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): **March 8, 2024**

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)

Not Applicable
(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, $0.001 par value 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 March 8, 2024, Pulse Biosciences, Inc. (the "Company") issued a press release announcing the FDA 510(k) Clearance for its CellFX® nsPFA™ Percutaneous Electrode System. A copy of the Company's press release is attached as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	**Description**
99.1	Press Release issued by Pulse Biosciences, Inc. dated March 8, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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, thereunto duly authorized.

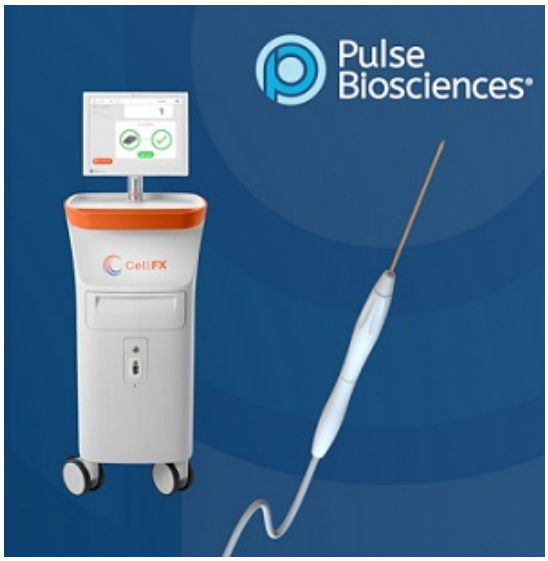
PULSE BIOSCIENCES, INC.

Date: March 11, 2024

By: /s/ Kevin P. Danahy
Kevin P. Danahy
President and Chief Executive Officer
(Principal Executive and Principal Financial Officer)

Pulse Biosciences Announces FDA 510(k) Clearance for its CellFX® nsPFA™ Percutaneous Electrode System

HAYWARD, Calif. [Business Wire] – March 8, 2024. Pulse Biosciences, Inc. (Nasdaq: PLSE), a company leveraging its novel and proprietary CellFX Nanosecond Pulsed Field Ablation™ (nsPFA™) technology, today announced receipt of U.S. Food and Drug Administration (FDA) 510(k) clearance for its novel CellFX nsPFA Percutaneous Electrode System for use in the ablation of soft tissue in percutaneous and intraoperative surgical procedures.



"The FDA clearance of our Percutaneous Electrode System is the initial major milestone for Pulse Biosciences in surgery. It opens a new set of clinical applications and opportunities wherein our proprietary, one of a kind, patented CellFX nsPFA technology is highly differentiated and holds the potential to change the present time standard of care. I couldn't be more proud of the engineering, clinical and regulatory teams at Pulse Biosciences for their commitment to bringing the safety and effectiveness benefits of nsPFA to our physician, caretaker and patient partners," said Kevin Danahy, President and Chief Executive Officer of Pulse Biosciences. "Internally, our team is pleased with its manufacturing and operational readiness as we initiate our training and commercialization programs in the coming weeks. We look forward to providing additional details and color on these commercial programs in our upcoming fourth quarter and full year 2023 earnings conference call scheduled for Thursday, March 28, 2024."

The CellFX nsPFA Percutaneous Electrode System consists of a percutaneous needle electrode for use with the Company's proprietary CellFX nsPFA Console. The novel electrode is designed to harness and deliver the key advantages of nsPFA energy, enabling precise, nonthermal removal of cellular tissue without damage to noncellular structures or inducing thermal necrosis. This percutaneous electrode is designed for non-cardiac applications.

"The CellFX nsPFA Percutaneous Electrode System represents a much needed and promising new minimally invasive nonthermal treatment option for patients. For physicians, the system offers intuitive usability, short procedure times and customizable energy delivery to treat a variety of patients requiring soft tissue ablation," said Dr. Ralph P. Tufano, the Company's Senior Advisor and Scientific Advisory Board Chair, Head and Neck Surgery, Clinical Professor of Surgery at the Florida State University College of Medicine and Medical Director, Head and Endocrine Surgery for the Sarasota Memorial Health Care System in Sarasota, Florida. "I am extremely encouraged by the early study results by my colleague, Professor Stefano Spiezia, demonstrating the rapid clearance of ablated cellular tissue and absence of any evidence of thermal damage or residual scarring."

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 CellFX® nsPFA™ technology delivers nanosecond pulses of electrical energy to non-thermally clear cells while sparing adjacent noncellular tissue. The Company is actively pursuing the development of its CellFX nsPFA technology for use in the treatment of atrial fibrillation and in a select few other markets where it could have a profound positive impact on healthcare for both patients and providers.

Forward-Looking Statements

All statements in this press release that are not historical are forward-looking statements, including, among other things, statements relating to the effectiveness of the Company's CellFX nsPFA technology and CellFX System to nonthermally clear cells without damaging adjacent noncellular structures or inducing thermal necrosis, statements concerning the Company's expected product development efforts, such as commercial launch of its CellFX nsPFA Percutaneous Electrode System for soft tissue ablation in percutaneous and intraoperative surgical procedures, statements concerning the Company's manufacturing and operational readiness to initiate a commercial launch of any product, statements concerning whether any clinical study will show that the Company's novel nsPFA mechanism of action and percutaneous electrode design will deliver fast and precise soft tissue ablations without evidence of residual scarring, statements concerning market opportunities, customer adoption and future use of the CellFX System to address a range of conditions such as benign thyroid nodules, statements concerning early clinical successes and whether they are predictive of the safety and efficacy of any medical device such as the CellFX nsPFA Percutaneous Electrode System, Pulse Biosciences' expectations, whether stated or implied, regarding whether the Company's CellFX nsPFA technology will become a disruptive and durable treatment option for treating any medical condition, 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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