



BUILT TO LAST

Company Update
January 31, 2022



Their life.



Your skills.



Our technology.

Safe Harbor

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The significant and specific risks pertaining to the Company are those described in the Universal Registration Document (“Document d’Enregistrement Universel”) filed with the Autorité des Marchés Financiers (AMF, the French stock market authorities) under number D.21-0076. Readers and investors’ attention is, however, drawn to the fact that other risks, unknown or not deemed to be significant or specific, may or could exist.

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 2022, CARMAT SA, France

Speakers



Stéphane Piat
*Chief Executive Officer,
CARMAT*

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



Dr Piet Jansen
*Chief Medical Officer,
CARMAT*

- 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



Carmelo A. Milano, MD
*Duke University Medical
Center*

- Professor of surgery
- Chief, section of adult cardiac surgery
- Surgical director for LVAD program
- Division of cardiothoracic surgery

Agenda

I.

2021 Review

II.

Quality Hold Update

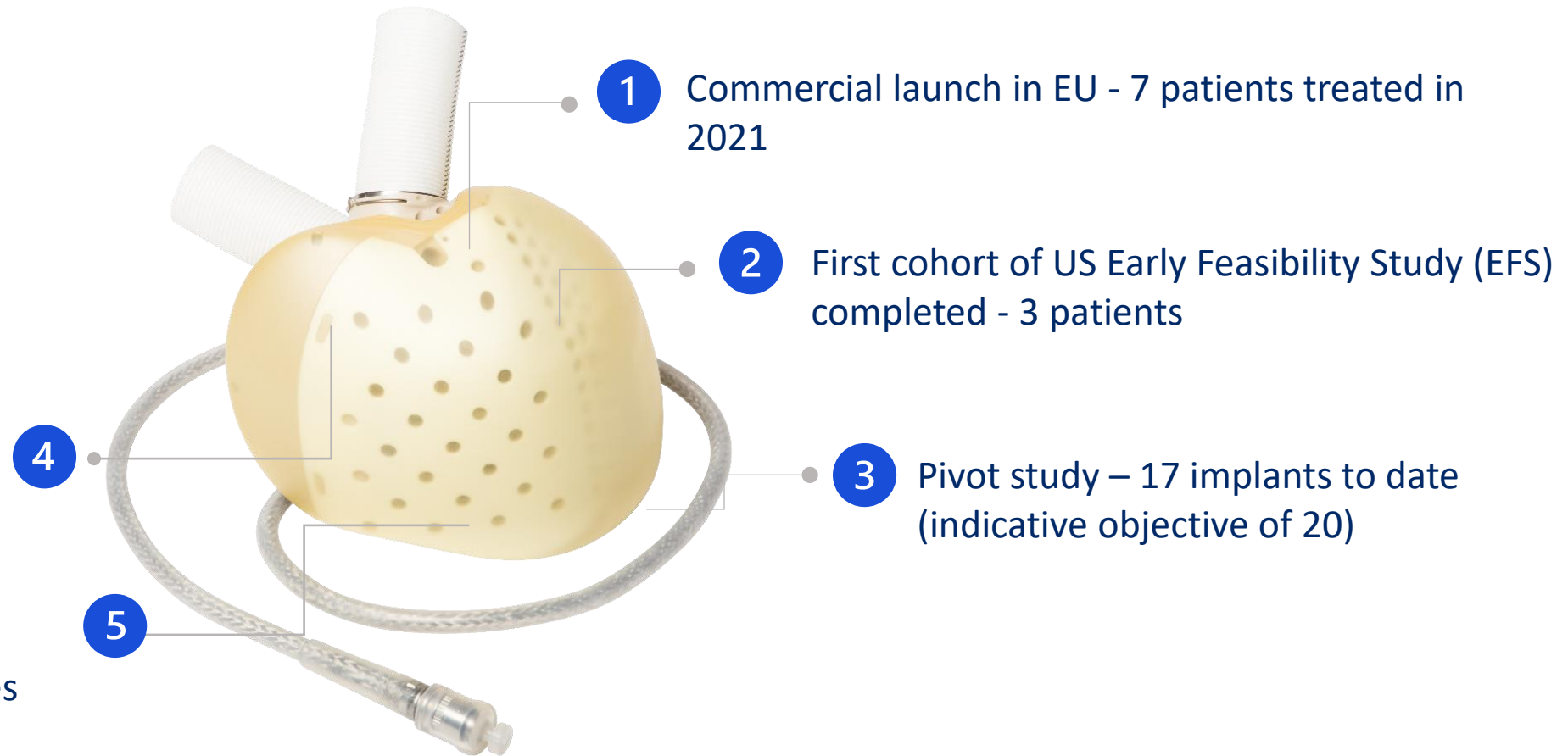
III.

Strategy and Outlook



I. 2021 Review

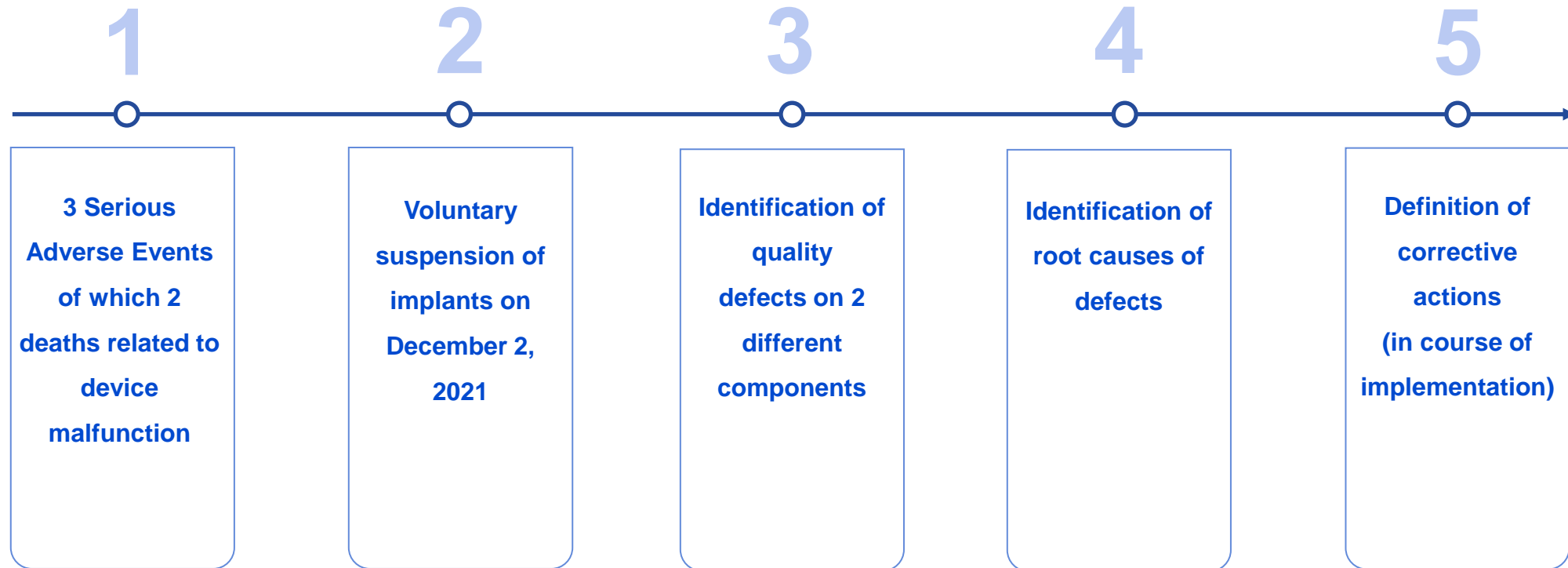
2021 at a glance





II. Quality Hold Update

Situation



 **Swift and responsible action taken through the whole process**

Next steps



 **Current expectation is to resume all implants in October 2022**

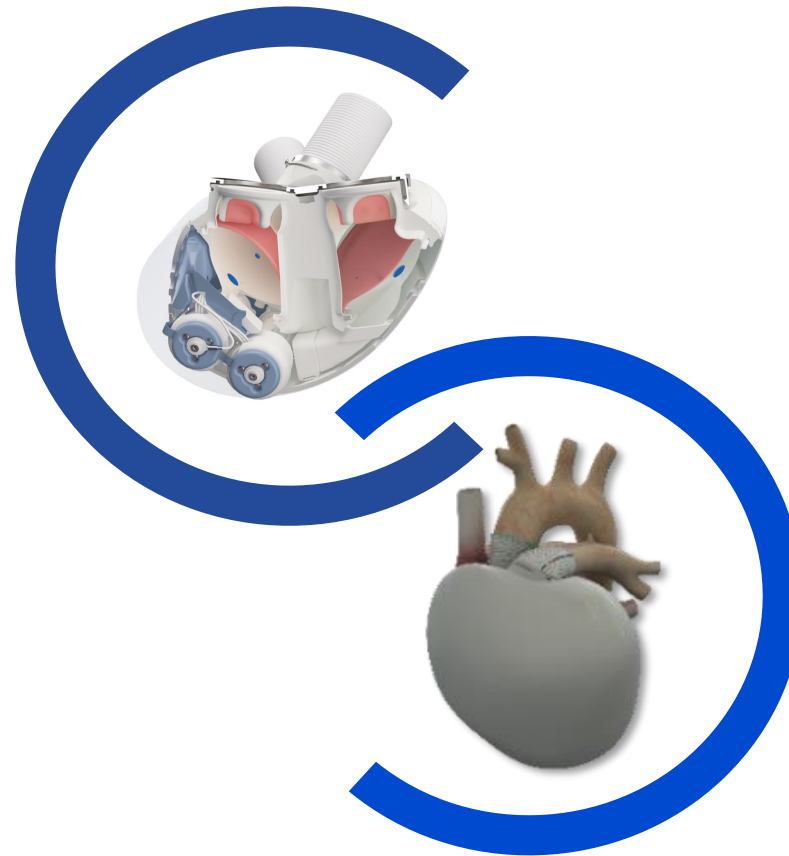


III. Strategy and Outlook

Vision and Mission

OUR VISION

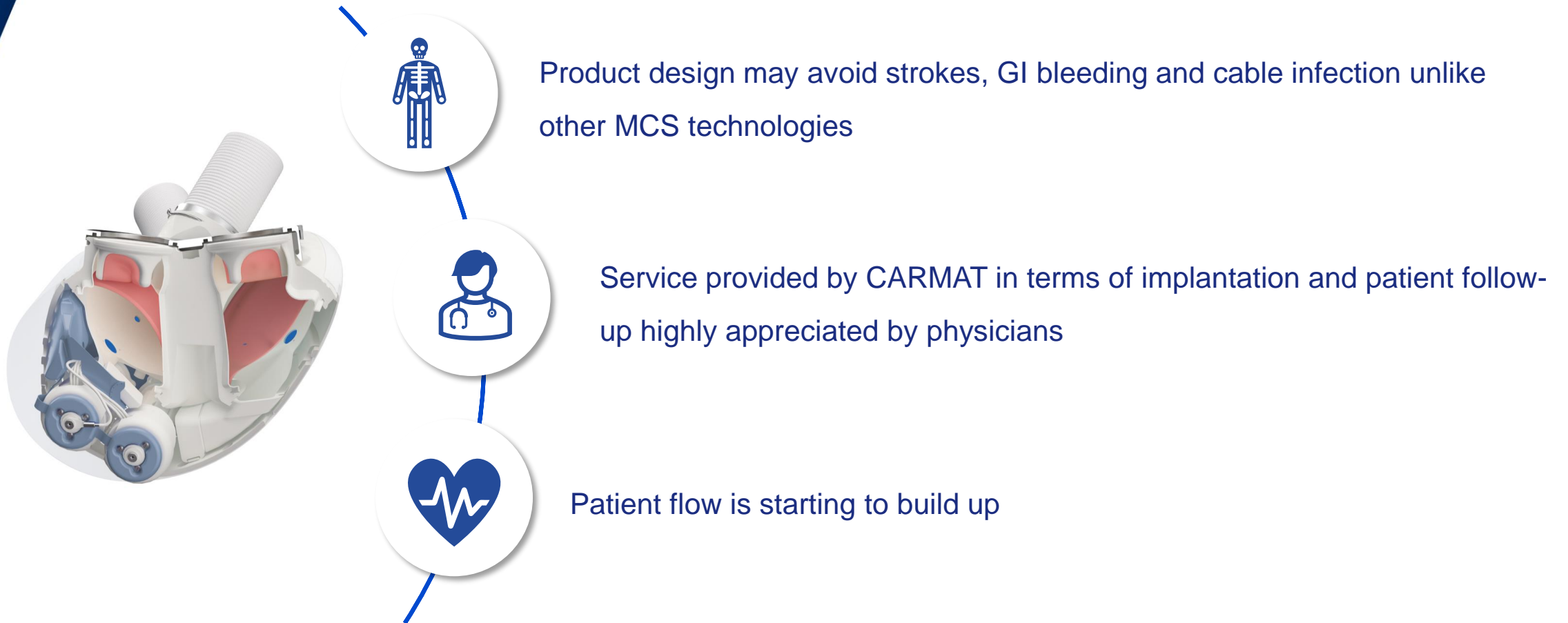
Aeson® to become the primary alternative to Heart Transplants



OUR MISSION

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

Learnings from clinical and commercial experience



 **The demand for Aeson® is high**

Voice of the customer

The Aeson[®] Artificial Heart distinctive features



A PHYSIOLOGIC HEART REPLACEMENT THERAPY



1

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

2

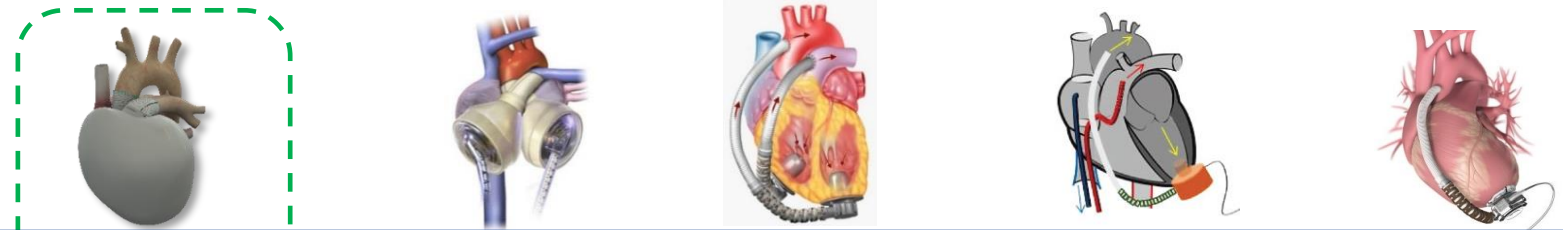
- Biventricular, full pulsatility
- Electro-hydraulic actuation
 - Physiological flow
 - Silent operation

3

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

Aeson[®]'s unique competitive advantages

4 essential requirements to provide physiologic replacement without complications



	Aeson TAH	SynCardia TAH	BVAD	LVAD + tRVAD	LVAD
1) Biventricular Support	✓	✓	✓	✓	✗
2) Pulsatility	✓	✓	✗	✗	✗
3) Autoregulation	✓	✗	✗	✗	✗
4) High hemocompatibility	✓	✗	✗	✗	✗



Full physiologic replacement

Unparalleled safety profile

The Aeson® TAH shows an outstanding 6-months safety profile in the Pivotal study, with a low rate of bleeding events, no strokes and no driveline infections.

Adverse Event Rates at 6 months				
	Re-operation for bleeding	Stroke	Gastrointestinal bleeding	Driveline infection
Aeson (n=15)*	20%	0%	0%	0%
SynCardia**	41%	23%	20%	22%
BIVAD***	n/a	7%	7%	7%
LVAD****	14%	10%	25%	10%

* Data from the Pivotal study

* Kirklin JK et al., JHLT 2018;37:685-691. Arabia F et al., JHLT, 2018;37:1304–1312. Demondion P et al., EJCS. 2013 Nov;44(5):843-8

** Lavee J et al., JHLT 2018;37:1399–1402. Arabia F et al., ATS 2018;105:548–56

*** Mehra MR, et al., NEJM. 2019 Apr 25;380(17):1618-27. Strueber M et al. JACC 2011;57:1375–82. Netuka I et al., JACC 2015;66:2579–89

Aeson[®] TAH positioning and experience

To become the first-line treatment for end-stage heart failure, as an alternative to heart transplant

Provide a reliable/durable electromechanical solution that mimics a natural healthy heart

- Without negative side effects on other organ systems
- Without impact on immune/defense system

Requirement	Aeson [®]	Clinical Experience
Hemocompatible	✓ Minimal anticoagulation requirement	▪ No stroke, no gastro-intestinal lesions/bleeding
Physiologic blood flow	✓ Pulsatile, self-regulated blood flow	▪ Automatic response to different loading conditions
Biocompatible	✓ No rejection No need for immunosuppression	▪ No device-related infection ▪ No driveline exit site infection
Long-term reliability/durability	▪ To be established	▪ Longest support 25 months
Fully implantability	▪ External power source can be embedded	



Duke University Experience

Carmelo A. Milano, MD

Professor of Surgery

Chief, Section of Adult Cardiac Surgery

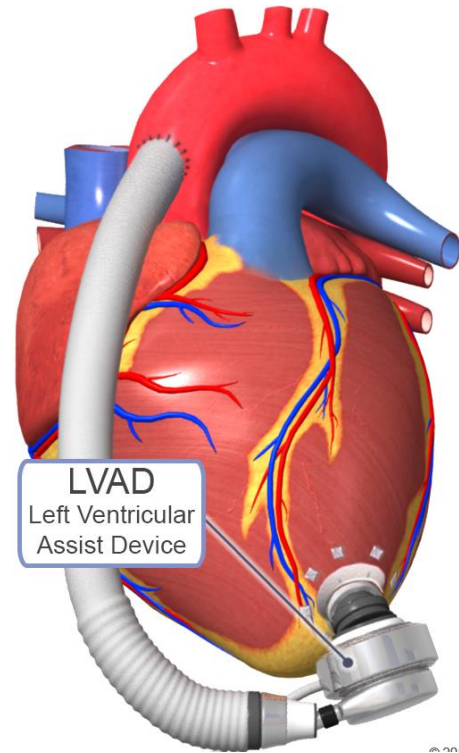
Surgical Director for LVAD Program

Division of Cardiothoracic Surgery

Duke University Medical Center

Most Common Form of Mechanical Circulatory Support is Durable LVAD

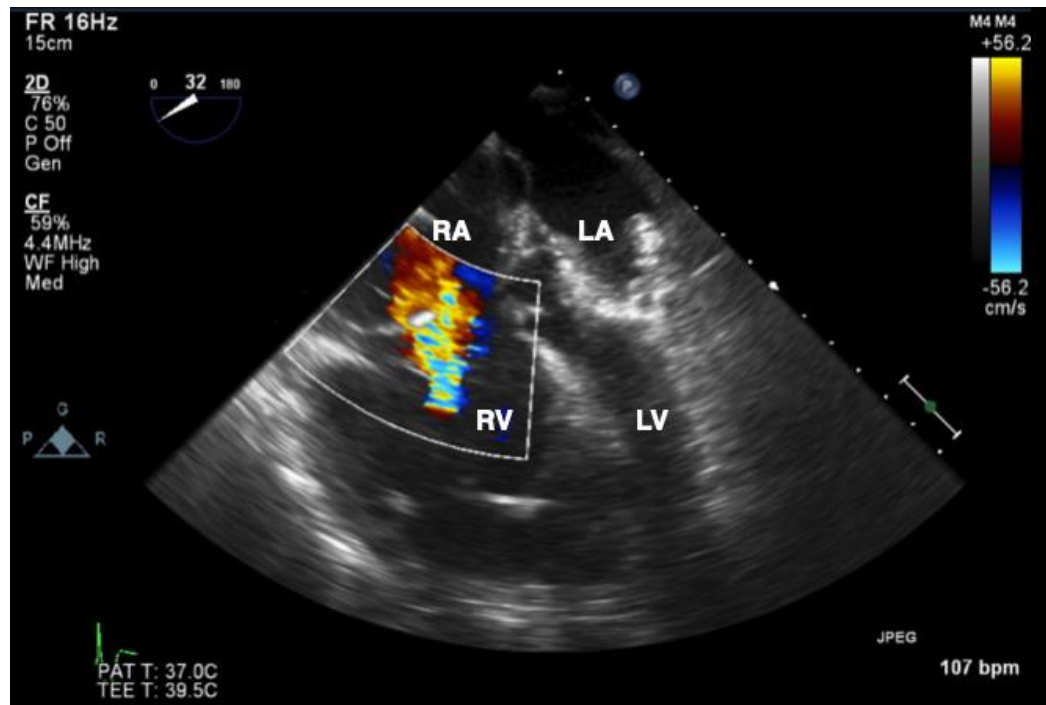
LVAD



- Duke has implanted over 1,500 patients both as a strategy to bridge them to transplant and as a final destination therapy
- Duke has been a leading enroller in LVAD trials
- Outcomes with LVAD as permanent treatment for end stage heart failure are improving (5-6 years average survival) (longest survival with durable LVAD is 13 years)

Indications for Total Artificial Heart

Failing RV after LVAD implant



- Severe biventricular dysfunction
- Restrictive cardiomyopathy
- Persistent ventricular tachycardia
- End-stage congenital heart conditions

Challenges to Total Artificial Heart Technology

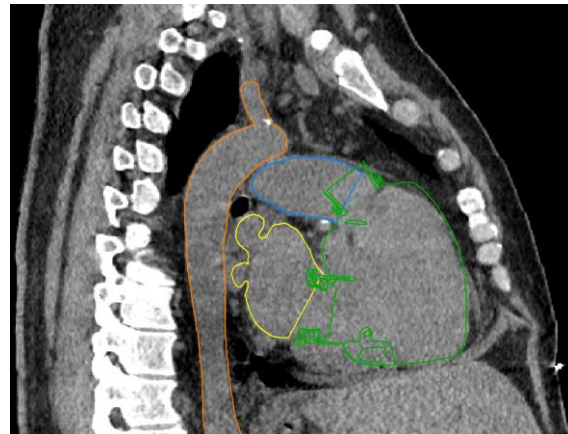
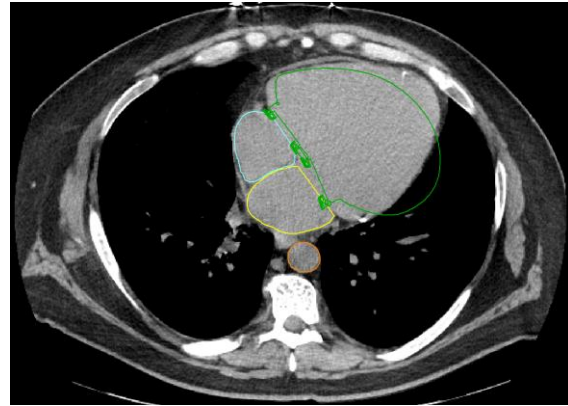
Barney Clark and Dr. William Devries



- Durable
- Thromboembolism and blood compatibility
- Balancing of right and left circulations
- Exercise response and livable

First Aeson® TAH implant in North America – Patient Screening

Anatomic compatibility assessed by CT Scan



- 39-year-old male patient from South Carolina with a history of heart attack and heart failure
- Cardiac arrest after transfer to Duke. Supported with VA ECMO and then Impella®
- Recurrent ventricular tachycardia

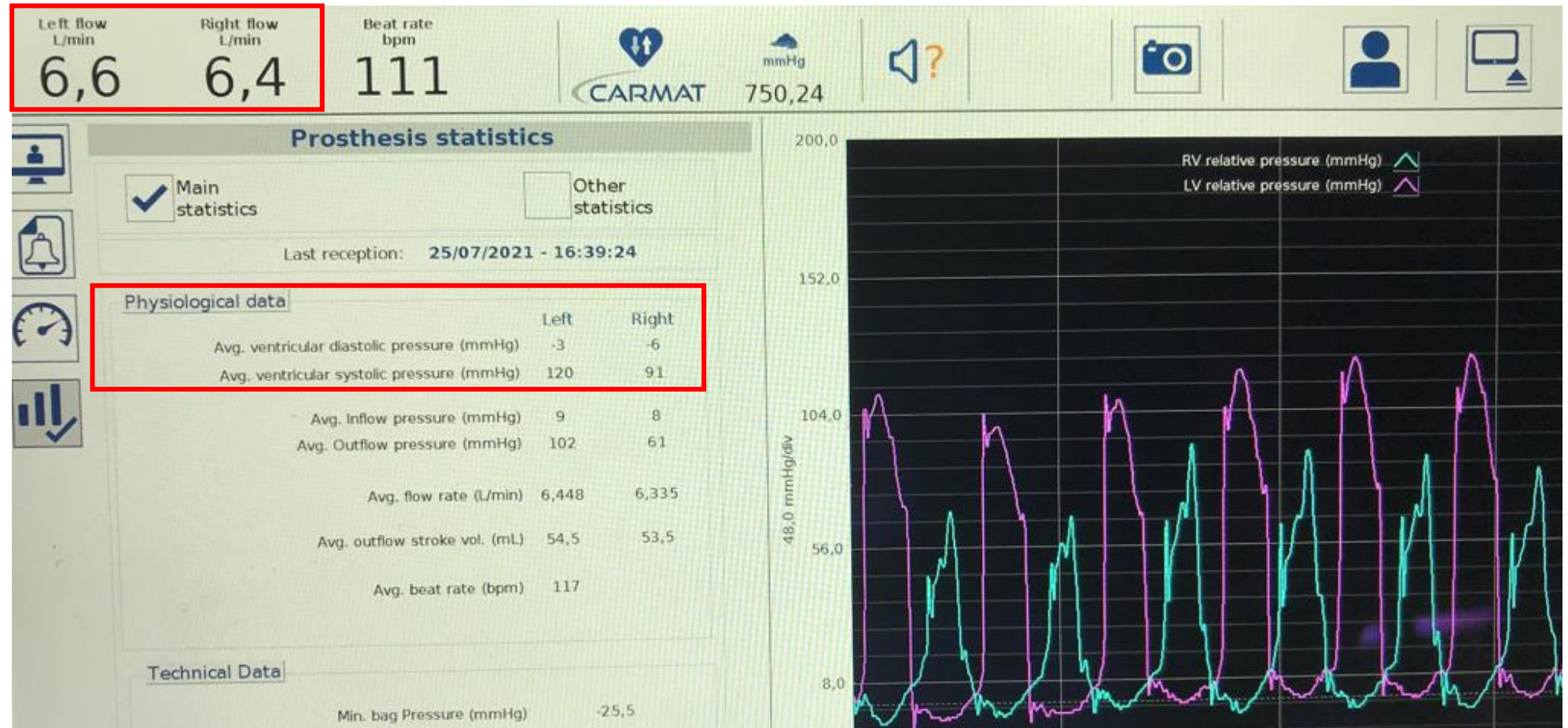
First Aeson® TAH implant in North America July 12, 2021

Aeson Implant procedure



- Duke University surgical team successfully implants new generation artificial heart in patient, first in U.S.

Patient Monitor Main Display



Restoration of Normal Hemodynamics

Patient's road to transplant

#DukeDataCenter (#Heart transplant)



- Discharged home on Aeson® TAH
- Successfully transplanted after 4.5 months on support



2022 key objectives

2022 key objectives

Manufacturing

- Implement corrective actions
- Continuous improvement on processes
- Build inventory for restart

Commercial

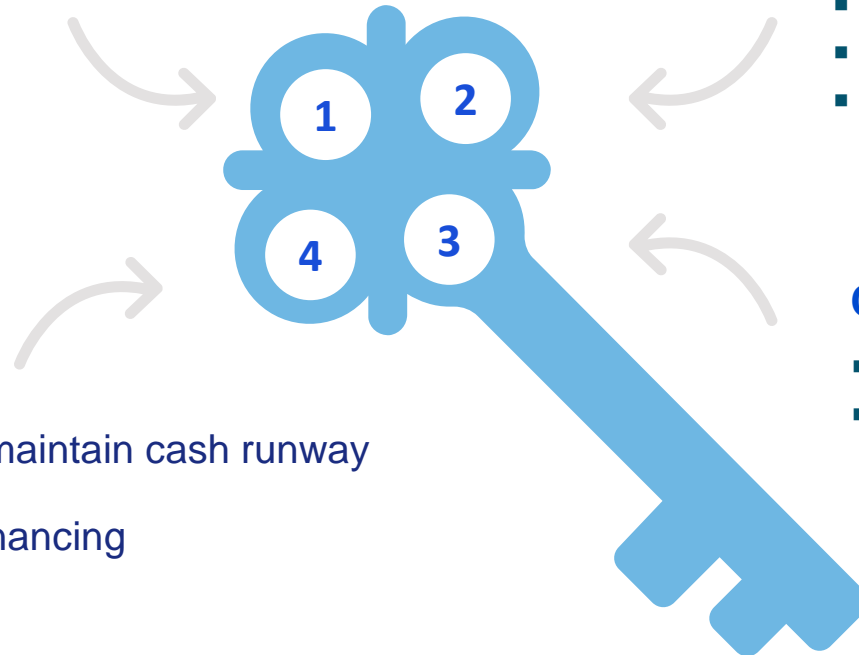
- Carry on training new centers
- Prepare for a strong restart
- Resume sales in October

Clinical studies

- Restart the EFS with cohort B in Q4
- Initiate EFICAS study in Q4

Financing

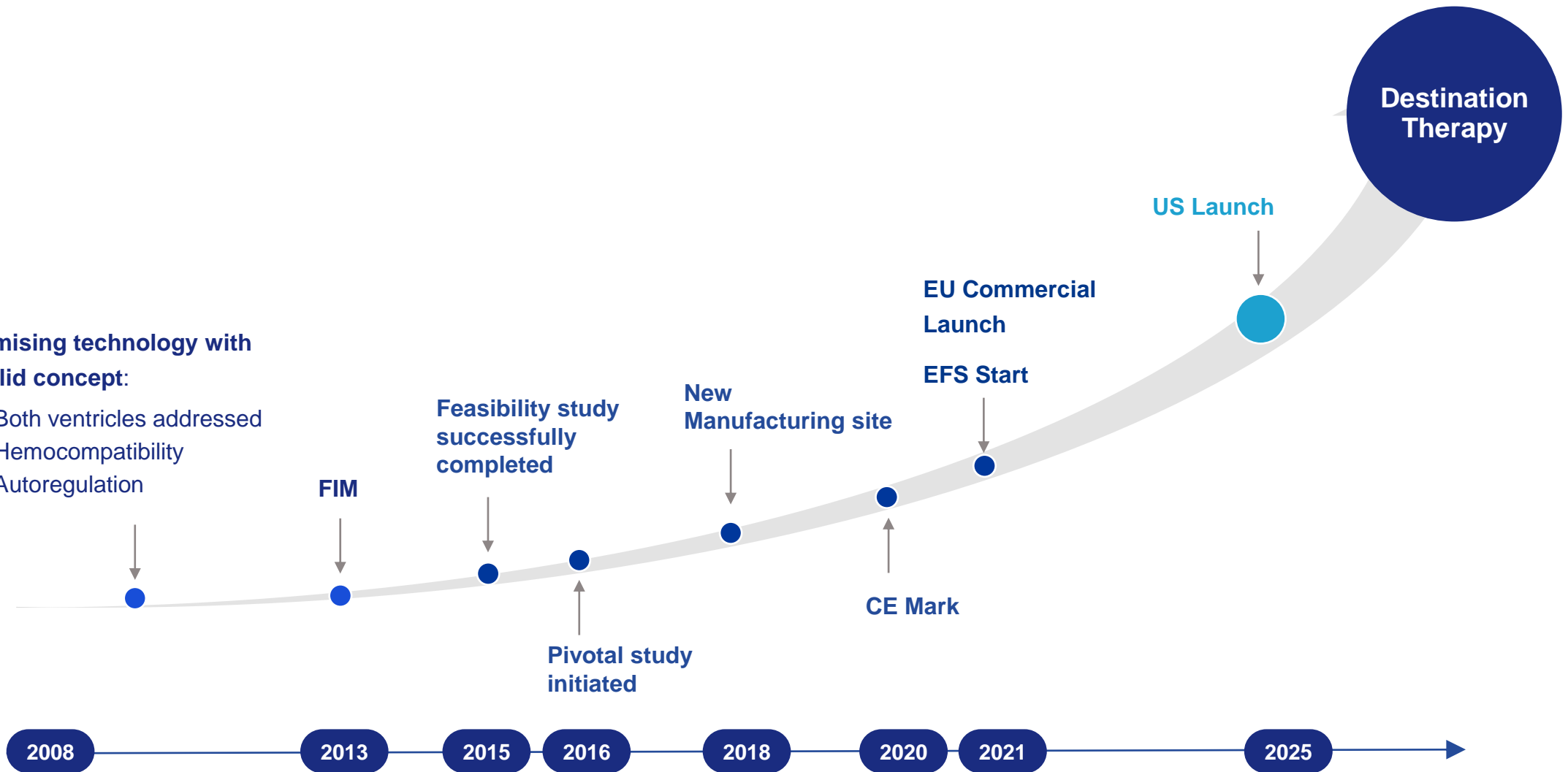
- All steps taken to maintain cash runway until July 2022
- Prepare for next financing



CARMAT – An accelerating path towards success

Promising technology with a solid concept:

- Both ventricles addressed
- Hemocompatibility
- Autoregulation





THANK YOU!

Their life. Your skills. Our technology.

The logo for CARMAT, featuring a stylized grey swoosh to the left of the word "CARMAT" in a bold, dark blue, sans-serif font.

Aeson® TAH positioning versus organ grafts

“ It will take 10-15 year before it may begin to affect practice ”
 (Dr Griffith, on Xenografts)

Unknowns: longevity (aging, growth, hemodynamics), Xenozoonosis risk, effects of immunosuppression

	Aeson®	Allograft (human heart)	Xenograft (pig heart)
Blood flow	<ul style="list-style-type: none"> Self-regulated blood flow. Automatic response to different loading conditions. Can handle high afterload pressures (aortic, pulmonary) 	<ul style="list-style-type: none"> Physiologic flow 	<ul style="list-style-type: none"> Hypertrophy may have impact on performance. Vulnerability, arrhythmia Unknow effect of aging
Biocompatibility	<ul style="list-style-type: none"> No rejection. No need for immunosuppression. Minimal anticoagulation 	<ul style="list-style-type: none"> Well-established immunosuppressive medication regimen. Known side effects on organ systems (renal, coronary). Risk of cancer 	<ul style="list-style-type: none"> Experimental immunosuppressive medication. Corticosteroids ? Unknown side effects on organ systems (renal, coronary). Anticoagulation required Susceptibility to infections.
Longevity	<ul style="list-style-type: none"> To be established via long-term reliability/durability 	<ul style="list-style-type: none"> Half-life approx. 10 years 	<ul style="list-style-type: none"> To be established (hypertrophy, CAD)
Accessibility	<ul style="list-style-type: none"> Limited by production 	<ul style="list-style-type: none"> Limited to ~6000 world-wide 	<ul style="list-style-type: none"> Experimental