

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 14, 2024**

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 February 14, 2024, Pulse Biosciences, Inc. (the “Company”) issued a press release announcing the successful remapping of the first four patients in its CellFX® nsPFA™ 360° Cardiac Catheter First-In-Human Feasibility Study. A copy of the Company’s press release is attached as Exhibit 99.1.

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 14, 2024
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 14, 2024

By: /s/ Kevin P. Danahy
Kevin P. Danahy
President and Chief Executive Officer
(Principal Executive and Principal Financial Officer)

Pulse Biosciences Announces Positive 60-Day Follow-Up Evaluations for Initial Patients treated in the CellFX® nsPFA™ 360° Cardiac Catheter First-in-Human Feasibility Study

HAYWARD, Calif. [Business Wire] – February 14, 2024. Pulse Biosciences, Inc. (Nasdaq: PLSE), a company with a primary focus on leveraging its novel and proprietary CellFX Nanosecond Pulsed Field Ablation (nsPFA) technology for the treatment of atrial fibrillation, today announced favorable findings from the 60-day post-procedure evaluations for four initial patients treated in the Company's CellFX® nsPFA™ 360° Cardiac Catheter First-In-Human Feasibility Study.

“The 60-day remap results for the initial patients treated with the CellFX nsPFA 360° Cardiac Catheter in this feasibility study reveal favorable durable pulmonary vein isolation data,” said Dr. Vivek Reddy, Director of Cardiac Arrhythmia Services at the Mount Sinai Fuster Heart Hospital, NY. “I look forward to sharing more details on the findings from this feasibility study, including the results of the 60-day mapping evaluation, at an upcoming scientific meeting. In the meantime, we are quite excited to continue to enroll and treat patients as we progress and assess this promising and novel CellFX nsPFA technology.”

“The 60-day treatment durability in these initial patients is an important step toward validating our unique nsPFA AF catheter solution. We are encouraged by the ease-of-use, speed, versatility, and now the initial durability outcomes of our novel catheter which is designed specifically for use with our nsPFA energy. I am extremely proud of the enthusiastic work and commitment to excellence manifested by team Pulse Biosciences. Our goal is to advance and reshape, for the betterment of all involved, the treatment of atrial fibrillation with the deployment of our CellFX nsPFA 360° Cardiac Catheter in electrophysiology,” said Kevin Danahy, President and Chief Executive Officer of Pulse Biosciences. “We are excited to complete this clinical trial and further validate our game-changing technology.”

Using the Company's CellFX nsPFA 360° Cardiac Catheter, 14 patients with atrial fibrillation (AF) have been successfully treated at Na Homolce Hospital in Prague, Czech Republic. Patients treated with the Company's CellFX nsPFA 360° Cardiac Catheter system are being evaluated at regular intervals to further document the safety and effectiveness of the treatments, and the Company expects to enroll up to a total of 30 patients in the current feasibility study. The Company has remapped the first four of the initial 14 patients treated. The observations to date have been positive, but the broad set of risks associated with cardiac surgery remain.

About Pulse Biosciences®

Pulse Biosciences is a novel bioelectric medicine company committed to health innovation that has the potential to improve the quality of life for patients. The Company's proprietary CellFX Nanosecond Pulsed Field (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 CellFX nsPFA could have a profound positive impact on healthcare for both patients and providers.

Pulse Biosciences, 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.

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 CellFX 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 fast and precise ablations in cardiac tissue, 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 CellFX nsPFA 360° Cardiac Catheter, Pulse Biosciences' expectations, whether stated or implied, regarding whether the Company's CellFX nsPFA technology will become a disruptive and durable treatment option for treating atrial fibrillation or any other medical condition, 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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