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 8, 2022

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

Delaware	**001-37744**	**46-5696597**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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 8, 2022, Pulse Biosciences, Inc. issued a press release announcing its receipt of a letter from the U.S. Food and Drug Administration concerning a recent 510(k) submission by the Company to expand the current labeling of its CellFX System. A copy of this press release is attached as Exhibit 99.1 and incorporated herein by this reference.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release issued by Pulse Biosciences, Inc. dated February 8, 2022.
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, and Treasurer
(*Principal Financial and Accounting Officer*)

Date: February 8, 2022

Pulse Biosciences Provides an Update on Recent FDA 510(k) Submission

HAYWARD, Calif. [Business Wire] – February 8, 2022. Pulse Biosciences, Inc. (Nasdaq: PLSE), a novel bioelectric medicine company commercializing the CellFX® System powered by Nano-Pulse Stimulation™ (NPS™) technology, today announced an update to its recent U.S. Food and Drug Administration (FDA) 510(k) submission to add the specific indication for treatment of sebaceous hyperplasia to expand the CellFX System's current labeling.

The Company submitted a 510(k) in December 2021 to add the treatment of sebaceous hyperplasia to the CellFX System's indications for use in the United States. On February 5, 2022, the Company received an Additional Information ("AI") letter from the FDA in response to the 510(k) submitted. In the AI letter, the FDA stated it did not believe the Company provided sufficient clinical evidence at this time to support the expanded indication for use, and that the Company had not met the primary endpoints of the sebaceous hyperplasia FDA-approved IDE study. The Company anticipates meeting with the FDA to discuss the contents of the AI letter and potential next steps, which may require additional clinical data and potentially a new 510(k) submission. The AI letter is a standard part of the 510(k) review process and places the review on hold until the Company responds within 180 days of the request in the AI letter. Based on FDA guidance, the Company believes its meeting with the FDA will take place in Q1 2022.

In Europe, the CellFX System is approved for the treatment of sebaceous hyperplasia, seborrheic keratosis and non-genital warts. In the United States, the CellFX System is cleared for dermatologic procedures requiring ablation and resurfacing of the skin and intended use of treating benign lesions.

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 Company's proprietary Nano-Pulse Stimulation technology delivers nano-second pulses of electrical energy to non-thermally clear cells while sparing adjacent non-cellular tissue. The CellFX® System is the first commercial product to harness the distinctive advantages of NPS technology to treat a variety of applications for which an optimal solution remains unfulfilled. 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. Visit pulsebiosciences.com to learn more.

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 its ongoing discussions with the FDA about the Company's sebaceous hyperplasia clinical study and its ability to address the FDA's concerns, statements about the Company's clinical and regulatory plans, including statements about potential future regulatory clearances more generally, statements relating to the effectiveness of the Company's NPS technology and the CellFX System to improve patient outcomes, statements relating to the Company's current and planned future clinical studies, including the Company's ability to execute such studies, and the anticipated results of any such studies, statements relating to the Company's pipeline of product candidates, market opportunities and commercial plans, as well as other future events. These statements are not historical facts but rather are based on Pulse Biosciences' current expectations, estimates, and projections regarding its 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 U.S. 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