July 21, 2020

Soliton Provides Commercialization Update for Rapid Acoustic Pulse Device

- On track to launch RAP device in 1H 2021 under COVID-19 Adjusted Commercialization Strategy -

- Present Cash Provides 2 years of runway through revenue initiation -

HOUSTON, July 21, 2020 /PRNewswire/ -- Soliton, Inc., (Nasdaq: SOLY) ("Soliton" or the "Company"), a medical device company with a novel and proprietary aesthetic platform technology, today provided an update regarding the U.S. commercialization of its Rapid Acoustic Pulse device indicating the initial U.S. commercial launch is now targeted for the first half of 2021.

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Anticipated Launch Timing

The Company expects to initiate its U.S. commercial launch in the first half of 2021. In April of 2020, Soliton announced a new launch plan for its acoustic pulse device electing to delay the originally planned mid-2020 launch for tattoo removal in response to the COVID-19 pandemic.

The impact of COVID-19 on the global economy continues to be significant. As we speak with our advising physicians in the aesthetic space, it is clear that, while slowly starting to reopen, practices remain limited by social distancing requirements that are constraining the number of patients that can be seen each day. As such, the most urgent patient needs are

being prioritized. We believe that we will continue to see this dynamic throughout 2020.

Given these conditions, we expect the most appropriate launch window for our new technology will open in the first half of 2021. We are making plans to launch the RAP device during the first half of 2021, which will include the tattoo removal and cellulite reduction indications, subject to FDA clearance of the latter. We believe the opportunity to launch both indications simultaneously will significantly enhance both physician and patient adoption and result in a stronger launch of our technology.

"Soliton has taken great strides in the past months towards the full U.S. commercialization of our RAP device," stated Walter Klemp, Executive Chairman and co-founder of Soliton. "Bolstered by our latest financing, we will continue to execute on our manufacturing, regulatory and marketing objectives to progress toward our goal of initial product launch in the first half of 2021."

Regulatory Progress

The Generation 1 RAP device received U.S. FDA clearance in May of 2019 for use as an accessory to the 1064 Q-Switched laser for black ink tattoo removal in Fitzpatrick Skin Type I-III patients. Commercial upgrades to the Generation 2.0 device to improve usability were subsequently approved through a Special 510(k) in March of 2020. This improved device was utilized in the Company's recently completed pivotal cellulite trial, the data from which was included in the 510(k) pre-market application of its Generation 2.0 device for the temporary reduction in the appearance of cellulite filed on June 30, 2020. The 510(k) notice was found administratively complete and is currently under substantive review. Soliton anticipates FDA clearance for this indication prior to the conclusion of the first quarter 2021. This timeline is based on our belief that there is a reasonable expectation that the FDA will allow us to remain on the 510(k) clearance pathway in order to market the product.

Engineering and Manufacturing

Soliton completed the design and initiated manufacturing of the Generation 2.0 RAP device with global manufacturing partner Sanmina and that device has passed all verification and certification testing. This technology was cleared by the FDA in the Special 510(k) which was cleared in March of 2020 and was the device used in the cellulite pivotal study.

Further usability and manufacturability enhancements are planned that will reduce the cost of goods and improve margins.

We have entered into a manufacturing agreement with our global contract manufacturer signaling the initiation of the transition from the design stage to the manufacturing stage of the final device. Fixtures and tooling to build the prototype devices that will be used to validate our production line have been ordered as well as the components for the prototype and commercial devices to be built.

Recent Financing and Cash Position

The Company recently completed a $35 million capital raise that it believes will extend the Company's cash runway through the third quarter of 2022 allowing the Company to support the eighteen months of the commercial launch of the RAP device. The proceeds from the

financing will fund the initial commercialization of the product described above, including the early manufacturing, fundamental brand development investment, and the initiation of a sales force and practice development team instrumental in developing relationships with key customers.

Sales and Marketing

Soliton's sales and marketing efforts to support the initial commercial launch are led by Jim Bucher, our previously announced Consulting Head of Sales, and newly appointed Vice President of Marketing, Ms. Jennifer Cook. Together Mr. Bucher and Ms. Cook will implement the strategic sales and marketing initiatives including initial practice management and marketing launch support materials to effectively support the commercial launch.

Ms. Jennifer Cook joined Soliton on July 1, 2020. Most recently, she was Director of Consumer Marketing and Marketing Communications at Apollo Endosurgery, a global leader in less invasive medical devices for gastrointestinal and bariatric procedures. While there, she built and launched a successful direct-to-consumer (DTC) marketing program that drove consumer demand and market development. Prior to Apollo Endosurgery, Ms. Cook successfully designed and executed multiple consumer DTC launches across health & wellness, retail, consumer packaged goods, and telecommunication industries. Jennifer earned a Bachelor of Science in Business Administration and Marketing at Miami University of Ohio.

During 2020, we plan to hire members of our Practice Development Team to support the initially placed devices through training programs regarding both the implementation of the technology and practice development tools designed to help doctors attract eligible patients to their offices for Soliton RAP treatments.

Ongoing Clinical Development

Given the state of the dermatology marketplace today, we have experienced significant follow-up visit cancellations in our ongoing 26-week cellulite clinical trial assessment and increased difficulty in executing the initiation of further clinical trials at sites around the country. We expect this to impact the timing of Soliton's planned additional fibrotic scar proof-of-concept study and the longer-term follow-up visits in our cellulite pivotal study.

As soon as it is feasible, we will continue our cellulite clinical trial 26-week follow up visits and initiate the additional fibrotic scar proof-of-concept study. We are also designing protocols for a proof-of-concept study specifically focused on skin laxity and will seek to initiate that trial as soon as possible.

During this period in which it is difficult to enroll and treat patients in human trials, we are exploring animal models that will allow us an opportunity to demonstrate efficacy against other specific fibrotic conditions of a medical nature.

Dr. Chris Capelli, Soliton's President, CEO and co-founder, commented, "I am enthusiastic and increasingly optimistic about Soliton's future potential. We continue to explore and identify new target indications for our RAP device. While we are steadfastly focused on our revised U.S. commercialization plans, we believe that we can demonstrate real value in other target indications and will work to do just that."

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 and the potential to treat keloid and hypertrophic scars by targeting the stiffened environment in the intracellular matrix. The RAP device has received 510(k) clearance for use in tattoo removal but remains investigational for use in improving the appearance of cellulite and scar treatment.

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 execute a limited launch, the potential for the cash on hand to support operations through the third quarter of 2022, the ability to receive FDA clearance for our cellulite indication, our ability to remain on a 510(k) clearance path and therefore receive clearance on our suggested timeline, our ability to successfully transition to manufacturing and build the commercial devices, and our ability to successfully attract and retain necessary personnel. 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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