

September 4, 2019



# Soliton Announces IRB Approval for Keloid Trial

## Protocol for Proof-of-Concept Clinical Trial for the Treatment of Keloid and Hypertrophic Scars Approved

HOUSTON, Sept. 4, 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 the Company has received approval for the trial protocol from the independent Institutional Review Board ("IRB") for its upcoming proof-of-concept fibrotic scar trial.

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The Institutional Review Board (IRB) is an FDA registered constituted group that has been formally designated to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, an IRB has the authority to approve, require modifications (to secure approval), or disapprove research. This group review serves an important role in the protection of the rights and welfare of human research subjects.

"We are very excited to begin this new clinical trial," commented Dr. Chris Capelli, Soliton's President, CEO and co-founder. "Not only would this represent a third potential indication (in addition to tattoo removal and reduction of cellulite), but in the case of keloid and hypertrophic scars, if we can demonstrate activity in this trial, it may well support the use of our RAP technology in a wider range of fibrotic disorders. Grand View Research estimates the global market for keloid and hypertrophic scars may reach \$10.2 billion by 2025."

### **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 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 preclinical testing, including the potential to assist existing fat reduction technology in the reduction of fat as well as improving the appearance of cellulite by creating mechanical stress at the cellular

level and inducing significant collagen growth.

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 Soliton RAP device to demonstrate safety and efficacy in the reduction of keloid and hypertrophic scars and the ability for Soliton to receive FDA clearance for these additional indications. 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 "Item 1A. Risk Factors" in the Form 10-K for year ended December 31, 2018 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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