



# THE NEXT REVOLUTION IN CARDIOLOGY

Business Update  
January 23, 2023



Their life.



Your skills.



Our technology.

# Safe Harbor

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*Aeson® is an active implantable medical device commercially available in the European Union and other countries that recognize CE marking. The Aeson® total artificial heart is intended to replace the ventricles of the native heart and is indicated as a bridge to transplant in patients suffering from end-stage biventricular heart failure (INTERMACS classes 1-4) who are not amenable to maximal medical therapy or a left ventricular assist device (LVAD) and are likely to undergo a heart transplant within 180 days of the device being implanted. The decision to implant and the surgical procedure must be carried out by healthcare professionals trained by the manufacturer. The documentation (clinician manual, patient manual and alarm booklet) should be read carefully to understand the characteristics of Aeson® and information necessary for patient selection and the proper use of Aeson® (contraindications, precautions, side effects). In the United States, Aeson® is currently exclusively available within the framework of an Early Feasibility Study authorized by the Food & Drug Administration (FDA).*

*January 2023, CARMAT SA, France*

# Speakers



**Stéphane Piat**  
*Chief Executive Officer*

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



**Francesco Arecchi**  
*Director of Global Market Development*

- Over 15-year experience in Sales and Marketing in global companies in the health sector
- Previously Product Manager EMEA Structural Heart at Abbott



**Dr Piet Jansen**  
*Chief Medical Officer*

- Over 20-year experience in cardiology sector, notably in Mechanical Circulatory Support devices
- Former Medical Director at World Heart Corp, & VP Clinical Affairs at Jarvik Heart



**Pascale d'Arbonneau**  
*Chief Financial Officer*

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

# Agenda

**I. CARMAT Achievements**

**II. Clinical Update**

**III. Commercial Strategy**

**IV. Manufacturing and Finance**

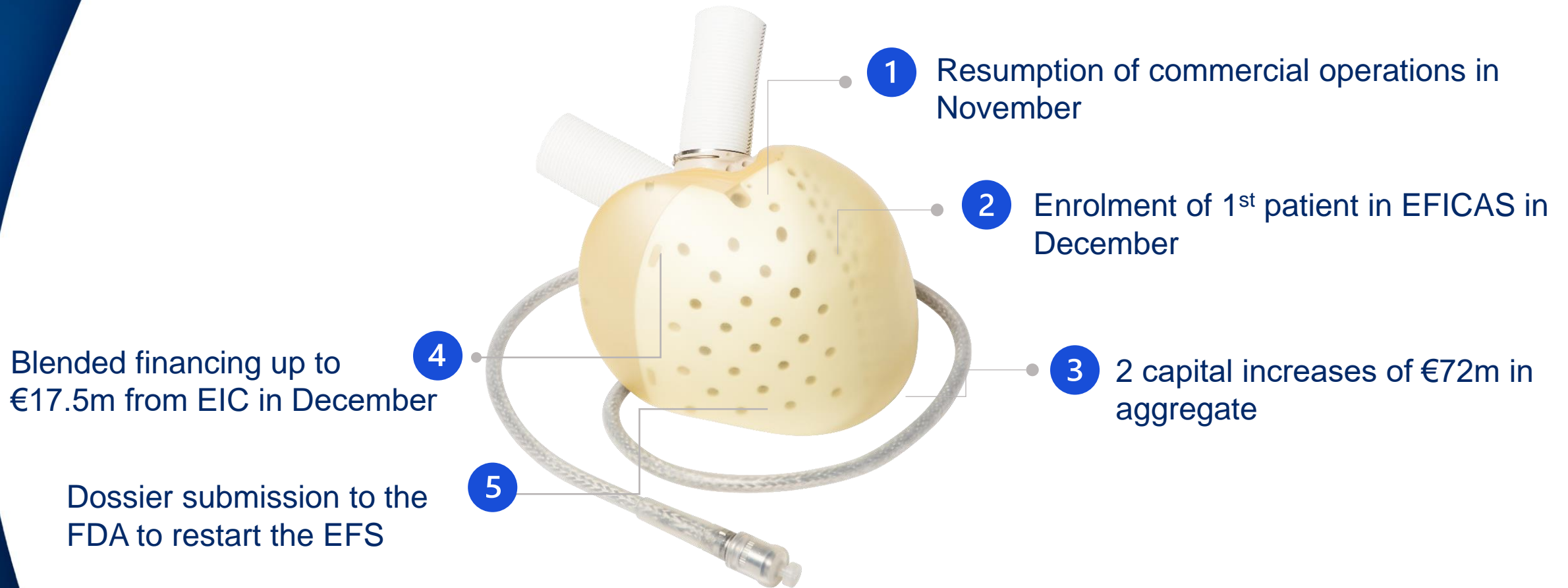
**V. Outlook**



## **I. CARMAT Achievements**

# 2022 milestones

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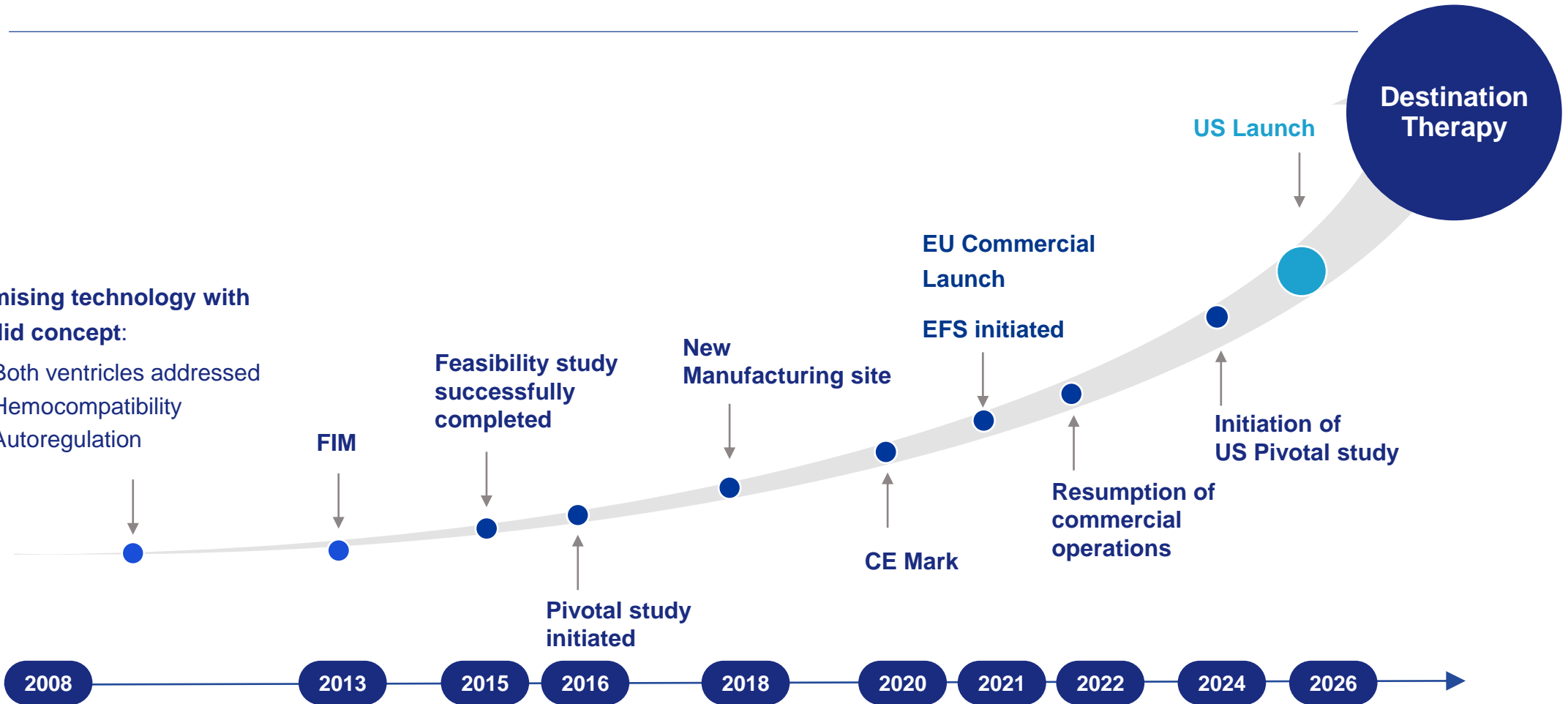


 The past year allowed us to build a strong relationship with our suppliers and our customers

# CARMAT roadmap

Promising technology with a solid concept:

- Both ventricles addressed
- Hemocompatibility
- Autoregulation



 CARMAT outperformed all competitive projects



## **II. Clinical Update**



# The Aeson<sup>®</sup> Artificial Heart distinctive features



1

- Biological blood-contacting surfaces
- Minimized shear-stress
  - Acquired Hemocompatibility
  - Low-intensity anticoagulation

2

- Biventricular, full pulsatility
- Electro-hydraulic actuation
  - Physiological flow
  - Silent operation

3

- Pre-load triggered flow autoregulation
  - Activity-based output variation

Combination of unique features provides for safety and quality of life improvement

# Clinical Experience



**33** patients

suffering from advanced heart failure have been treated with the Aeson® TAH



The longest support duration exceeded

**25** months



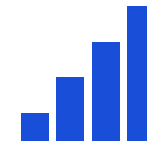
**11** patients

have been transplanted after Aeson® support

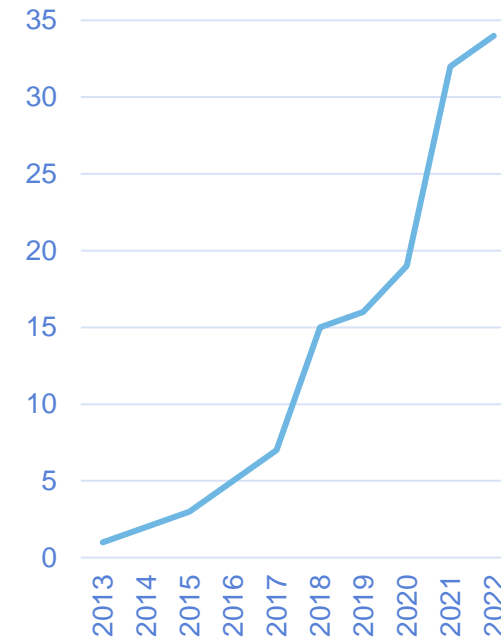


The cumulative experience is

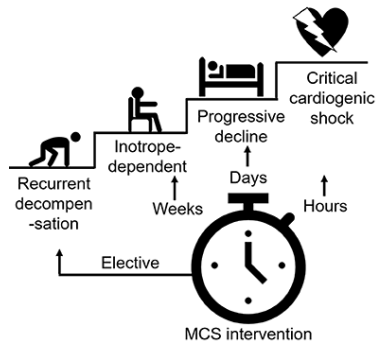
**15.5** patient years



Aeson® Implants (Cumulative)



# Patient Selection



**Knowledge base from Medical Proctors**

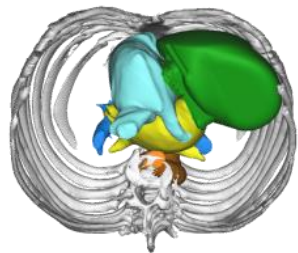


Available to assess benefit/risk for patient and define the right timing for intervention

**Growing Confidence**



It allows for selecting high risk patients in real-world-experience



**Carmat Virtual Implant Tool**



Anatomical compatibility has evolved with experience in smaller patients

# Surgical Procedure and Recovery



- **Evolved from experimental technique** to Proctor-guided approach
- Implant procedure **100% successful**
- **Growing experience from elective cases** to redo surgeries and patients already supported by another MCS



- **Flow autoregulation** delivers immediate recovery of physiological blood flow and organ perfusion
  - ⇒ **optimize condition for quick hospital discharge** for future heart transplant



- **Heart transplant done** in 11 Aeson<sup>®</sup> recipients
- Explant procedure **100% successful**

# Aeson<sup>®</sup>'s unique competitive advantages

4 essential requirements to provide physiologic replacement without complications



SynCardia TAH



BVAD



Aeson<sup>®</sup> TAH

|                          | SynCardia TAH | BVAD | Aeson <sup>®</sup> TAH |
|--------------------------|---------------|------|------------------------|
| 1 Biventricular Support  | ✓             | ✓    | ✓                      |
| 2 Pulsatility            | ✓             | ✗    | ✓                      |
| 3 Autoregulation         | ✗             | ✗    | ✓                      |
| 4 High hemocompatibility | ✗             | ✗    | ✓                      |

Full physiologic replacement

## Unparalleled Safety Profile



No stroke



No gastrointestinal bleeding



No infection at driveline exit site

# Game Changing Therapy for Advanced Heart Failure



## Their Life



### Quality of life

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

## Your Skills



### Safe surgical procedure

- Patient selection with Proctors
- Virtual implant tool
- 100% Successful procedure
- Fast recovery

## Our Technology



### Sustainable support

- Auto-pilot setting
- Immediate restoration of physiological flows
- Unique hemocompatibility profile



### **III. Commercial Strategy**

# Strong Customer Advocacy

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“ Aeson<sup>®</sup> works as  
a healthy heart

“ Best in class  
clinical support

“ Patients do not have the  
MCS complications

“ Excellent training



# Driving Good Clinical Outcome

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**Committed  
Field Team**

**Experts  
Training**

**Case  
Coverage**

**Medical  
Proctoring**

**Patient  
Screening  
Support**

# Flawless Medical Staff Journey to Autonomy



# Commercial Roll-out for 2023

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**PRIORITIES:** DACH region  
(Germany, Switzerland and  
Austria) and Italy

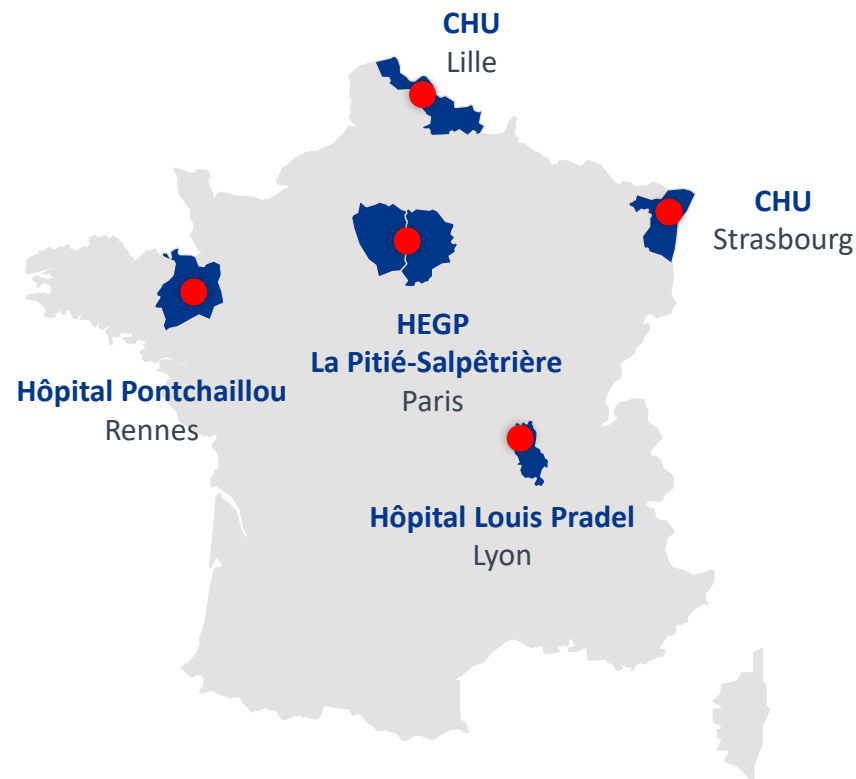


## OBJECTIVES

- 30 hospitals implant ready by end of 2023
- Secure reimbursement/funding
- Scale up organization for market expansion

# EFICAS study as platform for commercial launch in France

## EFICAS STUDY SITES



- **Objective:** safety & performance data and health economics data
- **Sample size:** 52 patients treated with Aeson<sup>®</sup> TAH
- **Enrollment:** started in Q4 2022, end expected in 2025
- **Study Results:** drive product adoption, support value proposition and get French reimbursement

# Game Changing Therapy in an Untapped Market

**The prevalence of cardiovascular diseases is constantly increasing**, and they have remained the leading causes of death worldwide. More than 20 million deaths in 2021<sup>1</sup>

Compared with **patients** dying of cancer, those **dying from Heart Failure have greater difficulty** with activities of daily living and are more likely to die suddenly<sup>2</sup>

**Less than 5% of patients** suffering from advanced heart failure in need of heart transplantation are treated<sup>3</sup>

**Game  
Changing  
Therapy**

**Aeson® is the first device** to provide physiologic replacement without complications<sup>4</sup>

**BTT indication** allows CARMAT to already access more than **2,500<sup>5</sup> patients a year on the waiting list in EU**



## **IV. Manufacturing and Finance**

# Manufacturing Update

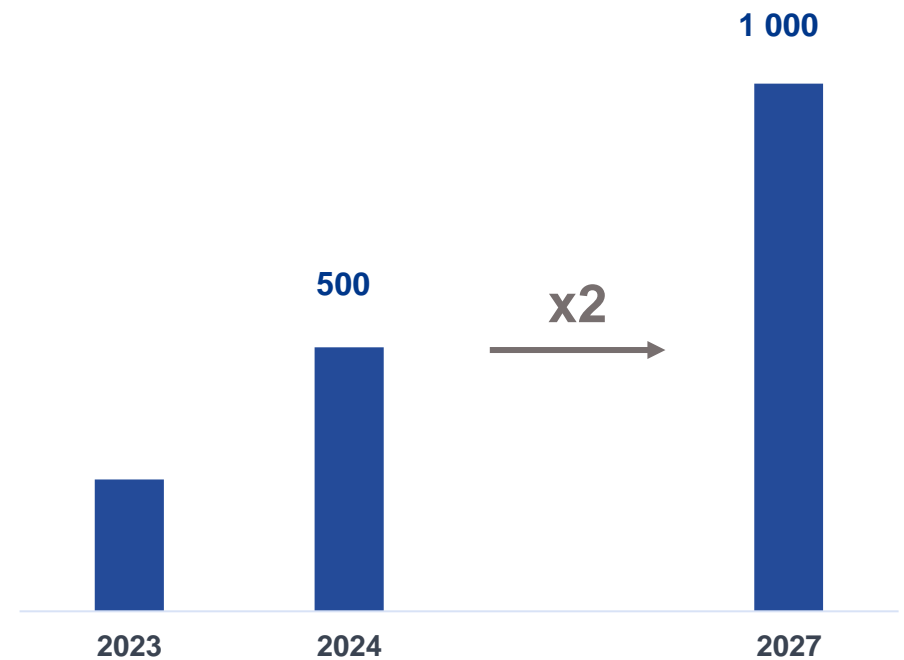
## 2023 - Gradual ramp-up of production

- Supply-chain = key challenge
- Manufacturing lead times and supply limitations
- Production in excess of 100 devices

## Beyond 2023

**Plan to reach manufacturing capacity of 500 in 2024 and 1 000 by 2027**

- 2-step roadmap in place



# Financial Guidelines

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2023

2027



## Annual Sales of €10-13m

- Phasing in line with manufacturing output
- 30 active centers commercially
- EFICAS deployment



## Breakeven

- Drastic COGS reduction
- US Launch in 2026



# Financing Update

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1

## Cash runway until July 2023

- April 2022 – Equity Raise of €41m
- Dec. 2022 – Equity Raise of €31m
- Dec. 2022 – Blended funding of up to €17.5m (€2.5m grant + €15m equity) from EU

2

## Working through a number of tangible options to extend cash runway in the short-term

3

## Path to breakeven

- Anticipate further capital increases – remain the first-line financing option
- All second-line financing options considered (dilutive and non-dilutive)



## V. Outlook

# CARMAT – a huge business potential

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1

## Total Addressable Market

- \$40+bn by 2030
- > 200,000 patients
- BTT leadership sufficient to generate more than \$1bn p.a. within a 10-year horizon

2

## CARMAT positioning

- Superior technology vs. alternatives
- Significantly ahead of all other projects
- Poised to lead Heart Transplant segment

3

## Hospital capacity

- No constraints in the short term

4

## Manufacturing scale-up

- Strong investment to increase manufacturing capacity on order to meet the demand for Aeson®

# Strategic roadmap and key forthcoming milestones

## Targets for 2023

- 1 Successful commercial take off in Europe
- 2 Enrolment in EFICAS study (France)
- 3 Complete EFS (US)
- 4 Double manufacturing capacity up to 500 devices p.a.
- 5 30 centers commercially active

**2023 – Annual Sales of €10-13m**

## Mid-term Objectives

- 1 Increase manufacturing capacity beyond 1,000 devices p.a. by 2027
- 2 Achieve reimbursement in all key geographies by 2025
- 3 Drastic COGS reduction
- 4 Strengthen manufacturing supplier base by end of 2024
- 5 Access the US market by 2026

**2027 - Breakeven**

 **Our ultimate objective: become the first Total Artificial Heart approved for Destination Therapy in order to address the donor organ shortage**



# THANK YOU

Their life. Your skills. Our technology.

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