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 14, 2025**

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 1080
Miami, Florida 33131
(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 14, 2025, 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 2025, 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 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

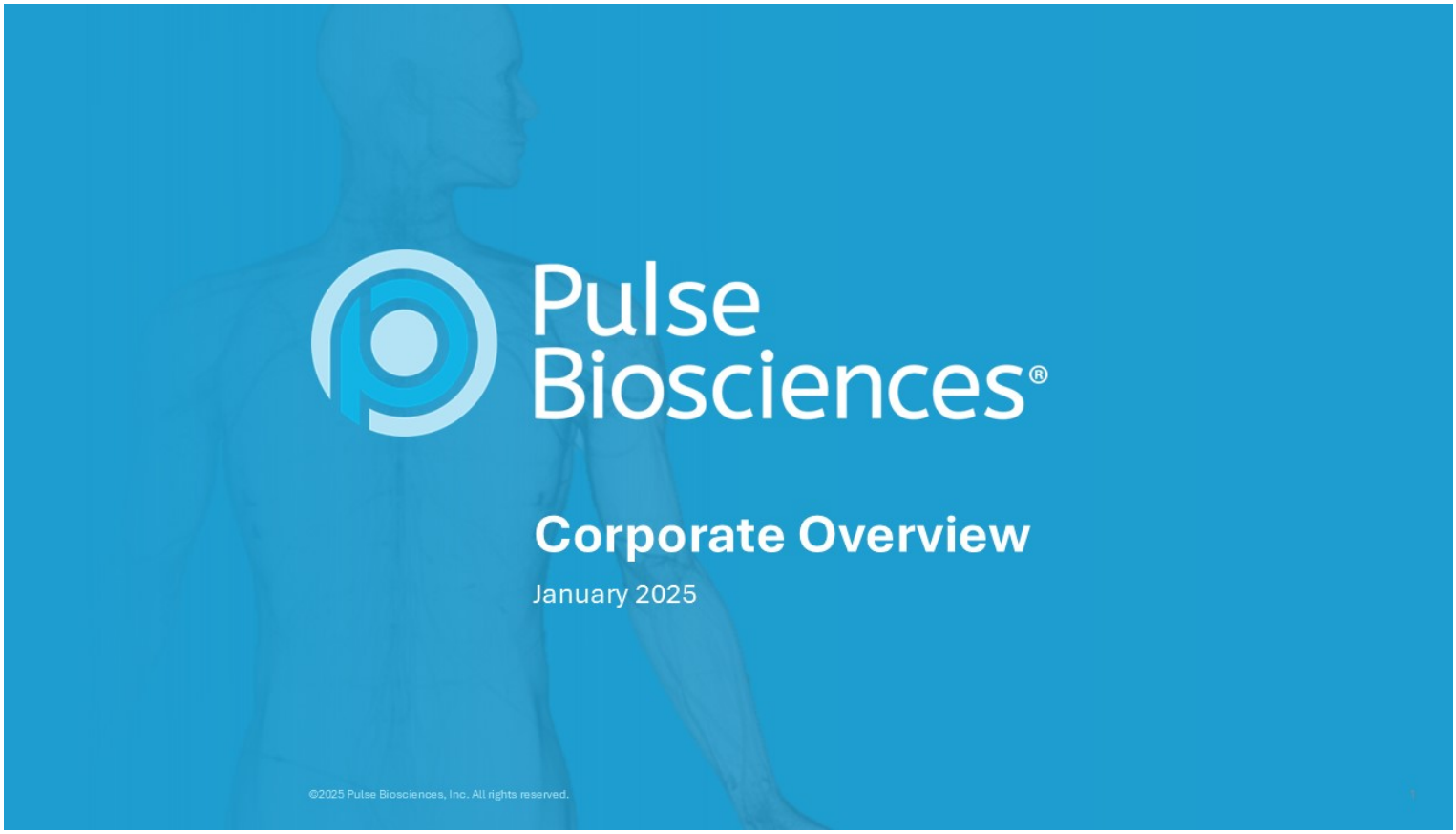
SIGNATURE

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 14, 2025

By: /s/ Paul A. LaViolette
Paul A. LaViolette
Chief Executive Officer
(Principal Executive and Principal Financial Officer)


Pulse Biosciences®
Corporate Overview
January 2025
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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 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 and future clinical studies and regulatory submissions, whether with the U.S. FDA or otherwise, statements concerning whether any clinical study will show that the Company's novel nsPFA mechanism of action 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 Cardiac Surgery System, 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 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.

This presentation and any documents incorporated by reference may contain market data that we obtain from industry sources. These sources do not guarantee the accuracy or completeness of the information. Although we believe that our industry sources are reliable, we do not independently verify the information. The market data may also include projections that are based on other projections. While we believe these assumptions and projections are reasonable and sound, as of the date hereof, actual results may differ from these projections.

Pulse Biosciences

Pulse Biosciences®

Our Mission

To build a thriving, viable company by providing revolutionary and life-changing therapy for multiple diseases with next-generation **Nanosecond Pulsed Field** technology.

“It was immediately clear to me that nanosecond pulsed field ablation (**nsPFA) has the potential to not only replace all other energy modalities in cardiac ablation,** including radiofrequency and cryo, but due to the speed, safety, and ablation performance of the system, **it also has the potential to significantly expand the number of patients we treat**.”

– Dr. Niv Ad,
One of the most published cardiac surgeons in the world

Financial Snapshot

Strong balance sheet as of 12/31/2024

- Cash and cash equivalents balance $118mm [unaudited] as of December 31st
- Pro forma cash and cash equivalents of $130mm including receipts from rights offering
- No debt

~2-Year cash runway

- Cash burn of approximately $36mm in 2024
- Cash burn increasing in 2025 to support commercialization and multiple IDEs

+80% Insider Ownership

Experienced Technologists, Operators and Clinicians
Form Proven Leadership Team

Paul LaViolette
Chief Executive Officer
Co-Chairman of the Board

Kevin Danahy
Chief Commercial Officer

Darrin Uecker
Chief Technology Officer
Director

Mitch Levinson
Chief Strategy Officer

SV Health Investors · Boston Scientific · BARD · Medtronic · Johnson & Johnson · Zimmer Biomet · Intuitive · gynesonics · computermotion · thermage · coolsculpting by ZELTIQ · NELLCOR

Renowned Scientific Expertise

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

Dr. Gan Dunnington
Chief Medical Officer,
Cardiac Surgery
AdventistHealth

Dr. David Kenigsberg
Chief Medical Officer,
Electrophysiology
HCA Florida Healthcare

Established Board of Directors

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

Richard van den Broek
Director

Manmeet S. Soni
Director

Mahkam "Maky" Zanganeh, DDS
Director

Proprietary Design and Engineering

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 patient care

Proprietary Treatments
nsPFA enabled applicators deliver highly differentiated value in their markets

Robust Patent Portfolio
Surrounding the technology, devices, and use of nsPFA

Robust Market Entry
Initiating 3 IDEs in 2025 and creating a commercial market in Thyroid

183
Issued Patents globally owned & licensed

+103
Patent Pending Applications

Pulse Biosciences' nsPFA Platform

Unlocks >$6B in first 3 target markets

to

>$16B

in global including U.S. markets

Thyroid Application

$1.3B U.S. Addressable Annual Market[1,2,3,4,5,*]

$2.8B Global Potential Market[1,2,3,4,5,*]

Cardiac Surgery Application

$1.8B U.S. Addressable Annual Market[6,7]

$6.0B Global Potential Market[6,7]

Endocardial Application (EP)

$3.0B U.S. Addressable Annual Market[8]

$8.0B Global Potential Market[9]

Pulse will create, expand, and upend these markets with penetration and global expansion

CellFX nsPFA Platform

*based on reimbursement updates and asp assumptions

RF / Heat CRYO / Cold

Existing ablative therapies **have limitations**

PFA is currently drastically affecting the EP market

A new treatment paradigm that allows for:

A fast, efficient treatment

- ↑ Increased throughput
- ↑ Increased predictability for scheduling and treatment

Safer treatment profile over RF and CRYO

- ↓ Less worry about the esophagus

With such marked improvements, **What gaps remain?**

Micro-PFA Compared to nsPFA for Electrophysiology

Current workflow and case time

Nanosecond technology can **revolutionize EP and multiple markets**

2	# Configurations	1
8	Energy deliveries per target	1
REQUIRED	Device rotations to "connect the dots"	NONE REQUIRED
30 minutes	Average ablation time	**10** minutes
4–6mm	Lesion quality/depth	6–9mm[10]
REQUIRED	Patient paralytics	NONE REQUIRED
Microsecond	Pulse duration	**Nanosecond**

Pulse Biosciences®

1. Koruth et al. *Circ Arrhythm Electrophysiol*. 2024;17:e012854. DOI: 10.1161/CIRCEP.124.012854

Energy + Design Matters

The nsPFA Difference for EP

Microsecond PFA
Low Amplitude, Long Duration

Millionth (.000001 sec)

Nanosecond PFA
High Amplitude, Short Duration

Billionth (.000000001 sec)

Microsecond PFA Catheters

Low amplitude → Shallow ablations
Long duration → High energy
- Significant nerve stimulation
- Cardiac synch and paralytics required

Design Implications
- Design constrained to small focal ablations
- Rotations and multiple shots to connect the dots

nsPFA 360 Catheter

High amplitude → Deep ablations
Short duration → Low energy
- Much reduced nerve stimulation
- No cardiac synch or paralytics

Design Implications
- Thin, flexible electrode for versatility
- Full ring—no connecting dots

Nanosecond PFA Advantage

- **Product designs** are purpose built for the application
- **Much lower energy** reduces electrode design constraints of standard PFA
- **Reduces stimulation** to nerves and muscle
- **Nonthermal**: no thermal damage or spread beyond the electrical field
- **Faster, deep ablations** with single energy delivery
- **Selectively treats only organelle**-bearing structures – spares nerves, vessels, structural tissue

nsPFA technology's novel mechanism
activates the body's natural healing process

History of Leading Nanosecond PFA Development

Pulse Biosciences is the leader in designing and engineering nsPFA technology

Inventing and harnessing nsPFA technology dates back two decades

- Differentiated approach focused on novel therapy development
- 10+ years in development at Pulse Biosciences
- $300mm Development Investment to date
- >1,100 industry-wide publications to date
- Multiple FDA Clearances
- Breakthrough Designation

Creating wide and deep IP portfolio covering nsPFA energy and system

Continued development and patent filings covering systems, applications, and methods

Patent Portfolio 2025

183	103
Issued patents globally owned & licensed	Pending patent applications

Business Model

>$6B
to start

Direct and Partnership approaches will be determined for each market based on the opportunity to enter or upend markets with capital efficiency

Direct
Candidate Markets

Partnership
Candidate Markets

FACTORS INFLUENCING THE STRATEGY INCLUDE:

- New or established market
- Presence of direct competition
- Efficiency of launch investment

- Scale and simplicity of platforms
- Therapy synergies
- Enabling differentiation for a strategic partner

Collapse time to access patients

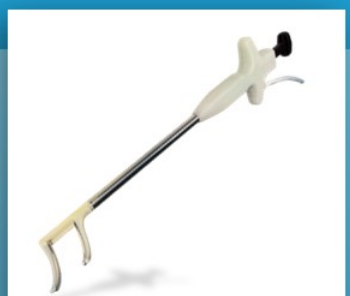
Market Entry Strategy

Thyroid Market

$1.3B Addressable Market*

Create an untapped market in Thyroid

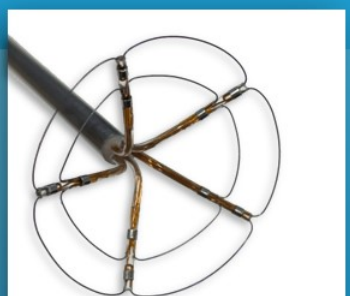
Thyroid: First use case for percutaneous soft tissue ablation electrode



Cardiac Surgery

$1.8B Addressable Market*

Expand usage in the Cardiac Surgery market



AF Ablation

$3.0B Addressable Market*

Upend the EP market

Pulse Biosciences

*U.S. Addressable Annual Market

FDA 510(k) March 2024

Create an Untapped Market in Thyroid

Opening a new era in therapy for soft tissue ablation such as benign thyroid nodules

Pulse Biosciences

Benign Thyroid Market Opportunity

Drivers for Pulse in the Benign Thyroid Market

- Thyroid-sparing procedure
- Nonsurgical intervention
- Potential to eliminate up to ~150k thyroidectomies yearly

BTN patients diagnosed in U.S. ~250k[3,4,5]

~150k
Benign thyroidectomies

~100k
Enter "Watchful Waiting"

$1B+
Annual U.S. TAM

nsPFA technology is a new paradigm for surgical patients and watchful waiters

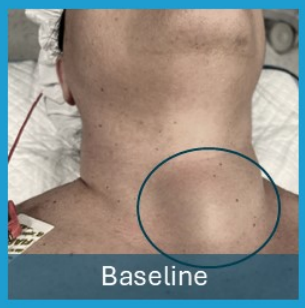
Newly created, untapped market

Pulse Biosciences

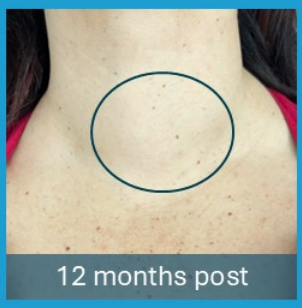
Create an Untapped Market in Thyroid

nsPFA provides significant therapeutic benefits for physicians and patients

- Spares nerves, vessels, critical structures
- Nonthermal - does not cause fibrosis or RF scar ball formation
- Significant volume reduction and symptomatic relief at 1 month
- Excellent safety profile
- Treated area feels soft, natural
- High patient satisfaction
  - Improved cosmesis


Baseline


1 month post


12 months post

Prof. Stefano Spiezia – ATA 2024 Presentation

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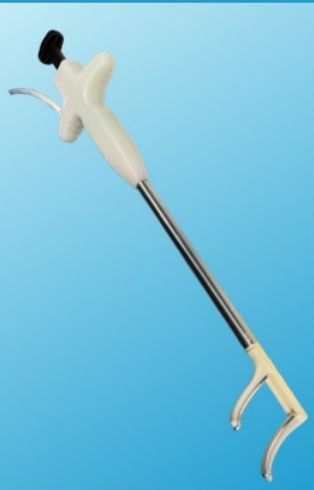
Thyroid Market Development Status

- **Soft Tissue Ablation – FDA Cleared**
- **510(k) Pilot launch underway**
- **Launch led by 10 KOL sites to drive adoption**
- **Initiating investigator-sponsored research to add clinical data and experience**

Initiating a pivotal clinical trial
for benign thyroid nodule ablation indication
in mid-2025



Expanding Usage in the Surgical Cardiac Ablation Market

nsPFA for Surgical AF

Pulse Biosciences®

Surgical Cardiac Ablation Market Opportunity

Drivers for Pulse in the Surgical Cardiac Ablation Market

- 84,000 U.S. patients per year with pre-operative AF
  - Only ~30% being treated with RF technology
- Pulse will be first to market with a PFA solution
- RF technology: safety and efficacy concerns

nsPFA technology expands the market

Annual open-heart procedures in U.S. 300K[11]

28%
Patients have pre-operative AF[12]

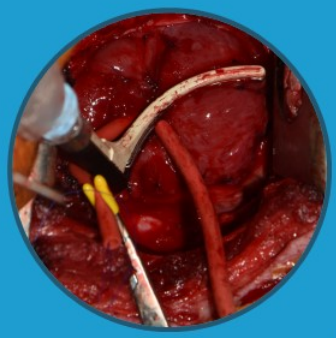
72%
Patients at high risk of developing post-op AF[13]

216k
Future Potential Prophylactic AF Annual U.S. Patients

Expanding Usage in the Surgical Cardiac Ablation Market

Speed and Versatility for Cardiac Surgical Applications

- Speed, ease of use and safety of nsPFA address key physician concerns limiting adoption of thermal modalities
  - Capable of transmural ablations in seconds
  - Fully automated ablation independent of tissue thickness or type
  - Nonthermal, eliminating risk of damage to surrounding critical structures, e.g. esophagus
  - Ability to perform ablation off cardiopulmonary bypass



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Surgical Cardiac Ablation Status

- Received FDA Breakthrough Device Designation in July 2024
- Enrolled in the FDA's Total Product Life Cycle (TPLC) Advisory Program (TAP)
- 30 patient multi-center feasibility study underway, expect enrollment completion in Q1 '25
- Recent publication in The Journal of Thoracic and Cardiovascular Surgery

Initiating a pivotal clinical trial for AF **mid 2025**

Pulse Biosciences®

Upending AF Ablation in the EP Market

nsPFA for AF

Pulse Biosciences

EP Market Opportunity
AF Ablation

Drivers for Pulse in the EP AF Ablation Market

- Drop-in workflow replacement
- Speed = Improved efficiency over 1st gen PFA devices
  - Less configurations, rotations, applications
- Enhanced lesion quality through nsPFA

Market growing at **10–15% CAGR**[14]

Global Atrial Fibrillation (AF) Disease State: **>$8B**[9] Electrophysiology Market

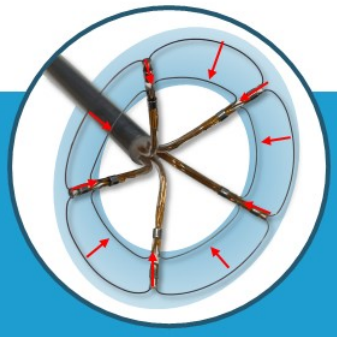
~1.9M[15]

U.S. patients diagnosed with AF annually

nsPFA technology upends the EP market with a novel and differentiated energy

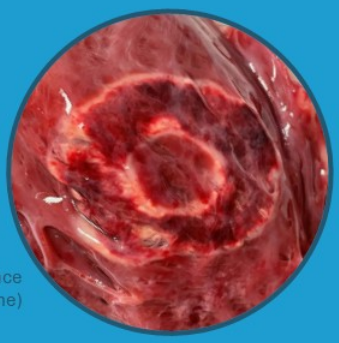
360 Catheter for Pulmonary Vein Isolation

Customized nsPFA Electrode Design



Achieves circumferential lesions with continuous ring electrodes for TRUE “single-shot” Pulmonary Vein Isolation (PVI) ablation

- “Drop in” workflow for speed and ease of use
- Eliminates need to rotate device to “connect the dots”
- Deeper lesions than micro PFA = improved transmurality
- Less dependent on tissue contact
- More rapid isolation of vein
- Nonthermal
- Design allows for versatility in left atrial utilization



2-Day Endocardial Surface
~5cm Diameter (Porcine)

Pulse Biosciences

360 Cardiac Catheter Status

Program Updates:

- Data read-out of initial 30 treated patients
- Enrollment ongoing in multiple centers
- 3rd site starting in January
  – Dr. Natale, Rome, IT

AF Symposium Boston, MA, January 16–18, 2025

Friday, January 17th

Pulsed Field Ablation Using a Compliant Circular Catheter Delivering Nanosecond Pulses to Treat Atrial Fibrillation

5:30–7:00pm ET, Vivek Reddy, MD
– Late Breaking Clinical Science Session

Saturday, January 18th

Nanosecond Pulsed Field Ablation for Atrial Fibrillation

7:30–9:30am ET, Petr Neuzil, MD, PhD
– Live Case Transmission from Homolka Hospital, Prague, Czech Republic

Initiating a pivotal clinical trial for Paroxysmal AF **mid 2025**

Pulse Biosciences®

Summary

Novel Energy
- Unique MOA
- Patent Protected
- Nonthermal

IP – 183 + 103
- Pulse will own the Nanosecond PFA Space

Clinical evidence
- Mounting and superior
- Paradigm shifting care

3 IDEs in 2025
- Funded
- Advancing
- Measurable Milestones

Target Market Values
- $6B U.S. Annual Addressable Mkt
- Create, Expand, Upend

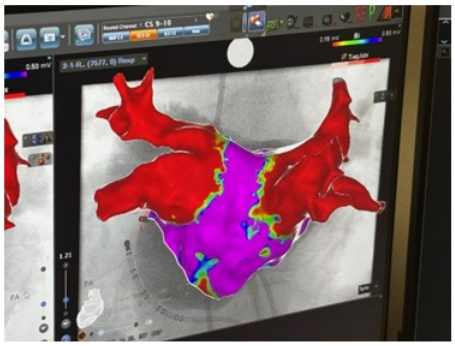
Portfolio of markets and pipeline of future indications
- Multiple clinical or commercial programs activated

Initializing commercialization
- Launch underway

Strong balance sheet
- Multi-year cash runway

360 Cardiac Catheter Feasibility Study Progress

Dr. Johan Vijgen
Jessa Hasselt Hospital



Post map after Jessa Hasselt's first case

nsPFA 360 Cardiac Catheter Value Proposition in Action

- 1st clinical case with the 360
- Ablation Time PVI : 10 min
- First-pass isolation of all pulmonary veins
- Low to no learning curve

Citations

1) Data on file. Thyroidectomy WW Procedure Data provided by iData
2) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8215427/
3) Fine-Needle Aspiration of the Thyroid Gland https://www.ncbi.nlm.nih.gov/books/NBK285544/
4) CMS - https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38968&ver=4
5) CDC - https://seer.cancer.gov/statfacts/html/thyro.html
6) Global Cardiac Surgical Volume and Gaps: Trends, Targets, and Way Forward. Annals of Thoracic Surgery. 2023, ISSN 2772-9931, https://doi.org/10.1016/j.atssr.2023.11.019.
7) Market size for 2023. 1% CAGR for Surgical Volume
8) Clarivate – US EP Market Report
9) Company filings, BofA Global Research. Revenue is BofA estimate
10) Neis et al. Circ Arrhythm Electrophysiol. 2024;17:e012854. DOI: 10.1161/CIRCEP.124.012854
11) Wyler von Ballmoos, Moritz C. et al.The Annals of Thoracic Surgery, Volume 117, Issue 2, 260 – 270
12) McCarthy, P. M. et al. Prevalence of atrial fibrillation before cardiac surgery and factors associated with concomitant ablation. J. Thorac. Cardiovasc. Surg. 159, 2245-2253.e15.
13) Burrage, P.S., Low, Y.H., Campbell, N.G. et al. New-Onset Atrial Fibrillation in Adult Patients After Cardiac Surgery. Curr Anesthesiol Rep 9, 174–193 (2019). https://doi.org/10.1007/s40140-019-00321-4
14) Wong CX, Brown A, Tse HF, et al. Epidemiology of Atrial Fibrillation: The Australian and Asia-Pacific Perspective. Heart Lung Circ. 2017;26(9):807-879
15) Joglar et al J.A.C.C. VOL. 83, NO. 1, 2024 2023 Guideline for the Diagnosis and Management of Atrial Fibrillation JANUARY 2/9, 2024:109–279 116 (Linear Interpolation)