

**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)**  
**February 13, 2020**

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

**Delaware**  
(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) (Zip Code)

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

**N/A**  
(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
<b>Common Stock, par value \$0.001 per share</b>	<b>PLSE</b>	<b>The Nasdaq Stock Market</b>

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.

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**Item 8.01 Other Events.**

On February 13, 2020, Pulse Biosciences, Inc. (the “**Company**”) issued a press release announcing that on February 13, 2020, it had received a letter from the U.S. Food and Drug Administration with regard to the Company’s 510(k) submission.

**ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS**

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release issued by Pulse Biosciences, Inc., dated February 13, 2020</a>



**PULSE BIOSCIENCES PROVIDES UPDATE ON FDA 510(k) SUBMISSION FOR THE CELLFX SYSTEM IN DERMATOLOGY**

*Schedules Business Update Call on February 18, 2020 at 2:00pm PT*

**HAYWARD, Calif. [Business Wire]– February 13, 2020.** Pulse Biosciences, Inc. (Nasdaq: PLSE), a novel bioelectric medicine company, today announced an update on its U.S. Food and Drug Administration (FDA) submission for the CellFX System. Previously, the Company submitted a 510(k) to FDA seeking clearance to commercialize its CellFX System. On February 13, 2020, the Company received a Not Substantially Equivalent (NSE) letter from FDA indicating that, based on the data provided, the Company has not demonstrated that the CellFX System is substantially equivalent to the predicate device. The Company will continue to work with FDA in pursuit of a clearance via a new 510(k) submission and is prepared to provide additional clinical data as required.

“We remain highly confident in the CellFX System and its safety and efficacy profile in aesthetic dermatology. We look forward to continuing to work with FDA to obtain a clearance for the CellFX system in dermatology.” said Darrin Uecker, President and CEO of Pulse Biosciences. “We will continue to generate additional clinical data in support of that effort with the great group of leading dermatologists we have been collaborating with in previous studies.”

“I am pleased our Board of Directors has approved Pulse Biosciences to take the steps necessary to pursue a rights offering to raise an additional \$30 million in net proceeds,” said Robert Duggan, Chairman of the Board of Directors. “In my position as our largest shareholder, I intend to subscribe to my ownership percent interest and all additional shares that may become available. I am a believer in our team, our technology, and what I perceive to be a substantive human healthcare opportunity.”

**Business Update Call**

The Company has scheduled a business update call for Tuesday, February 18, 2020 at 2:00pm PT. Investors interested in listening to the call may do so by dialing (844) 494-0190 from the US or (508) 637-5580 from outside the US, using conference ID: 2183594. A live and recorded webcast of the call will also be available at <http://investors.pulsebiosciences.com/>.

**Financial Update (Unaudited)**

As of December 31, 2019, cash, cash equivalents and investments were \$25.4 million.

A registration statement relating to these securities will be filed with the SEC and has not yet become effective. The securities may not be sold nor may offers to buy be accepted prior to the time the registration statement becomes effective. When available, a copy of the prospectus may be obtained free of charge at the website maintained by the SEC at [www.sec.gov](http://www.sec.gov). The rights will be issued to all shareholders as of a record date which has yet to be determined. The subscription price for the shares also has yet to be determined. We will provide notice of the record date and subscription price in the future at such time as they are determined.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such state. Any offer, if at all, will be made only by means of a prospectus forming a part of the registration statement.

## **About Pulse Biosciences**

Pulse Biosciences is a novel bioelectric medicine company committed to health innovation that has the potential to improve and extend the lives of patients. If approved, the CellFX System will be the first commercial product to harness the distinctive advantages of the Company's proprietary Nano-Pulse Stimulation (NPS) technology to treat a variety of applications for which an optimal solution remains unfulfilled. NPS technology delivers nano-second pulses of electrical energy to non-thermally clear cells while sparing adjacent non-cellular tissue. As a multi-application platform, the CellFX System offers customer value with a utilization-based revenue model across an expanding spectrum of clinical applications. Subject to regulatory approval, the initial commercial use is expected to be in the clearance of common and difficult-to-treat skin lesions that share high demand among patients and practitioners for improved and durable aesthetic outcomes that could lead to greater overall satisfaction.

Pulse Biosciences, CellFX and Nano-Pulse Stimulation are registered trademarks of Pulse Biosciences, Inc.

Caution: Pulse Biosciences' CellFX System and Nano-Pulse Stimulation (NPS) technology are for investigational use only.

## **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, the ability of the Company to prepare and provide data to FDA, the mechanism of action of NPS treatments, current and planned future clinical studies and the results of any such studies, other matters related to its pipeline of product candidates, the Company's market opportunity, the Company's ability to raise capital through the rights offering or consummate the rights offering, the intention of Robert Duggan to participate in the rights offering, the final terms of the rights offering including the offering amount, record date and the subscription price and the related registration statement, 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.

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