



# DRIVING THE REVOLUTION IN CARDIOLOGY

**Business Update**

April 24, 2024



# Safe Harbor

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# Speakers



**Stéphane Piat**

*Chief Executive Officer*

- Over 20-year experience in the medical device business
- Previously Divisional Vice President Global Market Development at Abbott



**Pascale d'Arbonneau**

*Chief Financial Officer*

- Over 25-year experience in finance and healthcare industry
- Previously VP Finance at GSK



# Agenda

**I. CARMAT recent achievements**

**II. Clinical Update**

**III. Commercial Strategy**

**IV. Manufacturing and Finance**

**V. Outlook**

# CARMAT's Critical Mission

To solve the advanced heart failure transplant and destination therapy crisis



## OUR VISION

Aeson® to become the primary  
**alternative to Heart  
Transplants**

## OUR MISSION

To provide **quality of life** to patients with  
advanced heart failure by creating innovative and  
reliable technologies that save lives



# High Unmet Medical Need in Heart Failure

**200,000**

Patients suffering  
from heart failure  
every year\*

**6,000**



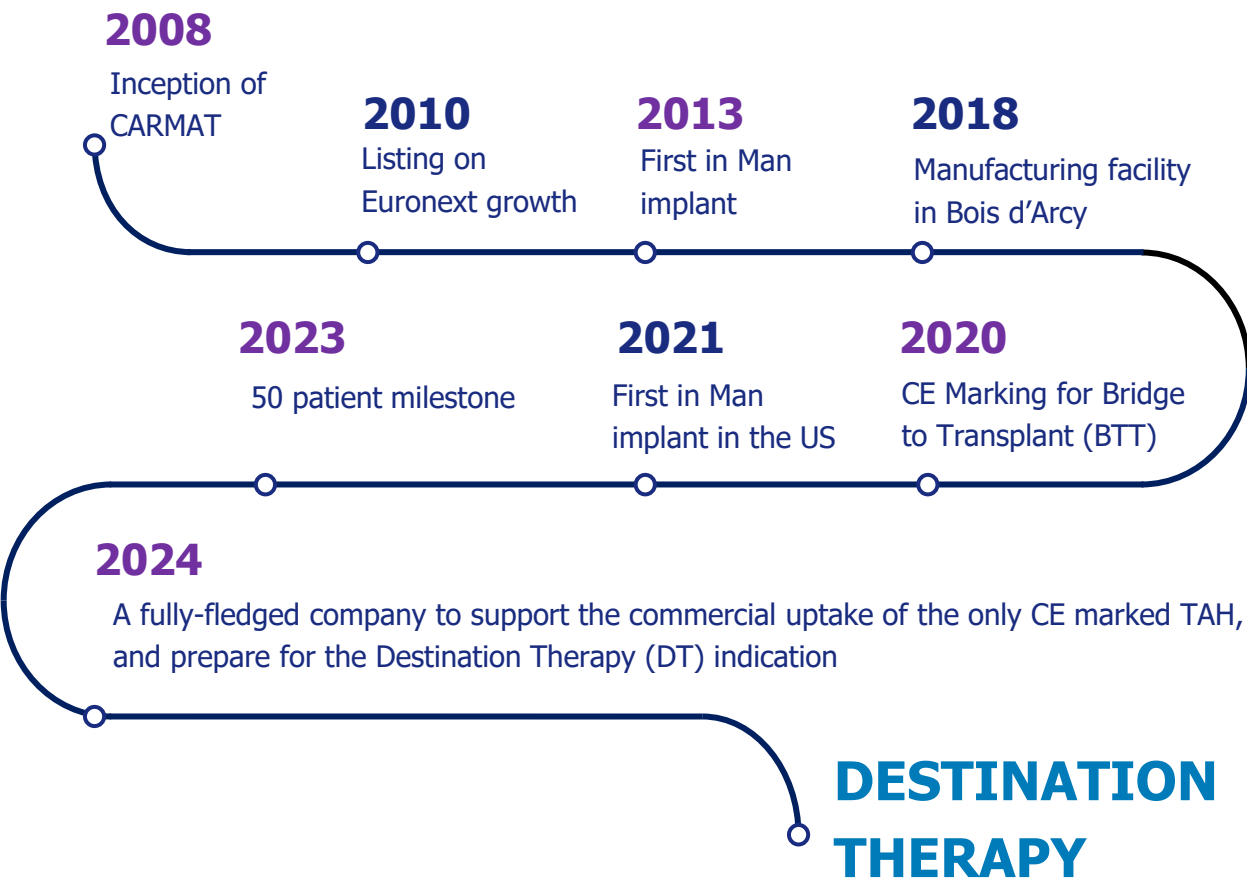
The number of  
hearts  
transplants\*\*



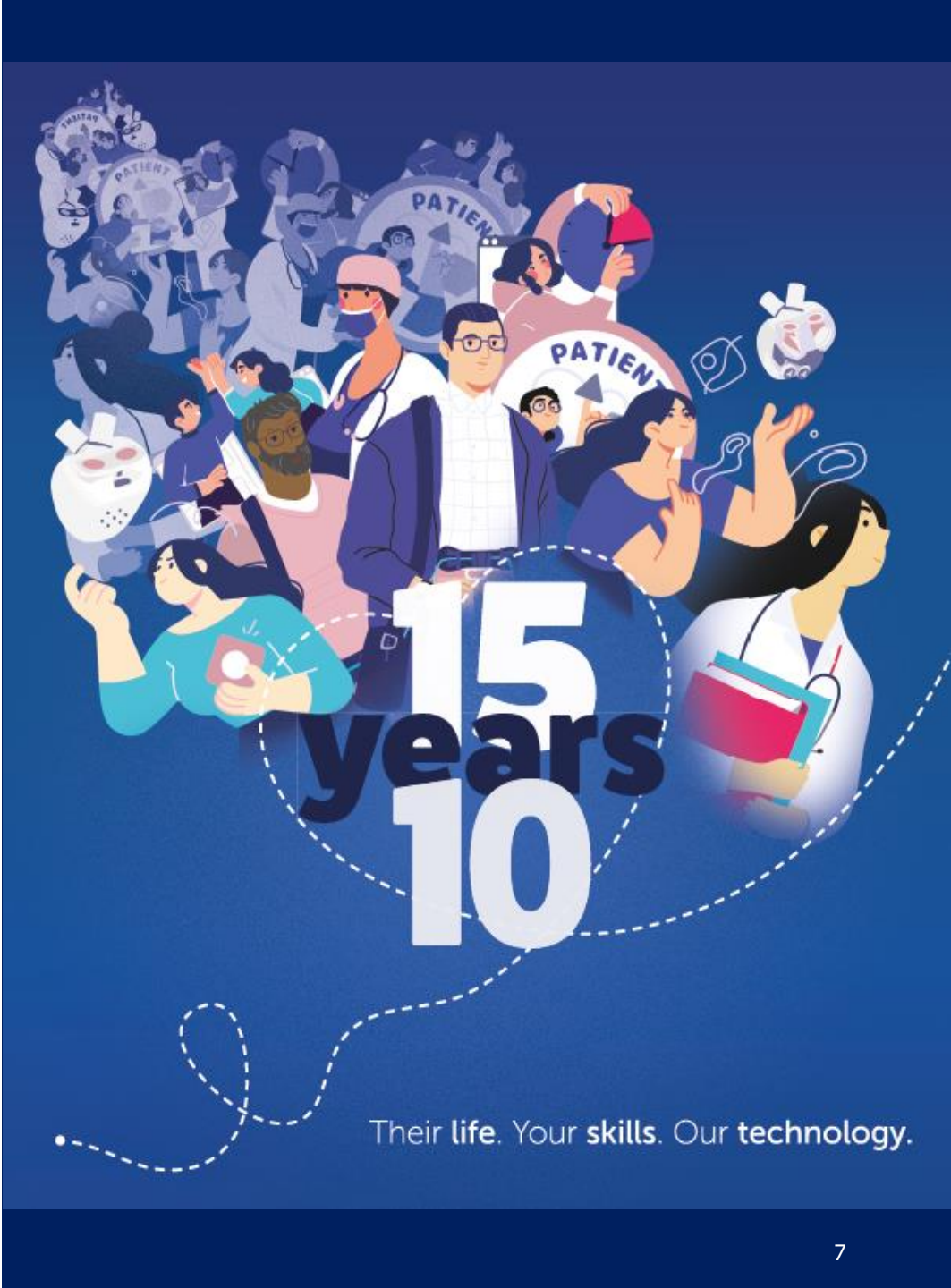
**97% of patients in need of a transplant are not treated**



# Our Successful Journey so far

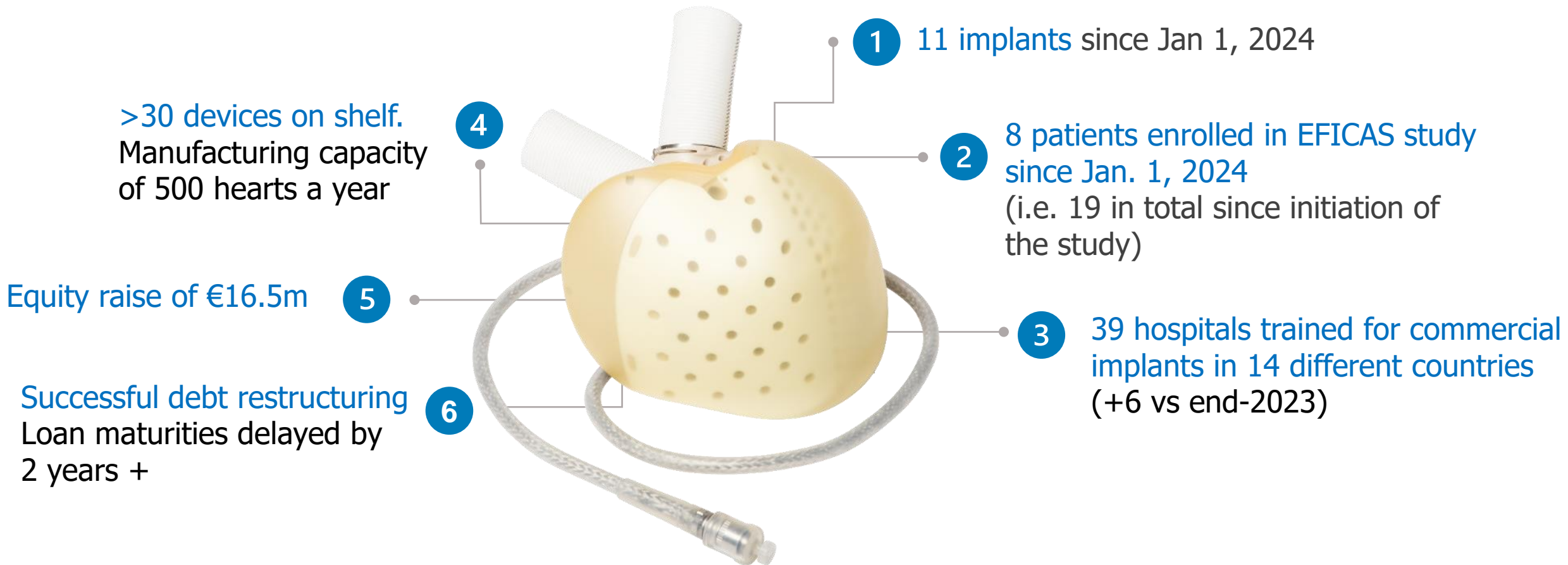


**CARMAT outperformed all competing projects in terms of technology and pace of development**



Their life. Your skills. Our technology.

# 2024 Key Achievements to date



**Sales forecast of c. €14m for 2024**



# Commercial development getting pace

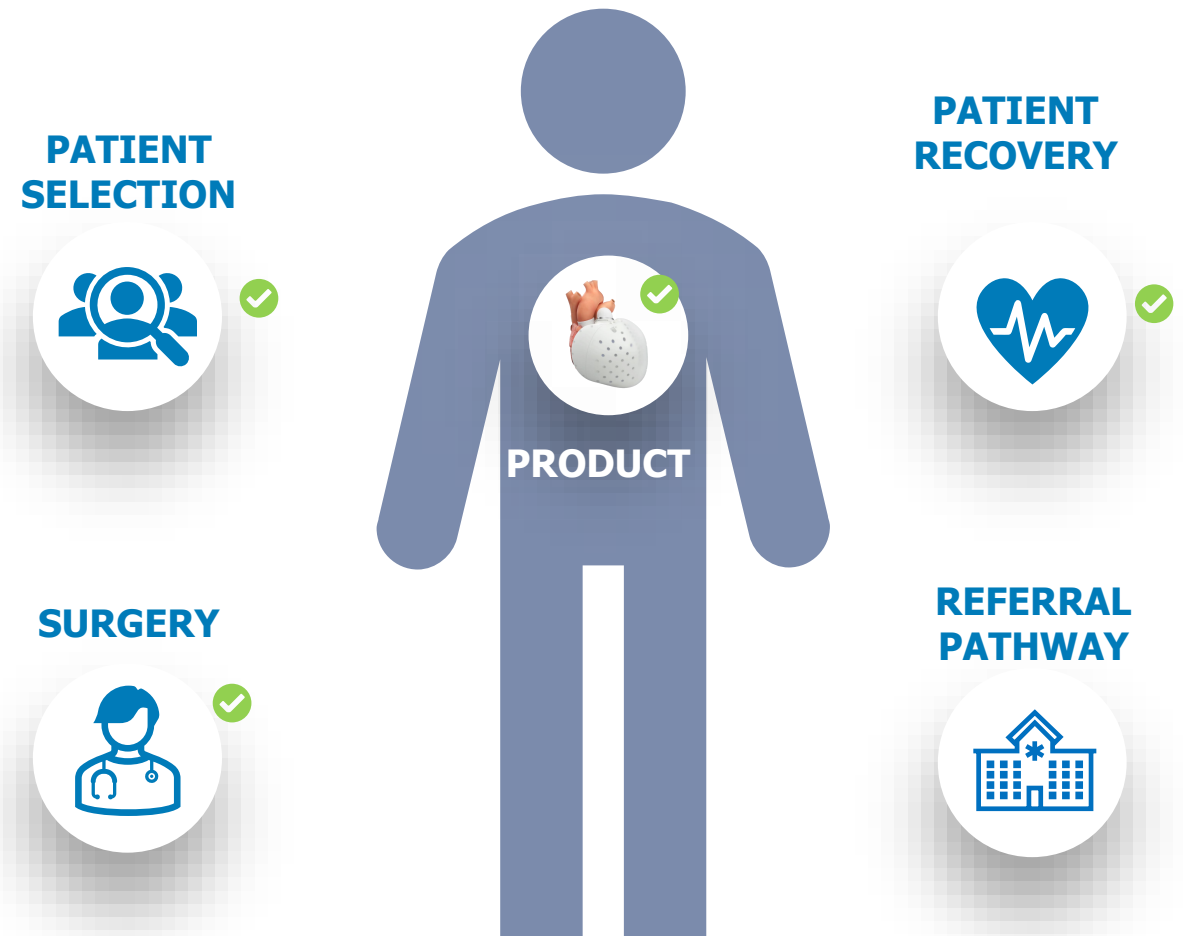
	2023 – Full Year	2024 – 4 Months*
Sales	€2.8m	€1.7m
Implants	17	11
EFICAS – Patients enrolled	10	8
Hospitals trained for commercial implants (end of period)	33	39 (+6)
Active countries (commercial)	Germany, Italy	Germany, Italy, Poland
Additional ready-for-implants countries	Austria, Slovenia, Greece, Israël	Austria, Slovenia, Greece, Israël, Switzerland
Inventory	c.20 devices	c.30 devices

## The WOW Effect!

experienced at each first implant reinforces our conviction that adoption of Aeson® will continue to get momentum in 2024

**Referral pathway to be progressively built to unlock Aeson®' full potential**

## Recent Learnings to Build-Upon to make Aeson® a first-line therapy





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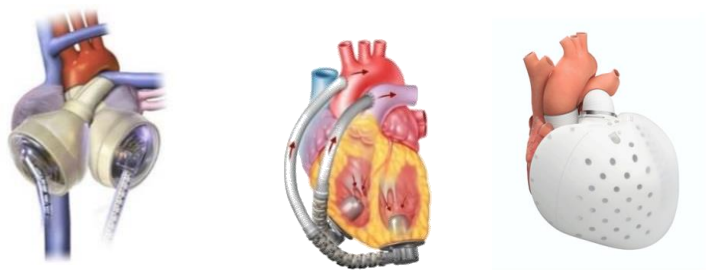
**III. Commercial Strategy**

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# Aeson®'s Unique Competitive Advantages

Four essential requirements to provide physiologic replacement without complications



	SynCardia TAH	BVAD	Aeson® TAH
01 Biventricular Support	✓	✓	✓
02 Pulsatility	✓	✗	✓
03 Autoregulation	✗	✗	✓
04 High hemocompatibility	✗	✗	✓

Full physiologic replacement

Unparalleled Safety Profile



No disabling stroke



No intestinal bleeding lesions

# 10 years of growing clinical experience since first implant in 2013

**61 PATIENTS**

suffering from advanced heart failure treated with Aeson® TAH



**15 PATIENTS**

transplanted after Aeson® support (Bridge To Transplant)



The longest support duration exceeded

**25 MONTHS**

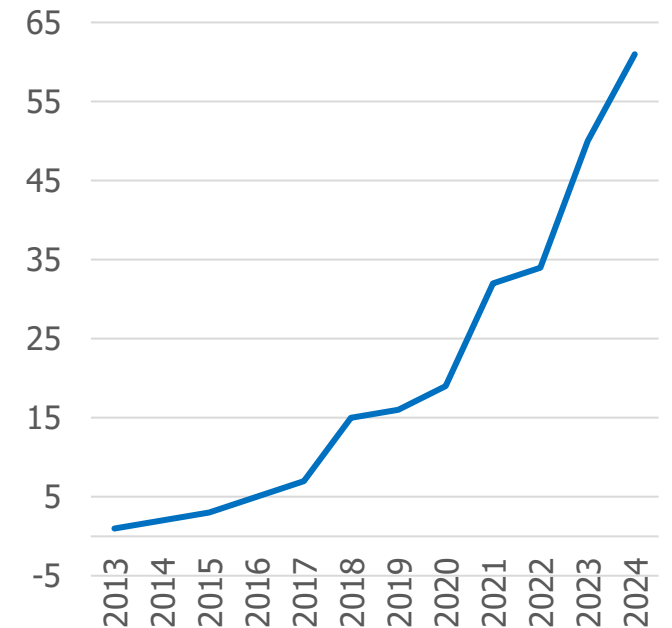


The cumulative experience is

**> 23 PATIENT YEARS**



Aeson® Implants (Cumulative)



# Game Changing Therapy for Physicians & Patients



## Safe surgical procedure

- Patient selection with proctors
- 3D virtual implant tool
- 100% Successful procedure
- Fast recovery



## Quality of Life

- Blood flow automatically responding to activities
- Few drugs and low-intensity anticoagulation
- Simple handling of external components

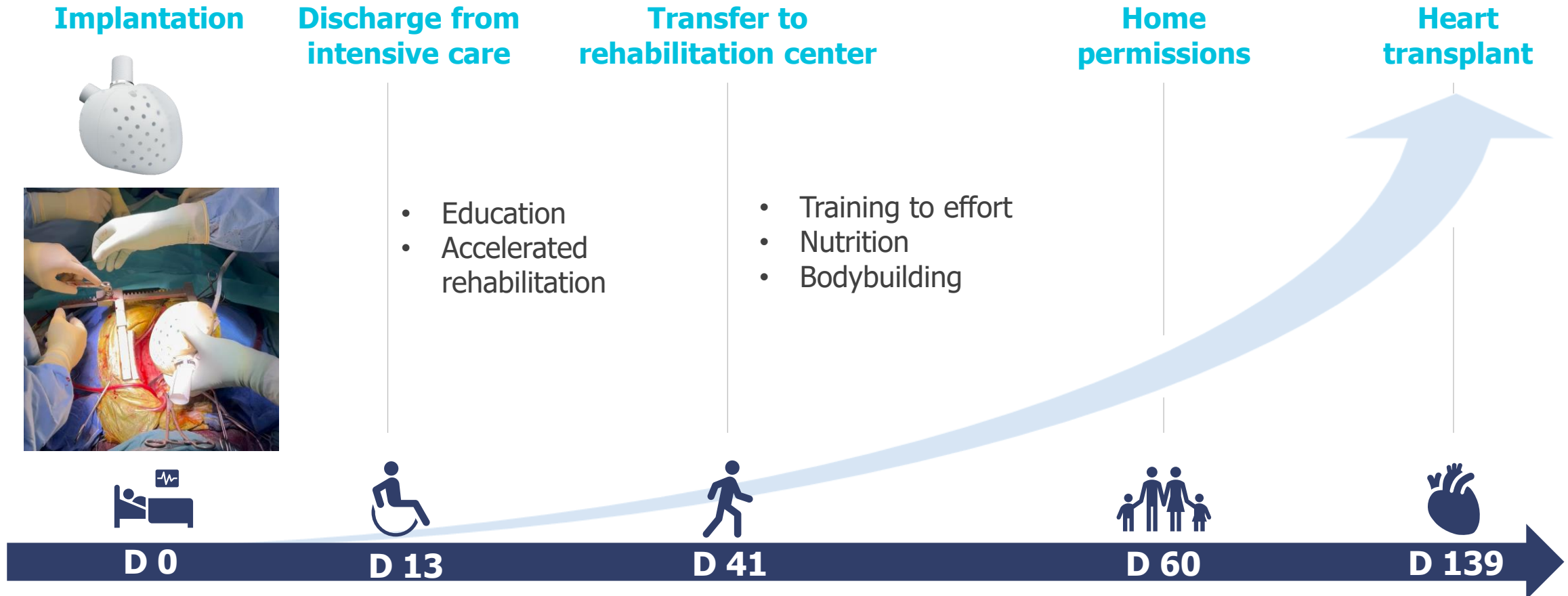


## Sustainable support

- Auto-pilot mode
- Unique hemocompatibility profile



# Real-life clinical experience



# The voice of the physicians : Towards making Aeson® a first-line therapy

1

## Trust the device

- Efficiency
- Reliability
- Safety (no stroke/bleeding)
- Ease of use

2

## Select the right patients at the right time

- Aiming for maximum possible benefit for each patient
- Expanding the universe of possibilities

3

## Integrating Aeson® into the therapeutic arsenal

- Make this therapy the first choice, rather than the exception
- Dare to take the plunge (as a team, with support from CARMAT)



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# Commercial Readiness



**39 centers trained in 14 different countries for commercial implants**



**Field force scaled for sales growth**



**Supply available to serve demand**



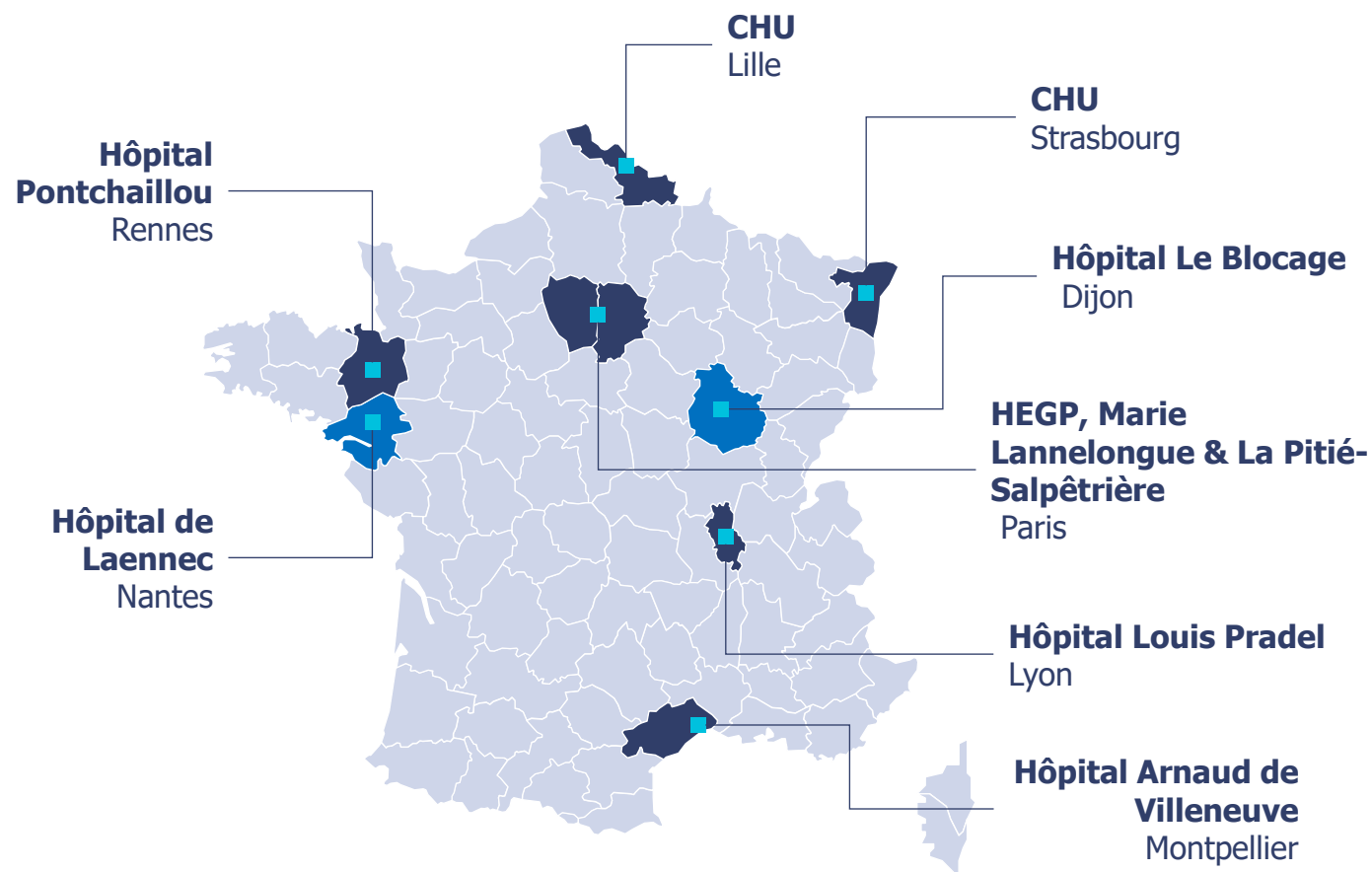
**Better understanding of patient referral pathway**



**Patient selection broadening-up**



# EFICAS Study on track for completion in H1 2025



**19 implants to date\***  
**10 hospitals fully trained**

**Data:** safety & performance data and health economics data

**Sample size:** 52 patients

**Calendar:** completion anticipated in H1 2025

## **Objectives:**

- drive product adoption
- support value proposition and get French reimbursement
- support PMA in the US

# Encouraging Sales Dynamics

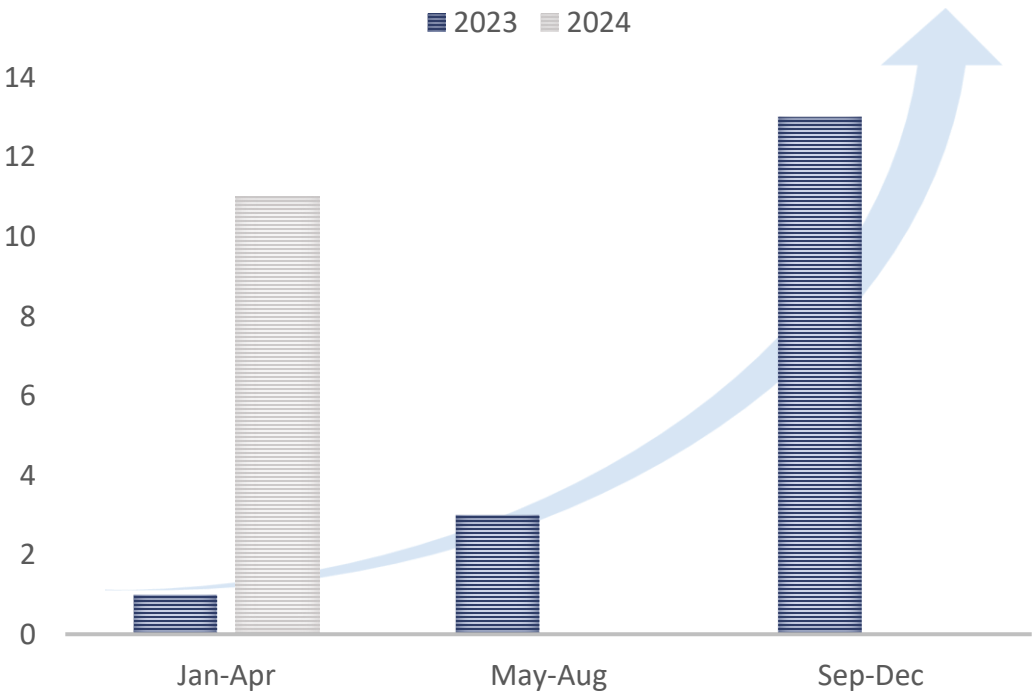
**67%** of trained hospitals referred patients

**39%** of trained hospitals made implants

**4** new sites performed their first implants in 2024

**3** patients a month over Jan-April 2024

## Sales Trajectory (# devices)



## Promising sales dynamics



# Commercial Levers Supporting Sales Momentum in 2024

## Market development

- Germany/DACH & Italy to remain key focus areas
- Market expansion in Europe and Middle-East
- Train additional hospitals and Convert trained hospitals into implanting sites

## Secure reimbursement for Aeson®

- Progressively extend reimbursement coverage in Germany
- Carve-out innovation funding in other countries

## Customer engagement

- Build upon growing customer experience and KOL support
- Carry-on building referral pathway

# Increase Customer Engagement Leveraging Growing Clinical Experience

Surgeons

+

Intensivists

Case Reports/Publications

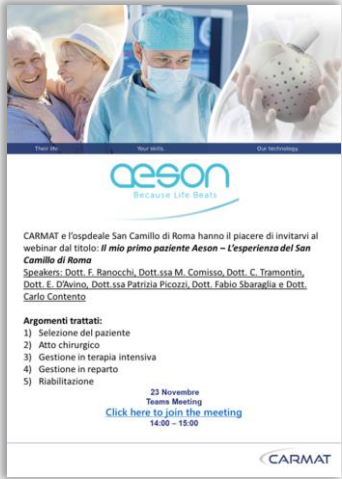
Webinars/Local Symposia

Dr. Acard (Paris) @ SITO Conference

Dr. Wilbring (Dresden) @ EACTS MCS SUMMIT



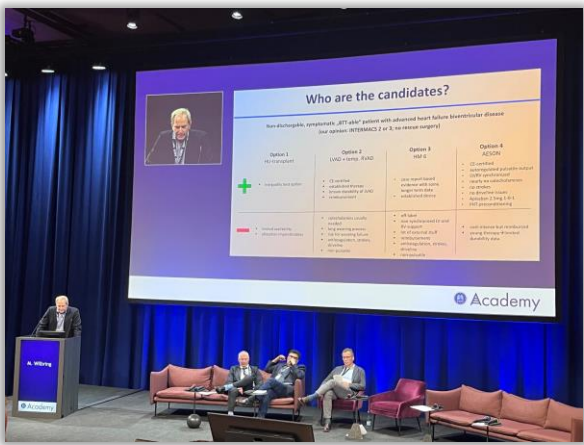
September 2023



November & December 2023



October 2023



November 2023

Towards wider adoption of Aeson® by the medical community



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# Manufacturing Scale-Up on Track

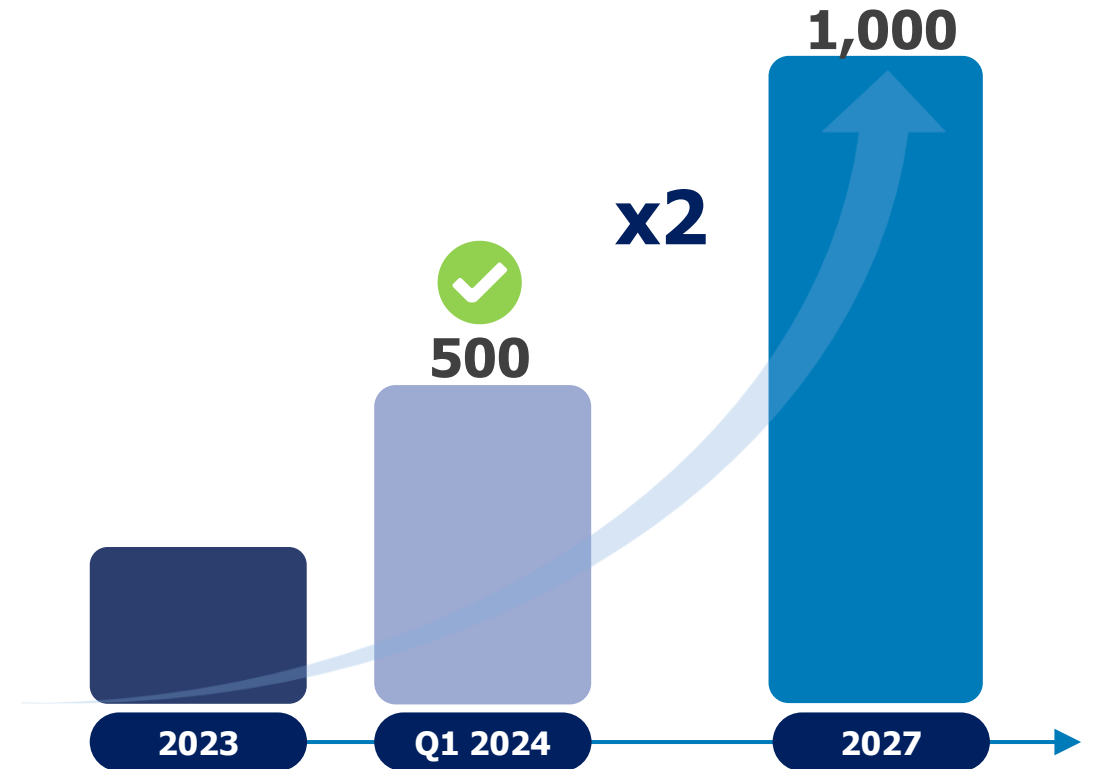
## Step 1 - Manufacturing capacity raised to 500

- 2<sup>nd</sup> production building ('BDA2') certified and active
- Ca. 30 products on shelf
- 2024 output in excess of 100 devices

## Step 2 – Further increase to 1,000+ by 2027

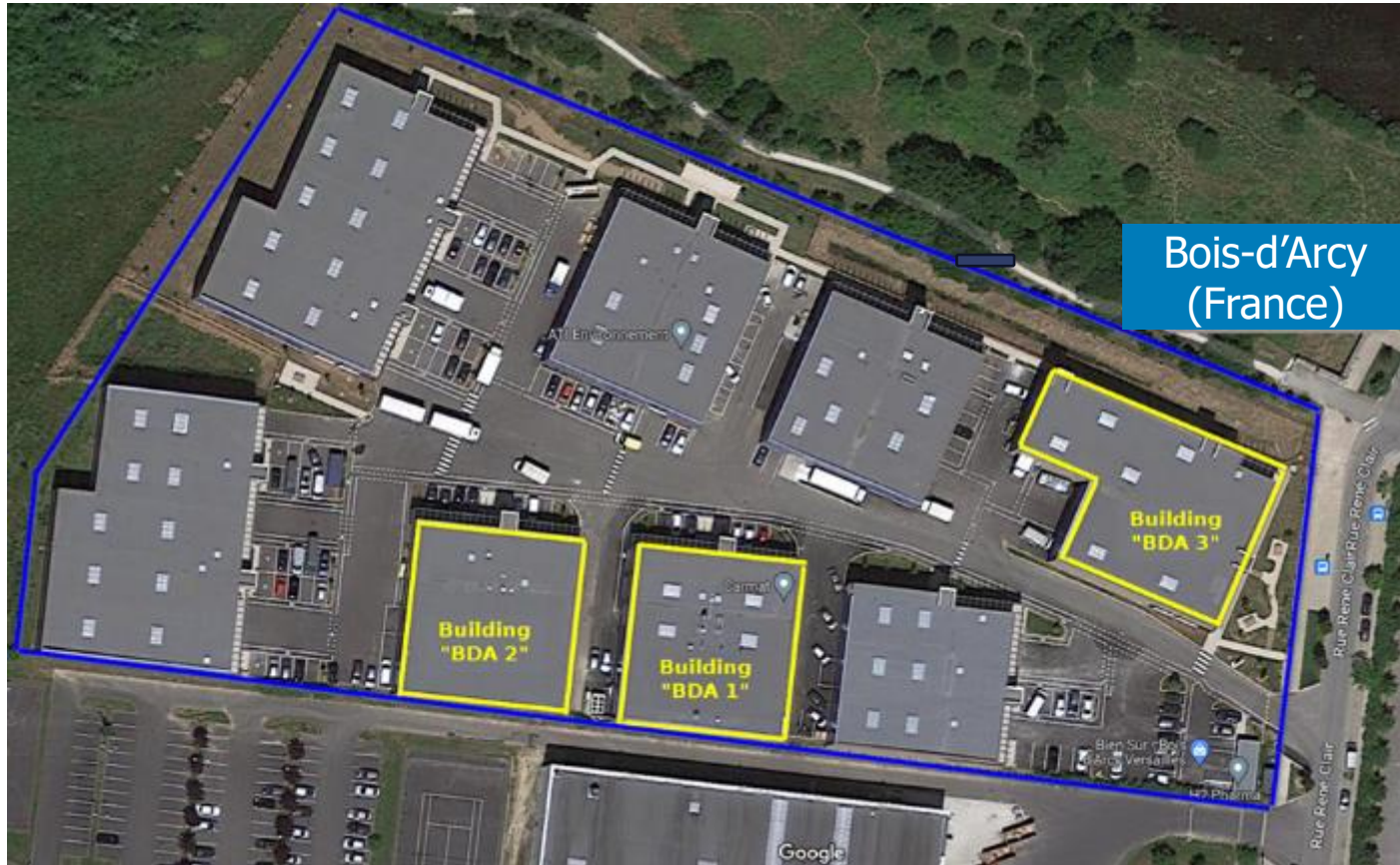
- Options currently being considered

## Ramping up manufacturing capacity





# New Production Building ('BDA2') Certified in Q4 2023 and Active



**Manufacturing capacity increased to 500 hearts/year as of Q1 2024**

# Financial Guidance

2024



**Annual Sales c. €14m**

- 50 hospitals trained for commercial implants by YE
- 30 implants in EFICAS study in 2024
- Right level of inventory

2027



**Breakeven**

- Strong sales momentum
- Drastic COGS reduction
- US Launch in 2027



# Navigating the road to breakeven

**Cash runway until end-May 2024**



- **Equity raise of €16.5m in January 2024**

**Financial debt successfully restructured**



- **Maturity of all loans postponed by 2+ years**
- **2024-2025 : No significant repayments**
- **2026-2028 : Repayments in cash reduced via 'equitization' of the EIB loan**

**Cash-burn reduction**



- **Strong financial discipline**
- **Targeting 20% cash-burn reduction between 2023 and 2024**

**Further financing in the short-term and beyond**



- **Equity raise in the very short-term to extend cash runway**
- **Further equity raise(s) within 12 months**

# Key Financial Metrics

€m	2021	2022	2023
Sales	2.2	0.3	2.8
Net Profit (Loss)	(61.9)	(53.7)	(53.9)
Cash (end of period)	39.2	51.4	8.0
Financial Debt	52.0	55.3	57.6

- Targeting cash-burn of c. €4m / month in 2024 (vs c.€5m in 2023)



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# A huge opportunity

**Total addressable market  
of \$40+ bn by 2030**



- Out of 200,000 patients p.a., only 6,000 benefit from a heart transplant
- Current indication (BTT) sufficient to generate more than \$1bn p.a. within a 10-year horizon

**CARMAT poised to lead heart  
replacement segment**



- Superior technology vs. alternatives
- Significantly ahead of all other artificial heart project

**Hospital capacity in place**



- Build referral pathway for advanced Heart Failure patients

**Manufacturing capacity in place**



- Current capacity of 500 devices a year
- Continued investment behind manufacturing capacity to meet the growing demand for Aeson®

# Strategic roadmap and key forthcoming milestones

## 2024 objectives

- 1 Successful sales uptake in Europe
- 2 Reach 75% in EFICAS study enrolment (France)
- 3 Ca. 50 centers trained for commercial implants
- 4 Ca. 20% cash burn reduction vs. 2023
- 5 Filing for EFS resumption (cohort 2) in the US

**2024 annual sales c. €14m**

## Mid-term objectives

- 1 Increase manufacturing capacity beyond 1,000 devices p.a. by 2027
- 2 Achieve reimbursement in all key geographies
- 3 Drastic COGS reduction
- 4 Strengthen manufacturing supplier base
- 5 US market launch in 2027

**2027 breakeven**

**Our ultimate objective: become the 1<sup>st</sup> total artificial heart approved for Destination Therapy (DT) to address the donor organ shortage**

# Why invest in CARMAT now?

- 1 A huge total addressable market
- 2 A superior and unique technology
- 3 A proven leadership team
- 4 A fully-fledged company at commercial stage
- 5 And considerably undervalued in view of current sales uptake







**THANK YOU**



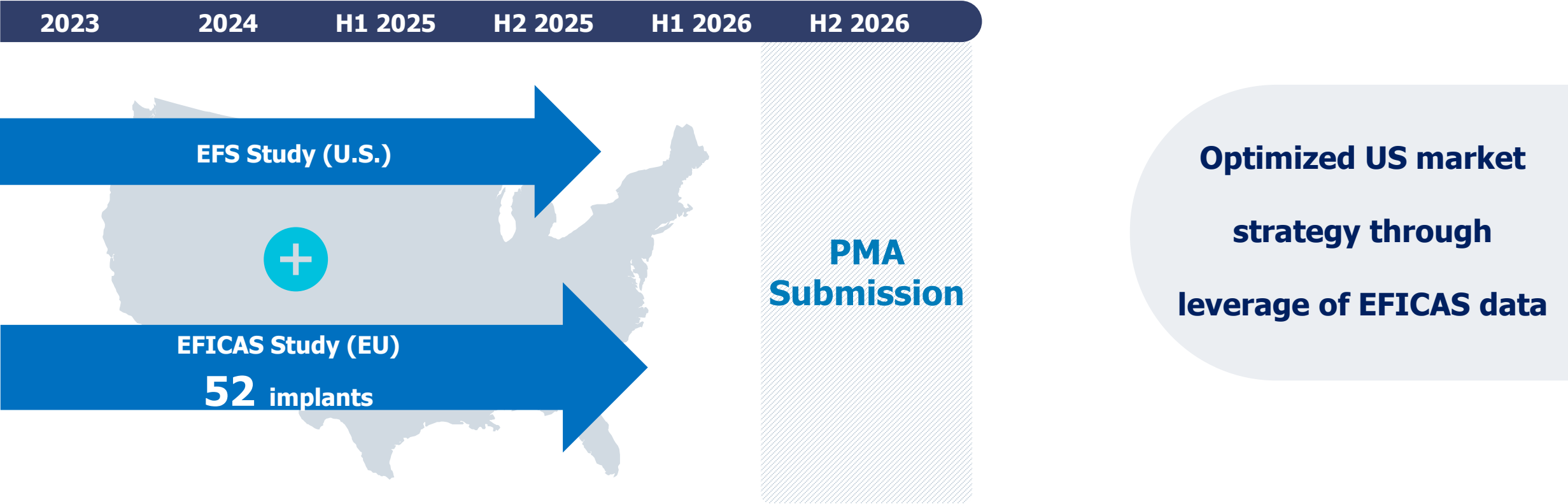


# BACK-UP SLIDES

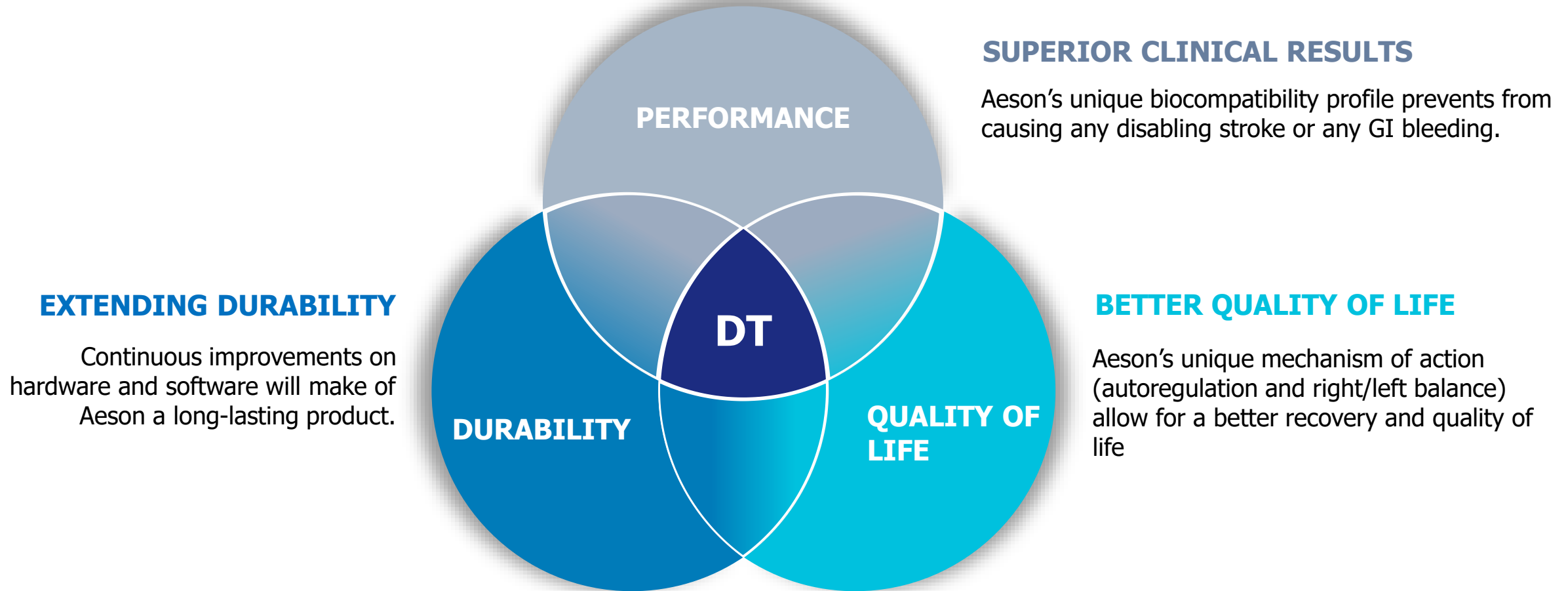


# U.S. Market Access

Early Feasibility Study (EFS) and EFICAS data: Gateway to US approval (PMA)



# Horizon Destination Therapy



**AESON® is the best positioned device for Destination Therapy (DT)**