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Soliton Receives FDA Acceptance for 510(k) Application

510(k) Application Acceptance for Rapid Acoustic Pulse ("RAP") device in tattoo removal

HOUSTON, March 27, 2019 /PRNewswire/ -- Soliton, Inc. (NASDAQ: SOLY) ("Soliton" or the "Company"), 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 ("MD Anderson"), today announced that its 510(k) application for premarket clearance filed with the U.S. Food and Drug Administration ("FDA") for its first generation Rapid Acoustic Pulse ("RAP") tattoo removal device has cleared the agency's acceptance review. The application now moves to a substantive review. The device is indicated as an accessory to the 1064 nm Q-Switched (pulsed) laser for black ink tattoo removal on the arms, legs and torso in Fitzpatrick Skin Type I-III individuals. Clinical trials have demonstrated that using the Company's RAP device, in conjunction with a Q-Switched laser, allows for multiple passes of laser treatment in a single treatment session. The current standard of care for tattoo removal is to use a Q-Switched laser to ablate the tattoo ink particles into pieces small enough for the body's natural processes to remove them, that independent studies have shown require on average ten or more office visits to achieve acceptable results. In our own clinical trial using the RAP device in conjunction with a Q-Switched laser, patients experienced 75% to 100% removal of their tattoos in just three office visits.

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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."

"We are excited about the prospects for our RAP technology as we enter the tattoo removal segment—estimated to be approximately $4.8 billion annually by 2023. And, we expect our higher energy version of this new technology will eventually take us into additional, and potentially bigger aesthetics markets. Because our technology relies upon replaceable cartridges for each treatment, we believe our business model will benefit from recurring revenue, allowing Soliton to share in the volume growth in the aesthetic category expected in the coming years," said Dr. Capelli.

About Soliton, Inc.

Soliton, Inc. is a medical device company with a novel and proprietary platform technology licensed from MD Anderson. The Company's first planned commercial product is designed to use rapid pulses of designed acoustic shockwaves in conjunction with existing lasers to accelerate the removal of unwanted tattoos (RAP device). In addition, higher energy versions of acoustic pulse devices are in early stages of development for potential stand-alone treatment of cellulite and other indications. Both products are investigational and are not available for sale in the United States.

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 Soliton RAP to accelerate tattoo fading or fat removal and/or to reduce cellulite, whether future clinical trials related to the acceleration of existing fat removal technologies and cellulite are successful, the ability of Soliton's RAP to receive FDA clearance, and the ability of Soliton's higher energy device to be proven safe and effective in other aesthetic procedures. 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 under in our SEC filings, including under the heading "Risk Factors" in the Form 1-A we filed with the SEC on February 13, 2019. 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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