UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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)
July 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.)**

601 Brickell Key Drive, Suite 1000
Miami, Florida 33131
(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)

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**

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))

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 July 8, 2024, Pulse Biosciences, Inc. (the "Company") issued a press release announcing that it has received Breakthrough Device Designation from the U.S. Food and Drug Administration ("FDA") for the Company's CellFX nsPFA Cardiac Surgery System for the treatment of atrial fibrillation. The FDA's Breakthrough Devices Program is a voluntary program for certain medical devices that potentially provide for more effective treatment or diagnosis of a life-threatening or irreversibly debilitating disease or condition. The program is designed to expedite the development and review of these medical devices.

The Company's Cardiac Surgery System with Surgical Clamp is designed to produce durable, continuous, transmural ablation lesions during cardiac surgery procedures for the treatment of atrial fibrillation. The bipolar clamp utilizes the Company's proprietary nanosecond PFA technology.

A copy of the press release related to the matters set forth herein is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits

Exhibit Number	**Description**
99.1	Press Release issued by Pulse Biosciences, Inc. dated July 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 hereunto duly authorized.

PULSE BIOSCIENCES, INC.

Date: July 8, 2024

By: /s/ Burke T. Barrett
Burke T. Barrett
President and Chief Executive Officer
(Principal Executive and Principal Financial Officer)

Pulse Biosciences, Inc. Announces Receipt of FDA Breakthrough Device Designation for CellFX® nsPFA Cardiac Surgery System for the Treatment of Atrial Fibrillation

Provides expanded access to FDA and prioritized review of submission

MIAMI, Florida, July 8, 2024 -- Pulse Biosciences, Inc. (Nasdaq: PLSE) (the "Company" or "Pulse Biosciences"), a company leveraging its novel and proprietary Nanosecond Pulsed Field Ablation™ (nsPFA™) technology, today announced that it has received the Breakthrough Device Designation from the U.S. FDA for the Company's Cardiac Surgery System for the ablation of cardiac tissue for the treatment of atrial fibrillation (AF).

Pulse Biosciences' Cardiac Surgery System with Surgical Clamp is designed to produce durable, continuous transmural ablation lesions during cardiac surgery procedures for the treatment of atrial fibrillation. The bipolar clamp utilizes the Company's proprietary nanosecond PFA technology. Based on pre-clinical studies, a single application of less than 2 seconds with the Surgical Clamp creates a consistent, transmural ablation, which is significantly faster, requiring approximately one-twentieth the time of currently available thermal ablation technologies. Also, due to the non-thermal mechanism of action of nano-PFA, there is no risk of thermal spread that may cause undesired injury to collateral tissues, which compares favorably to thermal radiofrequency ablation.

"The science behind nanosecond pulse field ablation was immediately compelling to me. The theoretical benefits of short-duration, high-amplitude energy pulses with a nonthermal mechanism of action suggest the potential for a safer and more effective treatment. The preclinical data convinced me this technology could significantly advance the surgical treatment of atrial fibrillation. The FDA recognized Pulse's Cardiac Surgery System as Breakthrough and we look forward to continuing our work to provide access to this technology to patients and surgeons as quickly as possible," said Dr. Niv Ad, Chief Science Officer, Cardiac Surgery of Pulse Biosciences.

The Breakthrough Devices Program is a voluntary program for certain medical devices with the potential to provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions, such as atrial fibrillation. The Breakthrough Devices Program is intended to provide patients and health care providers with timely access to medical devices by speeding up development, assessment, and review for premarket approval, 510(k) clearance, and De Novo marketing authorization. Breakthrough Devices must still meet the FDA's rigorous standards for device safety and effectiveness in order to be authorized for marketing.

"The Breakthrough Device Designation granted by the FDA is an exciting milestone for Pulse. It emphasizes the unique potential benefits of nanosecond PFA," added President and Chief Executive Officer Burke T. Barrett. "We plan to fully leverage the benefits of this designation and have chosen to seek PMA approval to achieve a specific indication for the treatment of atrial fibrillation. We look forward to aligning with the FDA on a pivotal clinical trial design in the near-term and towards initiating our planned first-in-human cases in the Netherlands soon."

The Company now plans to pursue the premarket approval (PMA) application pathway for FDA approval to market as opposed to the 510(k) route, and once FDA PMA approved, commercialize the nsPFA Cardiac Surgical System in the United States as a treatment for atrial fibrillation. Once granted by the FDA, a specific treatment indication would permit direct marketing of the treatment benefits provided by the device. The Company expects to begin its pivotal clinical trial for AF in 2025 and will provide additional details on the study and its regulatory and commercial implications later this year.

"The preclinical results we have generated with the Cardiac Surgery System have been outstanding and I expect to see similar results in the initial clinical procedures in the Netherlands later this year. Nanosecond PFA has the potential to be a revolutionary advancement for the surgical treatment of atrial fibrillation. I am excited to help design the pivotal clinical trial to support a future PMA submission," stated Dr. Gan Dunnington, Chief Medical Officer, Cardiac Surgery of Pulse Biosciences.

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. Pulse Biosciences is now headquartered in Miami, Florida and maintains its office in Hayward, California.

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 future clinical studies and regulatory submissions, whether with the U.S. FDA or otherwise, statements concerning whether any clinical study will show that the Company's novel nsPFA mechanism of action will deliver fast and precise ablations in cardiac tissue, statements concerning market opportunities, customer adoption and future use of the CellFX System to address a range of conditions such as atrial fibrillation, statements concerning early clinical successes and whether they are predictive of the safety and efficacy of any medical device such as the CellFX nsPFA Cardiac Surgery System, Pulse Biosciences' expectations, whether stated or implied, regarding whether the Company's CellFX nsPFA technology will become a disruptive, superior and durable treatment option for treating atrial fibrillation or any other 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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