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Soliton's Recent Positive Data Increases Potential Fibrotic Indications

Success in Treatment of Fibrotic Scar Could Lead to Other Indications

HOUSTON, Oct. 29, 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"), discussed multiple additional indications that may be possible targets given the preliminary results from the keloid and hypertrophic scars clinical trial during the Company's recent webcast.

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"We are excited about the impact our RAP technology could have on many fibrotic disorders," stated Christopher Capelli, MD, founder, president and CEO of Soliton. "We view our keloid and hypertrophic scar proof-of-concept clinical trial as the starting point for demonstrating efficacy in fibrosis. The same mechanism of action at work to reduce keloid and hypertrophic scars may extend to many other indications."

Discovering the nature of fibroblasts and the impact that acoustic shockwaves may have on them is critical to understanding why Soliton's Rapid Acoustic Pulse ("RAP") may have efficacy against other fibrotic disorders. A fibroblast is a type of biological cell that synthesizes the extracellular matrix and collagen, produces the structural framework for human tissues, and plays a critical role in wound healing. Fibroblasts are the most common cells of connective tissue in humans.

Considerable independent published research demonstrates that fibroblasts respond to mechanical stress. Published research has established that one way to restore beneficial fibroblast activity is through the use of shockwaves like those produced by our RAP device.

However, fibroblasts can function abnormally in the body which leads to a multitude of issues. In the case of fibrosis, it is believed that stiffness in the surrounding extracellular matrix, or ECM, can cause fibroblasts to become aberrant, switching on with no way to switch off, so they just keep producing collagen well beyond what is needed. Paradoxically, acoustic shockwaves have been shown to disrupt and loosen the ECM making the ECM 'less stiff'. This results in the replacement of aberrant fibroblasts with normally functioning fibroblasts. This then potentially leads to resolution of fibrosis.

A large body of scientific literature supports that the basic mechanism of action for addressing fibrotic scars could be applicable to a wide range of fibrotic disorders. This could include disorders such as capsular contracture, Peyronie's Disease, and even liver fibrosis.

Capsular contracture involves the fibrotic encapsulation of implants in the body, such as breast implants, and this can cause pain and physical deformity. Published research has now shown that acoustic shockwaves post-implant may actually prevent the onset of capsular contracture. So, Soliton's RAP technology may not only be important just for the patients who suffer from this complication (which can be as much as 30% of women whose implants follow resection and radiation treatment for breast cancer), but it could become a prophylactic treatment for all implants.

Peyronie's disease is a condition in which scar tissue in the penis causes the penis to bend. Independent research suggests that 11% of adult males in the United States may suffer from probable Peyronie's Disease. Current treatment options are primarily injectable and are painful for the patient.

Nonalcoholic steatohepatitis (NASH) is the most severe form of non-alcoholic fatty liver disease (NAFLD), and is characterized by the presence of an abnormal accumulation of fat in the liver which in some individuals can progress to liver cell injury (hepatocellular ballooning) and inflammation. Hepatocellular ballooning and inflammation – sometimes called necroinflammation – are commonly considered as the drivers of disease progression, or as the underlying causes of the disease. As NASH evolves, over time it can result in excessive scarring in the liver (fibrosis), a natural response to injury which can lead to liver cirrhosis or liver cancer. The overall NASH prevalence in the adult population of developed countries has been estimated as high as 12%.

We believe RAP is actually a platform technology that will have a wide range of applications. And, we believe that continued success with the current keloid trial could be instrumental in unlocking that opportunity. We look forward to reporting the longer-term results from this trial and to announcing the beginning of a larger pivotal registration trial to follow.

Our technology is not currently cleared by the FDA for the treatment of keloid or hypertrophic scars, capsular contracture, Peyronie's Disease or liver fibrosis.

To access the webinar discussing our keloid and hypertrophic scar trial results click here: <https://www.soliton.com/conference-call-10-25-19/>

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, the ability for Soliton to receive FDA clearance for these additional indications and the ability of Soliton to pursue treatment of other fibrotic disorders. 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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