amount of the ReShape vBloc inventories due to excess quantities of ReShape vBloc components. The write-down is included within selling, general and administrative expense. As a result of the acquisition of the Lap-Band product line, the Company will no longer be actively marketing its ReShape vBloc product.

**(7) Property and Equipment**

Property and equipment consist of the following:

	December 31,	
	2018	2017
Furniture and equipment	\$ 2,341,507	\$ 2,393,644
Computer hardware and software	781,724	774,697
Leasehold improvements	81,298	123,542
	3,204,529	3,291,883
Less accumulated depreciation and amortization	<u>(3,140,981)</u>	<u>(2,949,907)</u>
Property and equipment, net	<u>\$ 63,548</u>	<u>\$ 341,976</u>

**(8) Goodwill**

Goodwill resulted from the acquisition of BarioSurg in 2017. Goodwill and the changes in the carrying amount of goodwill for the years ended December 31, 2018 and 2017 are as follows:

Balance as of December 31, 2016	\$ —
BarioSurg acquisition	14,004,573
Balance as of December 31, 2017	14,004,573
Impairment	(14,004,573)
<b>Balance as of December 31, 2018</b>	<u>\$ —</u>

The gross amount and accumulated impairment loss of goodwill are as follows:

	December 31,	
	2018	2017
Gross amount	\$ 14,004,573	\$ 14,004,573
Accumulated impairment loss	(14,004,573)	—
Goodwill, net	<u>\$ —</u>	<u>\$ 14,004,573</u>

*Evaluation of Goodwill for Impairment*

Subsequent to the Company's registered direct securities offering on April 3, 2018, the price of the Company's common stock declined significantly. Management determined that this event was an indicator of potential impairment

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as the magnitude of the decline indicated that the net equity of the Company may be in excess of its fair market value and conducted an impairment analysis during the second quarter of 2018. The Company determined that the carrying values of the assets of BarioSurg and ReShape Medical, both of which were acquired during 2017 and accounted for as business combinations, exceeded their current fair values. The resulting impairment charge was \$14.0 million associated with BarioSurg and \$13.2 million associated with the ReShape Medical. The impairment charges represented a complete write-down of the goodwill associated with these acquisitions. As described in Note 5, the results of operations of ReShape Medical's ReShape Balloon product line are classified as discontinued operations, including the related goodwill impairment charge.

The fair market values were determined under an income approach using discounted cash flows. Fair value calculated using a discounted cash flow analysis is classified within level 3 of the fair value hierarchy and requires several assumptions including risk adjusted discount rates and financial forecasts.

The determination of the fair value of the reporting unit and the allocation of that value to individual assets and liabilities within the reporting unit requires the Company to make significant estimates and assumptions. These estimates and assumptions primarily include, but are not limited to, the selection of appropriate peer group companies, control premiums appropriate for acquisitions in the industries in which the Company competes, the discount rate, terminal growth rates, and forecasts of revenue, operating income, and capital expenditures.

**(9) Other Intangible Assets**

Identifiable intangible assets were recorded in connection with the acquisitions of the Lap-Band product line assets in 2018 and BarioSurg in 2017.

Other intangible assets consist of the following:

	Amortization Period (years)	December 31, 2018		
		Gross Carrying Amount	Accumulated Amortization	Net Book Value
<b>Finite-lived intangible assets:</b>				
Developed technology	10	\$14,361,732	\$ (59,841)	\$14,301,891
Trademarks/Tradenames	10	2,045,172	(176,615)	1,868,557
Covenant not to compete	3	75,884	(40,050)	35,834
		<u>16,482,788</u>	<u>(276,506)</u>	<u>16,206,282</u>
<b>Indefinite-lived intangible assets:</b>				
In-process research and development	indefinite	20,720,939	—	20,720,939
Total		<u>\$37,203,727</u>	<u>\$ (276,506)</u>	<u>\$36,927,221</u>
	Amortization Period (years)	December 31, 2017		
		Gross Carrying Amount	Accumulated Amortization	Net Book Value
<b>Finite-lived intangible assets:</b>				
Trademarks/Tradenames	10	\$ 1,090,363	\$ (63,604)	\$ 1,026,759
Covenant not to compete	3	75,884	(14,755)	61,129
		<u>1,166,247</u>	<u>(78,359)</u>	<u>1,087,888</u>
<b>Indefinite-lived intangible assets:</b>				
In-process research and development	indefinite	20,720,939	—	20,720,939
Total		<u>\$21,887,186</u>	<u>\$ (78,359)</u>	<u>\$21,808,827</u>

In conjunction with the evaluation of goodwill for impairment in the second quarter of 2018 discussed in Note 8, the Company performed a qualitative impairment analysis on indefinite-lived intangible assets other than goodwill, and assessed the recoverability of finite-lived intangible assets. The Company did not identify any impairments of such indefinite-lived or finite-lived intangible assets as a result of these analyses.

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Estimated amortization expense for each of the years ending December 31 is as follows:

<u>Year ending December 31,</u>	
2019	\$ 1,665,985
2020	1,651,229
2021	1,640,690
2022	1,640,690
2023	1,640,690
Thereafter	7,966,998
	<u>\$ 16,206,282</u>

**(10) Accrued and Other liabilities**

Accrued and other liabilities consist of the following:

	<u>December 31,</u>	
	<u>2018</u>	<u>2017</u>
Professional service related expenses	\$ 3,094,769	\$ 2,643,342
Payroll related expenses	1,146,114	2,480,219
Other accrued liabilities	588,293	831,957
Accrued and other liabilities	<u>\$ 4,829,176</u>	<u>\$ 5,955,518</u>

**(11) Commitments and Contingencies**

***Operating Lease***

The Company leases separate office and warehouse space in San Clemente, California under noncancelable operating leases that expire in June 2022 and October 2019, respectively. The Company also has certain office equipment that is subject to noncancelable operating leases that expire at various dates through 2022.

For the years ended December 31, 2018 and 2017, total rent expense recognized for all operating leases was \$767,000 and \$357,000, respectively. Future minimum lease commitments under noncancelable operating leases as of December 31, 2018 are as follows:

<u>Year ending December 31,</u>	
2019	\$ 449,226
2020	331,990
2021	331,229
2022	165,511
Total	<u>\$ 1,277,956</u>

***Clinical Trials***

The Company has ongoing commitments under the pre-approval ReCharge and post-approval ReNew clinical trials related to its ReShape vBloc product which are expected to be completed in 2019 and 2022, respectively. The Company is required to pay for patient follow up visits only to the extent they occur. In the event a patient does not attend a follow up visit, the Company has no financial obligation. The Company is also required to pay for explants or revisions, including potential conversions of ReCharge control devices to active devices, should a patient request or be required to have one during the course of the clinical trials. The Company has no financial obligation unless an explant, revision or conversion is requested or required. The Company recognizes expense when incurred with respect to these clinical trials.

***Litigation***

*Du.* On February 28, 2017, the Company received a class action and derivative complaint filed on February 24, 2017 in U. S. District Court for the District of Delaware by Vinh Du, one of the Company's shareholders. The complaint

named as defendants ReShape Lifesciences, the board of directors and four members of our senior management, namely, Scott Youngstrom, Nick Ansari, Peter DeLange and Paul Hickey, and contained a purported class action claim for breach of fiduciary duty against the board of directors and derivative claims for breach of fiduciary duty against the board of directors and unjust enrichment against our senior management. The allegations in the complaint related to the increase in the number of shares authorized for grant under our Second Amended and Restated 2003 Stock Incentive Plan (the “Plan”), which was approved by our shareholders at the Special Meeting of Shareholders held on December 12, 2016 (the “Special Meeting”), and to our subsequent grant of stock options on February 8, 2017, to the Company’s Directors and senior management to purchase an aggregate of 521 shares of our common stock (the “Option Grants”). In the complaint, the plaintiff contended that (i) the number of shares authorized for grant under the Plan, as adjusted by the board of directors after the Special Meeting for the subsequent recapitalization of the Company, resulted from an alleged breach of fiduciary duties by the board of directors, and (ii) our senior management was allegedly unjustly enriched by the subsequent Option Grants. The plaintiff sought relief in the form of an order rescinding the Plan as approved by the shareholders at the Special Meeting, an order cancelling the Option Grants, and an award to plaintiff for his costs, including fees and disbursements of attorneys, experts and accountants. The parties settled the matter on December 17, 2018. The terms of the settlement require us to (i) rescind and cancel the Option Grants, with the exception of options that were already rescinded when certain individuals left the company in the last fiscal quarter of 2017, (ii) amend the Plan to add a provision establishing the maximum total annual equity compensation for non-employee directors and to seek stockholder approval of this amendment at the Company’s next annual meeting of stockholders, and (iii) proportionally adjust all share reserves and limitations in the Plan (and any other equity compensation plan for the company) in connection with any future split of the company’s stock during the next five years unless otherwise brought to and approved by stockholder vote. The Company is required to make a payment to the plaintiff of \$197,000, which has been fully accrued in 2018 and is included in Selling, General and Administrative Expenses in the Consolidated Statement of Operations.

*Fulfillium.* On April 20, 2017, Fulfillium, Inc. filed a complaint against ReShape Medical, Inc. (which the Company acquired in October 2017 and which is now a wholly owned subsidiary of the Company) in the U.S. District Court for the District of Delaware, which alleged misappropriation of trade secrets and infringement of two U.S. Patents (“Fulfillium I”). On July 28, 2017, ReShape Medical moved to dismiss both the trade secret claim and certain aspects of the patent infringement claim, and to transfer the litigation to the U.S. District Court for the Central District of California. On October 16, 2017, the Court granted ReShape Medical’s motion to dismiss the trade secret and willful infringement claims, and ordered the case transferred to the U.S. District Court for the Central District of California. Fulfillium twice amended its complaint, narrowing its original trade secret claim and adding further patent infringement claims and additional parties. On June 4, 2018, ReShape Medical filed a motion to dismiss the patent infringement claims for lack of standing, which the Court granted on July 5, 2018. On August 10, 2018, the Court dismissed without prejudice the trade secret claim for lack of subject matter jurisdiction and terminated the case. Fulfillium has appealed these dismissals and ReShape Medical has appealed the grant and denial of certain attorney fee awards. On July 20, 2018, Fulfillium filed a new complaint against ReShape Lifesciences, Inc. (and its wholly owned subsidiary ReShape Medical LLC) in the U.S. District Court for the Central District of California (“Fulfillium II”) reasserting the patent infringement claims asserted in Fulfillium I. On August 15, 2018, Fulfillium amended its complaint in Fulfillium II to reassert the trade secret misappropriation claim asserted in Fulfillium I against ReShape Medical LLC and others. On September 7, 2018, Fulfillium filed a complaint in California state court alleging the same trade secret misappropriation claim asserted in both Fulfillium I and Fulfillium II. On November 7, 2018, the Court dismissed the non-Company parties from Fulfillium II. On April 20, 2018, ReShape Medical filed Inter Partes Review (“IPR”) petitions with the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office (the “PTAB”) to have all claims of both of the originally asserted Fulfillium patents canceled as unpatentable over various combinations of prior art. On November 6, 2018, the PTAB denied those petitions. The parties held a mediation on April 9, 2019, but were unable to resolve the matter. The Company intends to continue to vigorously defend itself against Fulfillium’s claims. We currently are unable to estimate the losses or range of loss for these two matters where there is a reasonable possibility of a loss or it is probable that a loss may have been incurred.

*Alpha and Iroquois.* On July 12, 2018, Alpha Capital Anstalt (“Alpha”) filed a complaint against the Company in the U.S. District Court for the Southern District of New York. In August 2017, Alpha acquired shares of the Company’s series B convertible preferred stock and warrants to purchase shares of the Company’s common stock in an underwritten public offering. Pursuant to the terms of the series B convertible preferred stock and warrants, the conversion price of the series B convertible preferred stock and exercise price of the warrants was subject to adjustment in the case of, among other things, dilutive issuances of securities by the Company. The complaint alleges breach of contract, claiming that the Company should have adjusted the conversion price of the series B convertible preferred stock and exercise price of the

warrants to not less than \$420.00 per share, rather than the \$1,575.00 per share to which the Company actually adjusted such conversion price and exercise price, in connection with its registered direct offering of series D convertible preferred stock and warrants to purchase common stock that it completed and announced in April 2018. Alpha seeks declaratory relief, damages of not less than approximately \$3.6 million (less the proceeds of actual sales of the Company's common stock made by Alpha) and attorneys' fees. The Company believes the claims alleged are without merit and intends to vigorously protect and defend itself. However, we are currently unable to estimate a loss or range of loss for this matter.

On July 26, 2018, Iroquois Capital Investment Group, LLC and Iroquois Master Fund, Ltd. filed a complaint against the Company in the U.S. District Court for the Southern District of New York, with substantially the same claims and seeking substantially the same relief as Alpha's complaint described above, except that Iroquois claims that the conversion price of the series D convertible preferred stock and exercise price of the warrants should have been adjusted to \$189.00 per share, and Iroquois is claiming damages estimated to exceed \$5 million. The Company believes the claims alleged are without merit and intends to vigorously protect and defend itself. However, we are currently unable to estimate a loss or range of loss for this matter.

Except as disclosed in the foregoing paragraphs, the Company is not currently a party to any litigation and the Company is not aware of any pending or threatened litigation against it that could have a material adverse effect on the Company's business, operating results or financial condition. The medical device industry in which the Company operates is characterized by frequent claims and litigation, including claims regarding patent and other intellectual property rights as well as improper hiring practices. As a result, the Company may be involved in various legal proceedings from time to time.

#### ***Product Liability Claims***

The Company is exposed to product liability claims that are inherent in the testing, production, marketing and sale of medical devices. Management believes any losses that may occur from these matters are adequately covered by insurance, and the ultimate outcome of these matters will not have a material effect on the Company's financial position or results of operations. The Company is not currently a party to any product liability litigation and is not aware of any pending or threatened product liability litigation that could have a material adverse effect on the Company's business, operating results or financial condition.

#### **(12) Equity**

The Company may issue preferred stock, common stock, or both, in connection with underwritten public offerings, registered direct offerings, or business acquisitions. Such issuances of equity typically include the issuance or sale of warrants to purchase common stock. Certain issuances of convertible preferred stock and warrants may contain anti-dilutive features apart from customary adjustments for splits and reverse splits of common stock (collectively, "down round features"). When a series of convertible preferred stock contains this non-standard down round feature, the Company is required to adjust the conversion price in the event of future stock sales at a lower unit price. In the event the anti-dilution is triggered, the Company is required to evaluate whether a contingent beneficial conversion feature has been met and, if so, evaluate and account for any value attributable to the contingent beneficial conversion feature. When warrants issued in connection with an equity transaction contain, or are amended to contain, this non-standard down round feature, the Company is required to adjust the exercise price upon the issuance of any shares of common stock or securities convertible into shares of common stock below the then-existing exercise price and evaluate and account for the value attributable to the reduced warrant exercise price.

All series of the Company's convertible preferred stock are classified in stockholders' equity, including those with the down round feature as discussed in more detail below, when applicable to the equity transaction. Warrants to purchase common stock are classified in stockholders' equity, including, beginning in 2017, those issued with the down round feature, as they are both indexed to the Company's own stock and meet the scope exception in ASC 815 "Derivatives and Hedging," paragraph 10-74(a), as amended by ASU 2017-11. In the event down round adjustments are triggered, the values attributable to the adjustment to the convertible preferred stock conversion price and warrant exercise price are recorded as an increase to additional paid-in capital and increase to accumulated deficit. During the year ended December 31, 2018, the Company recorded a total of \$0.2 million attributable to changes in the conversion price of convertible preferred stock and \$2.9 million attributable to the reductions in the exercise price of warrants.



Warrants issued to investors in connection with the sale of convertible preferred stock in April 2018 and August 2017 contain non-standard down round features. Effective September 17, 2018, warrants issued to investors in connection with the sale of common stock in June, July and August 2018 were amended to add the non-standard down round feature. As of December 31, 2018, the exercise price of these warrants was \$1.25 per share, as last reset effective with a direct financing completed on November 26, 2018. The value attributable to the exercise price reductions was estimated using the Black Scholes model using risk-free interest rates ranging from 2.13% to 2.96%; expected lives ranging from less than one year to 9.4 years; expected dividends of zero and expected volatility ranging from 111.63% to 293.32%.

The Company had the following equity transactions during the years ended December 31, 2018 and 2017:

***November 2018 Issuance of Common Stock and Warrants***

On November 28, 2018, the Company completed a registered direct offering with two healthcare focused institutional investors which included the sale of 670,000 shares of common stock at a purchase price of \$1.25 per share and pre-funded warrants to purchase 7,330,000 shares of common stock at a purchase price of \$1.24 per share. The exercise price of each pre-funded warrant is \$0.01 per share. The Company also issued Series A warrants to purchase 8,000,000 shares of common stock at an exercise price of \$1.50 per share. In connection with the registered direct offering, the placement agent received warrants to purchase 560,000 shares of common stock at an exercise price of \$1.5625 per share. Net proceeds from the registered direct offering were \$9.1 million, after deducting placement agent fees and other transaction costs.

***2018 At-the-Market Offering***

During the period from October 9, 2018 through November 28, 2018, the Company issued an aggregate of 6,263,576 shares of common stock in an at-the-market public offering ("2018 ATM") at an average price per share of \$2.39. In connection with the ATM, the placement agent received warrants to purchase a total of 438,450 shares of common stock at exercise prices ranging from \$1.2625 per share to \$7.4755 per share. Net proceeds from the ATM were \$13.4 million, after deducting placement agent fees and other transaction costs.

***September 2018 Issuance of Common Stock and Warrants and Exchange of Series D Convertible Preferred Stock for Common Stock and Warrants***

On September 20, 2018, the Company completed a public offering which included the issuance of 83,493 shares of common stock at a purchase price of \$6.30 per share and warrants to purchase 41,747 shares of common stock at an exercise price of \$6.30 per share. In connection with the public offering, the placement agent received warrants to purchase 5,845 shares of common stock at an exercise price of \$7.875 per share. Net proceeds from the public offering were \$0.4 million, after deducting placement agent fees and other transaction costs.

Pursuant to the terms of the April 2018 securities purchase agreement, on September 20, 2018, the purchasers exercised their right to exchange their shares of series D convertible preferred stock into the common stock and warrants included in the September 2018 public offering. As a result, an aggregate of 178,875 shares of series D convertible preferred stock was exchanged for the issuance of 28,393 shares of common stock and warrants to purchase 14,197 shares of common stock at an exercise price of \$6.30 per share.

***August 2018 Issuance of Common Stock and Warrants***

On August 3, 2018, the Company completed a registered direct offering which included the sale of 7,143 shares of common stock at a purchase price of \$84.00 per share and warrants to purchase 7,143 shares of common stock at an initial exercise price of \$154.00 per share. In connection with the registered direct offering, the placement agent received warrants to purchase 500 shares of common stock at an exercise price of \$105 per share. Net proceeds from the registered direct offering were \$0.5 million, after deducting placement agent fees and other transaction costs.

***July 2018 Issuance of Common Stock and Warrants***

On July 12, 2018, the Company completed a registered direct offering which included the sale of 8,868 shares of common stock at a purchase price of \$287.00 per share and warrants to purchase 8,868 shares of common stock at a

purchase price of \$17.50 per share. The initial exercise price of each warrant was \$288.40 per share. In connection with the registered direct offering, the placement agent received warrants to purchase 621 shares of common stock at an exercise price of \$380.66 per share. Net proceeds from the registered direct offering were \$2.2 million, after deducting placement agent fees and other transaction costs.

***June 2018 Issuances of Common Stock and Warrants***

On June 21, 2018, the Company completed a registered direct offering which included the sale of 3,354 shares of common stock at a purchase price of \$429.80 per share per share and warrants to purchase 3,354 shares of common stock at a purchase price of \$17.50 per share. The initial exercise price of each warrant was \$431.20 per share. In connection with the registered direct offering, the placement agent received warrants to purchase 163 shares of common stock at an exercise price of \$558.60 per share. Net proceeds from the registered direct offering were \$1.3 million, after deducting placement agent fees and other transaction costs. The Company used \$500,000 of the net proceeds of the offering to redeem 500 of the then currently 5,250 outstanding shares of its series D convertible preferred stock, which the Company agreed to as an inducement to obtain the required consent of the holder of series D convertible preferred stock for the Company to complete the offering.

On June 9, 2018, the Company completed a registered direct offering which included the sale of 2,676 shares of common stock at a purchase price of \$548.80 per share per share and warrants to purchase 2,007 shares of common stock at a purchase price of \$17.50 per share. The initial exercise price of each warrant was \$550.20 per share. In connection with the registered direct offering, the placement agent received warrants to purchase 188 shares of common stock at an exercise price of \$701.40 per share. Net proceeds from the registered direct offering were \$1.2 million, after deducting placement agent fees and other transaction costs.

***April 2018 Issuance of Convertible Preferred Stock and Warrants***

On April 3, 2018 the Company completed a registered direct offering which included the sale of 6,000 shares of series D convertible preferred stock, par value \$0.01 per share (“Series D Preferred Stock”), at a purchase price of \$1,000 per share and warrants to purchase 16,667 shares of common stock at an initial exercise price of \$1,575 per share. Net proceeds from the registered direct offering were \$5.1 million, after deducting placement agent fees and other transaction costs.

In connection with the registered direct offering completed on June 21, 2018, 500 shares of the Series D Preferred Stock were redeemed. During the year ended December 31, 2018, all of the remaining 5,500 shares of the Series D Preferred Stock were converted into 108,353 shares of common stock.

***October 2017 Issuance of Common Stock and Convertible Preferred Stock to Acquire Reshape Medical***

In connection with the Company’s acquisition of ReShape Medical on October 2, 2017, in addition to \$5.0 million of cash consideration, the Company issued equity securities valued at \$34.0 million, which included 1,123 shares of common stock and 187,772 shares of series C convertible preferred stock (“Series C Preferred Stock”). The valuation of the common stock and Series C Preferred Stock took into account (i) the conversion ratio of the series C convertible preferred stock, (ii) the closing price of common stock on the NASDAQ Stock Market on the date the transaction was announced, and (iii) a 20% discount for lack of marketability related to the shares issued in the transaction.

On December 19, 2017, the Company’s stockholders approved the issuance of up to 8,942 shares of common stock upon the conversion of 187,772 shares of Series C Preferred Stock issued to the former equity holders of ReShape Medical. On that date, a total 92,384 shares of Series C Preferred Stock were converted into 4,397 shares of common stock. At December 31, 2018, the remaining 95,388 shares of Series C Preferred Stock were convertible into 4,543 shares of common stock.

***August 2017 Issuance of Convertible Preferred Stock and Warrants***

On August 16, 2017, the Company completed an underwritten public offering which included the sale of 20,000 shares of series B convertible preferred stock, par value \$0.01 per share (the “Series B Preferred Stock”), and warrants to purchase an aggregate of 4,143 shares of common stock at an initial exercise price of \$4,830.00 per share. The Series B Preferred Stock was initially convertible into 4,143 shares of common stock based on an initial conversion price of

\$4,830.00 per share. Net proceeds from the Series B Preferred Stock offering were approximately \$18.0 million, after deducting approximately \$2.0 million of underwriting discounts and offering expenses.

The Series B Preferred Stock was determined to not be mandatorily redeemable under ASC 480. The Company identified two embedded features within the Series B Preferred Stock: (1) optional conversion by the holder, and (2) redemption in the event of a fundamental change and the Company determined that neither of these embedded features required bifurcation under ASC 815. Since the Series B Preferred Stock is only redeemable in an ordinary liquidation, upon the occurrence of a fundamental transaction which is solely within the Company's control, or in circumstances when all common shareholders are entitled to receive the same form of consideration, the Series B Preferred Stock is presented within permanent equity. The Series B Preferred Stock and the warrants issued with the Series B Preferred Stock each contain the down round feature discussed above.

During the years ended December 31, 2018 and 2017, 5,896 shares and 13,945 shares, respectively of Series B Preferred Stock were converted into 476,346 shares and 2,889 shares, respectively, of common stock. At December 31, 2018, the remaining 159 shares of Series B Preferred stock are convertible into 127,200 shares of common stock.

***May 2017 Issuance of Common Stock and Convertible Preferred Stock to Acquire BarioSurg***

As discussed in Note 4, in connection with the Company's acquisition of BarioSurg on May 22, 2017, in addition to \$2.0 million of cash consideration, the Company issued equity securities valued at \$26.3 million, which included 658 shares of common stock and 1,000,181 shares of Conditional Preferred Stock. On October 25, 2017, upon the post-closing approval of the Company's stockholders in accordance with the Nasdaq Stock Market Rules, all of the Conditional Preferred Stock converted into 2,381 shares of common stock.

***January 2017 Issuance of Common Stock, Convertible Preferred Stock and Warrants***

On January 23, 2017, the Company completed an underwritten public offering which included the sale of Class A units consisting of common stock and warrants to purchase common stock, and Class B units, consisting of series A convertible preferred stock, par value \$0.01 per share (Series A Preferred Stock), and warrants to purchase common stock. Net proceeds from the offering were \$16.5 million, after deducting underwriting discounts and commissions and offering expenses of \$2.5 million. A total of 581 shares of common stock, 12,531 shares of Series A Preferred Stock warrants to purchase 1,704 shares of common stock at an exercise price of \$12,264.00 were issued in the offering including the underwriters' exercise of their over-allotment option.

The conversion price of the Series A Preferred Stock did not contain any variable pricing features nor any nonstandard anti-dilution features. The Series A Preferred Stock included a beneficial ownership limitation of 4.99%, but had no dividend preference (except to the extent dividends are also paid on the common stock), liquidation preference or other preferences over common stock. On January 23 and January 24, 2017 all shares of Series A Preferred Stock issued in conjunction with the offering were converted by their holders into 1,123 shares of common stock.

**(13) Warrants**

The Company's grants of warrants to purchase common stock are primarily in connection with equity financings. See Note 12 for additional information about equity financings and the related issuance of warrants. Warrant activity was as follows:

	Shares	Weighted Average Exercise Price
<b>Balance, December 31, 2016</b>	27	\$ 501,690.00
Granted	7,074	6,615.00
Exercised	(286)	11,676.00
Cancelled	(1)	501,690.00
<b>Balance December 31, 2017</b>	6,814	11,464.67
Granted	16,429,804	2.82
Exercised	(1,131,892)	0.45
Cancelled	(4)	4,035,150.00
<b>Balance December 31, 2018</b>	<u>15,304,722</u>	2.96

Most of the warrants issued during the years ended December 31, 2018 and 2017 had terms ranging from 5.0 years to 5.5 years. At December 31, 2018 and 2017, the weighted-average remaining contractual term of outstanding warrants was 4.9 years and 6.1 years, respectively. Subject to certain ownership limitations of certain investors, all of the warrants outstanding are currently exercisable at the option of the holder into the equivalent number of shares of common stock.

On May 24, 2018, an institutional investor agreed to exercise an aggregate of 751 warrants to purchase common stock in exchange for a reduction in the warrant exercise price. The warrant exercise was accounted for as a warrant inducement and the related fair value adjustment to the exercised warrants of \$146,245 was recorded as Warrant expense in the Consolidated Statements of Operations for the year ended December 31, 2018. The value attributable to the exercise price reductions was estimated using the Black Scholes option pricing model using risk-free interest rates ranging from 2.28% to 2.65%; expected lives ranging from less than one year to 3.7 years; expected dividends of zero and expected volatility ranging from 120.44% to 142.78%.

In connection with the Company's public offering of Series B Preferred Stock, in August 2017, the Company issued warrants to purchase an aggregate of 1,226 shares of common stock to certain investors as consideration for the waiver by each investor of their right to participate in future securities offerings by the Company, which rights were granted pursuant to a financing transaction completed in November 2015. Because the Company received no additional consideration or future rights related to such warrants, the warrant value of \$4.4 million was recorded as Warrant expense in the Consolidated Statements of Operations for the year ended December 31, 2017. The value of the warrants was estimated using the Black Scholes option pricing model using a risk-free interest rate of 2.03%, an expected life of 7.0 years, expected dividends of zero and expected volatility of 112.03%.

Certain of the Company's outstanding warrants to purchase common stock originally issued in July 2015 ("July 2015 Warrants") were recorded at fair value and classified as a liability. The fair value of the July 2015 Warrants was re-measured at each financial reporting period and immediately before exercise, with any changes in fair value recorded as Warrant expense in the Consolidated Statements of Operations. The fair value of the July 2015 Warrant liability was \$0 and \$1,600 at December 31, 2018 and 2017, respectively. The fair value at December 31, 2017 was calculated using a

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Black-Scholes option pricing model using a risk-free interest rate of 1.76%, an expected life of 12 months, expected dividends of zero and expected volatility of 193.28%.

**(14) Revenue Recognition**

The following table presents the Company's revenue disaggregated by product and geography, based on management's assessment of available data:

	Year Ended December 31, 2018			
	U.S.	OUS *	Total Revenues	% of Total Revenues
Lap-Band product	\$ 446,895	\$ 3,470	\$ 450,365	74.2%
ReShape vBloc product	156,345	—	156,345	25.8%
Total	\$ 603,240	\$ 3,470	\$ 606,710	100.0%

  

	Year Ended December 31, 2017			
	U.S.	OUS *	Total Revenues	% of Total Revenues
ReShape vBloc product	\$ 319,160	\$ —	\$ 319,160	56.1%
Other	250,000	—	250,000	43.9%
Total	\$ 569,160	\$ —	\$ 569,160	100.0%

\*All revenues outside the United States for the year ended December 31, 2018 were in Canada.

Lap-Band product sales are for the period from the date of acquisition of the product line assets of December 17, 2018 through December 31, 2018. As a result of the acquisition of the Lap-Band product line, the Company will no longer be actively marketing its ReShape vBloc product. The Company's standard payment terms for its customers are generally 30 to 60 days after the Company satisfies the performance obligations.

***Variable Consideration***

The Company records revenue from customers in an amount that reflects the transaction price it expects to be entitled to after transferring control of those goods or services. Returns and exchanges of ReShape vBloc product have not been significant. Customers and distributors of Lap-Band product generally have the right to return or exchange products purchased for up to thirty days from the date of product shipment. Any such return or exchange of Lap-Band products will be recorded as a reduction of revenue in the period incurred until sufficient historical information is available to enable management to estimate returns and exchanges as variable consideration when determining the amount of revenue to recognize.

Certain Lap-Band customers may in the future receive volume rebates or discounts. These incentives, when offered, will be accounted for as variable consideration. The estimate of the expected amount to be provided to customers will reduce the revenue recognized. The Company has not offered rebate incentives with respect to sales of its ReShape vBloc product.

***Warranty***

The Company generally provides one-year warranties against defects in materials and workmanship and will either repair the products or provide replacements at no charge to customers. As they are considered assurance-type warranties, the Company does not account for them as separate performance obligations. Warranty reserve requirements are based on a specific assessment of the products sold with warranties where a customer asserts a claim for warranty or a product defect.

***Contract Balances***

The Company records a receivable when it has an unconditional right to receive consideration after the performance obligations are satisfied.

**Practical Expedients**

The Company has elected the practical expedient not to determine whether contacts with customers contain significant financing components.

**(15) Income Taxes**

Income tax expense (benefit) consists of the following:

	<b>Year ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
Deferred:		
Federal	\$ (3,585,679)	\$ (2,538,611)
State	137,685	224,000
Deferred income tax benefit	(3,447,994)	(2,314,611)
Current state and local income tax expense	1,286	—
Total income tax benefit, net	<u>\$ (3,446,708)</u>	<u>\$ (2,314,611)</u>

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	<b>Year ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
Income tax benefit at U.S. federal statutory rate	21.0 %	34.0 %
Goodwill impairment	(7.6)	—
Other permanent differences	(0.4)%	(6.0)%
Research and development credit	0.9 %	0.8 %
Impact of U.S. Tax Cuts and Jobs Act	— %	(112.0)%
Change in state tax rate	(1.1)	—
Change in valuation allowance	(3.9)%	90.3 %
Effective income tax rate	<u>8.9 %</u>	<u>7.1 %</u>

The components of deferred tax assets and liabilities are as follows:

	<b>December 31,</b>	
	<b>2018</b>	<b>2017</b>
Deferred tax assets:		
Start-up costs	\$ 1,239,000	\$ 4,166,000
Capitalized research and development costs	728,000	12,494,000
Reserves and accruals	7,465,000	7,642,000
Property and equipment	—	46,000
Research and development credit	1,334,000	4,387,000
Net operating loss carryforwards	22,721,000	63,794,000
Total gross deferred tax assets	33,487,000	92,529,000
Valuation allowance	(29,904,000)	(86,033,000)
Deferred tax assets, net of valuation allowance	3,583,000	6,496,000
Intangible assets	(5,385,000)	(11,788,000)
Property and equipment	(42,000)	—
Total gross deferred tax liabilities	(5,427,000)	(11,788,000)
Net deferred tax liability	<u>\$ (1,844,000)</u>	<u>\$ (5,292,000)</u>

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during periods in which those temporary differences become deductible. Based on the level of historical losses, projections of losses in future periods and potential limitations pursuant to changes in ownership under Internal Revenue Code (“IRC”) Section 382, the Company provided a valuation allowance at both December 31, 2018 and 2017. The remaining net deferred tax liability at December 31, 2018 is the

result of the deferred tax liability associated with the indefinite-lived intangible asset of \$5.1 million, less the deferred tax asset associated with U.S. federal net operating loss carryforwards that do not expire of \$3.3 million. At December 31, 2017, the remaining net deferred tax liability was due to the deferred tax liability associated with the indefinite-lived intangible asset of \$5.3 million.

As of December 31, 2018 and 2017, the Company had U.S. federal net operating loss carryforwards of \$350.1 million and \$253.8 million, respectively. Of the total U.S. federal net operating loss carryforwards at December 31, 2018, \$302.6 million will be limited as a result of Section 382 as described below and will expire unused. Losses generated in 2018 will carryover indefinitely. The Company had state net operating loss carryforwards of \$200.4 million and \$160.9 million at December 31, 2018 and 2017, respectively and had foreign net operating loss carryforwards of \$0.2 million at both December 31, 2018 and 2017. Net operating loss carryforwards of the Company are subject to review and possible adjustment by the taxing authorities. With certain exceptions (e.g. the net operating loss carryforwards), the Company is no longer subject to U.S. federal, state or local examinations by tax authorities for years prior to 2015. There are no tax examinations currently in progress.

The Company'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. In 2018, the Company completed an IRC Section 382 review and determined that ownership changes had occurred, which resulted in the determination that \$302.6 million of U.S. federal net operating loss carryforwards and \$3.5 million of U.S. federal research and development credit will expire unused as a result of ownership changes and the resulting Section 382 limitations. Further, an aggregate of \$40.8 million of other future tax deductible amounts have been reduced. Both the deferred tax assets and the deferred tax valuation allowance were reduced by \$67.2 million for the tax effect of these lost benefits, with no net effect on results of operations for the year ended December 31, 2018. Due to the valuation allowance against deferred tax assets at December 31, 2018, the net effect of any further limitation will have no impact on results of operations.

The enactment of the Tax Cuts and Jobs Act in December 2017 ("2017 Act") reduced the federal corporate income tax rate to 21% effective January 1, 2018. The rate change resulted in a remeasurement of deferred tax assets and liabilities and the effect on the Company's effective income tax rate for the year ended December 31, 2017 is shown in the table above.

In December 2017, Staff Accounting Bulletin No. 118 ("SAB 118") was issued, which allowed for the recording of provisional amounts during a measurement period not to extend beyond one year of the enactment date of the 2017 Act in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the 2017 Act. As a result of the 2017 Tax Act, NOLs generated in taxable years ending after December 31, 2017 have an indefinite carryforward period. In accordance with SAB 118, a provisional tax benefit of \$2.3 million was recorded during the year ended December 31, 2017. The Company completed its analysis during 2018 and concluded no further adjustments were required in 2018.

## **(16) Stock-based Compensation**

The ReShape Lifesciences Inc. Second Amended and Restated 2003 Stock Incentive Plan (the "Plan") provides for the grant of stock options or other stock-based awards to employees, officers, non-employee directors and outside consultants of the Company. In 2018 and 2017, the Company's stockholders approved amendments to the Plan that increased the number of shares authorized for issuance by 3,096 shares and 2,620 shares, respectively. The Plan amendment in 2018 also added an automatic share increase provision that provides for an annual increase on January 1 of each year beginning in 2019 such that the number of shares of common stock authorized for issuance under the Plan is equal to 15% of the total shares of common stock outstanding, on an as converted basis, as of the last day of the immediately preceding fiscal year. The increased number of shares available for issuance under the Plan is subject to adjustment in accordance with certain provisions of the Plan. As of January 1, 2019, the number of shares authorized for

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issuance increased from 7,143 to 3,631,035 and there were 3,627,053 shares of common stock available for issuance under the Plan.

The Plan is administered by the board of directors, which determines the types of awards to be granted, including the number of shares subject to the awards, the exercise price and the vesting schedule. Options granted under the Plan expire no later than ten years from the date of grant. The exercise price of each option may not be less than 100% of the fair market value of the common stock at the date of grant. Options may be granted to stockholders possessing more than 10% of the total combined voting power of all classes of stocks of the Company at an exercise price at least 110% of the fair value of the common stock at the date of grant and the options are not exercisable after the expiration of 10 years from the date of grant. Employee stock options generally vest over four years.

***Stock Options***

Stock option activity for the Plan is as follows:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life (years)
<b>Outstanding at December 31, 2016</b>	4	\$ 3,832,227.00	
Options granted	1,280	8,946.00	
Options exercised	—	—	
Options cancelled	(78)	34,923.00	
<b>Outstanding at December 31, 2017</b>	1,206	178,872.14	
Options granted	2,868	1,336.72	
Options exercised	—	—	
Options cancelled	(92)	214,040.20	
<b>Outstanding at December 31, 2018</b>	3,982	48,910.71	8.8
<b>Exercisable at December 31, 2018</b>	661	283,490.51	7
<b>Vested and expected to vest at December 31, 2018</b>	3,979	34,035.16	8.9

As of December 31, 2018, stock options under the Plan that were outstanding, exercisable and vested and expected to vest under had no intrinsic value.

In addition to the stock options granted pursuant to the Plan, the Company from time to time grants options to individuals as an inducement to accepting positions as employees (Inducement Grants). These Inducement Grants are made at the discretion of the board of directors and are issued outside of the Plan. Each of the Inducement Grants vests



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over a period of four years from the date of the officer's employment agreement. Inducement Grants are summarized below:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life (years)
<b>Outstanding at December 31, 2016</b>	7	\$ 401,352.00	
Options granted	657	4,284.00	
Options exercised	—	—	
Options cancelled	(44)	8,778.00	
<b>Outstanding at December 31, 2017</b>	620	7,733.48	
Options granted	—	—	
Options exercised	—	—	
Options cancelled	(377)	4,163.63	
<b>Outstanding at December 31, 2018</b>	243	—	8.4
<b>Exercisable at December 31, 2018</b>	86	25,298.42	7.8
<b>Vested and expected to vest at December 31, 2018</b>	243	13,595.10	8.4

As of December 31, 2018, Inducement Grants outstanding, exercisable and vested and expected to vest had no intrinsic value.

The total estimated grant date fair value of stock options granted during the years ended December 31, 2018 and 2017 was \$3.5 million and \$11.5 million, respectively. Compensation cost for stock options granted to employees is based on the estimated grant-date fair value and is recognized over the vesting period of the applicable award on a straight-line basis. The fair value of stock option awards was estimated at the date of grant using a Black-Scholes option pricing model with the following assumptions:

	Year Ended December 31,	
	2018	2017
Risk-free interest rates	2.85%	1.94% - 2.38%
Expected term (in years)	6.25	6.25 - 10.0
Expected dividends	0%	0%
Expected volatility	121.52%	114.94% - 131.24%

*Risk-Free Interest Rate.* The risk-free interest rate is estimated using the U.S. Treasury yield curve and is based on the expected term of the award.

*Expected Term.* The expected term of stock option awards granted is estimated based on the "simplified" method described in the SEC Staff Accounting Bulletin, Topic 14: *Share-Based Payment*. The Company uses historical data to estimate stock option forfeitures.

*Expected Dividends.* The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock.

*Expected Volatility.* Expected volatility is estimated based on the Company's historical stock price volatility and expected stock price volatility over the term of the awards.

Compensation expense related to stock options was recognized as follows:

	Year Ended December 31,	
	2018	2017
Selling, general and administrative	\$ 2,923,834	\$ 4,313,907
Research and development	173,972	122,890
Total	\$ 3,097,806	\$ 4,436,797

As of December 31, 2018, there was approximately \$6.2 million of total unrecognized compensation related to unvested stock option awards, which is expected to be recognized over a weighted-average period of 2.5 years.

**(17) Retirement Plan**

The Company has a 401(k) profit-sharing plan that provides retirement benefits to employees. Eligible employees may contribute a percentage of their annual compensation, subject to Internal Revenue Service limitations. The Company's matching is at the discretion of the Company's board of directors. For the years ended December 31, 2018 and 2017, the Company did not provide any matching of employees' contributions.

**(18) Subsequent Events**

On February 1, 2019, pursuant to an exchange agreement with Sabby Volatility Warrant Master Fund, Ltd. ("Sabby") 1,192,000 shares of the Company's common stock were exchanged for an aggregate of 1,192,000 shares of series E convertible preferred stock, par value \$0.01 per share ("Series E Preferred Stock") in a noncash transaction. Each share of Series E Preferred Stock will initially be convertible into one share of common stock at Sabby's election. The Series E Preferred Stock includes a provision which limits the holder's right to convert shares of Series E Preferred Stock into common stock such that its beneficial ownership may not exceed 9.99% of the Company's outstanding common stock.

On March 29, 2019, the Company completed a private placement with two healthcare focused institutional investors for the sale of secured subordinated original issue discount convertible debentures for a purchase price of \$2 million. The debentures are due June 28, 2019 and have a face amount of \$2.2 million, reflecting a 10% original issue discount. At any time after June 28, 2019, if the debentures have not been repaid, subject to certain investor ownership limitations, the debentures will be convertible into shares of common stock at a conversion price equal to the lesser of \$0.33 and 80% of the average of the lowest two volume weighted average prices of the Company's common stock during the 20 trading days prior to conversion. As collateral for the Company's obligations under the debentures, the Company has granted the debenture holders a subordinated security interest in all of the assets of the Company and its subsidiary.

In connection with the financing, the Company amended the exercise price of warrants to purchase up to 8 million shares of common stock held by the investors that were issued on November 28, 2018 from \$1.50 per share to \$0.01 per share.

## **ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

### **ITEM 9A. CONTROLS AND PROCEDURES**

#### **Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”)), that are intended to ensure that information that would be required to be disclosed in Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

We carried out an evaluation, under the supervision, and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2018. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective as of December 31, 2018 due to the material weaknesses in internal control over financial reporting described below.

#### **Management’s Report on Internal Control Over Financial Reporting**

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) promulgated under the Exchange Act as a process, designed by, or under the supervision of the Company’s principal executive and principal financial officers and effected by the Company’s Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. Internal control over financial reporting includes maintaining records that, in reasonable detail, accurately and fairly reflect our transactions and disposition of assets; providing reasonable assurance that transactions are recorded as necessary for preparation of our financial statements; providing reasonable assurance that receipts and expenditures are made only in accordance with management and Board authorizations; and providing reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Management excluded from its assessment the internal control over financial reporting of transactions arising from the acquisition of the Lap-Band product line on December 17, 2018. The Lap-Band product line assets constituted 36 percent of consolidated assets from continuing operations and revenues were 74 percent of consolidated revenues from continuing operations as of and for the year ended December 31, 2018. This exclusion was in accordance with SEC guidance that an assessment of a recently acquired business may be omitted in management’s report on internal control over financial reporting in the year of acquisition.

Because of its inherent limitations, internal control over financial reporting is not intended to provide absolute assurance that a misstatement of our financial statements would be prevented or detected. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with policies or procedures may deteriorate. Management, with the participation of the Company’s principal executive and principal financial officers, conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2018 based on the framework and criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. This evaluation included review of the documentation of controls, evaluation of the design effectiveness of controls, testing of the operating effectiveness of controls and a conclusion on this evaluation. Based on the foregoing, management concluded that the Company’s internal control over financial reporting was not effective as of December 31, 2018 for the reasons described below.

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Management has determined that the Company has not maintained adequate accounting resources with a sufficient understanding of GAAP to allow the Company to identify and properly account for new complex transactions. Management has determined that this represents a material weakness in the Company's internal control over financial reporting. As a result of this material weakness, management has identified the following additional material weakness in the Company's internal control over financial reporting:

- The Company did not design and implement internal controls around research and development expenses paid to a CRO. This material weakness resulted in the Company not identifying that certain research and development expenses paid to the CRO in connection with the clinical trial of the ReShape Vest are required to be capitalized under GAAP, and recognized into expense as the value of the capitalized asset is realized.

This annual report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to permanent exemption rules of the Dodd-Frank Wall Street Reform and Consumer Protection Act that permit the Company to provide only management's report in this annual report.

### **Changes in Internal Control Over Financial Reporting**

#### *Material Weakness Remediation Activities*

The Company, the Audit Committee and the Company's Board of Directors are committed to maintaining a strong internal control environment, and are currently evaluating remediation efforts that will be designed to enhance our control environment.

We expect that the remediation efforts relating to the adequacy of accounting resources with a sufficient understanding of GAAP will involve a re-evaluation of our overall staffing levels within the accounting department, evaluating the extent to which additional resources are required and what qualifications such resources must possess, and attracting and hiring those resources. We also plan to re-evaluate the trainings and ongoing professional education that is provided to, and required of, our accounting personnel.

Remediation efforts pertaining to the research and development expenses paid to the CRO are expected to consist of establishing transactional level controls to evaluate and monitor the accounting treatment for research and development-related costs.

Once the remediation plans are finalized and are implemented, the identified material weaknesses in internal control over financial reporting will be considered fully addressed when the relevant internal controls have been in operation for a sufficient period of time for our management to conclude that the material weaknesses have been fully remediated and our internal control over financial reporting is effective. The Company will work to design, implement and rigorously test these new controls in order to make these final determinations.

We previously disclosed that in 2017 management concluded there to be a material weakness in the design of the Company's income tax controls in that our external income tax specialist was not adequately engaged to assist in the determination of deferred taxes associated with material transactions, such as the business acquisitions which occurred in 2017. To remediate the material weakness in our internal control over financial reporting, we implemented the following control:

- We enhanced our existing controls over income taxes to better integrate our external income tax specialist in our quarterly and annual financial reporting process, in order to ensure that all relevant information relating to new business activities which may have an impact on the Company's income tax accounting and disclosures, including information concerning significant transactions, is considered.

As a result of the remediation activities and controls in place as of December 31, 2018 described above, we have remediated the previously disclosed material weakness.

Other than these items and the material weaknesses noted above, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that occurred during the

quarter ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

None.

**PART III.**

Certain information required by Part III is omitted from this report, and is incorporated by reference to our Definitive Proxy Statement to be filed with the SEC pursuant to Regulation 14A (the Proxy Statement) in connection with our 2019 Annual Meeting of Stockholders.

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The information required by this Item concerning our directors and executive officers is hereby incorporated by reference to the sections of our Proxy Statement under the headings “Nominees,” “Executive Officers,” “Section 16(a) Beneficial Ownership Reporting Compliance” and “Board Meetings and Committees—Audit Committee.”

We have adopted a code of business conduct and ethics, which applies to all directors and employees, including executive officers, including, without limitation, our principal executive officer, principal financial officer, principal accounting officer and persons performing similar functions. A copy of this code of business conduct and ethics is available on our website at [www.reshapelifesciences.com](http://www.reshapelifesciences.com) (under “Investors,” “Corporate Governance”) and we intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding any waivers from or amendments to any provision of the code of business conduct and ethics by disclosing such information on the same website.

In addition, we intend to promptly disclose (1) the nature of any amendment to our code of business conduct and ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of business conduct and ethics that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver on our website in the future.

**ITEM 11. EXECUTIVE COMPENSATION**

The information required by this Item is hereby incorporated by reference to the sections of our Proxy Statement entitled “Director Compensation,” “Executive Compensation,” “Compensation Committee Interlocks and Insider Participation” and “Compensation Committee Report.”

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

**(a) Equity Compensation Plans**

The following table sets forth information as of December 31, 2018 with respect to our equity compensation plans:

<b>Plan Category</b>	<b>Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights</b>	<b>Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights</b>	<b>Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Second Column)</b>
Equity compensation plans approved by security holders	3,982 (1)	\$ 48,910.71	3,161 (2)
Equity compensation plans not approved by security holders	243 (3)	13,595.10	—
<b>Total</b>	<b>4,225</b>	<b>46,879.54</b>	<b>3,161</b>

- (1) Consists of options awarded under the Second Amended and Restated 2003 Stock Incentive Plan, which was amended (the “Plan), as amended.
- (2) Represents the maximum number of shares of common stock available to be awarded under the Plan as of December 31, 2018. Pursuant to an automatic share increase provision in the Plan that provides for an annual increase on the first day of each year beginning in 2019 such that the number of shares of common stock available under the Plan equals 15% of the total shares of common stock outstanding as of the last day of the immediately preceding fiscal year, an additional 3,623,892 shares of common stock became available for issuance under the Plan on January 1, 2019.

(3) Consists of the inducement grants awarded to newly hired executives and other employees.

**(b) Security Ownership**

The information required by this Item is hereby incorporated by reference to the section of our Proxy Statement entitled “Security Ownership of Certain Beneficial Owners and Management.”

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information required by this Item is hereby incorporated by reference to the section of our Proxy Statement entitled “Certain Relationships and Related Transactions, and Director Independence.”

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The information required by this Item is hereby incorporated by reference to the section of our Proxy Statement entitled “Principal Accountant Fees and Services” and “Administration of Engagement of Independent Auditor.”

**PART IV.**

**ITEM 15. EXHIBITS, FINANCIAL STATEMENTS AND FINANCIAL STATEMENT SCHEDULES**

(a) *Financial Statements and Schedules:* Consolidated Financial Statements for the three years ended December 31, 2017 are included in Part II, Item 8 of this Annual Report on Form 10-K. All schedules are omitted because they are not applicable or the required information is shown in the consolidated financial statements or notes thereto.

(b) *Exhibits:* The list of exhibits on the Exhibit Index on page 76 of this report is incorporated herein by reference.

**ITEM 16. FORM 10-K SUMMARY**

Not applicable

## EXHIBIT INDEX

<b>Exhibit Number</b>	<b>Description of Document</b>
2.1	<a href="#">Asset Purchase Agreement, dated December 17, 2018, by and between the Company and Apollo Endosurgery, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 19, 2018).</a>
3.1	<a href="#">Sixth Amended and Restated Certificate of Incorporation of the Company. (Incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on December 28, 2016 (File No. 1-33818)).</a>
3.2	<a href="#">Amended and Restated Bylaws of the Company, as currently in effect. (Incorporated herein by reference to Exhibit 3.4 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed on July 6, 2007 (File No. 333-143265)).</a>
3.3	<a href="#">Certificate of Designation of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 16, 2017).</a>
3.4	<a href="#">Certificate of Designation of Series C Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 3, 2017).</a>
3.5	<a href="#">Certificate of Designation of Series E Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 4, 2019).</a>
3.6	<a href="#">Certificate of Amendment to Sixth Amended and Restated Certificate of Incorporation of the Company, dated October 20, 2017 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 23, 2017).</a>
3.7	<a href="#">Certificate of Amendment to Sixth Amended and Restated Certificate of Incorporation of the Company, dated October 26, 2017 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 30, 2017).</a>
3.8	<a href="#">Certificate of Amendment to Sixth Amended and Restated Certificate of Incorporation, dated June 1, 2018 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 1, 2018).</a>
3.9*	<a href="#">Certificate of Amendment to Sixth Amended and Restated Certificate of Incorporation, dated November 7, 2018 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 7, 2018).</a>
4.1	<a href="#">Form of Secured Subordinated Original Issue Discount Convertible Debenture due June 28, 2019 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 3, 2019).</a>
4.2	<a href="#">Form of Series A Common Stock Purchase Warrant issued November 28, 2018 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 28, 2018).</a>
4.3	<a href="#">Form of Pre-Funded Common Stock Purchase Warrant issued November 28, 2018 (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 28, 2018).</a>
4.4	<a href="#">Form of Placement Agent's Common Stock Purchase Warrant issued November 28, 2018 (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 28, 2018).</a>
4.5	<a href="#">Form of Common Stock Purchase Warrant issued September 20, 2018 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 20, 2018).</a>



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<b>Exhibit Number</b>	<b>Description of Document</b>
4.6	<a href="#">Form of Placement Agent’s Common Stock Purchase Warrant issued September 20, 2018 (incorporated by reference to Exhibit 4.2 to the Company’s Current Report on Form 8-K filed with the Securities and Exchange Commission on September 20, 2018).</a>
4.7	<a href="#">Form of Common Stock Purchase Warrant issued August 3, 2018 (incorporated by reference to Exhibit 4.1 to the Company’s Current Report on Form 8-K filed with the Securities and Exchange Commission on August 2, 2018).</a>
4.8	<a href="#">Form of Placement Agent’s Common Stock Purchase Warrant issued August 3, 2018 (incorporated by reference to Exhibit 4.2 to the Company’s Current Report on Form 8-K filed with the Securities and Exchange Commission on August 2, 2018).</a>
4.9	<a href="#">Form of Common Stock Purchase Warrant issued July 12, 2018 (incorporated by reference to Exhibit 4.1 to the Company’s Current Report on Form 8-K filed with the Securities and Exchange Commission on July 12, 2018).</a>
4.10	<a href="#">Form of Placement Agent’s Common Stock Purchase Warrant issued July 12, 2018 (incorporated by reference to Exhibit 4.2 to the Company’s Current Report on Form 8-K filed with the Securities and Exchange Commission on July 12, 2018).</a>
4.11	<a href="#">Form of Common Stock Purchase Warrant issued June 21, 2018 (incorporated by reference to Exhibit 4.1 to the Company’s Current Report on Form 8-K filed with the Securities and Exchange Commission on June 21, 2018).</a>
4.12	<a href="#">Form of Placement Agent’s Common Stock Purchase Warrant issued June 21, 2018 (incorporated by reference to Exhibit 4.2 to the Company’s Current Report on Form 8-K filed with the Securities and Exchange Commission on June 21, 2018).</a>
4.13	<a href="#">Form of Common Stock Purchase Warrant issued June 8, 2018 (incorporated by reference to Exhibit 4.1 to the Company’s Current Report on Form 8-K filed with the Securities and Exchange Commission on June 8, 2018).</a>
4.14	<a href="#">Form of Placement Agent’s Common Stock Purchase Warrant issued June 8, 2018 (incorporated by reference to Exhibit 4.2 to the Company’s Current Report on Form 8-K filed with the Securities and Exchange Commission on June 8, 2018).</a>
4.15	<a href="#">Form of Common Stock Purchase Warrant issued April 3, 2018 (incorporated by reference to Exhibit 4.1 to the Company’s Current Report on Form 8-K filed with the Securities and Exchange Commission on April 3, 2018).</a>
4.16	<a href="#">Form of Warrant, dated August 16, 2017 (incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed with the Securities and Exchange Commission on August 16, 2017).</a>
4.17	<a href="#">Form of Series C Warrant, dated as of July 8, 2015, by and between the Company and several accredited investors. (Incorporated herein by reference to Exhibit 4.2 to the Company’s Current Report on Form 8-K filed on July 7, 2015 (File No. 1-33818)).</a>
4.18	<a href="#">Form of Warrant. (Incorporated herein by reference to Exhibit 4.2 to the Company’s Current Report on Form 8-K filed on November 5, 2015 (File No. 1-33818)).</a>
4.19	<a href="#">Form of Warrant to purchase shares of Common Stock. (Incorporated herein by reference to Exhibit 4.3 to the Company’s Registration Statement on Form S-1 filed on January 11, 2017 (File No. 333-213704)).</a>
10.1	<a href="#">Security Agreement, dated December 17, 2018, by and between the Company and Apollo Endosurgery, Inc. (incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed with the Securities and Exchange Commission on December 19, 2018).</a>
10.2	<a href="#">Form of Securities Purchase Agreement, dated March 28, 2019, by and between the Company and the holders of Secured Subordinated Original Issue Discount Convertible Debentures due June 28, 2019 (incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed with the Securities and Exchange Commission on April 3, 2019).</a>

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<b>Exhibit Number</b>	<b>Description of Document</b>
10.3	<a href="#">Form of Security Agreement, dated March 28, 2019, by and between the Company and the holders of Secured Subordinated Original Issue Discount Convertible Debentures due June 28, 2019 (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 3, 2019).</a>
10.4	<a href="#">Form of Registration Rights Agreement, dated March 28, 2019, by and between the Company and the holders of Secured Subordinated Original Issue Discount Convertible Debentures due June 28, 2019 (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 3, 2019).</a>
10.5†	<a href="#">Second Amended and Restated 2003 Stock Incentive Plan, as amended on May 23, 2018 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 25, 2018).</a>
10.6†	<a href="#">Form of Stock Option Grant Notice and Stock Option Agreement under Second Amended and Restated 2003 Stock Incentive Plan (Incorporated herein by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed on November 14, 2017).</a>
10.7	<a href="#">Form of Indemnification Agreement entered into by and between the Company and each of its executive officers and directors. (Incorporated herein by reference to Exhibit 10.17 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed on July 6, 2007 (File No. 333-143265)).</a>
10.8†	<a href="#">Executive Employment Agreement, dated October 28, 2015, by and between the Company and Dan W. Gladney. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 2, 2015 (File No. 1-33818)).</a>
10.9†	<a href="#">Executive Employment Agreement, dated January 19, 2016, by and between the Company and Naqeeb "Nick" Ansari. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 22, 2016 (File No. 1-33818)).</a>
10.10†	<a href="#">Executive Employment Agreement, dated October 3, 2016, by and between the Company and Scott Youngstrom. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 6, 2016 (File No. 1-33818)).</a>
10.11†	<a href="#">Executive Employment Agreement, dated as of May 22, 2017, by and between the Company and Dr. Raj Nihalani (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 23, 2017)</a>
10.12	<a href="#">Non-Competition and Non-Solicitation Agreement, dated as of May 22, 2017, by and between the Company and Dr. Raj Nihalani (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 23, 2017)</a>
10.13†	<a href="#">2017 Employment Inducement Incentive Award Plan (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on November 14, 2017).</a>
10.14†	<a href="#">Form of Stock Option Grant Notice and Stock Option Agreement under 2017 Employment Inducement Incentive Award Plan (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on November 14, 2017 (File No. 1-33818)).</a>
10.15†	<a href="#">Management Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 12, 2008 (File No. 1-33818)).</a>
10.16†	<a href="#">Amendments to the Management Incentive Plan described in Item 5.02(e). (Incorporated herein by reference to Item 5.02(e) of the Company's Current Report on Form 8-K filed on May 10, 2016 (File No. 1-33818)).</a>
10.17†	<a href="#">Amendments to the Management Incentive Plan described in Item 5.02(e). (Incorporated herein by reference to Item 5.02(e) of the Company's Current Report on Form 8-K filed on September 20, 2016 (File No. 1-33818)).</a>

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<b>Exhibit Number</b>	<b>Description of Document</b>
10.18	<a href="#">Lease agreement, entered into January 20, 2017, by and between ReShape Medical, Inc. and San Clemente Holdings, LLC (incorporated by reference to Exhibit 10.38 to the Company's Annual Report on Form 10-K filed on April 2, 2018).</a>
10.19	<a href="#">Lease agreement, entered into March 28, 2008 and as amended, by and between ReShape Medical, Inc. and Richard G. Henderson (incorporated by reference to Exhibit 10.39 to the Company's Annual Report on Form 10-K filed on April 2, 2018).</a>
10.20	<a href="#">Clinical Trial Agreement by and between the Company and Southern California Permanente Medical Group effective as of June 1, 2017 (Incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 15, 2017 (File No. 1-33818)).</a>
14.1	<a href="#">Code of Conduct and Ethics of the Company. (Incorporated herein by reference to Exhibit 14.1 to the Company's Registration Statement on Form S-1 filed on May 25, 2007 (File No. 333-143265)).</a>
23.1*	<a href="#">Consent of Deloitte &amp; Touche LLP, Independent Registered Public Accounting Firm.</a>
24.1*	<a href="#">Power of Attorney (included on signature page to this Form 10-K).</a>
31.1*	<a href="#">Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
31.2*	<a href="#">Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
32.1*	<a href="#">Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
32.2*	<a href="#">Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
101*	Financial statements from the Annual Report on Form 10-K of the Company for the year ended December 31, 2018, formatted in Extensible Business Reporting Language: (i) the Consolidated Statements of Operations, (ii) the Consolidated Balance Sheets, (iii) the Consolidated Statements of Stockholders' Equity; (iv) the Consolidated Statements of Cash Flows and (v) the Notes to Consolidated Financial Statements.

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\* Filed herewith.

† Indicates management contract or compensation plan or agreement.



**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in Registration Statement Nos. 333-211940, 333-196646, 333-184181, 333-176174, 333-171244, 333-159592, and 333-149662 on Form S-8, Registration Statement Nos. 333-216600, 333-205353, 333-195855, 333-183313, 333-171944, 333-170503, 333-171052, 333-166011, 333-158516, 333-224066, and 333-225083 on Form S-3, and Registration Statement Nos. 333-215590 and 333-123704, on Form S-1 of our report dated May 16, 2019, relating to the financial statements of ReShape Lifesciences Inc. and subsidiary (which report expresses an unqualified opinion and includes an explanatory paragraph relating to the substantial doubt about the entity's ability to continue as a going concern as described in Note 3 to the financial statements) appearing in this Annual Report on Form 10-K of ReShape Lifesciences Inc. for the year ended December 31, 2018.

/s/ DELOITTE & TOUCHE LLP

Minneapolis, MN

May 16, 2019

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## CERTIFICATIONS

I, Barton P. Bandy, certify that:

1. I have reviewed this Annual Report on Form 10-K of ReShape Lifesciences Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/BARTON P. BANDY

**Barton P. Bandy**  
**President and Chief Executive Officer**

Date: May 14, 2019

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## CERTIFICATIONS

I, Scott P. Youngstrom, certify that:

1. I have reviewed this Annual Report on Form 10-K of ReShape Lifesciences Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ SCOTT P. YOUNGSTROM  
\_\_\_\_\_  
**Scott P. Youngstrom**  
**Chief Financial Officer**  
**and Senior Vice President, Finance**

Date: May 14, 2019

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**CERTIFICATION PURSUANT TO  
18 U.S.C. §1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of ReShape Lifesciences Inc. (the Company) on Form 10-K for the period ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the Report), I, Barton P. Bandy, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934;  
and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

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/S/BARTON P. BANDY  
**Barton P. Bandy**  
**President and Chief Executive Officer**

May 14, 2019

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