

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): March 2, 2020



**Soliton, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**001-38815**  
(Commission File Number)

**36-4729076**  
(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))
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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:

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

## Item 2.02. Results of Operations and Financial Condition

On March 2, 2020, Soliton, Inc. issued a press release reporting its financial results for the fourth quarter and year ended December 31, 2019. 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 2.02 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	<a href="#">Press release of Soliton, Inc. dated March 2, 2020</a>

### 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: March 2, 2020



Soliton, Inc.  
5304 Ashbrook Drive  
Houston, TX 77081

## Soliton Reports Fourth Quarter and Full Year 2019 Results

**March 2, 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 reported financial results for the fourth quarter and full year ended December 31, 2019.

### Recent Company Highlights:

- Completed pivotal cellulite clinical trial with all required patients successfully treated across four clinical sites and initiated patient follow-up visits
- Completed 12-week keloid proof-of-concept clinical trial with positive results
- Submitted 510(k) for the updates to the Gen 2 device for the tattoo removal indication
- Entered into 3-year development agreement with Emphysys for design and engineering services related to the acoustical shockwave therapy

### Significant 2019 Company Milestones:

- Completed initial public offering and listing on NASDAQ on February 19, 2019
- Received FDA Clearance of initial device on May 24, 2019, clearing the device for use as an accessory to a 1064 Q-switch laser for tattoo removal
- Honored with the “Best in Session” award by the American Society for Laser Medicine & Surgery, the world’s largest scientific organization in the field of medical laser applications
- Added to the Russell 2000 and 3000 Indexes in June 2019
- Demonstrated in proof-of-concept trial the ability of technology to deliver “acoustic subcision,” a key step for the potential treatment using the device, if approved, of cellulite dimples and ridges
- Initiated a full, four-site pivotal clinical trial for the treatment of cellulite, with results expected in Q1 2020
- Increased the size of the patent portfolio with an additional 31 patents filed and 17 patents granted
- Closed two private placements for a total of \$15.95 million in gross proceeds

Dr. Chris Capelli, Soliton’s President, CEO and co-founder, commented, “We achieved significant clinical and corporate milestones in 2019 that we believe will prove fundamental to Soliton’s future success. The completion of Company’s initial public offering last February highlights the long-term opportunity for our investors. In conjunction with an FDA clearance of our Rapid Acoustic Pulse (“RAP”) device for tattoo removal in May, we look forward to leveraging the platform technology for the potential

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treatment, if approved, of cellulite and keloid scars. We believe the positive results from our 12-week keloid proof-of-concept study further validate our growth opportunity.”

“Based on the solid foundation we built in 2019, we are entering 2020 with strong momentum and look forward to a number of key milestones we believe will drive our future success. We are on track to release the results from our cellulite pivotal study in the first quarter and to submit our FDA filing for the treatment of cellulite in the second quarter of 2020. Most notable is our anticipated mid-2020 launch of our RAP device for tattoo removal. While we expect the early revenues from this launch to be limited, we expect the applicable market dynamic and physician use information generated to be invaluable. 2020 will be a turning point in Soliton’s history as we seek to transition into a commercial entity,” Dr. Capelli concluded.

#### **Fourth Quarter and Full Year 2019 Financial Results:**

Operating expenses for the fourth quarter ended December 31, 2019 were \$3.3 million, as compared to \$2.1 million in the fourth quarter 2018. The increase was primarily attributable to higher general and administrative expenses resulting from hiring new employees, including executives, and increases in costs related to operating as a public company. Operating expenses for the full year ended December 31, 2019 were \$12.9 million, as compared to \$8.2 million in the full year 2018. The increase was primarily attributable to higher general and administrative expenses resulting from the hiring of new employees, including executives, and increases in the costs related to operating as a public company.

Net loss for the fourth quarter ended December 31, 2019 was \$3.3 million, or \$0.20 basic and diluted net loss per share, compared with net income of \$2.7 million, or \$1.41 basic and diluted net loss per share, for the fourth quarter 2018. Net loss for the full year ended December 31, 2019 was \$13.9 million, or \$1.01 basic and diluted net loss per share, compared with net loss of \$10.6 million, or \$5.64 basic and diluted net loss per share, for the full year 2018.

Total cash was \$12.1 million as of December 31, 2019, compared to \$8.7 million as of September 30, 2019. During the fourth quarter Soliton entered into definitive agreements with certain institutional and accredited investors to raise aggregate gross proceeds of approximately \$6.25 million through the private placement of its equity securities. The financing was led by Reditex Ventures, LLC, the Company's largest shareholder.

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Join our more than 200K fans here to follow the Company:<https://soly-investors.com>  
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#### **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 clinical and preclinical testing, including the potential to improve the appearance of cellulite by creating mechanical stress at the cellular level and inducing significant collagen growth and the potential to treat keloid and hypertrophic scars by targeting the stiffened environment in the intracellular matrix.

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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 to successfully complete the clinical trials planned for 2020 and to report data from such trials on a timely basis, to submit our FDA filing for the treatment of cellulite in the second quarter of 2020 and to receive FDA clearance for such indication, to effectively commercialize our products, and the ability of the RAP device to successfully treat cellulite and fibrotic scars. 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, 2019 we filed with the SEC on March 2, 2020 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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