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)
August 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 August 8, 2024, Pulse Biosciences, Inc. (the "Company") issued a press release announcing successful enrollment and treatment of two subjects in its first-in-human feasibility study using its novel Cardiac Surgery System for the ablation of cardiac tissue for the treatment of atrial fibrillation. The first-in-human feasibility study is a multicenter study of up to 30 patients that will include an endocardial catheter-based remapping to confirm chronic isolation at approximately three months post treatment.

The Company also announced the enrollment of its nano-PFA Cardiac Surgical System in the FDA's Total Product Life Cycle (TPLC) Advisory Program (TAP). The FDA's Center for Devices and Radiological Health (CDRH) launched the TAP program to help generate more rapid development of high-quality, safe, effective, and innovative medical devices that are critical to public health. TAP's primary goal is to expedite patient access to innovative medical devices by providing early, frequent and strategic communications with the FDA and facilitating engagement with other key parties for developers of devices of public health importance.

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 August 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: August 8, 2024

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

Exhibit 99.1

Pulse Biosciences, Inc. Announces Successful Treatment of Patients in First-in-Human Study with its Nano-PFA Cardiac Surgery System

Company's proprietary system used in study for patients with atrial fibrillation

*Cardiac Surgery System enrolled in the FDA's Total Product Life Cycle (TPLC) Advisory Program (TAP)**

MIAMI, Florida, August 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 treatment of the first two patients in the first-in-human feasibility study using its novel Cardiac Surgery System for the ablation of cardiac tissue for the treatment of atrial fibrillation.

Dr. Bart Van Putte, Cardiothoracic Surgeon at St. Antonius Hospital, used the Company's Cardiac Surgery System to successfully treat two patients with atrial fibrillation at St. Antonius Hospital, Nieuwegein, The Netherlands. Dr. Van Putte was joined by colleagues and Pulse Biosciences' Chief Medical Officer, Cardiac Surgery, Dr. Gan Dunnington and Chief Science Officer, Cardiac Surgery, Dr. Niv Ad during the concomitant procedure. The first-in-human feasibility study is a multicenter study of up to 30 patients that will include an endocardial catheter-based remapping to confirm chronic isolation at approximately three months post treatment.

"We are honored to partner with Pulse Biosciences and to be the first team to use this next-generation nano-PFA technology for the treatment of atrial fibrillation in cardiac surgery. The initial procedure results showed effective pulmonary vein and 'box' isolation with Pulse's Cardiac Surgery System," said Dr. Bart Van Putte, Cardiothoracic Surgeon at St. Antonius Hospital. "We were impressed by how rapidly and effectively we were able to produce linear ablations in a fraction of the time it takes with the current thermal modalities we use, such as radiofrequency or cryoablation."

"These initial treatment results confirm our preclinical work with the cardiac surgical system. The patients tolerated our procedure well. We are pleased to see how the intuitive design of the device facilitates an efficient procedure where surgeons can create controlled lesions with adequate depth very rapidly," added Dr. Gan Dunnington, Chief Medical Officer, Cardiac Surgery of Pulse Biosciences. "We are excited to continue enrollment in this feasibility clinical study, which is intended to demonstrate the device's safety, effectiveness and durability profile."

Pulse'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. Based on pre-clinical studies, a single application of less than two seconds with the Surgical Clamp creates a consistent, transmural, durable 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 nano-PFA Cardiac Surgical System received FDA Breakthrough Device Designation in early July 2024. Recently the device was enrolled in the FDA's TAP program. The FDA's Center for Devices and Radiological Health (CDRH) launched the TAP program to help generate more rapid development of high-quality, safe, effective, and innovative medical devices that are critical to public health. TAP's primary goal is to expedite patient access to innovative medical devices by providing early, frequent and strategic communications with the FDA and facilitating engagement with other key parties for developers of devices of public health importance. According to its website, the FDA has enrolled 46 devices in the TAP program to date, while there have been over 900 Breakthrough Device Designations granted.

"We continue to make great strides on the development of our current nano-PFA devices, three of which have now been used in patients with initial promising results. We are grateful for all the key opinion leader clinicians who have partnered with us to advance nano-PFA technology for the benefit of patients and clinicians worldwide," stated President and Chief Executive Officer Burke T. Barrett. "These initial clinical results with the Cardiac Surgical System will inform the next steps of our clinical and regulatory strategy. We are excited to continue the momentum with the System following its Breakthrough Device Designation and recent enrollment into the prestigious TAP program. Moving forward, we intend to submit for IDE approval from the FDA to begin U.S. clinical work."

The Company plans to pursue FDA premarket approval (PMA) to commercialize its nano-PFA Cardiac Surgical System in the United States as a treatment for atrial fibrillation. If granted by the FDA, a specific treatment indication would permit direct marketing of the device's treatment benefits. The Company intends to begin its pivotal clinical study of its nano-PFA Cardiac Surgical System as a treatment for atrial fibrillation in early 2025 and will provide additional details on the study and its regulatory and commercial implications later this year.

*https://www.fda.gov/medical-devices/how-study-and-market-your-device/total-product-life-cycle-advisory-program-tap

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 create consistent, transmural, durable ablations in cardiac tissue in approximately one-twentieth the time of currently available thermal ablation technologies, statements concerning the Company's expected product development efforts and future clinical studies and regulatory submissions and whether breakthrough designation or enrollment in the FDA's TAP program can accelerate regulatory approval to market the Company's Cardiac Surgery System in the United States, 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 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, and

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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