

**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): **February 5, 2026**

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 February 5, 2026, Pulse Biosciences, Inc. (the “Company”) issued a press release announcing 6- and 12-month data from its nPulse™ Cardiac Catheter first-in-human feasibility study (the “Study”). These data were presented by Dr. Vivek Reddy, Director of Cardiac Arrhythmia Services at the Mount Sinai Fuster Heart Hospital in New York, at the 31st Annual AF Symposium 2026 meeting in Boston.

The Study has been assessing the initial safety and effectiveness of the Company's nPulse Cardiac Catheter System for the treatment of atrial fibrillation, a form of heart arrhythmia. The Company's endocardial catheter ablation device has been uniquely designed to provide a circumferential, or circular, ablation in a single treatment cycle using proprietary nanosecond PFA energy. To date, in the Study, a total of 165 patients have been treated by nine investigators in Europe, including clinicians at the Na Homolce Hospital in Prague. The initial cohort of 150 treated patients has been evaluated by remapping at approximately 3 months and for rhythm control completed at 6 and 12 months post ablation procedure.

Key findings from the Study reported by the Company include:

- 96% procedural success of evaluable patients at one year (45/47)
- 100% procedural success of evaluable patients at 6 months (75/75)
- Average number of applications were 16.1 ± 5.2 per procedure
- Total procedure and fluoroscopy times were 65 ± 28 and 9.8 ± 5.8 minutes, respectively
- Left atrial dwell time was 21.0 ± 13.3 minutes
- Safety profile: 1.3% (2/150) subjects had an SAE related to the primary safety endpoint

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 February 5, 2026 - Pulse Biosciences Presents Late-Breaking Data from nPulse Cardiac Catheter System First-in-Human Feasibility Study at the AF Symposium
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: February 5, 2025

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

Pulse Biosciences Presents Late-Breaking Data from nPulse™ Cardiac Catheter System First-In-Human Feasibility Study at the AF Symposium

Procedural success was achieved in 100% of evaluable patients at 6 months and 96% in 12 months

HAYWARD, California, February 5, 2026 [Business Wire] – Pulse Biosciences, Inc. (Nasdaq: PLSE), developer of the novel nPulse™ technology using proprietary Nanosecond Pulsed Field Ablation™ (nanosecond PFA or nsPFA™) energy, today announced late-breaking clinical data from the nPulse Cardiac Catheter first-in-human feasibility study. The study demonstrates successful treatment of atrial fibrillation in 150 patients with rapid procedure times and minimal adverse effects. The data were presented today at the 31st Annual AF Symposium 2026 meeting, taking place February 5-7, 2026, in Boston, MA.

Key study findings include:

- 100% procedural success of evaluable patients at 6 months (75/75)
- 96% procedural success of evaluable patients at one year (45/47)
- Average number of applications were 16.1 ± 5.2 per procedure
- Total procedure and fluoroscopy times were 65 ± 28 and 9.8 ± 5.8 minutes, respectively
- Left atrial dwell time was 21.0 ± 13.3 minutes
- Safety profile: 1.3% (2/150) subjects had an SAE related to the primary safety endpoint

“These 6- and 12-month data demonstrate a strong safety profile with highly effective and durable PVI achieved with the nPulse Cardiac Catheter Ablation System, suggesting that this system has the ability to considerably advance the treatment of atrial fibrillation (AF),” said Vivek Reddy, MD, Director of Cardiac Arrhythmia Services at the Mount Sinai Fuster Heart Hospital, NY. “The conformable catheter design, differentiated energy, and zero rotation workflow have produced highly efficient and effective results when compared to other AF feasibility studies in my experience, highlighting the nPulse Cardiac Catheter’s simple and effective workflow for PVI.”

The ongoing feasibility study is assessing the initial safety and efficacy of the nPulse Cardiac Catheter System for the treatment of AF (NCT06696170). To date, a total of 165 patients have been treated by nine investigators in Europe, including the Na Homolce Hospital in Prague led by Dr. Vivek Reddy and Prof. Petr Neuzil, Jessa Hospital in Hasselt led by Dr. Johan Vijgen, and Tor Vergata Hospital in Rome, led by Dr. Andrea Natale. The initial cohort of treated patients has been evaluated by remapping at ~3 months and for rhythm control completed at 6 and 12 months post ablation procedure.

“This dataset marks an important milestone for Pulse Biosciences and highlights an exceptional combination of improved workflow and outcomes results. These results validate the safety, effectiveness, lesion quality, and speed benefits that clearly differentiate the nPulse Cardiac Catheter Ablation System as a first in class system showing the potential to be best in class,” said Paul LaViolette, CEO and Co-Chairman of Pulse Biosciences. “We extend our gratitude to all the electrophysiologists, staff and patients who continue to support our clinical work.”

“These impressive results highlight the nPulse Cardiac Catheter as a first-in-class system for treating AF. In a clinical field where a 20-25% recurrence rate is expected, these results exceed expectations for PVI. Nanosecond PFA energy and integration into a 3D mapping system has the ability to offer precise, lasting pulmonary vein isolation. We’re poised to revolutionize atrial fibrillation treatment, and we are excited to begin treating additional patients in Europe and the U.S. as we initiate our pivotal IDE study,” said Dr. David Kenigsberg, Chief Medical Officer, Electrophysiology at Pulse Biosciences.

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 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 and the stylized logos are among the trademarks and/or registered trademarks of Pulse Biosciences, Inc. in the United States and other countries.

Glossary of Terms

- Arrhythmia: Any abnormal heart rhythm where the heart beats too fast, too slow, or irregularly due to electrical disturbances.
- Atrial arrhythmia: Any abnormal heart rhythm originating in the atria, including AF, atrial flutter, and atrial tachycardia.
- Atrial fibrillation (AF): Irregular, often rapid heartbeat starting in the atria that can cause symptoms and increase stroke risk.
- Catheter ablation: Minimally invasive procedure using catheters to deliver energy and destroy small areas of heart tissue causing abnormal rhythms.
- Cohort: A defined group of study participants sharing specific characteristics and followed over time to assess outcomes.
- Electroanatomic mapping: 3D mapping of heart chambers that combines anatomy and electrical data to guide ablation.
- Electrophysiology (EP): Cardiology subspecialty focused on the heart’s electrical system and the diagnosis and treatment of arrhythmias.
- Feasibility study: Early, usually small clinical study evaluating whether a procedure or device can be performed safely and as intended.
- Paroxysmal atrial fibrillation: AF episodes that start and stop on their own, typically lasting less than seven days.
- PFA (Pulsed Field Ablation): Non-thermal ablation using short, high-voltage pulses to selectively injure cardiac cells via irreversible electroporation.
- Pulmonary vein isolation (PVI): Ablation technique that electrically isolates the pulmonary veins from the left atrium to prevent AF triggers.

Forward-Looking Statements

All statements in this press release that are not historical are forward-looking statements, including, among other things, statements concerning early clinical successes and whether they are predictive of the safety and effectiveness of any medical device such as the nPulse Cardiac Catheter, Pulse Biosciences’ expectations, whether stated or implied, about whether the Company’s nsPFA technology will become either a disruptive treatment option or a superior option for treating atrial fibrillation or any other medical condition, statements relating to the effectiveness of the Company’s nsPFA technology and nPulse 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 nPulse Cardiac Catheter to treat paroxysmal atrial fibrillation, statements concerning whether any clinical study will show that the Company's novel nsPFA mechanism of action and catheter design will deliver fast and precise ablations in cardiac tissue and streamline workflow, statements concerning market opportunities, customer adoption and future use of the nPulse System to address a range of conditions such as atrial fibrillation, 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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