UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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 31, 2024

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 1000
Miami, Florida 33131
(Address of principal executive offices) (Zip Code)

(510) 906-4600
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

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, par value $0.001 per share	**PLSE**	**The Nasdaq Stock Market**

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))

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 31, 2024, Pulse Biosciences, Inc. (the "Company") issued a press release announcing positive preliminary results from its first-in-human feasibility study using Nanosecond Pulsed Field Ablation for the treatment of benign thyroid nodules. Dr. Stefano Spiezia, Chief of Endocrine Surgery Division at Napoli Ospedale del Mare, in Naples, Italy, presented these results at the 2024 American Thyroid Association Annual Meeting.

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

Exhibit Number	**Description**
99.1	Press Release issued by Pulse Biosciences, Inc. dated October 31, 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 hereunto duly authorized.

PULSE BIOSCIENCES, INC.

Date: October 31, 2024

By: /s/ Burke T. Barrett
Burke T. Barrett
President and Chief Executive Officer
(Principal Executive and Principal Financial Officer)

Pulse Biosciences Announces Positive Clinical Data Presented at the American Thyroid Association

European feasibility study demonstrates using nano-PFA in benign thyroid nodules reduces nodule volume by greater than 50% and provides symptomatic relief within the first month of treatment

MIAMI, Florida. [Business Wire] – October 31, 2024. Pulse Biosciences, Inc. (Nasdaq: PLSE), a company leveraging its novel and proprietary Nanosecond Pulsed Field Ablation™ (nano-PFA or nsPFA™) technology, today announced positive preliminary results from its first-in-human feasibility study using Nanosecond Pulsed Field Ablation for the treatment of benign thyroid nodules. Dr. Stefano Spiezia presented these excellent results today at the 2024 American Thyroid Association Annual Meeting.

The preliminary data demonstrate that nano-PFA pulses effectively delivered by the Company's Percutaneous Electrode System reduced nodule sizes on average by over 50%, without evidence of residual fibrosis or scarring, and provided symptomatic relief within the first month of treatment. The nonthermal and minimally invasive nature of nano-PFA energy has shown potential to mitigate the risk of complications from thermal ablation procedures or surgical removal of benign thyroid nodules.

"I am proud to report that in the treated nodules, we observed significant nodule volume reductions which led to great improvements in symptoms for the patients in our study. We are excited to finish the long-term follow-up, complete the study, and continue the utilization of nano-PFA to advance the standard of care for patients with benign thyroid nodules," said Dr. Stefano Spiezia, Chief of Endocrine Surgery Division at Napoli Ospedale del Mare and principal investigator of the study and founder of "Save Your Thyroid" institute.

Pulse Biosciences' nsPFA Percutaneous Electrode System is currently being investigated by Stefano Spiezia, Chief of Endocrine Surgery Division at Napoli Ospedale del Mare, Naples Italy. The study has completed enrollment in the 30-patient first-in-human feasibility clinical trial (NCT06117085) to support the initial safety and effectiveness profile of the nsPFA electrode or needle in treating and reducing the volume of benign thyroid nodules leading directly to a reduction in patient symptoms.

"These groundbreaking results suggest nano-PFA energy can provide symptomatic relief to patients with benign thyroid nodules across the first month after the treatment," said Burke T. Barrett, Pulse Biosciences President and Chief Executive Officer. "We would like to thank Dr. Spiezia and his team for all the clinical work they continue to do with the System. This feasibility study and our ongoing U.S. pilot program will inform the design of the pivotal trial we intend to commence mid-2025. The study will be designed to support a specific labeling indication to commercialize the system in the United States as a treatment for benign thyroid nodules."

About Percutaneous Electrode System
The Percutaneous Electrode System consists of a percutaneous needle electrode for use with the Company's proprietary nano-PFA Console. The proprietary and novel electrode is designed to harness and deliver the key advantages of nano-PFA energy, enabling precise, nonthermal removal of cellular tissue without damage to noncellular structures or inducing thermal necrosis. The system has received U.S. Food and Drug Administration (FDA) 510(k) clearance for use in the ablation of soft tissue in percutaneous and intraoperative surgical procedures. This proprietary system is designed for non-cardiac applications.

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® 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.

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 safely and effectively provide symptomatic relief to patients with benign thyroid nodules or cause significant nodule volume reductions, whether within a month or otherwise, statements concerning the Company's expected product development efforts and future clinical studies and regulatory submissions and whether the Company might obtain regulatory approval to market and sell the nsPFA Percutaneous Electrode System as a treatment for benign thyroid nodules, statements concerning whether any clinical study will show that the Company's novel nsPFA mechanism of action will deliver fast and precise ablations, statements concerning early clinical successes and whether they are predictive of the safety and effectiveness of any medical device such as the nsPFA Percutaneous Electrode System, and Pulse Biosciences' expectations, whether stated or implied, regarding whether the Company's CellFX nsPFA technology will become a disruptive, superior and durable treatment option for treating benign thyroid nodules or any other medical condition or otherwise advance current medical standards of care, 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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