June 4, 2018

ReShape Lifesciences Provides Update on FDA Letter to Health Care Providers Related to Intragastric Balloons

Conference Call Scheduled for June 4, 2018 at 1:30 PM Pacific Time

SAN CLEMENTE, Calif., June 4, 2018 /PRNewswire/ -- ReShape Lifesciences Inc. (NASDAQ:RSLS), a developer of minimally invasive medical devices to treat obesity and metabolic diseases, today provided an explanation and clarifying details to a letter dated June 4, 2018 that the U.S. Food and Drug Administration (FDA) posted on their website addressed to Health Care Providers. The FDA letter updates the agency's August 10, 2017 letter regarding the potential risks of death associated with liquid-filled intragastric balloons manufactured by Apollo Endosurgery and ReShape Lifesciences™.

FDA's most recent communication updates the healthcare community regarding additional reports of deaths they have received since August 2017 and discusses the collaborative effort taken with industry to understand these occurrences and enhance product labeling accordingly. In relation to the ReShape Balloon™, the facts are:

- ReShape Balloon is approved by the FDA as safe and effective for weight reduction when used in conjunction with diet and exercise, in obese patients with a Body Mass Index (BMI) of 30 - 40 kg/m^2 and one or more obesity-related comorbid conditions. It is indicated for use in adult patients who have failed weight reduction with diet and exercise alone.
- There has been one (1) reported death of a patient implanted with a ReShape Balloon since the August 10, 2017 letter from FDA
- The patient death was due to a pulmonary embolization secondary to a surgical repair of a gastric perforation
- ReShape has received no product liability-related claims in connection with this case

"Patient safety is our highest priority at ReShape Lifesciences, and safety was the main driver behind the unique dual balloon design of our ReShape Balloon," stated Dan Gladney, Chairman and Chief Executive Officer of ReShape Lifesciences. "We worked closely with FDA to review and enhance our Instructions for Use (IFU), patient information and physician training materials and we will continue to work with the FDA to mitigate patient risk and optimize outcomes so that we can continue to safely and effectively change lives with our obesity solutions."

"Unfortunately, all health care procedures have a certain amount of associated risk, especially when they are dealing with a patient population that often has many associated difficult medical conditions," commented Scott A. Shikora, MD, FACS; Professor of Surgery, Harvard Medical School; Director, Center for Metabolic and Bariatric Surgery, Brigham and Women's Hospital. "It is important to note that FDA's recommendation to providers remains the same: Intragastric balloon patients should be closely monitored during the entire term of their treatment."

The FDA letter to Health Care Providers can be found here:

https://www.fda.gov/MedicalDevices/Safety/LetterstoHealthCareProviders/ucm609597.htm

The MDR related to the death mentioned in FDA's letter can be found here:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=6967005&pc=LTI

Management will host an investment community conference call today beginning at 1:30 p.m. Pacific Time /4:30 p.m. Eastern Time.

Individuals interested in listening to the conference call may do so by dialing 877-317-6789 for domestic callers or 412-317-6789 for international callers and requesting to join the ReShape Lifesciences call. To listen to a live webcast or a replay, please visit the investor relations section of the Company website at: http://ir.reshapelifesciences.com/.

About ReShape Lifesciences Inc.

ReShape Lifesciences™ is a medical device company focused on technologies to treat obesity and metabolic diseases. The FDA-approved ReShape Balloon™ System involves a non-surgical weight loss procedure that uses advanced balloon technology designed to take up room in the stomach to help people with a 30-40 kg/m^2 Body Mass Index (BMI) and at least one co-morbidity lose weight. ReShape vBloc™ Therapy, delivered by an FDA-approved pacemaker-like device called the ReShape vBloc System, is designed to help patients with a 40-45 kg/m^2, or a 35-39.9 kg/m^2 BMI and at least one co-morbidity feel full and eat less by intermittently blocking hunger signals on the vagus nerve. The ReShape Vest™ System is an investigational, minimally invasive, laparoscopically implanted medical device that wraps around the stomach, emulating the gastric volume reduction effect of conventional weight-loss surgery, and is intended to enable rapid weight loss in obese and morbidly obese patients without permanently changing patient anatomy.

Forward-Looking Safe Harbor Statement:

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements generally can be identified by the use of words such as "expect," "plan," "anticipate," "could," "may," "intend," "will," "continue," "future," other words of similar meaning and the use of future dates. These forward-looking statements are based on the current expectations of our management and involve known and unknown risks and uncertainties that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others: risks and uncertainties related to our acquisitions of ReShape Medical, Inc. and BarioSurg, Inc.; risks related to the U.S. Food and Drug Administration's announcement to alert health care providers of unanticipated deaths involving the ReShape Balloon; our proposed ReShape Vest product may not be successfully developed and commercialized; our ability to continue as a going concern if we are unsuccessful in our pursuit of various funding options; our limited history of operations; our losses since inception and for the foreseeable future; our limited commercial sales experience; the competitive industry in which we operate; our ability to maintain compliance with the Nasdaq continued listing requirements; our dependence on third parties to initiate and perform our clinical trials; the need to obtain regulatory approval for our ReShape Vest and any modifications to our vBloc system or ReShape Balloon; physician adoption of our products; our ability to obtain third party coding, coverage or payment levels; ongoing regulatory compliance; our dependence on third party manufacturers and suppliers; the successful development of our sales and marketing capabilities; our ability to raise additional capital when needed; international commercialization and operation; our ability to attract and retain management and other personnel and to manage our growth effectively; potential product liability claims; the cost and management time of operating a public company; potential healthcare fraud and abuse claims; healthcare legislative reform; and our ability to obtain and maintain intellectual property protection for our technology and products. These and additional risks and uncertainties are described more fully in the Company's filings with the Securities and Exchange Commission, particularly those factors identified as "risk factors" in our annual report on Form 10-K filed April 2, 2018. We are providing this information as of the date of this press release and do not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

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