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): **May 9, 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 May 9, 2024, Pulse Biosciences, Inc. (the "Company") issued a press release announcing the first U.S. procedure with the 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 May 9, 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: May 9, 2024

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

Pulse Biosciences Announces First U.S. Procedure with the CellFX nsPFA Percutaneous Electrode System

HAYWARD, Calif. [Business Wire] – May 9, 2024. Pulse Biosciences, Inc. (Nasdaq: PLSE), a company leveraging its novel and proprietary CellFX® Nanosecond Pulsed Field Ablation™ (nsPFA™) technology, today announced the first procedure with the CellFX nsPFA Percutaneous Electrode System in the United States has been completed. The successful case is the first in the Company's pilot program which follows the March 2024 U.S. FDA 510(k) clearance for the ablation of soft tissue in percutaneous and intraoperative surgical procedures with the system.

"I am very proud and excited that the first U.S. patient treatment with soft tissue ablation by the CellFX nsPFA system was performed this week in our Thyroid and Parathyroid Center here at Sarasota Memorial Hospital," said Dr. Ralph P. Tufano, Medical Director, Head and Neck Endocrine Surgery for the Sarasota Memorial Health Care System in Sarasota, Florida. "The cell-specific mechanism of action of nsPFA allowed me to treat this patient with confidence, knowing that I was not going to cause collateral damage to acellular structures. The patient was treated for a large, symptomatic, benign, thyroid nodule in our office with just local lidocaine and tolerated the procedure extremely well, reporting no pain during nsPFA energy delivery, and is doing great. Based on the impressive results we have seen come out of Italy, I am confident the outcome of the procedure will be excellent. I am looking forward to continuing my collaboration with Pulse Biosciences to further refine the procedure and offer this life-changing new technology to my patients and to help to train other experts in this exciting new procedure."

The CellFX nsPFA Percutaneous Electrode System consists of a percutaneous needle electrode for use with the Company's proprietary CellFX nsPFA Console. Our proprietary and 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 proprietary system is designed for non-cardiac applications.

"Treating our first patient under our newly FDA-cleared nsPFA percutaneous system is a fundamental and opportune milestone for Pulse Biosciences," said Mitch Levinson, Chief Strategy Officer of Pulse Biosciences. "It is inspiring to see the difference our physicians can make in their patients' lives with our unique proprietary technology, giving them the potential to set new standards for safety and efficacy as well as decreased workflow time from patient set-up to procedure finish. The administration of local anesthesia at the treatment site with the patient awake, without the need for general anesthesia, in cases to date, is a noteworthy positive. Team Pulse Biosciences is deeply grateful to Dr. Tufano for his partnership over the past 3 years. We are all looking forward to evolving the standard of medicine as together we optimize and introduce the CellFX nsPFA percutaneous procedure on a controlled and measured basis through the balance of 2024."

Thyroid nodule soft tissue ablation procedures were performed on 30 patients with the CellFX nsPFA Percutaneous System in Italy from April 2023 through January 2024. Per amended study protocols, patients were observed and evaluated in follow-up visits to assess the procedure as early as one week post procedure, and up to this point, as late as 180 days post procedure. Patient follow-ups were conducted weekly for the first 4 weeks, then at 30-, 90-, 180-, and 360-day timepoints following the procedures. No evidence of scarring or injury to surrounding tissue has been observed, and patient treatments have been judged to be successful.

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 non-thermally clear cells while sparing adjacent non-cellular tissue, statements concerning the Company's expected product development efforts and plans to sell products commercially, such as its plans to demonstrate advantages of its CellFX nsPFA Percutaneous Electrode over current treatment options, statements concerning the timing and nature of the Company's pilot program to optimize and introduce the CellFX nsPFA percutaneous procedure on a controlled and measured basis, statements concerning customer adoption and future use of the CellFX System to address a range of conditions, such as benign thyroid nodules, and whether any future procedures using the CellFX System may or may not require general anesthesia, 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, 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.

Investor Contacts:
Pulse Biosciences
Kevin Danahy, President and CEO
510.241.1077
IR@pulsebiosciences.com

or
Gilmartin Group
Philip Trip Taylor
415.937.5406
philip@gilmartinir.com