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 4, 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 2.02. Results of Operations and Financial Condition

On March 4, 2021, Soliton, Inc. (the "Company") issued a press release reporting its financial results for the fourth quarter and year ended December 31, 2020. 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	Soliton, Inc. Earnings Release dated March 4, 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: March 4, 2021

Soliton, Inc.
5304 Ashbrook Drive
Houston, TX 77081

Soliton Reports Fourth Quarter and Full Year 2020 Results

March 4, 2021 – Houston, TX –Soliton, Inc., (Nasdaq: SOLY) ("Soliton" or the "Company"), a medical device company with a novel and proprietary platform technology, today reported financial results for the fourth quarter and full year ended December 31, 2020.

Recent Company Highlights:

- Received FDA 510(k) clearance for short-term improvement in the appearance of cellulite;
- Selected RESONIC™ as the brand name for the Rapid Acoustic Pulse (RAP) device;
- Appointed Sean J. Shapiro, a seasoned sales executive in the aesthetics device industry, as Vice President of Sales, effective January 1, 2021;
- Entered into a collaboration with the US Navy to conduct a 12-week proof-of-concept clinical study to evaluate the safety and efficacy of RESONIC™ for the improvement in the appearance of fibrotic scars; and
- Announced positive pre-clinical results for RESONIC™ in treating liver fibrosis.

Brad Hauser, Soliton's President and CEO, commented, "Despite the challenges presented by 2020, this was a transformative year for the Company, which has positioned us for long-term success and the upcoming initial launch of our RAP device in cellulite reduction and tattoo removal during the second quarter of 2021. We are extremely encouraged by the progress we made in preparation for our upcoming initial launch, as we received FDA 510(k) clearance for the RAP device in cellulite, bolstered our sales team by hiring aesthetic veteran Sean Shapiro as VP of Sales, and initiated the transition to manufacturing with our manufacturing partner. I am very excited to share that we have selected RESONIC™ as the brand name for our RAP device, which we believe captures our technology's foundation in sound and will provide a true identity for our technology with customers and consumers. While ensuring a successful initial launch remains our key priority, we are also encouraged by the promise our RAP device has demonstrated in selected adjacent indications, such as fibrotic scars and liver fibrosis. 2021 will be a pivotal year for the Company as we transition to a commercial company. We look forward to launching our RESONIC™ device in cellulite reduction and tattoo removal and driving its clinical progress across adjacent indications with our goal of delivering shareholder value."

Fourth Quarter and Full Year 2020 Financial Results:

Operating expenses for the fourth quarter ended December 31, 2020 were $4.6 million compared to $3.3 million in the fourth quarter 2019. Operating expenses for the full year ended December 31, 2020 were $14.7 million compared to $12.9 million in the full year 2019. The increases in the three and twelve months ended December 31, 2020 were primarily attributable to increases is general and administrative and sales and marketing expenses. The increase in general and administrative expense resulted from the hiring of new employees, including executives, and stock-based compensation and incentives tied to these new employees, as well as overall expenses related to operating as a public company. The increase in sales and marketing expenses resulted as we prepared to commercialize our product, with

specific increases attributed to social media marketing development, website demos and videos and salaries and related expenses.

Net loss for the fourth quarter ended December 31, 2020 was $4.5 million, or ($0.22) basic and diluted per share, compared with net loss of $3.3 million, or ($0.20) basic and diluted per share, for the fourth quarter 2019. Net loss for the full year ended December 31, 2020 was $14.5 million, or ($0.77) basic and diluted per share, compared with net loss of $13.9 million, or ($1.00) basic and diluted per share, for the full year 2019.

Total cash, cash equivalents and restricted cash was $31.8 million as of December 31, 2020 compared to $12.1 million as of December 31, 2019. The Company's cash, cash equivalents and restricted cash on hand is expected to be sufficient to fund the Company's operations into the third quarter of 2022 and is expected to fully support the initial phase of the commercial launch of the RAP device.

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

---

Conference Call Information

Soliton will host a conference call with a live presentation on Thursday, March 4, 2021, at 4:30 p.m. ET to discuss the results. The dial-in numbers for the conference call are (833) 423-0479 for domestic callers and (918) 922-2373 for international callers. The conference ID number is 7559148.

A live webcast of the call and an updated investor presentation will be available on the Investor relations page of the Soliton, Inc. website, https://www.soliton.com/. A replay of the webcast will be archived on Soliton's website for 30 days following the completion of the call.

In addition, a telephonic replay of the call will be available until March 11, 2021. The replay dial-in numbers are (855) 859-2056 for domestic callers and (404) 537-3406 for international callers. Please use the replay conference ID number 7559148.

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. Soliton is investigating potential additional capabilities of the RAP technology. The device is currently cleared in the United States only for use in tattoo removal and 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. These statements relate to future events, future expectations, plans and prospects. Forward-looking statements in this release include, but are not limited to, our ability to successfully commercialize our technology, our ability to complete our commercial launch in the second quarter of 2021, our ability to make clinical progress on additional potential indications such as liver fibrosis and fibrotic scars, and our ability to successfully manufacture our device. 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.

Investor Contact

James Salierno
The Ruth Group
jsalierno@theruthgroup.com
973-255-8361

Media Contact

Annika Parrish
The Ruth Group
aparrish@theruthgroup.com
720-412-9042