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)
January 25, 2021

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 January 25, 2021, Pulse Biosciences, Inc. (the "**Company**") issued a press release announcing that on January 22, 2021, it had received CE mark approval of its CellFX® System in the European Union for the treatment of general dermatological conditions.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release issued by Pulse Biosciences, Inc. dated January 25, 2021.
99.2	Press Release issued by Pulse Biosciences, Inc. dated January 5, 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: January 25, 2021

Pulse Biosciences Announces CE Mark Approval for CellFX® System

- CellFX System Delivers Nano-Pulse Stimulation Technology to Clear Hard-to-Treat Benign Skin Lesions
- First CellFX System Shipment Scheduled to Commence Controlled Launch Program with Clinical Aesthetic Experts in the European Union

HAYWARD, Calif. [Business Wire]– January 25, 2021. Pulse Biosciences, Inc. (Nasdaq: PLSE) ("Pulse Biosciences" or the "Company"), a novel bioelectric medicine company progressing Nano-Pulse Stimulation™ (NPS™) technology, today announced Conformité Européene (CE) mark approval for the CellFX® System. The CE mark confirms that the CellFX System meets the requirements of the European Medical Devices Directive. This allows the Company to proceed with its planned controlled launch of the CellFX System to medical practices within the European Union (EU) for the treatment of general dermatologic conditions, including sebaceous hyperplasia (SH), seborrheic keratosis (SK) and cutaneous non-genital warts. Controlled launch participants selected from the top aesthetic centers in Europe will receive the first CellFX Systems for commercial use.

The CellFX System is a multi-application platform that harnesses the Company's proprietary NPS technology which delivers 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 lesions while limiting collateral damage to the surrounding healthy skin, resulting in the potential to clear benign lesions with aesthetically pleasing outcomes.

"We are excited about this major milestone for Pulse Biosciences which keeps us on track to commercialize the CellFX System in the EU this quarter. The CE mark is the first commercial regulatory clearance for the CellFX System and an important validation of the capabilities of NPS technology. Most importantly, it verifies the clinical evidence supporting the beneficial use of the system in these difficult-to-treat lesions. We appreciate all the work and effort from the notified body, scientific investigators and our team that has led to the successful outcome of this process," said Darrin Uecker, President and Chief Executive Officer of Pulse Biosciences. "Our controlled commercial launch in Europe will be conducted by thought-leading aesthetic dermatologists who will further validate and expand the potential of the system. We look forward to working with this group to advance a solution for a significant unmet need while delivering a best-in-class experience."

In the coming weeks, renowned dermatologist Dr. Afschin Fatemi of Dusseldorf, Germany, will receive training on the first commercial CellFX System. "I am honored to work with Pulse Biosciences and to be the first dermatologist in the world to offer procedures with the CellFX System using Nano-Pulse Stimulation technology. Across our 13 clinics in Germany, we focus on providing our patients the most innovative and effective aesthetic procedures. I see patients with SH, SK and warts often in my practice and am excited to now have an elegant solution to address these cellular-based lesions," said Dr. Fatemi, MD, Founder of the S-thetic Group.

The prevalence of SH, SK and common, non-genital warts among patients visiting aesthetic dermatologists today is widespread. Based on a 2020 survey among aesthetic physicians from Germany, Spain and France, an average of 200 patients per month who visit aesthetic dermatology practices present with each lesion type (SH, SK, non-genital warts). Further, patients place greater value on the CellFX procedure over other popular aesthetic procedures they currently receive, and are willing to pay cash to treat multiple lesions in a single visit.[1]

"In my extensive investigational work with Nano-Pulse Stimulation technology, I am continually impressed by its cellular-focused ability to fully remove lesions that extend into the dermis without permanently damaging the healthy surrounding dermal foundation," said Girish (Gilly) Munavalli, MD, Medical Director of Dermatology, Laser & Vein Specialists of the Carolinas and member of the Pulse Biosciences Scientific Advisory Board. "I view this as just the beginning of the clinical potential of NPS technology to clear a broad range of challenging benign lesions with a favorable aesthetic outcome and believe the CellFX System using NPS technology could represent a fundamental change in aesthetic dermatology."

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.

Caution: Outside the EU Pulse Biosciences' CellFX System and Nano-Pulse Stimulation technology are considered 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, Health Canada and other regulatory filings or approvals, and the ability of the Company to successfully complete a 510(k) submission for the CellFX System or for any specific indications, the ability of the Company to prepare and provide data to FDA, Canadian and other regulatory bodies, NPS technology including the effectiveness of such technology and the effectiveness of related clinical studies in predicting outcomes resulting from the use of NPS technology, the CellFX System including the benefits of the CellFX System and commercialization 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 Europe, 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.

[1] 2020 Physician (n=46) and Patient (n=190) surveys conducted in the EU by third-party market research firm on behalf of Pulse Biosciences, Inc.

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