May 17, 2019

Soliton Provides FDA Update and Addresses Recent Anonymous Article

HOUSTON, May 17, 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 provided an update on its application for FDA clearance and addressed a recent anonymous article published on SeekingAlpha.com.

"We know there is a lot of focus on whether or not, and when, Soliton can achieve FDA clearance to market its new Rapid Acoustic Pulse (RAP) technology," commented Dr. Chris Capelli, President and CEO of Soliton. "So, we would like to provide some insight regarding where we stand in this process. We submitted our request for marketing clearance, referred to as a "510(k)," in March of this year. The targeted time period for review of a 510(k) application is 90 days. This means we should be receiving feedback from the FDA before the end of this month. Importantly, we have not been notified that our application must be converted to a "De Novo" process, the approval of which can take considerably longer to secure. While we cannot be certain that our application will continue as a 510(k) or that our application will eventually be cleared, we are now cautiously optimistic that our RAP device could be cleared sooner than we have been estimating."

Dr. Capelli continued, "While we normally don't comment on matters relating to our stock price, we are aware that the posting of an article by an anonymous author on SeekingAlpha.com has coincided with a precipitous drop in our stock price. Given that this article contains numerous misstatements of fact, we feel compelled to comment on the most egregious of those misstatements to ensure that investors are not further misled. The following recites a few of the misleading claims made in this article, followed by the factual reality:

CLAIMED: Remeditex has dumped every position that it has filed that it held on sec.gov. And they were smart decisions, as they all turned out to be dogs and are trading at a fraction today of what they traded at when Remeditex had its position. Will Remeditex follow this pattern and dump its entire position of SOLY? We believe it will.

FACTUAL: Mr. Brett Ringle, President of Remeditex, responded, "This statement is patently false. We continue to hold our positions in a number of publicly traded portfolio companies. We believe strongly in the underlying science and ultimate potential of Soliton. Our commitment to Soliton is evidenced by our investing over $27 million and having stuck by the Company throughout its existence. In fact, we even participated in the IPO. We always carefully analyze our portfolio companies and we are convinced that Soliton has a bright future and we will continue to be a part of that future."

CLAIMED: The company is years from having an FDA approved product.

FACTUAL: We have said in our filings and press releases that we expect clearance of our device by end of this year. However, as described above, it appears that we may receive notice back from the FDA regarding our 510(k) application this month. While we cannot be sure, we are cautiously optimistic that our device may be cleared sooner than the Company previously indicated.

CLAIMED: Right now, they don't even have a finished product to submit to the FDA.

FACTUAL: Only fully engineered, tested and documented finished products can be successfully submitted for FDA clearance, which is what we have done. Future generation products are intended to incorporate planned improvements. Our Generation 3 RAP device we expect to offer in our nationwide launch will have significant changes from the Generation 2 device that we intend to offer in our initial market launch, which in turn will have significant changes from the Generation 1 device we have submitted for FDA review and clearance. We expect the changes made to our device from Generation 1 to Generation 2 will necessitate the filing of an additional 510(k) before being launched. We cannot be certain that the changes we deem appropriate to make to the Generation 3 RAP device prior to the nationwide launch will not require another 510(k) filing.

CLAIMED: SOLY's study results are only shown on its website, and not in a peer reviewed journal, which makes the data less legitimate.

FACTUAL: Our clinical trial results were peer reviewed and published via the American Society For Laser Medicine & Surgery (ASLMS), one of the most respected bodies in laser medicine. Our device was also awarded "Best in Show" by the ASLMS.

CLAIMED: Zimmer also recommends using ZWave for cellulite treatment. So, what exactly is new or original in SOLY's RAP technology?

FACTUAL: Soliton's RAP shockwaves are 50 times faster (rise and fall time of peak pressure wave), 10 times higher in pressure and 4 times faster in repetition rate (click this link to see a direct comparison of the two devices: https://www.soliton.com/acoustic-shockwave/) than Zimmer ZWave. Eight patent families and 68 issued and pending patents distinguish the unique attributes of Soliton RAP that we believe make it unlike any other acoustic pulse device available. The repetition rate combined with the rapid rise and fall times alone are carefully designed to exploit the relaxation time and susceptibility to shear waves of the cellular and other structures we target. We are the only device we know of with this capability other than "focused" acoustic devices, which can't cover enough area to be practical for indications like tattoo removal and cellulite reduction and can result in significant heat and pain.

Dr. Capelli concluded, "We would encourage investors to consider the source. These misleading claims, which appear to have led to significant financial loss to some of our shareholders come from an anonymous source identified only as a short-seller, someone who stands to benefit by instilling fear in those who may not know better. This is so egregious that we feel compelled to explore all potential options against the perpetrators, including legal and regulatory. Regardless, long after this short-seller, who believes they face no consequences for their tortious misstatements, profits from those who are misled,

we will continue to stand in the full light of day by our claims, cautions and actions. For those who have not been misled, we thank you for you continued support and encouragement. We believe firmly that Soliton has tremendous potential and we remain committed to realizing that potential on your behalf."

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 reduce the number of treatment visits to remove 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's acoustic shockwave device to receive marketing clearance from the FDA. 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.