

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): **January 9, 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 7.01 Regulation FD Disclosure.

On January 9, 2024, Pulse Biosciences, Inc., a Delaware corporation (the “Company”), posted an updated investor presentation on its website. The updated investor presentation (the “Investor Deck”) discloses recent progress in the Company’s ongoing product development programs relating to its proprietary CellFX™ nsPFA™ 360 Cardiac Catheter, its CellFX nsPFA Cardiac Clamp, and its CellFX nsPFA Percutaneous Electrode. The Company expects to use this updated investor presentation, either in whole or in part, and possibly with modifications, in connection with presentations to investors, analysts and others. A copy of the Investor Deck is attached hereto as Exhibit 99.1 and incorporated by reference in this Item 7.01. The Investor Deck is also available on the Company’s website at www.pulsebiosciences.com under “Investors.”

Except for the Investor Deck, information contained on, or accessible through, the Company’s website is not a part of, and is not incorporated by reference in, this Current Report on Form 8-K. The information contained in the Investor Deck itself is summary information only and it contains forward looking statements that are subject to risks and uncertainties, including those set forth in the Company’s filings with the U.S. Securities and Exchange Commission. Also, the information in the Investor Deck is as of January 2024, and the Company undertakes no obligation to publicly update or revise the information contained in the Investor Deck or this Item 7.01, except as required by law, although it made do so from time to time.

The information contained in Item 7.01 to this Current Report on Form 8-K and Exhibit 99.1 attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing by the Company under the Securities Act of 1933, as amended, or the Exchange Act, unless expressly stated otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

**Exhibit
Number****Description**

99.1	Investor Deck, dated January 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: January 9, 2024

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



Pulse Biosciences®



Investor Presentation

January 2024

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Forward Looking Statements

All statements in this presentation that are not historical are forward-looking statements, including, among other things, statements relating to the effectiveness of the Company's 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, statements concerning the Company's future regulatory strategies and possible government clearances and approvals, statements concerning the Company's future commercial plans, such as the possible launch of two revenue-generating nsPFA products in 2024, statements concerning customer adoption and future use of the CellFX System to address a range of conditions such as atrial fibrillation and benign thyroid nodules, statements about the Company's future financing opportunities and operating expenses, and Pulse Biosciences' expectations, whether stated or implied, regarding whether the Company's nsPFA technology will become a disruptive treatment option for treating cardiac arrhythmias, benign thyroid nodules or any other medical condition and whether future clinical studies will show the CellFX System is safe and effective to treat any medical condition, and other future events. These statements are not historical facts but rather are based on the Company's current expectations, estimates, and projections regarding its 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 the Company's filings with the U.S. Securities and Exchange Commission. Pulse Biosciences undertakes no obligation to revise or update information in this presentation to reflect events or circumstances in the future, even if new information becomes available.



Powering the next generation in
bioelectric medicine with
Nanosecond Pulsed Field Ablation
technology.

Proven Leadership Team



Kevin Danahy
Chief Executive Officer & President



Darrin Uecker
Chief Technology Officer & Director



Mitch Levinson
Chief Strategy Officer



Renowned Scientific Expertise



Dr. Gan Dunnington
Chief Medical Officer
Adventist Health



Dr. Niv Ad
Chief Science Officer,
Cardiac Surgery
Adventist HealthCare
White Oak Medical Center

Established Board of Outside Directors



Robert (Bob) W. Duggan
Executive Chairman of the
Board of Directors



Richard van den Broek
Director



Manmeet S. Soni
Director



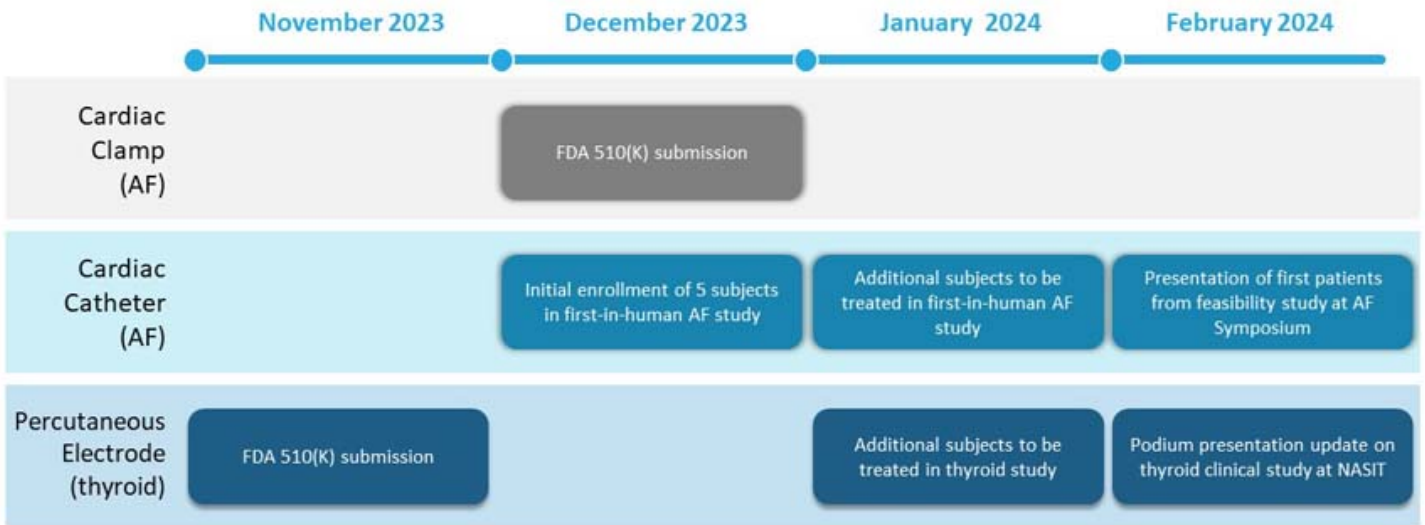
Mahkam "Maky" Zanganeh,
DDS
Director



Shelley D. Spray
Director

Accelerated Clinical Progress with CellFX nsPFA Devices

Recently Achieved Milestones and Upcoming Clinical Timelines



Positioned to Unlock the \$8 Billion Cardiac Atrial Fibrillation (AF) Market

Powering the next generation in bioelectric medicine with Nanosecond Pulsed Field Ablation (nsPFA) Technology



Proprietary Technology

Only company bringing novel Nanosecond Pulsed Field Ablation (nsPFA) technology to the health care of patients



Novel AF nsPFA Devices

nsPFA enabled applicators deliver highly differentiated value in the treatment of AF



Robust Patent Portfolio

Surrounding the technology, devices, and use of nsPFA

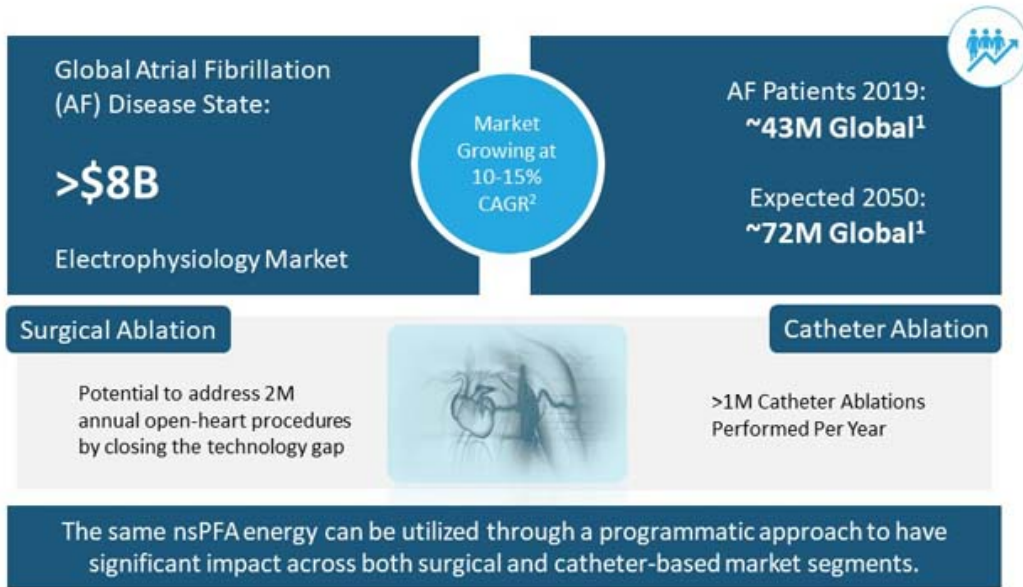


Broad Medical Device Expertise

Development expertise across many disciplines



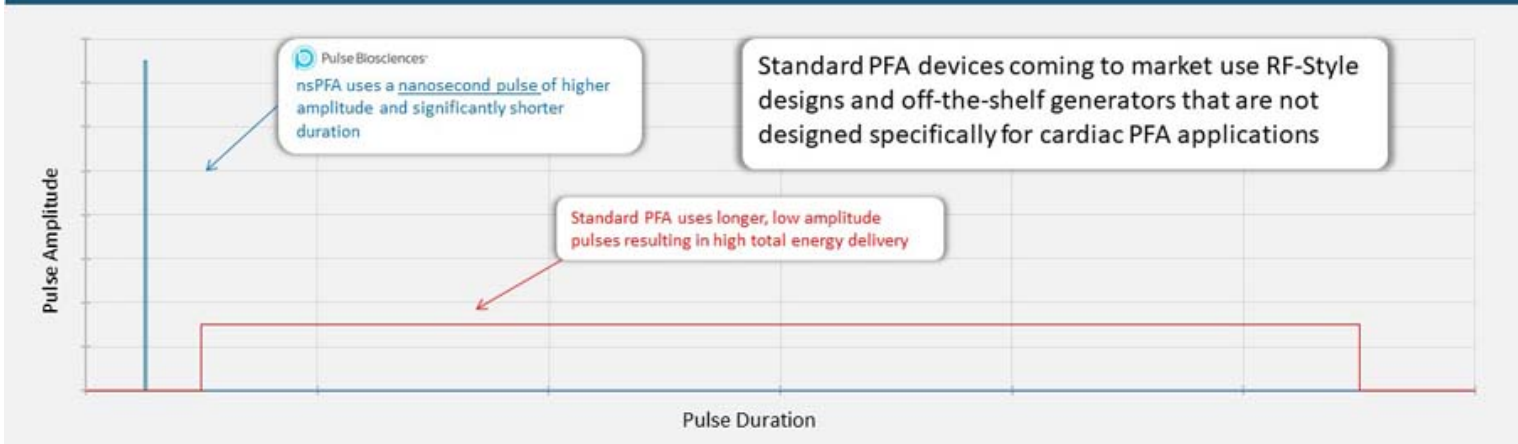
Addressing the Entirety of the Growing AF Market



Differentiated Properties of nsPFA Energy Pulses



Nanosecond pulses can be **~500 times shorter** than microsecond pulses
As a result, nsPFA can require **~20 times less energy** to ablate cardiac tissue



Advantages of nsPFA Technology

Catheter and clamp devices designed to improve patient outcomes

Novel Energy Modality



Devices that Leverage the Energy

Differentiated Clinical Results

Eliminating the substantial tradeoff between safety and efficacy



CellFX nsPFA cardiac ablation catheter:

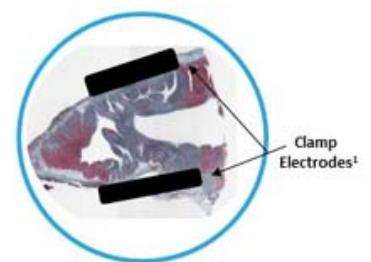
- Precisely focused, circumferential ablation targeted for pulmonary vein isolation **in a single 5 second** application with CellFX nsPFA
- Mitigates need for repeated repositioning and treating



CellFX nsPFA cardiac ablation clamp:

- Consistency in achieving continuous linear transmural ablations in **1.25 seconds**, independent of tissue type or thickness
- ~1/20th of the time it takes for radiofrequency ablation

Open Surgical Delivery of nsPFA Energy – Cardiac Ablation



- A nonthermal cardiac ablation clamp capable of complete transmural ablations in **under 3 seconds**
- Initial preclinical studies have demonstrated **speed, precision and transmurality up to ~25mm between electrodes**
- Collaborating with top institutions and physicians in pursuit of **regulatory clearance**
- **Fundamental IP** for nsPFA energy in cardiac ablation



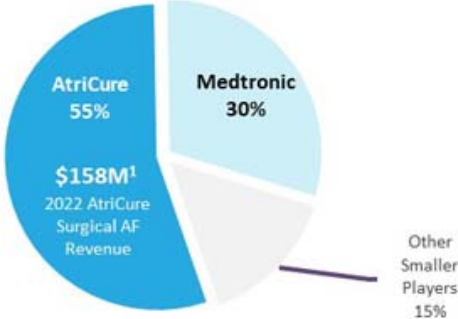
Cardiac Clamp Strategic Opportunity

High Strategic Value

- 1. Fast and Easy Market Entry
- 2. nsPFA Superior Product Offering
- 3. Ability to **Prove Effectiveness for AF** Prior to Catheter Launch
- 4. Provides Complete Solution
- 5. Sizable Revenue Opportunity Prior to Catheter Launch

Global Market Overview²

Total AF Surgical Market 2022 >\$250M^{1,2}



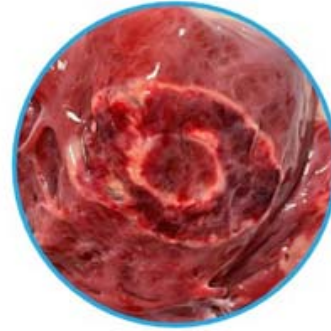
Catheter Delivery of nsPFA Energy – Cardiac Ablation



nsPFA Generator Platform



Proprietary nsPFA-Optimized Catheter Design



2-Day Endocardial Surface
~5cm Diameter

- Circumferential ablation catheter enabled by nsPFA energy for single-shot PVI ablation
- Reduced muscle spasm and nerve capture due to short duration nsPFA pulses
- No thermal injury due to lower energy of nsPFA pulses
- Preclinical data demonstrating safe, fast and effective ablations

nsPFA Preclinical Evidence Supporting Safety, Tolerability and Effectiveness

Tolerance/Effectiveness

Nanosecond Pulsed Field Ablation: Demonstration of Halo-Shaped Lesions with a Novel Multielectrode System – Initial Preclinical Experience

nsPFA can create clinically relevant circumferential wide lesions with minimal phrenic muscular stimulation.

Nanosecond Pulsed Field Ablation: Demonstration of Halo-Shaped Lesions with a Novel Multielectrode System: Initial Preclinical Experience (Jacob S Koruth MD, et al.)

Tolerance/Safety

Creating Deep Ventricular Lesions with Nanosecond Pulsed Field Ablation: Pathological and Imaging Insights from Preclinical Evaluation

nsPFA can create clinically relevant deep and wide lesions, which did not demonstrate any evidence of thermal injury and delivery was associated with only mild muscle and nerve stimulation.

Creating Deep Ventricular Lesions with Nanosecond Pulsed Field Ablation: Pathological and Imaging Insights from Preclinical Evaluation (Iwanari Kawamura MD, et al)

Tolerance/Effectiveness

Electron Microscopic Insights from An Acute Pulsed Field Myocardial Lesion

This electron microscopy study demonstrates significant rapid disappearance of myocytes after PFA (~ 1 hour). The cell membrane structure and organelle structure progressively deteriorate by 4 hours post ablation.

Electron Microscopic Insights from An Acute Pulsed Field Myocardial Lesion (Iwanari Kawamura MD, et al)

Application Milestones for Treatment of AF

Recently Accelerated Development Timelines



Versatile Generator Platform Delivers nsPFA Across the Anatomy

Enables rapid development of new applications

Thyroid

- Completed phase 1 enrollment of study, phase 2 in progress
- Preclinical and clinical data demonstrating safety to collateral structures including nerves, vessels, trachea & esophagus.
- Rapid ablation of thyroid tissue
 - < 10 seconds per cc of treated tissue
- Single treatment efficacy with evidence of 100% clearance within ablation zone in less than 90 days



FDA 510k submission
filed November 2023

Robust IP Portfolio

Wide and deep IP coverage of nsPFA energy & system

148

issued patents globally
owned & licensed

+103

Patent Pending
Applications

Patent Portfolio 2024

Multipronged Patent Strategy

- Pioneering IP for the use of nanosecond pulses in medicine
- Covering methods and tools for the application of nanosecond pulses in biology
- Continued development and patent filings covering systems, applications, and methods of combining nanosecond pulsing with other biological technologies and agents



Expect to be revenue-generating with 2 of 3 product lines in 2024



CellFX nsPFA cardiac ablation clamp – filed FDA 510(k) submission December 2023 with plans to commercialize following clearance



CellFX nsPFA cardiac ablation catheter – commenced first-in-human catheter ablation feasibility study in December 2023 with plans to expand enrollment



CellFX nsPFA percutaneous electrode – filed FDA 510(k) submission in November with plans to commercialize following clearance