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): May 12, 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 May 12, 2021, Soliton, Inc. (the "Company") issued a press release reporting its financial results for the first quarter ended March 31, 2021. 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 May 12, 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: May 13, 2021

Soliton, Inc.
5304 Ashbrook Drive
Houston, TX 77081

Soliton Reports First Quarter 2021 Results

May 12, 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 first quarter ended March 31, 2021.

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 Company's Rapid Acoustic Pulse (RAP) device;
- Received FDA Special 510(k) clearance for modifications to the RESONIC device to facilitate ease of use in commercial settings;
- Successfully completed all required safety testing including Quality System/Current Good Manufacturing Practice regulations for medical devices (21 CFR Part 820) inspection from the FDA;
- Expanded sales team through appointment of Sean J. Shapiro as Vice President of Sales, and two Senior Practice Development Managers with experience in the aesthetics space;
- 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
- Initiated second pre-clinical study in animals for treatment of liver fibrosis to validate positive results demonstrated in initial pre-clinical study.

First Quarter 2021 Financial Results:

Operating expenses for the first quarter ended March 31, 2021 were $5.2 million compared to $3.3 million in the first quarter of 2020. The increase in the three months ended March 31, 2021 was primarily attributable to increases in general and administrative ("G&A") and sales and marketing expenses. The increase in G&A was a result of increased salary and stock compensation expenses, as well as board-related and legal expenses. Sales and marketing expenses increased as we continued to prepare for our upcoming commercialization, with specific increases attributed to social media marketing development, new brand website development and supporting explanatory video creation.

Net loss for the quarter ended March 31, 2021 was $5.2 million, or ($0.25) basic and diluted per share, compared with net loss of $3.3 million, or ($0.19) basic and diluted per share, for the first quarter of 2020.

Total cash, cash equivalents and restricted cash was $26.3 million as of March 31, 2021 compared to $31.8 million as of December 31, 2020. 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 RESONIC.

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

Given the strategic announcement made earlier this week, the Company is cancelling the conference call previously scheduled for Thursday, May 13, 2021 at 4:30 p.m. ET.

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, RESONIC™, will use rapid pulses of acoustic shockwaves for the treatment of cellulite and as an accessory to lasers for the removal of unwanted tattoos. The Company is based in Houston, Texas, and is actively engaged in bringing RESONIC to the market. The Company believes the technology will provide the first non-invasive acoustic technology to target the underlying causes of dimples and ridges in cellulite. The Company also 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. 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 belief that our cash, cash equivalents and restricted cash on hand will be sufficient to fund our operations into the third quarter of 2022 and to fully support the initial phase of the commercial launch of RESONIC, our belief that RESONIC will provide the first non-invasive acoustic technology to target the underlying causes of dimples and ridges in cellulite, and our belief that our "Soliton" method has the potential to lower tattoo removal costs for patients, while increasing profitability to practitioners, compared to current laser removal methods. Although we believe 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. 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