
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, DC 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)
September 8, 2017

Pulse Biosciences, Inc.
(Exact name of registrant as specified in its charter)

Nevada
(State or other jurisdiction
of incorporation)

001-37744
(Commission
File Number)

46-5696597
(IRS Employer
Identification No.)

3957 Point Eden Way
Hayward, California 94545
(Address of principal executive offices, including zip code)

(510) 906-4600
(Registrant's telephone number, including area code)

(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):

- 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 _____

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.

ITEM 8.01. OTHER EVENTS

On September 11, 2017, Pulse Biosciences, Inc. issued a press release announcing that, on September 8, 2017, Pulse Biosciences Inc. withdrew its 510(k) Application for the PulseTx™ Nano-Pulse Stimulation System and plans to submit the supplemental information in a subsequent 510(k) application in the coming months.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS**(d) Exhibits.**

Exhibit Description

No.

99.1 Press Release issued by Pulse Biosciences, Inc. dated September 11, 2017.

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.

Pulse Biosciences, Inc.

By: /s/ Brian B. Dow
 Brian B. Dow
 Chief Financial Officer, Senior Vice President,
 Secretary and Treasurer
 (Principal Financial and Principal Accounting
 Officer)

Date: September 11, 2017

EXHIBIT INDEX

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|---------------------------------------------------------------------------|
| 99.1 | Press Release issued by Pulse Biosciences, Inc. dated September 11, 2017. |

PULSE BIOSCIENCES ANNOUNCES WITHDRAWAL AND PLANNED RESUBMISSION OF 510(k) APPLICATION FOR THE PULSETX™ SYSTEM

HAYWARD, Calif.— (BUSINESS WIRE) – September 11, 2017 – Pulse Biosciences, Inc. (Nasdaq: PLSE), a medical technology company developing a proprietary therapeutic tissue treatment based on its Nano-Pulse Stimulation (NPS) platform, announced today that it has withdrawn its initial application to the United States Food and Drug Administration (FDA) for 510(k) clearance of its PulseTx™ System.

The voluntary withdrawal on September 8, 2017, was the result of the FDA's appropriate request for additional data that could not be provided within the Agency's 90-day review period that would have otherwise ended on September 10, 2017. Pulse Biosciences is committed to generating the requested data and analysis, and the company plans to submit the supplemental information in a subsequent 510(k) application in the coming months.

"Over the past several months, we have been engaged in very productive and positive conversations with the FDA staff, and we remain confident in our ability to obtain a 510(k) clearance for the PulseTx™ System and more broadly for Nano-Pulse Stimulation," noted Darrin Uecker, Pulse Biosciences President and Chief Executive Officer.

About Pulse Biosciences

Pulse Biosciences is a medical technology company developing a therapeutic tissue treatment platform based on Nano-Pulse Stimulation, a proprietary cell signaling technology. Nano-Pulse Stimulation is a non-thermal, precise, focal drug-free tissue treatment technology that directly affects the cell membrane and intracellular structures to stimulate unique behaviors in cells. NPS can initiate a cell death process that allows for the treatment of tissue cells with minimal inflammatory response which improves healing outcomes and supports the replacement of treated tissue cells with healthy tissue cells. In cancerous lesions, NPS has been shown in preclinical models to induce immunogenic cell death (ICD) exposing the unique antigens of the treated cells to the immune system, resulting in the generation of cytotoxic T-cells and the mounting of an adaptive immune response targeted against those cells. Pulse Biosciences is investigating a variety of applications for its technology that exploits the technology's unique biologic effect, including immuno-oncology, dermatology, and veterinary medicine. More information is available at www.pulsebiosciences.com.

Forward-Looking Statements

All statements in this press release that are not historical are forward-looking statements, including, among other things, statements relating to Pulse Biosciences' expectations regarding regulatory clearance and the timing of FDA filings or approvals, current and planned future business plans, clinical studies, other matters related to its pipeline of product candidates, future financial performance and other future events. These statements are not historical facts but rather are based on Pulse Biosciences' current expectations, estimates, and projections regarding Pulse Biosciences' business, operations and other similar or related factors. Words such as "may," "will," "could," "would," "should," "anticipate," "predict," "potential," "continue," "expects," "intends," "plans," "projects," "believes," "estimates," and other similar or related expressions are used to identify these forward-looking statements, although not all

forward-looking statements contain these words. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and assumptions that are difficult or impossible to predict and, in some cases, beyond Pulse Biosciences' control. Actual results may differ materially from those in the forward-looking statements as a result of a number of factors, including those described in Pulse Biosciences' filings with the Securities and Exchange Commission. Pulse Biosciences undertakes no obligation to revise or update information in this release to reflect events or circumstances in the future, even if new information becomes available.

Investors:
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