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): **August 12, 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)

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 August 12, 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 Surgery System, 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 August 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 August 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: August 12, 2024

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


Pulse Biosciences®
Investor Presentation
August 2024

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 nano-PFA 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 nano-PFA 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 nano-PFA Cardiac Surgery System, Pulse Biosciences' expectations, whether stated or implied, regarding whether the Company's CellFX nano-PFA 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.

Advancing ablation therapy with next-generation **Nanosecond Pulsed Field** technology to deliver health innovation that improves the quality of life for patients and benefits clinician users.

Ablation is a Ubiquitous Treatment Modality

Widely adopted procedures used by a diverse set of clinicians for the treatment of many disease states

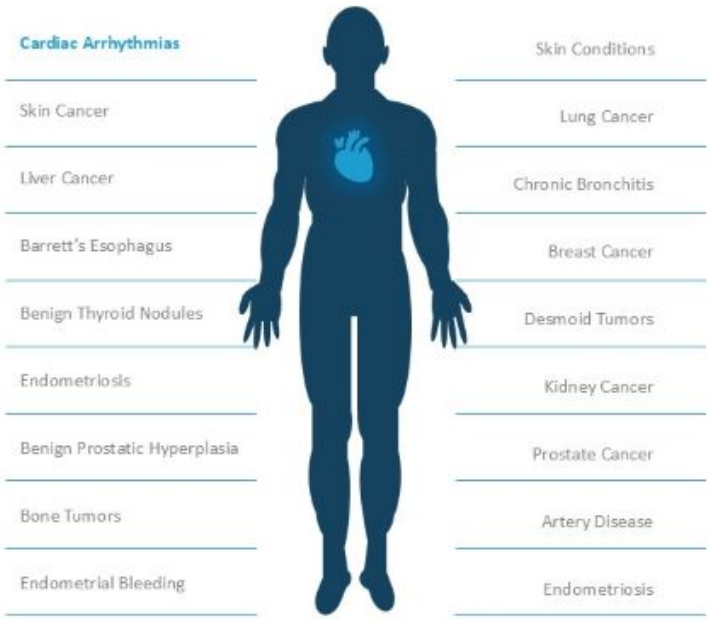
- Cardiac Arrhythmias
- Skin Cancer
- Liver Cancer
- Barrett's Esophagus
- Benign Thyroid Nodules
- Endometriosis
- Benign Prostatic Hyperplasia
- Bone Tumors
- Endometrial Bleeding

- Skin Conditions
- Lung Cancer
- Chronic Bronchitis
- Breast Cancer
- Desmoid Tumors
- Kidney Cancer
- Prostate Cancer
- Artery Disease
- Endometriosis

However, it is challenging to precisely control where ablative energy is delivered

X **Because of constraints with existing ablation technologies, physicians may use suboptimal energy parameters, for example to protect surrounding tissues**

Pulsed Field Ablation Represents an Ablation Breakthrough



PFA technology is exploding in the treatment of arrhythmias such as Atrial Fibrillation (AF)

Pulsed Field Ablation (PFA) technology is being rapidly adopted in electrophysiology due to ease of use, speed and improved clinical outcomes for patients

- **However, outcomes are variable; dependent on user experience and specific catheter design**
- **Speed and perceived safety can lead to over ablation**
- **Most standard PFA devices coming to market use RF-Style catheter designs that are not designed specifically for cardiac PFA applications**

Pulse Biosciences' Nanosecond Pulsed Field Ablation (nano-PFA) is the Next Generation of PFA

Microsecond PFA
Long Duration, Low Amplitude

- x Constrains or limits electrode and catheter design (requires point electrodes)
- x Limited ablation depth
- x Requires multiple energy deliveries

vs.

Nanosecond PFA
Short Duration, High Amplitude

- ✓ Controlled ablation footprint
- ✓ Deep ablations
- ✓ Single energy delivery
- ✓ Faster ablations
- ✓ Ability to deliver energy treatment zones of various sizes

Designed to enable:

- Better procedural efficacy than point electrodes
- Reduce potential for over ablation
- Faster procedure times

Pulse Biosciences

Fundamental & Novel Innovation

Pulse Biosciences is the pioneer designing and engineering nano-PFA technology from the ground up

Inventing and harnessing nano-PFA technology dates back two decades

- ✓ Differentiated approach focused on novel therapy development

Richard Nuccitelli, Ph.D., Pulse Biosciences innovator since November, 2014.

Creating wide and deep IP portfolio covering nano-PFA energy and system

- ✓ Continued development and patent filings covering systems, applications, and methods of combining nanosecond pulsing with other biological technologies and agents

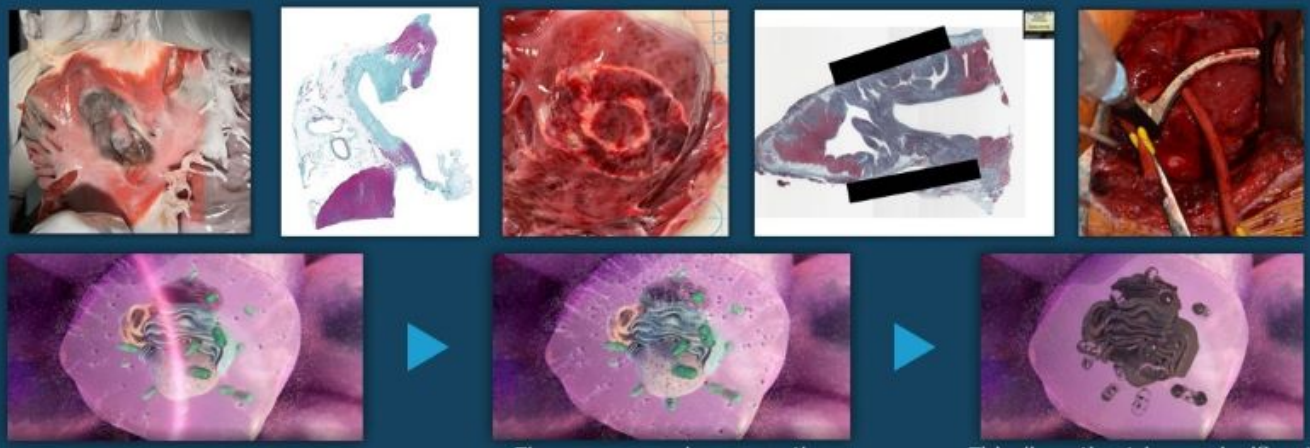
>150
Issued patents globally owned & licensed

~100
Patent Pending Applications

Patent Portfolio 2024

Largest Preclinical Library of nano-PFA Histology in the World

Demonstrates the effects of different nano-PFA energy parameters on different kinds of tissue



Nano-PFA technology delivers ultrafast energy pulses

These energy pulses cause the creation of tiny pores which allows ions to move within the cell

This disruption triggers significant changes deep within cellular organelles leading to regulated cell death (RCD)

Pulse Biosciences®

Experienced Technologists, Operators and Clinicians Form Proven Leadership Team

Burke T. Barrett
President & Chief Executive Officer

Kevin Danahy
Chief Commercial Officer

Darrin Uecker
Chief Technology Officer

CARDIOFOCUS · Cyberonics · cyberKINETICS · Medtronic · Johnson & Johnson · ZIMMER BIOMET · INTUITIVE · gynesonics · compartmentia

Renowned Scientific Expertise

Dr. Gan Dunnington
Chief Medical Officer, Cardiac Surgery

Adventist HealthCare

Dr. Niv Ad
Chief Science Officer, Cardiac Surgery

Adventist HealthCare White Oak Medical Center

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

Paul LaViolette
Co-Chairman of the Board of Directors

Burke T. Barrett
Director

Darrin Uecker
Director

Pulse Biosciences is Pioneering a Faster, More Predictable and Easier-to-Use Ablation Therapy

Focused on improving the standard of care in currently identified ablation markets and reaching significant areas of unmet clinical need

Proven nano-PFA applications → **Current and future nano-PFA applications**

Dermatology

Dermatology System

- ✓ FDA 510(k) Clearance
- ✓ CE Mark Approval
- ✓ Health Canada Approval
- ✓ Australian TGA Approval

- ✓ Demonstrated results in dermatology applications and treated 6,000 patients
- ✓ Proven track record of success in commercial scale

Soft Tissue Ablation

Percutaneous Electrode System

- ✓ FDA 510(k) Clearance for soft tissue ablation

Arrhythmias

Cardiac Surgery System

- ✓ FDA Breakthrough Device Designation

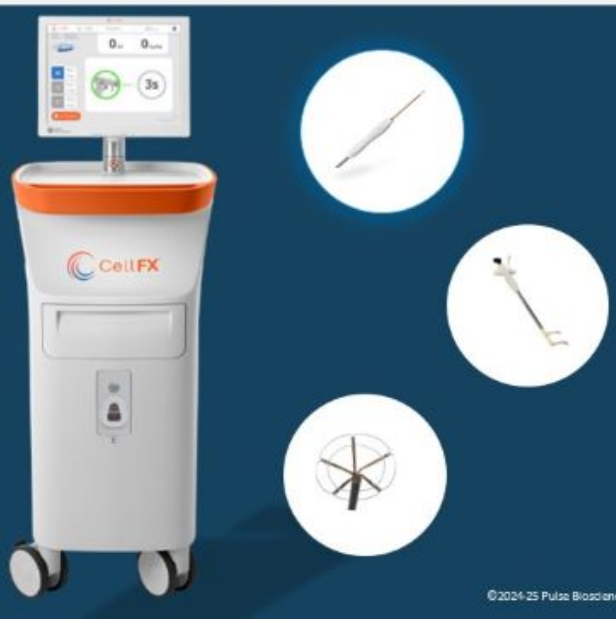
360° Cardiac Catheter

- Addressing the growing AF market through catheter ablation

Versatility of nano-PFA Technology Delivered Across the Anatomy

through a single console compatible with all Pulse devices

- Cloud-enabled analytics
- Allows software-tunable treatment settings for each different clinical application
- Tracks utilization



Pulse Biosciences

Focused on Delivering Novel Nano-PFA Therapies for Patients

Plan to pursue regulatory pathways that will optimize clinical value

Benefits of these pathways include:

1. **Solid Clinical Evidence Development**
   - Validate clinical performance via high-quality studies
2. **Strong Foundation for Commercial Adoption**
   - Allow for marketing the device as a specific treatment option rather than as a tool
   - The ability to market, sell and train for approved indication(s) can enable quicker clinician adoption and market penetration

Pulse Biosciences®

	Clinical	Regulatory	Commercial
Soft Tissue Ablation 	• Feasibility in benign thyroid completed • Plan to continue benign thyroid clinical studies throughout 2024-2025 • Plan to explore additional soft tissue ablation indications	• Received FDA 510(k) clearance for soft tissue ablation in March of 2024 • Plan to commence pivotal clinical trial in 2025 to support a specific indication submission	• Initiated pilot program for soft tissue ablation in 2024
Epicardial Ablation 	• Initiated FIH study in Netherlands in July 2024	• Received FDA Breakthrough Device Designation • Enrolled in the FDA's Total Product Life Cycle Advisory Program (TAP) • Expect to commence a pivotal clinical trial in early 2025 to support a PMA application for treatment of AF	
Endocardial Ablation 	• 39 patients treated in FIH study in Prague (enrolling up to 60 patients) • Additional feasibility studies planned	• Expect to commence a pivotal clinical trial in 2025 to support a PMA application for treatment of AF	

Soft Tissue Ablation

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

FDA 510(k) March 2024

Pulse Biosciences

Benign Thyroid Nodule Market Size of 1.3M Patients Worldwide

Benign Thyroid Nodule Ablation Market Size

- Approximately 3 in 4 patients undergoing thyroidectomy have benign thyroid nodules
- It is estimated that more than 8 million[6] people worldwide have a palpable thyroid nodule that is not being treated
- ~50% of patients have a thyroidectomy with most of the remainder choosing not to undergo surgery and electing to tolerate their thyroid nodule[1]

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/NBK238554/
4) CMS - https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=38968&ver=4
5) CDC - https://www.cdc.gov/cancer/thyroid/index.htm. At an estimated WW Mixed ASP of ~$2,2305 per procedure, this leads to a total addressable market of more than $2.8B and growing
6) Data on file. Based on WW incidence rates. Based on Internal Market Model.

Transforming the Thyroidectomy Market

Minimally Invasive

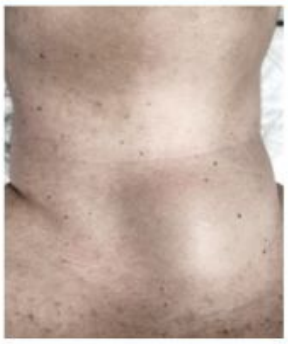
- Completed treatments in FIH Feasibility Study
- Preclinical and clinical data demonstrating initial safety
- Rapid ablation of tissue
  - 8 seconds per ablation zone (nano zone)
- Promising initial results; volume and symptom reduction

FDA 510(k) Cleared March 2024

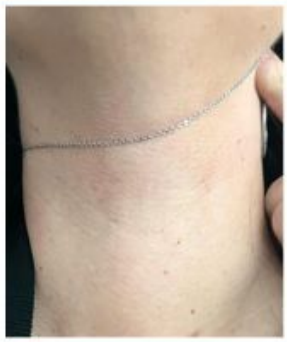
The CellFX Percutaneous Electrode System is indicated for ablation of soft tissue in percutaneous, and intraoperative surgical procedures. The CellFX Percutaneous Electrode System (Percutaneous Electrode) is not indicated for use in cardiac procedures.

Successful Patient Treatments in FIH Study

Before nano-PFA



30 Days After Procedure



Reduced Nodule Volume

- ✓ *Leads to improved cosmesis compared to surgical resection*
- ✓ *Leads to symptom reduction*

Pilot Commercial Program Guided by Experienced Clinicians

Soft Tissue Ablation

- ✓ Commencing pilot US commercial launch under 510(k) soft tissue ablation indication
- ✓ Launch is led by KOLs to ensure and enhance adoption campaign:
  - ✓ Currently partnering with leading clinicians
  - ✓ Plan to conduct investigator-sponsored research to add additional clinical data and experience

Benign Thyroid Nodule Ablation

- Targeting a specific regulatory indication for treatment of benign thyroid nodules
- Plan to initiate a pivotal clinical trial for benign thyroid nodule ablation in early 2025
- Upon approval, plans to commercialize the system in the United States as a treatment for benign thyroid nodule ablation

Epicardial Ablation

Nano-PFA for AF

✓FDA Breakthrough Device Designation
✓Enrolled in the FDA's Total Product Life Cycle Advisory Program (TAP)*

Addressing the Growing AF Market Through Surgical Ablation

- WW Current Market Size = ~$200M
  - Estimated 50-60k Procedures WW
- WW Concomitant Market Opportunity = >$1.7B
  - 28% of Open Heart Patients have Pre-OP AF
  - Est. 420k WW Patients
- WW Total Concomitant Market Opportunity = >$6B
  - Est. 1.5M WW Patients

Market Growing at 10-15% CAGR[2]

AF Patients 2019:
~43M Global[1]

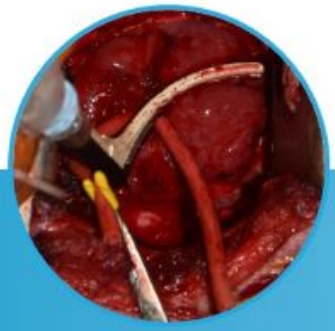
Expected 2050:
~72M Global[1]

Surgical Ablation

- An estimated 1.5M open heart procedures are performed each year worldwide[3]
- ~30% of open-heart patients have diagnosed Atrial Fibrillation (AF) prior to their surgery and should be treated concomitantly[2]

1. Prevalence Data: Institute for Health Metrics and Evaluation (IHME). Global Health Data Exchange. Seattle, WA: IHME, University of Washington. Available at http://ghdx.healthdata.org/gbd-results-tool. Location: Countries, Year: 2019, Context: cause, Age: all ages, Metric: number, Measure: prevalence, Sex: both, Cause: G 2.3. Atrial fibrillation and flutter. (Accessed August 24, 2021)
2. Wong CX, Brown A, Lau DH, et al. Epidemiology of Atrial Fibrillation. The Australian and Asia-Pacific Perspective. Heart Lung Circ. 2019;28(10):1476
3. Wolfe AF Symposium Report 2019
4. Oppenheimer Report 2020

Pulse's Cardiac Ablation Clamp



- A non-thermal cardiac ablation clamp capable of ablations in **under 2 seconds**
- Preclinical studies have demonstrated **durability, precision and transmurality**
- Initiated FIH study in EU
- **Existing IP** for Pulse's energy and energy delivery covers cardiac surgical ablation

Pulse Biosciences

1) 2-Day Histology: Gomori trichrome stain showing treated tissue through the left atrial appendage in a porcine model

Planned U.S. Regulatory Pathway Underway

- ✓ **Received FDA Breakthrough Device Designation in July 2024**
  - For the ablation of cardiac tissue for the treatment of AF
  - Designation speeds up assessment and review for premarket approval
- ✓ **Enrolled in the FDA's Total Product Life Cycle (TPLC) Advisory Program (TAP)**
  - Provides additional opportunities to expedite US clinical and regulatory pathway

- The Company expects to begin its pivotal clinical trial for AF in early 2025
- Upon approval, plans to commercialize the system in the United States as a treatment for AF

Pulse Biosciences®

Endocardial Ablation

Next-Generation PFA for AFib

Pulse Biosciences

Addressing the Growing AF Market with Catheter Ablation

Global Atrial Fibrillation (AF) Disease State:

>$8B

Electrophysiology Market

Market Growing at 10-15% CAGR[2]

AF Patients 2019:
~43M Global[1]

Expected 2050:
~72M Global[1]

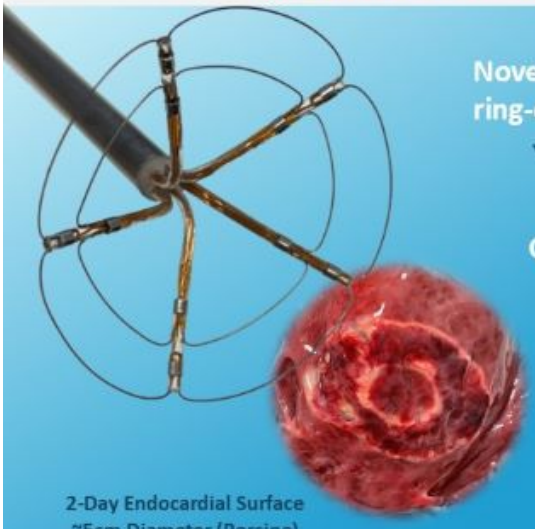
Catheter Ablation

>1M Catheter Ablations Performed Per Year

1. Prevalence Data: Institute for Health Metrics and Evaluation (IHME). Global Health Data Exchange. Seattle, WA: IHME, University of Washington. Available at http://ghdx.healthdata.org/gbd-results-tool. Location: Countries, Year: 2019, Context: cause, Age: all ages, Metric: number, Measure: prevalence, Sex: both, Cause: G 2.8. Atrial fibrillation and flutter. (Accessed August 24, 2021)
2. Wong CX, Brown A, Lau DH, et al. Epidemiology of Atrial Fibrillation. The Australian and Asia-Pacific Perspective. Heart Lung Circ. 2019;28(10):1476
3. Wolfe AF Symposium Report 2019
4. Oppenheimer Report 2020

Customized nano-PFA Electrode Design

nano-PFA technology provides greater flexibility to design devices with larger footprint electrodes without concerns of having significant thermal effects



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

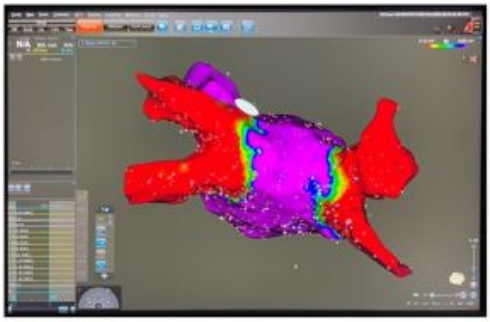
Novel nano-PFA design achieves circumferential lesions with continuous ring-electrodes for "single-shot" Pulmonary Vein Isolation (PVI) ablation

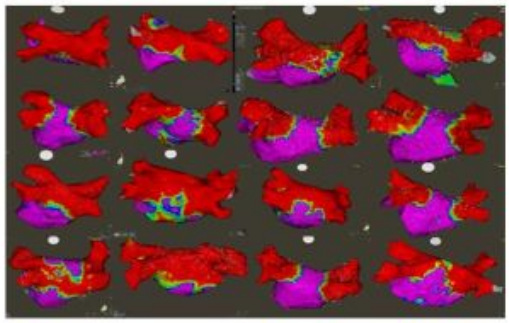
- ✓ Mitigates need to deliver between pairs of discrete electrodes

Circumferential catheter design leads to...

- ✓ Increase in speed and ease of use
- ✓ Deeper lesions than micro PFA
- ✓ Improved transmurality
- ✓ More rapid isolation of vein
- ✓ Less thermal effect

360 Cardiac Catheter Feasibility Study Preliminary Results





N=16 Remap Results 60-90 Days Post Treatment

- Total of 39 patients treated at Homolce Hospital, Prague
- Avg. Ablation Time PVI (n=24) : 10.7 min
- Expanding clinically to additional patients in Prague and sites in Europe
- Plans to initiate discussions with FDA about clinical and regulatory path to market by the end of 2024

Pulse Summary

In pre-clinical testing, nano-PFA has significant advantages over microsecond PFA

Extensive IP and know-how that covers nano-PFA

Developed 4 clinical products using nano-PFA

- ✓ Dermatology – initial clinical indication
- ✓ Soft tissue ablation needle – commercial pilot program underway
- ✓ Surgical AF ablation – FIH completed
- ✓ Catheter AF ablation – FIH completed

Demonstrated operational and commercial capabilities

Pipeline of additional products for other clinical indications under development