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): **December 20, 2023**

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.)

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 December 20, 2023, Pulse Biosciences, Inc. (the "Company") issued a press release announcing first-in-human procedures with its novel CellFX™ Nanosecond Pulsed Field Ablation (nsPFA™) Cardiac Catheter. A copy of the Company's press release is attached as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	**Description**
99.1	Press Release issued by Pulse Biosciences, Inc. dated December 20, 2023
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: December 20, 2023

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

Pulse Biosciences Announces First-in-Human Procedures with its Novel CellFX™ Nanosecond Pulsed Field Ablation (nsPFA™) Cardiac Catheter

Company's proprietary system used to treat initial five patients in first-in-human feasibility study for patients with atrial fibrillation

HAYWARD, Calif. [Business Wire] – December 20, 2023. Pulse Biosciences, Inc. (Nasdaq: PLSE), a company primarily focused on leveraging its novel and proprietary CellFX Nanosecond Pulsed Field Ablation (nsPFA) technology for the treatment of atrial fibrillation, today announced the completion of the first five procedures in its first-in-human feasibility study with its novel CellFX nsPFA cardiac catheter. All patients were successfully discharged by treating physicians. Patients will continue to be monitored and evaluated over the coming months to assess safety and effectiveness with the primary safety endpoint at 30 days.

Dr. Vivek Reddy, Director of Cardiac Arrhythmia Services at Mount Sinai Hospital, NY, and Dr. Petr Neuzil, Chief of Cardiology at Na Homolce Hospital, Prague, and colleagues used the Company's CellFX nsPFA 360 cardiac catheter integrated with 3D mapping and navigation technologies (iMap System, CardioNXT) to successfully treat five patients with atrial fibrillation (AF) at Na Homolce Hospital, a renowned research institution hospital in Prague, Czech Republic.

"We have been collaborating with Pulse Biosciences to bring their novel nsPFA technology to the clinical realm, and are excited to report that our experience with these first five patients has validated our belief that this may represent the next generation of PFA technology for the treatment of AF," said Dr. Reddy. "The results were consistent with our preclinical experience. Importantly, the speed and ease with which we were able to isolate the pulmonary veins with the nsPFA 360 catheter was impressive and all patients tolerated the procedure well. Now we look forward to completing enrollment in this study to fully assess the safety and durability of nsPFA treatment."

Pulse Biosciences' CellFX nsPFA 360 cardiac catheter, which is still in the investigational stage, is uniquely designed to produce a nonthermal ablation, initially targeted for pulmonary vein isolation, using the Company's proprietary CellFX nsPFA energy in the treatment of atrial fibrillation. The catheter is designed to deliver a fast, transmural and fully circumferential ablation in a single energy delivery. The CellFX nsPFA cardiac catheter is integrated with 3D mapping and navigation to deliver a comprehensive visualization and precise ablation delivery solution.

"We're honored to work with Dr. Reddy and his team and Prof. Petr Neuzil and his team at Na Homolce to bring our next generation nsPFA technology to the clinic. The unique value of nsPFA to deliver fast, precise, transmural and contiguous ablations in thick cardiac tissue is extremely exciting for the treatment of AF and we could not have found better partners," said Dr. Gan Dunnington, Chief Medical Officer, Cardiac Surgery of Pulse Biosciences. "This initial clinical experience delivered as expected. We look forward to continuing our catheter clinical program and to starting our cardiac surgery clinical program with our surgical nsPFA clamp in 2024."

Kevin Danahy, President and CEO of Pulse Biosciences, having attended all patient cases, remarked on the recent milestone, "As we embark on this new era of advancement in medical device technology, our mission is clear: to revolutionize healthcare with CellFX nsPFA, with the intention of significantly improving clinical outcomes for both patients and physicians. Through relentless innovation, unwavering dedication, and commitment to pushing the boundaries of what is possible in bioelectric energy, we are reshaping the future of the treatment for atrial fibrillation with our cardiac catheter in electrophysiology and with our cardiac clamp in cardiothoracic surgery. CellFX nsPFA will empower doctors, inspire patients to seek life-altering treatment, and create a world where CellFX nsPFA technology can become a catalyst for healing and hope."

The Company expects to enroll up to a total of 30 patients in the current feasibility study. Treated patients will be evaluated at regular intervals to further assess the safety and effectiveness of the treatments. The Company expects to provide additional updates on the first-in-human procedures with the CellFX system in the upcoming months. Pulse Biosciences will inform stakeholders promptly if results differ materially from the stated expectations addressing safety and efficacy. The observations to date have been positive but the broad set of risks associated with cardiac surgery remain. The Company anticipates initiating the regulatory process with the U.S. FDA and appropriate regulatory authorities worldwide including Europe in the coming quarters and expects additional studies will be required.

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 Ablation (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.

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 cardiac catheter to treat atrial fibrillation, statements concerning the Company's future clinical and regulatory strategies and possible government clearances and approvals, including the possibility of successfully enrolling up to 30 patients in the ongoing clinical study in Prague, statements concerning whether the ongoing clinical study or any other clinical study will show that the Company's novel nsPFA mechanism of action and catheter design will deliver fast, precise, transmural, and contiguous ablations in thick 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 cardiac catheter, Pulse Biosciences' expectations, whether stated or implied, regarding whether the Company's CellFX nsPFA technology will become a disruptive 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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