

**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): **September 8, 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 September 8, 2025, Pulse Biosciences, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration had granted approval for the Company's Investigational Device Exemption ("IDE"), allowing the Company to proceed with the initiation of its nsPFA Cardiac Surgery System Study, NANOCLAMP AF, for the treatment of atrial fibrillation ("AF"). This single-arm, prospective study is designed to demonstrate primary effectiveness of the nsPFA Cardiac Surgical System for the treatment of AF in concomitant surgical procedures. Up to twenty sites, including two outside the United States, are planned to enroll up to 136 patients in the study.

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.

Forward Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements regarding enrollment into the Company's IDE clinical trial of its nsPFA Cardiac Surgical System and whether the study can be completed successfully, and whether the study data will demonstrate the safety and effectiveness of the Company's nsPFA Cardiac Surgical System for the treatment of AF. Forward-looking statements are based on management's current expectations and assumptions and are subject to risks and uncertainties, such as clinical, regulatory and technological risks, that could cause actual results to differ materially from those expressed or implied from such statements. The Company undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by law.

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 September 8, 2025 - Pulse Biosciences Announces FDA Approval to Initiate its nsPFA Cardiac Surgery System Study for the Treatment of Atrial Fibrillation
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: September 8, 2025

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

Pulse Biosciences Announces FDA IDE Approval to Initiate its nsPFA Cardiac Surgery System Study for the Treatment of Atrial Fibrillation

HAYWARD, Calif. [Business Wire]—September 8, 2025. Pulse Biosciences, Inc. (Nasdaq: PLSE)(the “Company” or “Pulse Biosciences”), a company leveraging its novel and proprietary Nanosecond Pulsed Field Ablation™ (nanosecond PFA or nsPFA™) technology, today announced that the U.S. Food and Drug Administration (FDA) has granted approval for the Company’s Investigational Device Exemption (IDE), allowing Pulse Biosciences to proceed with the initiation of its nsPFA Cardiac Surgery System Study, NANOCLAMP AF, for the treatment of atrial fibrillation (AF).

This single-arm, prospective study is designed to demonstrate primary effectiveness of the nsPFA Cardiac Surgical System for the treatment of AF in concomitant surgical procedures. Up to twenty sites, including two outside the United States, are planned to enroll up to 136 patients. Additional details of the study will be made available on clinicaltrials.gov.

“We believe nsPFA’s novel and proprietary nonthermal mechanism of cardiac ablation offers significant safety, effectiveness and speed improvements over current thermal modalities, such as radiofrequency ablation. The first-in-human feasibility data we are generating in Europe gives us confidence in our ability to successfully execute the IDE study, and we look forward to enrolling our first patients,” said Dr. Niv Ad, Chief Science Officer, Cardiac Surgery at Pulse Biosciences.

“This FDA IDE approval is a major milestone for Pulse Biosciences. The study approval is a testament to the quality of the preclinical and human clinical data that has been generated in support of this breakthrough technology. Pulse Biosciences is the first company to advance PFA into the cardiac surgical field for the treatment of AF,” said Paul LaViolette Co-Chairman and CEO of Pulse Biosciences.

The nsPFA Cardiac Clamp is designed to deliver continuous, linear, transmural ablations during concomitant cardiac surgeries. The bipolar device leverages the Company’s proprietary nonthermal nsPFA technology, which early clinical data suggest may offer safety and performance advantages over traditional thermal ablation methods. Unlike thermal approaches, nsPFA energy minimizes the risk of collateral tissue damage due to its nonthermal mechanism of action. The nsPFA Cardiac Surgical System received FDA Breakthrough Device Designation in July 2024 and is enrolled in the FDA’s Total Product Life Cycle (TPLC) Advisory Program (TAP).

“The nsPFA Cardiac Clamp is designed to be an optimal replacement for conventional radiofrequency ablation devices, offering a faster, more consistent, and safer approach to surgical cardiac ablation. The ability to achieve full thickness, contiguous, durable lesions with reduced ablation times highlights the unique clinical value of the nsPFA technology,” said Dr. Gan Dunnington, Chief Medical Officer, Cardiac Surgery at Pulse Biosciences. “We believe the benefits of nsPFA technology for cardiac ablation will increase the overall adoption of surgical cardiac ablation for AF well beyond what radiofrequency ablation has been able to do.”

The Company’s first-in-human feasibility study has been underway in the EU since August 2024, with over 40 patients treated across three sites in The Netherlands. Surgeons have reported rapid ablation times—as short as 2.5 seconds—along with consistent, contiguous, and fully transmural lesions. The Company expects to add additional sites to this study throughout 2025. The accelerating clinical rollout is building a strong foundation of real-world evidence to support broader global adoption of nsPFA. Pulse Biosciences is looking forward to presentations highlighting its nsPFA Cardiac Clamp at the upcoming annual European Association for Cardio-Thoracic Surgery meeting October 8-11, 2025 in Copenhagen, Denmark.

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 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, such as surgical soft tissue ablation.

Pulse Biosciences, 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 the effectiveness of the Company’s CellFX nsPFA technology and nsPFA Cardiac Surgery System to create consistent, contiguous, fully transmural lesions in cardiac tissue in as little as 2.5 seconds, 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 technology minimizes the risk of collateral tissue damage due to its nonthermal mechanism of action, statements concerning early clinical successes and whether they are predictive of the safety and efficacy of any medical device such as the 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, as well as statements concerning whether the perceived benefits of nsPFA technology for cardiac ablation will increase the overall adoption of surgical cardiac ablation for AF well beyond what radiofrequency ablation has been able to do, 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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