UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 27, 2020

Soliton, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-38815**	**36-4729076**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

5304 Ashbrook Drive
Houston, Texas 77081
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (844) 705-4866

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

☐

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbols(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	SOLY	The NASDAQ Stock Market LLC

Item 7.01. Regulation FD Disclosure

On January 27, 2020, Soliton, Inc. (the "Company") issued a press release announcing positive data from extended keloid and hypertrophic scar trials. A copy of the press release is attached to this report as Exhibit 99.1 and is incorporated by reference herein.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, is being furnished and shall not be deemed to be "filed" for the purpose of the Securities Exchange Act of 1934, as amended ("Exchange Act"), nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, unless specifically identified therein as being incorporated by reference.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Exhibit
99.1	Press release of Soliton, Inc. dated January 27, 2020

Signature

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SOLITON, INC.

By: /s/ Lori Bisson
Lori Bisson
Executive Vice-President,
Chief Financial Officer

Dated: January 27, 2020

Exhibit 99.1

Soliton, Inc.
5304 Ashbrook Drive
Houston, TX 77081

Soliton Announces Positive Data from Extended Keloid and Hypertrophic Scar Trials

12-Week clinical data demonstrates ongoing improvement from single initial treatment; could address market where multiple standard-of-care treatments can see recurrence rates as high as 50%

January 27, 2020 – Houston, TX – 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 positive proof-of-concept (POC) study results out to 12-weeks using its Rapid Acoustic Pulse (RAP) Device for the treatment of fibrotic (keloid and hypertrophic) scars.

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"We were excited to share the 12-week follow-up results at this key dermatology conference, amongst some of the top physicians in this field," stated Christopher Capelli, MD, founder, President and CEO of Soliton. "The clinical results clearly demonstrate that an overall average reduction in both the volume of the scars and the height of the scars at the 12-week follow-up after the intial single 6-minute treatment is continuing without the need for further dosing. We are very encouraged by these positive results that further substantiate the merit of our RAP device and look forward to continuing the development and enhancement of its clinical program."

The data was presented in the abstract, "Volume And Height Reduction of Fibrotic Scars Shown With 3D Imaging 12-Weeks After Non-Invasive Treatment With a Rapid Acoustic Pulse (RAP) Device In a Proof Of Concept Study" at the Maui Derm for Dermatologists 2020 meeting.

The objective of this single-site POC IRB-approved human clinical study was to evaluate the safety, tolerability, and efficacy of the RAP device for the temporary improvement in the appearance of fibrotic scars. A single 6-minute RAP session was used to treat 11 fibrotic scars in 10 participants. Images were analyzed using proprietary software for changes in scar volume and height from pretreatment to the 12-week follow-up. 3D scar assessment of the pre- and post-treatment photographs of 11 treated scars demonstrated an average reduction in volume of 29.6% ($p<0.01$) and an average reduction in height of 14.6% ($p<0.005$). While the 12-week data represents an improvement in volume reduction over the 6 week volume reductions of 27%

previously announced, this was without any additional treatment, suggesting that the scars continued to improve over time. This continued improvement from a single treatment is especially important as keloid scars are prone to recurrence after treatment with existing therapies. Patients treated with steroid injections see recurrence rates as high as 50%, while patients treated with a chemotherapeutic agent have recurrence rates as high as 47%.

Overall, the treatment of fibrotic scars using the RAP device proved safe and tolerable during this POC study. Follow up results at 12-weeks demonstrate that the RAP device provides significant improvements in the appearance of fibrotic scars from a single 6-minute noninvasive treatment, with minimal pain, and most patients express satisfaction with the scar improvement.

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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