

**Investor Presentation** 

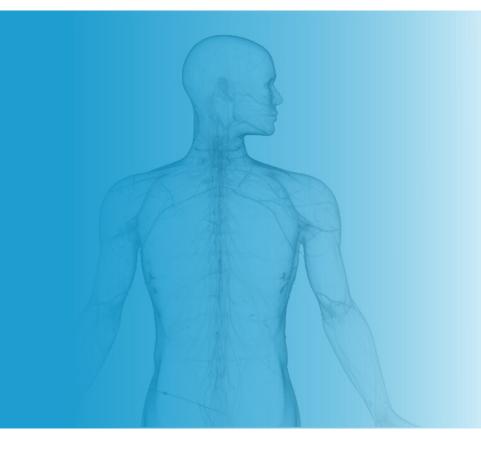
August 2024

## **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," "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. Ac

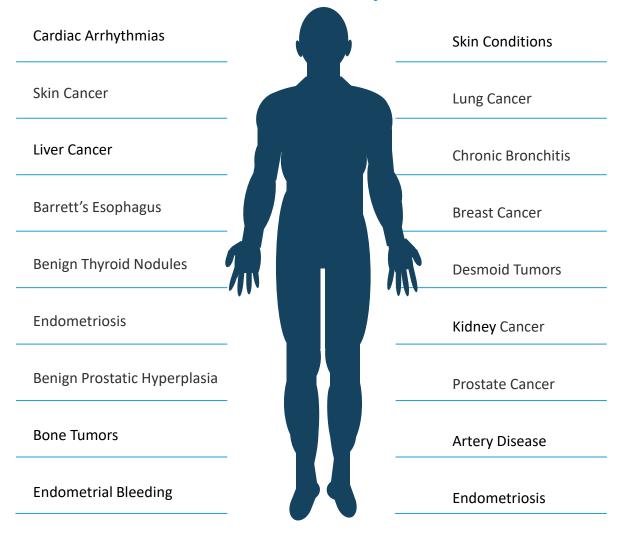
This presentation and any documents incorporated by reference may contain market data that we obtain from industry sources. These sources do not guarantee the accuracy or completeness of the information. Although we believe that our industry sources are reliable, we do not independently verify the information. 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

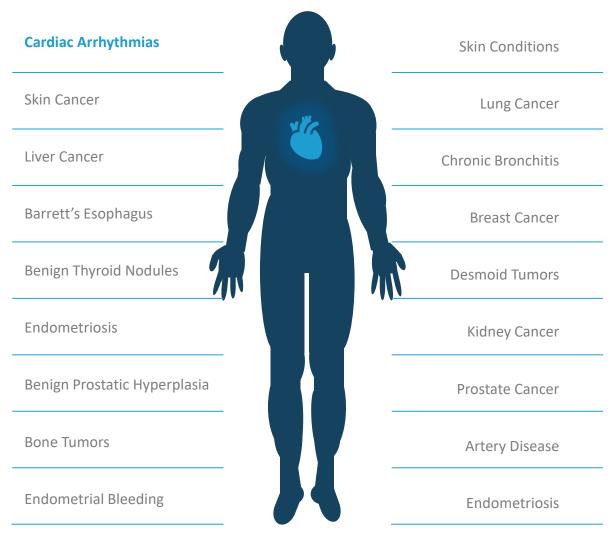


However, it is challenging to precisely control where ablative energy is delivered



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 based 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

VS.

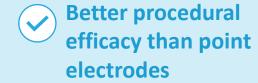
- x Constrains or limits electrode and catheter design (requires point electrodes)
- Limited ablation depth
- Requires multiple energy deliveries

**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:**





**Faster procedure times** 

### **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

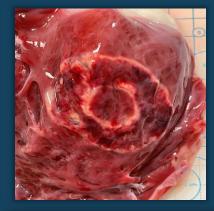


## Largest Preclinical Library of nano-PFA Histology in the World

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

















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)



# **Experienced Technologists, Operators and Clinicians Form Proven Leadership Team**



**Burke T. Barrett** 

President & Chief Executive Officer

CARDI\*FOCUS

Cyberonics cyberkinetics



**Kevin Danahy** 

**Chief Commercial Officer** 





**Darrin Uecker** 

**Chief Technology Officer** 



### **Renowned Scientific Expertise**



Adv



**Cardiac Surgery** 

**Dr. Gan Dunnington** 

Chief Medical Officer,





#### **Established Board of Directors**



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



Paul LaViolette
Co-Chairman of the Board
of Directors



Richard van den Broek Director



**Burke T. Barrett**Director



Manmeet S. Soni
Director



Darrin Uecker
Director



Mahkam "Maky"
Zanganeh, DDS
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)

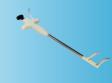
Clearance for soft

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





## 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





## Soft Tissue Ablation

- Feasibility in benign thyroid completed
- Plan to continue benign thyroid clinical studies throughout 2024-2025

**Clinical** 

 Plan to explore additional soft tissue ablation indications

- Regulatory
- 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

- Commercial
- 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

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## **Soft Tissue Ablation**

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





## 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<sup>6</sup> 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<sup>1</sup>

- Data on file. Thyroidectomy WW Procedure Data provided by iData
- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8215427/
- Fine-Needle Aspiration of the Thyroid Gland https://www.ncbi.nlm.nih.gov/books/NBK285544/
- CMS https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38968&ver=4
- CDC https://www.cdc.gov/cancer/thyroid/index.htm. At an estimated WW Mixed ASP of ~\$2,2505 per procedure, this leads to a total
- 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

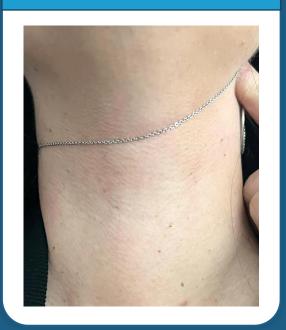
The CellFX Percutaneous Electrode System is indicated for ablation of soft tissue in percutaneous, and intraoperative surgical procedures. The CellFX Percutaneous Electrode System (Percutaneous Electrode) is not indicated for use in cardiac procedures.

## **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<sup>2</sup> AF Patients 2019: ~43M Global¹

Expected 2050: ~72M Global¹



### **Surgical Ablation**

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



Pulse Biosciences<sup>®</sup>

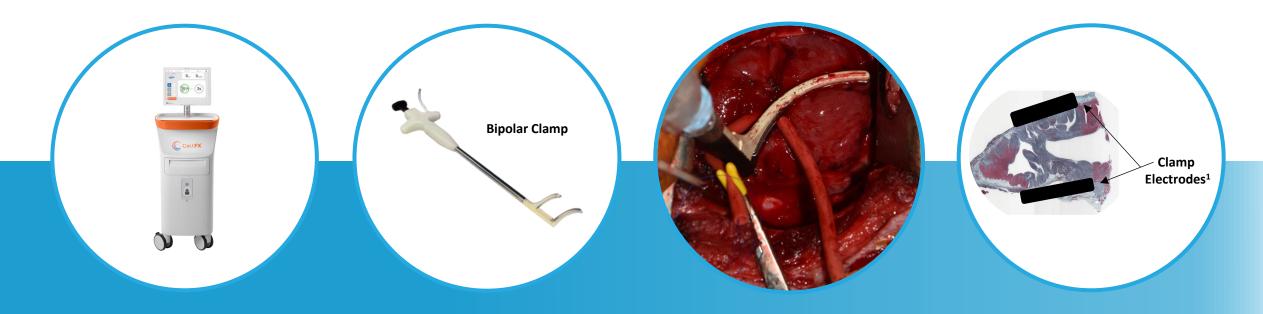
<sup>1.</sup> Prevalence Data: Institute for Health Metrics and Evaluation (IHME). Global Health Data Exchange. Seattle, WA: IHME, University of Washington. Available at http://ghdx.healthdata.org/gbd-results-tool. Location: Countries, Year: 2019, Context: cause, Age: all ages, Metric. number, Measure: prevalence, Sex: both, Cause: B.2.8. Atrial fibrillation and flutter. (Accessed August 24, 2021)

<sup>2.</sup> 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

Wolfe AF Symposium Report 2023

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



## 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



## **Endocardial Ablation**

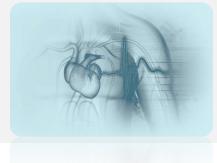
Next-Generation PFA for AFib





## Addressing the Growing AF Market with Catheter Ablation





>1M Catheter Ablations Performed Per Year

<sup>1.</sup> 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: B.2.8. Atrial fibrillation and flutter. (Accessed August 24, 2021)

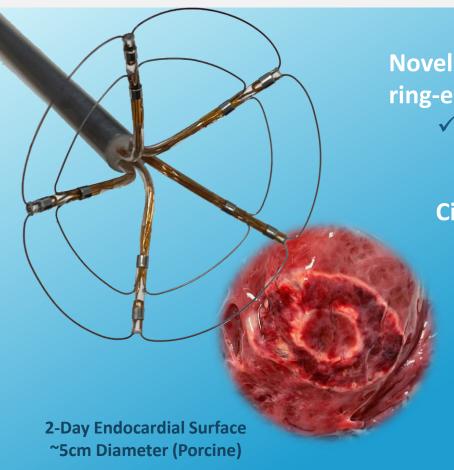
<sup>2.</sup> Wong CX, Brown A, Tse HF, et al. Epidemiology of Atrial Fibrillation: The Australian and Asia-Pacific Perspective. Heart Lung Circ. 2017;26(9):807-879

Wolfe AF Symposium Report 202

<sup>.</sup> 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



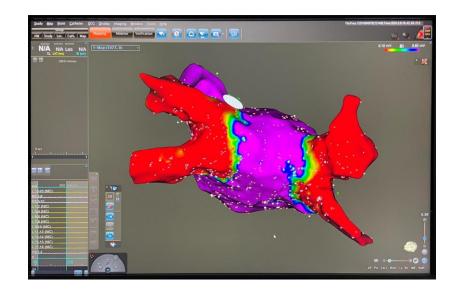
Novel nano-PFA design achieves circumferential lesions with continuous ring-electrodes for "single-shot" Pulmonary Vein Isolation (PVI) ablation

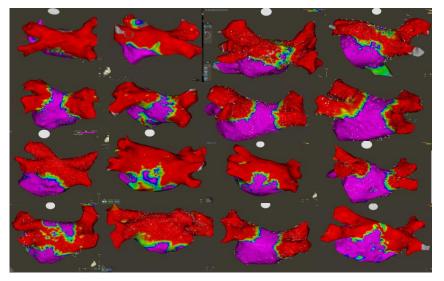
✓ Mitigates need to deliver between pairs of discrete electrodes

### 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