

**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): **October 24, 2025**

Pulse Biosciences, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-37744
(Commission
File Number)

46-5696597
(IRS Employer
Identification No.)

601 Brickell Key Drive, Suite 1080
Miami, Florida 33131
(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 October 24, 2025, Pulse Biosciences, Inc. (the “Company”) issued a press release announcing the enrollment of the first patient in its NANOCLAMP AF clinical trial, a single-arm, prospective multicenter study designed to demonstrate the safety and effectiveness of the Company's nPulse™ Cardiac Surgical System for the treatment of atrial fibrillation in concomitant surgical procedures. The successful first procedure was completed at St. Helena Hospital in St. Helena, California.

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

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release issued by Pulse Biosciences, Inc. dated October 24, 2025 - Pulse Biosciences Announces First Enrollment in the NANOCLAMP AF Study
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: October 24, 2025

By: /s/ Paul A. LaViolette
Paul LaViolette
Chief Executive Officer
(Principal Executive Officer)

Pulse Biosciences Announces First Enrollment in the NANOCLAMP AF Study

First U.S. Surgical Treatments with PFA Clamp for Patients with Atrial Fibrillation During Concomitant Surgical Procedure

HAYWARD, Calif. [Business Wire]—October 24, 2025 Pulse Biosciences, Inc. (Nasdaq: PLSE), a company leveraging its novel nPulse™ technology using its proprietary Nanosecond Pulsed Field Ablation™ (nanosecond PFA or nsPFA™) energy, today announced the enrollment of the first patient in its NANOCLAMP AF Study for the treatment of atrial fibrillation (AF). The successful first procedure was completed at St. Helena Hospital in St. Helena, California, with the nPulse™ Cardiac Surgical System following its recent FDA IDE approval.

NANOCLAMP AF is a single-arm, prospective multicenter study designed to demonstrate the safety and effectiveness of the nPulse Cardiac Surgical System for the treatment of AF in concomitant surgical procedures. Multiple sites, including two outside the United States, are planned for patient enrollment.

“After years of development, it is an honor to perform the first NANOCLAMP AF surgical procedure in the U.S. for the treatment of AF using nanosecond PFA with Dr. Aaron Kime and the team here at Adventist Health,” said Dr. Gan Dunnington, Cardiothoracic Surgeon for Adventist Health. “I’m excited for my fellow surgeon colleagues to experience this technology as we aim to bring faster, safer, and more effective treatment options to patients suffering from AF. While I have seen this technology used in the European clinical experience, my team was impressed by the nPulse Cardiac Clamp’s ease of use, and the speed of treatment exceeded their expectations.”

“This trial marks a pivotal moment in our journey to transform patient care. nPulse technology has the potential to revolutionize how we approach concomitant ablation procedures. This device offers an improved safety profile as a result of the nonthermal mechanism of action while enabling consistent, precise, contiguous and durable full-thickness lesions in a fraction of the time compared to existing technology. This should ultimately translate to improved outcomes for our patients and expand treatment to more people in need,” said Dr. Matthew Romano, National Principal Investigator and Professor of Cardiac Surgery at the University of Michigan.

The nPulse™ Cardiac Surgical System is a next-generation, bipolar surgical device engineered to create continuous, full-thickness ablation lines during concomitant cardiac procedures. The system utilizes a nonthermal energy modality which is expected to provide significant safety and procedural advantages over conventional thermal ablation methods. The nsPFA Cardiac Surgical System was granted FDA Breakthrough Device Designation in July 2024 and is enrolled in the FDA’s Total Product Life Cycle (TPLC) Advisory Program (TAP).

“Treating our first patient so quickly following the IDE approval demonstrates the excitement about nanosecond PFA among cardiovascular surgeons,” said Dr. Niv Ad, Chief Scientific Officer, Cardiac Surgery at Pulse Biosciences. “Proving the benefits of nsPFA in this study could drive significant future adoption of surgical cardiac ablation. We are grateful to all the clinicians who continue to support our clinical work. Together we are poised to advance the standard of care for AF and increase the number of patients being treated.”

About Pulse Biosciences®

Pulse Biosciences is a novel bioelectric medicine company committed to health innovation that has the intention as well as the potential to improve the quality of life for patients. The Company’s proprietary nPulse™ 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 nPulse 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, such as surgical soft tissue ablation.

Pulse Biosciences, nPulse, Vybrance, CellFX, Nano-Pulse Stimulation, NPS, nsPFA, CellFX nsPFA, nanosecond PFA and the stylized logos are among the trademarks and/or registered trademarks of Pulse Biosciences, Inc. in the United States and other countries.

Forward-Looking Statements

All statements in this press release that are not historical are forward-looking statements, including, among other things, statements relating to whether the nPulse™ Cardiac Surgical System can create continuous, full-thickness ablation lines during concomitant cardiac procedures or whether it can provide important safety and procedural advantages over conventional thermal ablation methods for treating atrial fibrillation, statements concerning the effectiveness of the Company’s nPulse technology to non-thermally clear cells while sparing adjacent noncellular tissue, statements concerning the potential market opportunities for the use of nsPFA to treat AF and whether the market might grow in the future; statements concerning early clinical successes and whether they are predictive of the safety and effectiveness of any medical device, such as the nPulse Cardiac Surgical System and statements concerning the Company’s future clinical and regulatory initiatives anywhere in the world, 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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