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): **January 21, 2025**

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 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 8.01OTHER EVENTS.

On January 21, 2025, Pulse Biosciences, Inc. (the "Company") issued a press release announcing late-breaking data from the Company's first-in-human feasibility study of its Nanosecond PFA 360° Cardiac Catheter System. To date, 77 patients have been treated by six investigators in the study. The initial cohort of the first 30 patients treated have been evaluated by remapping completed at approximately three months post ablation procedure. Initial cohort study results include:

- All (100%) lesions were acutely successful with conduction block
- Success rate of pulmonary vein isolation (PVI) at ~3 months was 92.4% (109/118)
- Total PVI ablation time was 11.6 ± 4.5 minutes
- Total procedure and fluoroscopy times were 88.3 ± 30.1 and 6.9 ± 2.4 minutes, respectively
- Left atrial dwell time was 29.6 ± 15.3 minutes
- 1 Primary SAE (cardiac perforation) and 2 AEs including vertigo (n=1; managed conservatively) and creatinine elevation (n=1; treated with IV saline), with all AEs resolved without sequelae

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 9.01FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits

Exhibit Number	**Description**
99.1	Press Release of Pulse Biosciences, Inc. dated January 21, 2025.
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: January 23, 2025

By: /s/ Paul A. LaViolette
Paul A. LaViolette
Chief Executive Officer

Pulse Biosciences Announces Late-Breaking Data from its Nanosecond PFA 360° Cardiac Catheter System First-In-Human Feasibility Study Presented at the AF Symposium

Successfully treated atrial fibrillation (AF) in initial 30 patients with the Nanosecond PFA 360° Cardiac Catheter

MIAMI, Florida. [Business Wire]– January 21, 2025. Pulse Biosciences, Inc. (Nasdaq: PLSE), a company leveraging its novel and proprietary Nanosecond Pulsed Field Ablation™ (nsPFA™) technology, today announced the late-breaking data from its Nanosecond PFA 360° Cardiac Catheter System first-in-human feasibility study, which data were recently presented at the 30th Annual AF Symposium 2025 meeting.

The feasibility study is intended to assess the initial safety and efficacy of the Nanosecond PFA 360° Cardiac Catheter System for the treatment of AF (NCT06696170). To date, 77 patients have been treated by six investigators, including Dr. Vivek Reddy and Prof. Petr Neuzil, in cases performed at Na Holmolce Hospital in Prague and Dr. Johan Vijgen at Jessa Hospital in Hasselt. The initial cohort of the first 30 patients treated have been evaluated by remapping completed at ~3 months post ablation procedure.

“The remap results for the first 30 patients treated with the Nanosecond PFA 360° Cardiac Catheter demonstrate strong pulmonary vein isolation (PVI) with short case times,” said Vivek Reddy, MD, Director of Cardiac Arrhythmia Services at the Mount Sinai Fuster Heart Hospital, NY. “This novel technology offers a unique user experience that has the potential to improve workflow with a pliable catheter for nimble and precise positioning in the anatomy, and combined with the differentiated energy, enables consistent, durable transmural ablations.”

Initial Cohort Study Results

- All (100%) lesions were acutely successful with conduction block
- Success rate of PVI at ~3 months was 92.4% (109/118)
- Total PVI ablation time 11.6±4.5 minutes
- Total procedure and fluoroscopy times were 88.3±30.1 and 6.9±2.4 minutes, respectively.
- Left atrial dwell time was 29.6±15.3 minutes.
- 1 Primary SAE (cardiac perforation) and 2 AEs including vertigo (n=1; managed conservatively) and creatinine elevation (n=1; treated with IV saline). All AEs were resolved without sequelae

Also, at the AF Symposium, a live case transmission highlighted the nsPFA 360° Cardiac Catheter with 3D mapping and navigation on the Abbott Ensite X System. Prof. Petr Neuzil and Drs. Moritoshi Funasako and Jan Petru performed a successful live case highlighting the nsPFA 360° Cardiac Catheters’ ability to rapidly isolate the pulmonary veins with a fast, efficient procedure workflow.

“We appreciate the support of the renowned EPs who are performing the initial clinical work with our catheter ablation system and are presenting its clinical performance to their peers in the scientific community. We believe nanosecond PFA represents the next generation energy modality that will improve the safety, efficacy and efficiency of AF ablation through a more straightforward and clinician-friendly procedure,” said Paul LaViolette, CEO and Co-Chairman of Pulse Biosciences. “We remain on track to begin an IDE study this year for clinical validation of our devices and look forward to continuing our work with thought leading physicians to achieve commercial approval and deliver this technology to more patients and providers.”

About Pulse Biosciences®

Pulse Biosciences is a novel bioelectric medicine company committed to health innovation that has the intention as well as 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.

Note: Dr. Reddy serves as a consultant to Pulse Biosciences (as well as other companies developing pulsed field ablation catheters).

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, such as advancement of its nsPFA 360° Cardiac Catheter to treat atrial fibrillation, statements concerning whether any clinical study will show that the Company’s novel nsPFA mechanism of action and catheter design will deliver strong pulmonary vein isolation (PVI) or consistent and durable transmural ablations, 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 nsPFA 360° Cardiac Catheter, Pulse Biosciences’ expectations, whether stated or implied, regarding its future clinical studies and regulatory submissions, 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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