

**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 7, 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.)

3957 Point Eden Way
Hayward, California 94545
(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 7, 2026, Pulse Biosciences, Inc. (the “Company”) announced that it had achieved its enrollment target of 164 evaluable patients in its NANOPULSE-AF clinical study evaluating the Company’s nPulse™ Cardiac Catheter System for the treatment of atrial fibrillation (the “Study”). The Study is a prospective, multicenter, non-randomized IDE pivotal clinical investigation designed to evaluate the safety and effectiveness of the nPulse Cardiac Catheter System in patients with drug-resistant, symptomatic, paroxysmal atrial fibrillation. The Study achieved target enrollment of 164 evaluable participants across 15 clinical sites, with the first patients treated in April 2026. The primary safety and effectiveness endpoints of the Study will be assessed at 6 and 12 months post-ablation.

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>
<u>99.1</u>	<u>Press Release issued by Pulse Biosciences, Inc. dated October 7, 2026 - Pulse Biosciences Achieves Enrollment Target in NANOPULSE-AF IDE Pivotal Clinical Study.</u>
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 7, 2026

By: /s/ Jon Skinner
Jon Skinner
Chief Financial Officer
(Principal Financial Officer)

Pulse Biosciences Achieves Enrollment Target in NANOPULSE-AF IDE Pivotal Clinical Study Evaluating nPulse™ Cardiac Catheter System for Atrial Fibrillation Treatment

164 evaluable patients enrolled across 15 clinical sites

HAYWARD, California, October 7, 2026 — Pulse Biosciences, Inc. (Nasdaq: PLSE), a company leveraging its novel and proprietary Nanosecond Pulsed Field Ablation™ (nano-PFA or nsPFA™) technology, today announced that its NANOPULSE-AF Study has reached its enrollment target of 164 evaluable patients across 15 clinical sites.

“The compelling first-in-human dataset from the nPulse Cardiac Catheter System created significant investigator interest within the EP community across the United States,” said Vivek Reddy, MD, Director of Cardiac Arrhythmia Services at the Mount Sinai Fuster Heart Hospital, New York, and National Principal Investigator of the NANOPULSE-AF Study. “With so many leading centers eager to evaluate this new catheter and nsPFA technology, we were able to activate 15 world-class clinical sites quickly. The rapid learning curve, seamless integration into current practice and efficient workflow allowed operators to enroll steadily once they started. This is one of the fastest-enrolling trials I have seen or participated in.”

“Having participated in numerous catheter clinical trials and ablation technologies over the course of my career, I have found the early experience with the nPulse system to be potentially transformative,” said Shephal Doshi, MD, FACC, of Pacific Heart Institute and an investigator in the NANOPULSE-AF Study. “In my experience to date, the catheter design and one-shot approach have allowed for a straightforward and efficient procedural workflow. I look forward to seeing the results of the NANOPULSE-AF Study and gaining a better understanding of the technology as the clinical experience continues to grow.”

“On behalf of the entire Pulse Biosciences team, I want to thank our investigators, their research teams, and the clinical sites that participated in the NANOPULSE-AF IDE study,” said David Kenigsberg, MD, FACC, FHRS, Chief Medical Officer of Pulse Biosciences. “We are proud of the commitment to quality as well as patient betterment at each study site and pleased by the speed with which this study reached its enrollment target, three months ahead of our original 9-month timeline. The enrollment pace reflects the enthusiasm we saw at sites from their first cases- once operators did one or two cases, they were amazed and hooked and eager to do more. Participation across all 15 centers has been excellent, and their care and commitment will help ensure we maintain the highest level of scientific rigor as we follow patients through study completion.”

About the NANOPULSE-AF Study

The NANOPULSE-AF Study is a prospective, multicenter, non-randomized IDE pivotal clinical investigation designed to evaluate the safety and effectiveness of the nPulse Cardiac Catheter System in patients with drug-resistant, symptomatic, paroxysmal atrial fibrillation. The Study achieved target enrollment of 164 evaluable participants across 15 clinical sites, with the first patients treated at St. Bernards Medical Center in Jonesboro, Arkansas, under the leadership of Devi Nair, MD, Principal Investigator of the Arrhythmia Research Group. Vivek Reddy, MD, Director of Cardiac Arrhythmia Services at the Mount Sinai Fuster Heart Hospital, NY, serves as National Principal Investigator of the Study. Primary endpoints will be assessed at 6 and 12 months post-ablation to measure procedural success and safety outcomes, supporting the broader clinical development of the nPulse™ System. The Company plans to provide additional updates on the Study as patients complete follow-up and expects to present pivotal data at a future medical society conference.

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 non-cellular 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.

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.

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 System, 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 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 the Company’s expected clinical and other new product development efforts, including its planned completion of the NANOPULSE-AF Study and presentation of clinical data, 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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