**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): July 15, 2019**

---

# 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 July 15, 2019, Soliton, Inc. (the "Company") issued a press release announcing additional positive data from its proof of concept clinical trial for the reduction 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 9.01. Financial Statements and Exhibits**

**(d) Exhibits**

| Exhibit No. | Exhibit |
|---|---|
| 99.1 | Press release of Soliton, Inc. dated July 15, 2019 |

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: July 15, 2019

**Exhibit 99.1**

**Soliton, Inc.**
**5304 Ashbrook Drive**
**Houston, TX 77081**

**CONTACT:** **Joe Dorame, Joe Diaz & Robert Blum**
**Lytham Partners, LLC**
**602-889-9700**
**soly@lythampartners.com**

## Soliton Announces Positive 26-week Cellulite Clinical Trial Results Demonstrate Long-Term Improvement

***6-Month Data from Proof of Concept Clinical Trial Show Average Cellulite Severity Scores Continued to Improve After Single 20-Minute Non-Invasive Procedure***

July 15, 2019 – 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 additional positive data from its proof of concept clinical trial for the reduction of cellulite.

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

Dr. Chris Capelli, President, CEO and co-founder of Soliton, commented, "Most cellulite treatments today generally provide only temporary improvement. In fact, the only FDA-cleared treatment to produce long-term (6 months or longer) cellulite improvement is an invasive procedure that requires the injection of anesthesia and can result in bruising and bleeding and significant post treatment discomfort and downtime. In light of this treatment landscape, our results that not only lasted 6 months, but actually improved 20% on the GAIS scale from months 3 to 6 from a single non-invasive procedure with no post-treatment discomfort or downtime are very encouraging."

The Global Aesthetic Improvement Scale (GAIS) 5-point scale was used to evaluate changes between the 3-month and 6-month timepoints and patients improved, on average, a full point on this scale. As reported earlier, the initial improvement at 3-months on the Cellulite Severity Score (CSS) ranged from 20% to 47%, with the average improvement being 29%. At the 6-month time point, CSS continued to improve with an average improvement of 31%. As a point of reference, the only invasive procedure approved by the FDA for long-term reduction of cellulite (Cellfina) produced an average improvement on the same CSS scale in their own clinical trial of about 2 points. It is important to note that Soliton RAP was not directly compared with Cellfina in our clinical trial.

The Soliton proof of concept trial involved a study of five patients with moderate to severe cellulite, each treated on their thighs, with a higher-powered version of Soliton's recently cleared RAP device intended to assist in tattoo removal. Three blinded reviewers, who are trained in the use of the CSS and GAIS scoring systems, scored the before and after photos, including both a 3-month and 6-month timepoints post treatment. The average improvement for all patients was 1.24 and 1.31 on the 0 to 5-point CSS scale, for the 3-month and 6-month timepoints, respectively.

"The market for cellulite treatments is about $1 billion in the U.S., so it is clear that many women who are affected by the condition are interested in finding ways to reduce or eliminate it," said Walter Klemp, co-founder and Executive Chairman of Soliton. "The very encouraging results of the proof of concept clinical trial suggest we may be able to improve the appearance of cellulite with a single, non-invasive procedure in a long-term manner. This will now be evaluated in a larger pivotal trial."

Cellulite affects up to 90% of women and over a billion dollars per year is spent on treatment in the U.S. Now, results from this initial proof of concept clinical trial suggest the potential for our RAP device to effectively treat cellulite. In a single 20-minute, non-invasive treatment, the Rapid Acoustic Pulse (RAP) device was applied to the surface of the patients' skin. The treatments required no anesthesia, caused no bruising, swelling or infection, and were evaluated by the trial participants as a "0" on a pain scale of 0-10 in 97% of the treatments. None of the study participants experienced any post-treatment downtime. This device is investigational and not yet available for sale for the treatment of cellulite. Similar results may not be achieved in subsequent clinical trials.

**How the Soliton Device Treats Cellulite with Potential Long-term Effects**

Although cellulite has many contributing factors, a primary cause of the deep dimples and ridges associated with cellulite is the presence of sclerotic septa connecting the dermis to the body's fascia through the layer of subcutaneous fat. Septa normally provide structure and uniformity to the skin, but over time they can lose uniformity and become stiff and less resilient with larger pockets of subcutaneous fat in-between. As the presence of subcutaneous fat increases, it can push up against the dermis causing it to bulge between these septa, leaving dimples and ridges where the septa refuse to yield.

Superficial therapies generally provide only temporary cellulite reduction. Severing the septa may offer long-term improvement of dimples and ridges. The Soliton technology is designed to couple this with tightening of the skin to remove the "orange peel" or "cottage cheese" appearance often associated with cellulite.

Soliton was recently awarded "Best in Show" by the American Society for Laser Medicine and Surgery (ASLMS) and has shown in animal models that its technology is capable of selective disruption of sclerotic septa without penetrating the skin. In clinical trials, the procedure created no bleeding or bruising and resulted in no post-treatment discomfort or downtime.

"Many patients are looking to reduce the appearance of cellulite with a convenient, non-invasive, long-lasting approach" explained Dr. Chris Capelli, President, CEO, and co-founder of Soliton. "The Soliton technology uses very fast, compressed acoustic pulses in the form of shockwaves that may be able to achieve these effects."

The study was conducted by Dr. Michael Kaminer at SkinCare Physicians in Boston in collaboration with Dr. Elizabeth Tanzi of Capital Laser and Skin Care.

Dr. Kaminer stated: "Having led the clinical development of Cellfina, the only treatment with FDA clearance for producing long-term reduction of cellulite, I am particularly aware of the unmet need in the treatment of cellulite. Having a non-invasive alternative treatment with lasting results could provide a real benefit for patients while also expanding the breadth of services offered by clinicians."

Drs. Kaminer and Tanzi are members of Soliton's Scientific Advisory Board.

**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 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 Soliton's acoustic shockwave device to prove safe and effective at reducing cellulite and the ability of this device to receive FDA clearance. 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.