

**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)
February 3, 2021**

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
Common Stock, par value \$0.001 per share	PLSE	The Nasdaq Stock Market

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.

ITEM 8.01 OTHER EVENTS.

On February 3, 2021, Pulse Biosciences, Inc. issued a press release announcing U.S. Food and Drug Administration clearance for use of its CellFX[®] System for dermatologic procedures requiring ablation and resurfacing of the skin.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits.

<u>Exhibit</u> <u>No.</u>	<u>Description</u>
99.1	Press Release issued by Pulse Biosciences, Inc. dated February 3, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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/ Sandra A. Gardiner _____
Sandra A. Gardiner
Chief Financial Officer, Executive Vice President of
Finance and Administration, Secretary and Treasurer
(Principal Financial and Accounting Officer)

Date: February 3, 2021

Pulse Biosciences Announces FDA Clearance for the CellFX® System

- *CellFX System delivers Nano-Pulse Stimulation Technology in dermatologic procedures*
- *U.S. controlled launch to commence*

HAYWARD, Calif. [Business Wire]– February 3, 2021. Pulse Biosciences, Inc. (Nasdaq: PLSE), a novel bioelectric medicine company progressing Nano-Pulse Stimulation™ (NPS™) technology, today announced U.S. Food and Drug Administration (FDA) clearance of the CellFX[®] System for dermatologic procedures requiring ablation and resurfacing of the skin. In the coming weeks a controlled commercial launch in the U.S. will begin with a group of selected Key Opinion Leaders (KOLs) in aesthetic dermatology.

“The CellFX System offers a unique non-thermal mechanism that in my experience can clear epidermal and mid-dermal cellular structures without damaging the non-cellular dermal collagen, which can lead to remarkable improvements in common skin problems that I see every day,” said Brian Zelickson, MD, Founder and Medical Director, Zel Skin and Laser Specialists in Edina, Minnesota. “We look forward to adding the CellFX System to our practice and foresee a promising future of new applications for this versatile technology platform.”

The CellFX System is a multi-application platform that harnesses the Company’s proprietary NPS technology delivering nano-second pulses of electrical energy to non-thermally clear cells while sparing adjacent noncellular tissue. NPS technology provides the ability to clear unwanted cellular structures while limiting collateral damage to the surrounding healthy skin, resulting in the potential to clear cellular skin structures with aesthetically pleasing outcomes.

“FDA clearance for the CellFX System is a tremendous achievement for Pulse Biosciences. We received the indication we were pursuing and believe this will be the first of many in this stepwise approach with FDA. This continued progress on our regulatory strategy, following the recent receipt of the CE mark, is another strong validation of the safety and efficacy of our technology. We are proud of our team and thankful to the investigators and FDA for their diligent efforts as part of this accomplishment,” said Darrin Uecker, President and Chief Executive Officer of Pulse Biosciences. “We look forward to proceeding with our Controlled Launch program with KOLs in the United States. This measured approach to launching the CellFX System is our top priority for 2021 and will be key to long-term commercial success of the CellFX platform.”

About Pulse Biosciences®

Pulse Biosciences is a novel bioelectric medicine company committed to health innovation that has the potential to improve the quality of life for patients. The CellFX[®] System is the first commercial product to harness the distinctive advantages of the Company’s proprietary Nano-Pulse Stimulation™ (NPS™) technology, such as the ability to non-thermally clear cells while sparing non-cellular tissue, to treat a variety of applications for which an optimal solution remains unfulfilled. Nano-Pulse Stimulation technology delivers nano-second pulses of electrical energy. The initial commercial use of the CellFX System is to address a range of dermatologic conditions that share high demand among patients and practitioners for improved dermatologic outcomes. Designed as a multi-application platform, the CellFX System offers customer value with a utilization-based revenue model. To learn more, please visit pulsebiosciences.com.

To stay informed about the CellFX System, please visit CellFX.com and sign up for updates.

Pulse Biosciences, CellFX, Nano-Pulse Stimulation, NPS and the stylized logos are among the trademarks and/or registered trademarks of Pulse Biosciences, Inc. in the United States and other countries.

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 regulatory filings or approvals, NPS technology including the effectiveness of such technology, the CellFX System including the benefits of the CellFX System and commercialization and adoption of the CellFX System, current and planned future clinical studies and the ability of the Company to execute such studies and results of any such studies, other matters related to its pipeline of product candidates, the Company's market opportunity and commercialization plans, including the timing and results of the controlled launch in the US, the market for the treatment of certain lesions, the experience of using the CellFX System, 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.

Contacts**Investors:**

Pulse Biosciences
Sandra Gardiner, EVP and CFO
510.241.1077
IR@pulsebiosciences.com
or
Gilmartin Group
Philip Trip Taylor
415.937.5406
philip@gilmartinir.com

Media:

Tosk Communications
Nadine D. Tosk
504.453.8344
nadinepr@gmail.com or
press@pulsebiosciences.com
