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 29, 2021

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

Item 7.01. Regulation FD Disclosure

On February 1, 2021, Soliton, Inc. (the "Company") issued a press release announcing that the U.S. Food & Drug Administration has cleared its Rapid Acoustic Pulse ("RAP") technology for the short-term improvement in the appearance of cellulite. The clearance was received on January 29, 2021. The device is indicated for use as an accessory to the 1064 nm Q-Switched laser for black ink tattoo removal in Fitzpatrick Skin Type I-III patients. The RAP device is also indicated for short-term improvement in the appearance of cellulite. 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 8.01. Other Events

On January 29, 2021, the U.S. Food & Drug Administration cleared the Company's Rapid Acoustic Pulse ("RAP") technology for the short-term improvement in the appearance of cellulite. The device is indicated for use as an accessory to the 1064 nm Q-Switched laser for black ink tattoo removal in Fitzpatrick Skin Type I-III patients. The RAP device is also indicated for short-term improvement in the appearance of cellulite. In the clinical trials submitted to the FDA as part of the 510(k) application that was cleared, patient results were generated by a single, non-invasive treatment that required no anesthesia, caused no unexpected or serious adverse events, received strong patient satisfaction ratings and was well tolerated by the trial subjects, with an average pain score of 2.4 out of 10. The RAP device induces mechanical disruption in fibrous structures, such as the septae contributing to dimples in cellulite, that results in release of the dimples and general smoothing of the skin.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Exhibit
99.1	Soliton, Inc. press release dated February 1, 2021

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: February 1, 2021

Soliton, Inc.
5304 Ashbrook Drive
Houston, TX 77081

Soliton Announces FDA Clearance of Rapid Acoustic Pulse Technology for Use in Cellulite

February 01, 2021 – Houston, TX– Soliton, Inc., (Nasdaq: SOLY) ("Soliton" or the "Company"), a medical device company with a novel and proprietary aesthetic platform technology, today announced that the U.S. Food and Drug Administration ("FDA") has cleared its Rapid Acoustic Pulse ("RAP") technology for the short-term improvement in the appearance of cellulite. This innovative technology harnesses the power of sound for the treatment of cellulite. The unique, rapid-pulsed technology safely and comfortably breaks apart the fibrous septa bands beneath the skin that cause cellulite to deliver efficacious results in just one, 40–60-minute treatment.

"We're thrilled to receive this latest clearance for our RAP technology," said Brad Hauser, President & CEO of Soliton. "Our technology will now provide physicians a new, innovative and non-invasive approach for patients seeking a non-surgical option to improve the appearance of cellulite. This latest clearance also marks the next step in the planned commercialization of our RAP technology and we look forward to introducing this new approach to treating cellulite to physicians in the months to come."

For full details on the clearance and the Company's commercialization plans, watch this short video:https://ir.soliton.com/soliton-leadership-discusses-fda-510k-clearance-for-cellulite

In the clinical trials submitted to the FDA as part of the 510(k) application that was cleared, patient results were generated by a single, non-invasive treatment that required no anesthesia, caused no unexpected or serious adverse events, received strong patient satisfaction ratings and was well tolerated by the trial subjects, with an average pain score of 2.4 out of 10. The RAP device induces mechanical disruption in fibrous structures, such as the septae contributing to dimples in cellulite, that results in release of the dimples and general smoothing of the skin.

"Until now, patients have had limited options to effectively improve the appearance of cellulite other than cutting into the skin or less invasive procedures that can have low patient satisfaction. The clearance of this technology for cellulite fills this gap in available treatments and is an exciting development for healthcare professionals who are committed to providing patients effective procedures without any downtime, "said Elizabeth Tanzi, Director at Capital Laser & Skin Care, Chevy Chase, MD and a

member of Soliton's Scientific Advisory Board. "This non-invasive technology gives us a new cellulite reduction option to help address this unmet need for our patients."

- Leveraging its proprietary technology, the Soliton RAP device is designed to safely deliver rapid, high-pressure acoustic shockwaves at a rate of up to 100 pulses per second through a replaceable treatment cartridge. This results in physical effects on targeted structures and tissues, such as fibrous septa.
- Importantly, the negative pressure component of each acoustic pulse is attenuated so therapy can be provided without creating cavitation or heating that could result in surrounding tissue damage. As a result, the RAP technology can provide meaningful results within a single, comfortable treatment that has minimal side effects and no downtime.
- Soliton RAP technology also received 510(k) clearance from the FDA for the removal of tattoos in mid 2019.

The Company plans to begin selling the device for both tattoo removal and cellulite treatment in the first half of 2021.

Join our more than 200K subscribers here to follow the Company:https://soly-investors.com
---

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 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 and the temporary improvement in the appearance of cellulite. 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. The Company also believes the technology will provide the first non-invasive acoustic technology to be able to target the underlying cause of dimples and ridges in cellulite.

For more information about the Company, please visit: http://www.soliton.com

Forward-Looking Statements

This press release includes 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 statements involve risks and uncertainties. Forward-looking statements in this press release include, without limitation, our ability to successfully treat patients for tattoo removal and cellulite and to launch our product in the first half of 2021. 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, actual results or outcomes may prove to be materially different from the expectations 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," “would,” "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 filings with the Securities and Exchange Commission (“SEC”), including under the heading " Risk Factors" in our most recently filed Form 10-K filed with the SEC and as updated in our Form 10-Q filings and in our other 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.

####