July 15, 2020

Soliton Receives FDA Acceptance for 510(k) Application

- Rapid Acoustic Pulse ("RAP") device 510(k) Application Accepted for cellulite reduction -

HOUSTON, July 15, 2020 /PRNewswire/ -- Soliton, Inc., (Nasdaq: SOLY) ("Soliton" or the "Company"), a medical device company with a novel and proprietary aesthetic platform technology, today announced that its 510(k) application for premarket clearance filed with the U.S. Food and Drug Administration ("FDA") for its second generation Rapid Acoustic Pulse ("RAP") device for cellulite reduction has cleared the agency's acceptance review. The application now moves to a substantive review. The device is already indicated as an accessory to the 1064 nm Q-Switched laser for black ink tattoo removal in Fitzpatrick Skin Type I-III patients and this latest new application is for the temporary improvement of the appearance of cellulite. Clinical trials have demonstrated an average 32.5% improvement in the Cellulite Severity Score in our subjects and strong patient satisfaction with 91.9% of subjects agreeing or strongly agreeing that their cellulite appeared improved. Further, there were no unexpected or serious adverse events and the average pain scores were 2.4 on a 10-point scale.

Dr. Christopher Capelli, president and CEO of Soliton, said, "We are very pleased with the progress of our premarket notification through the FDA review process." Dr. Capelli continued, "Having found that our submission contained all the necessary elements and information, we look forward to the substantive review and FDA clearance of the RAP device."

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Cellulite affects between 80% and 90% of women and over a billion dollars per year is spent on treatment in the U.S. The Soliton clinical trial protocol provided for a single 20 to 30-minute, non-invasive treatment in which the Rapid Acoustic Pulse (RAP) device was applied to the surface of the subjects' skin. The treatment required no anesthesia, caused no unexpected or serious adverse events, and was evaluated as relatively painless by the trial subjects, with an average pain score of 2.4 out of 10.

The Company believes there is a reasonable expectation that the FDA will allow it to remain on the 510(k) clearance pathway in order to market the product. However, acceptance of our application does not indicate that the FDA has accepted the Company's predicate argument. Should the FDA deem our choice of predicate device to be inadequate, we would be required to convert our application to a De Novo request, which we estimate would extend the filing and review process by approximately six to nine months.

About Soliton, Inc.

Soliton, Inc. is a medical device company with a novel and proprietary platform technology licensed from The University of Texas on behalf of the MD Anderson Cancer Center. The Company's first FDA cleared commercial product will use rapid pulses of acoustic shockwaves as an accessory to lasers for the removal of unwanted tattoos. The Company is based in Houston, Texas, and is actively engaged in bringing the Rapid Acoustic Pulse ("RAP") device to the market. The Company believes this "Soliton" method has the potential to lower tattoo removal costs for patients, while increasing profitability to practitioners, compared to current laser removal methods. Soliton is investigating potential additional capabilities of the RAP technology in clinical and preclinical testing, including the potential to improve the appearance of cellulite by creating mechanical stress at the cellular level and inducing significant collagen growth and the potential to treat keloid and hypertrophic scars by targeting the stiffened environment in the intracellular matrix.

For more information about the Company, please visit: http://www.soliton.com

Forward-Looking Statements

Some of the statements in this release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, which involve risks and uncertainties. Forward-looking statements in this press release include, without limitation, the ability of the Company to receive clearance from the FDA to market the device for the reduction of cellulite. These statements relate to future events, future expectations, plans and prospects. Although Soliton believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, expectations may prove to have been materially different from the results expressed or implied by such forward-looking statements. Soliton has attempted to identify forward-looking statements by terminology including "believes," "estimates," "anticipates," "expects," "plans," "projects," "intends," "potential," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, including those discussed in our SEC filings, including under the heading "Item 1A. Risk Factors" in the Form 10-K for year ended December 31, 2019 we filed with the SEC and updated from time to time in our Form 10-Q filings and in

our other public filings with the SEC. Any forward-looking statements contained in this release speak only as of its date. Soliton undertakes no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

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