



## BECAUSE WE BELIEVE THE FUTURE STARTS NOW

Investor Presentation June 2020





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### Vision and Mission



alternative to Heart Transplants with the implementation of our Total Artificial Heart (TAH).



Our mission at CARMAT is to provide quality of life for patients with advanced heart failure by creating innovative and reliable technologies that save lives.



CARMAT





### **Advanced Heart Failure**

6,000

*The number of heart transplants per year in the U.S. and EU*  60-94%

*The mortality rate of Advanced Heart Failure within a year*  The percentage of patients treated in need of transplants

**3%**<br/>
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## **CARMAT – A Combined Approach**



#### Medical

#### **Professor Alain Carpentier:**

International medical leadership in biomaterials and pericardial valves. Carpentier invented the first valve bioprostheses and developed standard techniques for plastic and reconstructive surgery of heart valves.

#### Aerospace



#### Airbus Group (EPA: AIR):

Formerly EADS MATRA, Airbus is an aerospace industry leader for the creation of complex embedded systems.

### The only bio-prosthetic, self-regulated artificial heart

- A **physiological** artificial heart that offers a viable alternative to heart transplantation
- An implantation technique easily **reproducible** by cardiac transplant surgeons
- A return to a **full life** for otherwise critically ill patients



<sup>1-4</sup> Please refer to page 27 for references

## **A Proven Leadership Team**





#### Stéphane Piat

Chief Executive Officer

- > Over 20-year experience in the medical device business
- Previously Divisional Vice President Global Market Development at Abbott
- > Johnson & Johnson Cordis (2002-2007)



#### Piet Jansen Chief Medical Officer

- Experience in cardiology sector, notably in Mechanical Circulatory Support devices
- Former Medical Director at WorldHeart, Clinical Affairs Manager at Jarvik Heart

#### Alexandre Eleonore

Director of Manufacturing

- > Manufacturing background, notably in cardiology sector
- Previously Vice President Operations and Customer Service at MicroPort CRM
- Former Manager at Faurecia, Paint Network Manager at Plastic Omnium, Vice President Manufacturing CRM and Neuromodulation at LivaNova



#### **Raouia Bouyanzer** HR Manager

- 20 years in human resources including benefits, employee relations, payroll, talent acquisition and training
- Former manager at Morgan Stanley where she held positions in social benefits, payroll and audit











#### Pascale D'Arbonneau CFO, IT

**Marc Grimmé** 

- Over 25-year experience in Finance
- Previously CFO and Head of EIBV (family office)
- Several local, regional and global VP positions at GSK in Finance, Compliance and Controlling



### Thierry Dupoux

#### Sr. Director of QA and Regulatory Affairs

- Solid QA / RA and R&D background in cardiology sector, notably in CRM and Surgery
- > Previously WW Vice-President of QA at LivaNova

#### Eric Richez BD Director

Over 13 years' experience in sales & marketing with Thoratec, a global leader in ventricular assistance devices, where he served as Sales & Marketing Director from 2002 to 2011 and Sales Director EMEA from 2011 to 2013.

#### Francesco Arecchi Marketing Manager

Career in Life Sciences companies such as Johnson & Johnson and Abbott, where he held a number of positions from sales to marketing in Cardiology breakthrough technology products such as Cypher and MitraClip.







### Market Opportunity

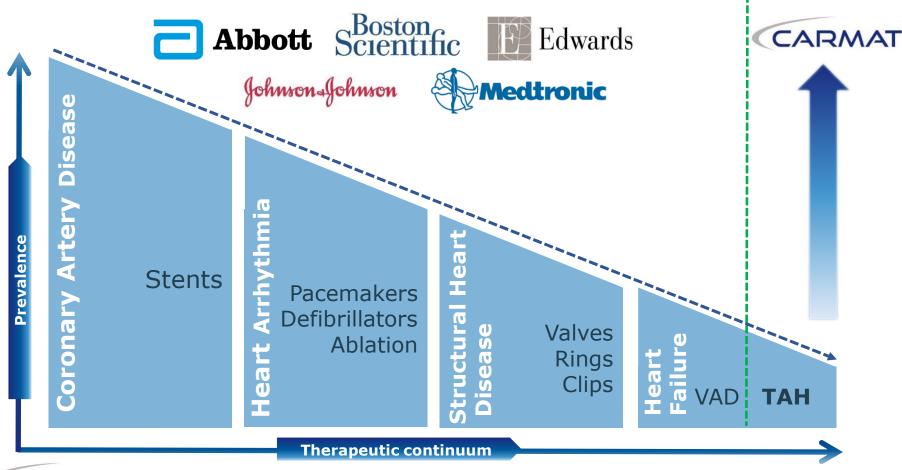




### Market Opportunity in Cardiology for Medtech Companies



#### **GLOBAL MAJOR PLAYERS IN CARDIOLOGY**



CARMAT

## Severe Unmet Need with Few Treatment Options

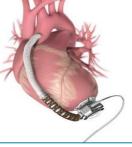


### Few treatments available with mixed outcomes

NYHA Class	INTERMACS Patient Profiles	Time to intervene	Prevalence <sup>7</sup>		SY
	1 – Critical cardiogenic shock	Hours	14%	Total	
	2 – Progressive decline	Days	41%	Total Artificial Heart	
TV	3 – Stable, inotrope dependent	Weeks	28%	Heart	
IV	4 – Resting symptoms	Months	12%		THORA
	5 – Exertion intolerant		5%		19
	6 – Exertion limited			VAD	
111	7 – Advanced NYHA Class III				













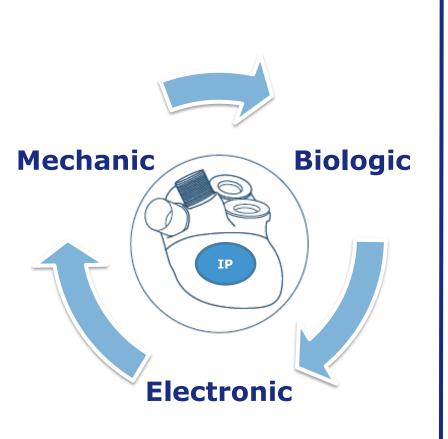


The World's Only Bioprosthetic Self-Regulated Artificial Heart



### **CARMAT's Solution**







#### **BIOCOMPATIBILITY**



Built with surfaces **made of biocompatible materials** in contact with blood that potentially reduces thromboembolic risks

#### **AUTO-REGULATION**



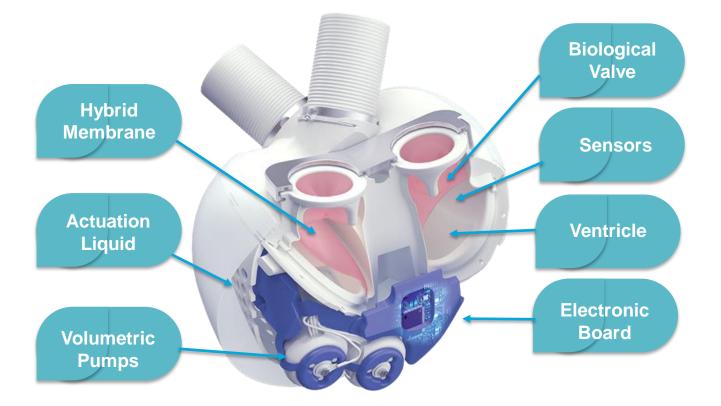
Immediate, automated response to patient's physiological needs whether they be active, inactive or transitioning activity levels





The pump unit hydraulic mimics the two parts of the heartbeat: **diastole when heart muscle relaxes and fills the chambers with blood; systole when muscle contracts and pumps blood into the arteries** 

### **Device at a Glance**

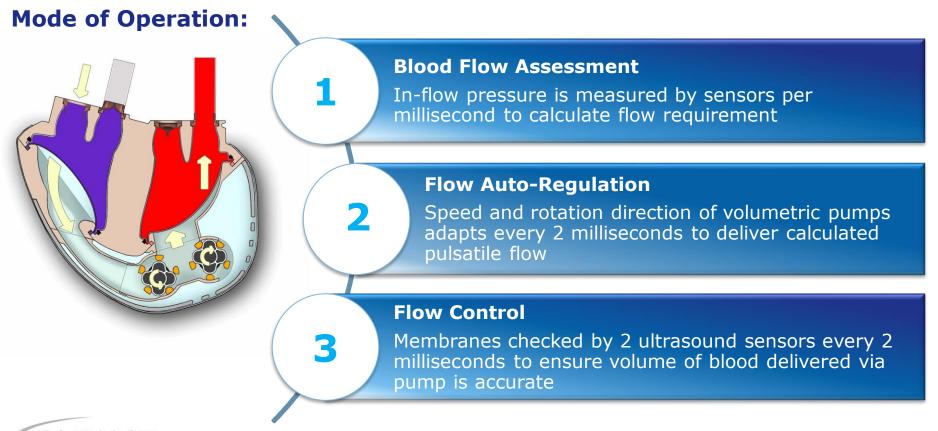




## **The Pump Mechanism**

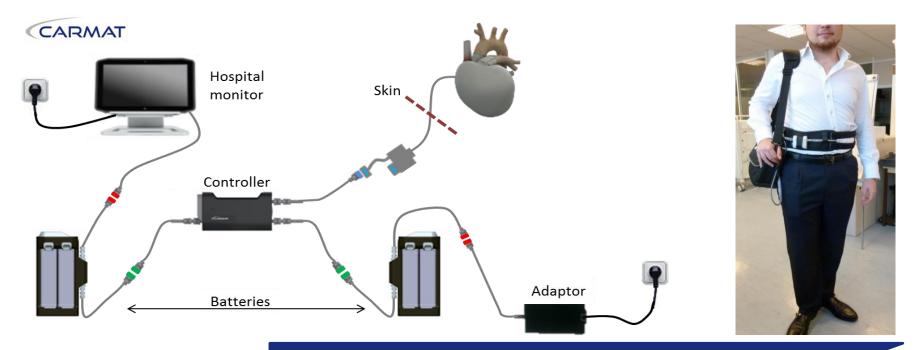
#### **Mechanic Overview:**

Volumetric pumps contained within the silicone chamber, activate the hybrid membranes allowing for blood to enter and exit the chambers





### **Portable System Overview**





CARMAT

#### **Wearable System**

- Significantly increases patient convenience and autonomy
- Controller/monitor and 2 sets of batteries
- Rechargeable power source provides between four to six hours of autonomy depending on activity level
- Total weight 3kg/6.6lbs

## **CARMAT's Unique Solution**

#### 4 essential requirements to provide physiological support without complications\*

- Biventricular Support
- Pulsatility
- Self-Regulation
- High Biocompatibility



	CARMAT TAH	Syncardia TAH	BVAD	LVAD + pRVAD	LVAD
Biventricular support	$\checkmark$	✓	$\checkmark$	$\checkmark$	×
Pulsatility	$\checkmark$	$\checkmark$	×	×	×
Self-Regulation	$\checkmark$	×	×	×	×
High Biocompatibility	✓	×	×	×	×

#### Full physiological support



\* Rogers JC et al. N Engl J Med 2017; Money L et al. ASAIO J 2020; Lai JV et al. ASAIO J 2020 Mehra M. Eur Heart J 2017; Murase S et al. J Heart Lung Transpl 2020





### **Clinical Development**





## **Ongoing EU PIVOTAL Study**



### **Cohort One**

• Completion of 10 patient enrollment for the first cohort of the study



#### **Cohort Two**

3 of 10 patients enrolled to date



#### **Enrollment Objective**

• 20 patient enrollment objective in the next 4-5 months



### **Primary Objective**

• 6 months survival



### **PIVOTAL Study Initial Results**

6-month survival rate among the first 8 of 11 patients: **73%** 

Accounting for experience factors, we expect improvement with second patient cohort

	Six Month Survival Rate			
1	CARMAT FIM	50%		
	CARMAT PIVOT (11 Patients)	73%		
<b>Ö</b>	SynCardia*	54% - 62%		
200	BIVAD**	46% - 68%		
<b>(</b>	LVAD***	90% - 92%		

\* Kirklin JK et al, J Heart Lung Transplant 2018;37:685-691. Arabia F et al, J Heart Lung Transplant, 2018;37:1304–1312 \*\* Lavee J et al, J Heart Lung Transplant 2018;37:1399–1402. Arabia F et al, Ann Thorac Surg 2018;105:548–56 \*\*\* Strueber M et all. J Am Coll Cardiol 2011;57:1375–82. Netuka I et al, J Am Coll Cardiol 2015;66:2579–89



## **Unparalleled Safety Profile**



Product A	Stroke	Surgical Repair Bleeding	Gastrointestinal Bleeding	Percutaneous Cable Infection
CARMAT FIM	0%	75%	0%	0%
CARMAT PIVOT (Part 1)	0%	27%	0%	0%

- Compared to alternative therapies, CARMAT boasts a positive 6-month safety profile in 11 patients participating in Part 1 of our Pivotal Study
- No CARMAT patients have displayed stroke, hemolysis or digestive system bleeding in the first cohort study

SynCardia*	23%	41%	20%	22%
BIVAD**	7%	n/a	7%	7%
LVAD***	8%	14%	8%	10%

\* Arabia F et al, J Heart Lung Transplant, 2018;37:1304–1312. Demondion P et al, Eur J Cardiothorac Surg. 2013 Nov;44(5):843-8. \*\* Lavee J et al, J Heart Lung Transplant 2018;37:1399–1402 \*\*\* Netuka I et al, J Am Coll Cardiol 2015;66:2579–89

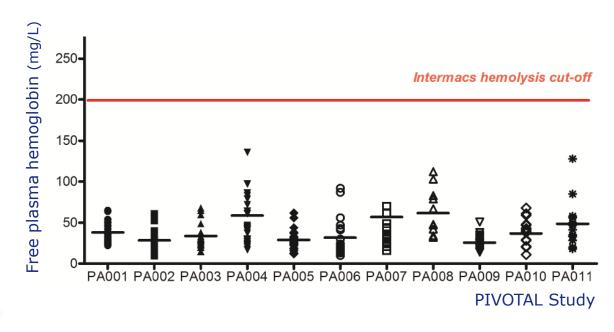


### **No Hemolysis**



- Factors causing hemolysis (red blood cell rupture) negligible for CARMAT
- Hemolysis markers (free plasma hemoglobin) ↓↓ in all patients

Factor causing hemolysis is present	LVAD	SynCardia	CARMAT
Shear Stress	++	+++	-
Synthetic Material	+++	+++	+



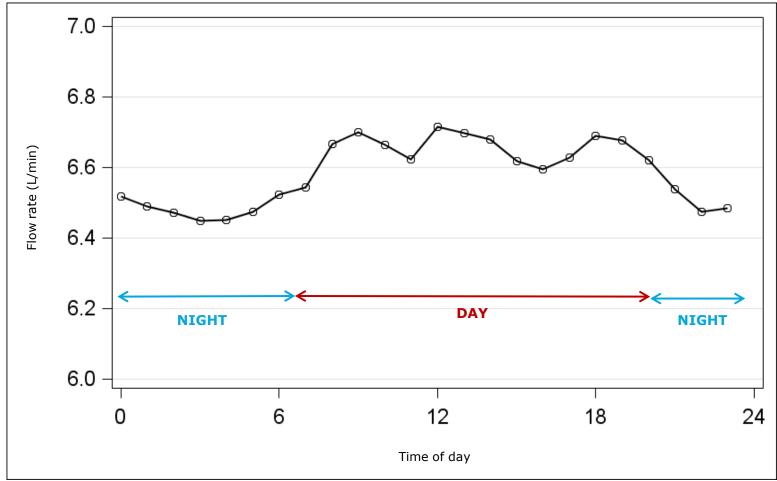


## The Prosthesis Continues to Replicate a Human Heart



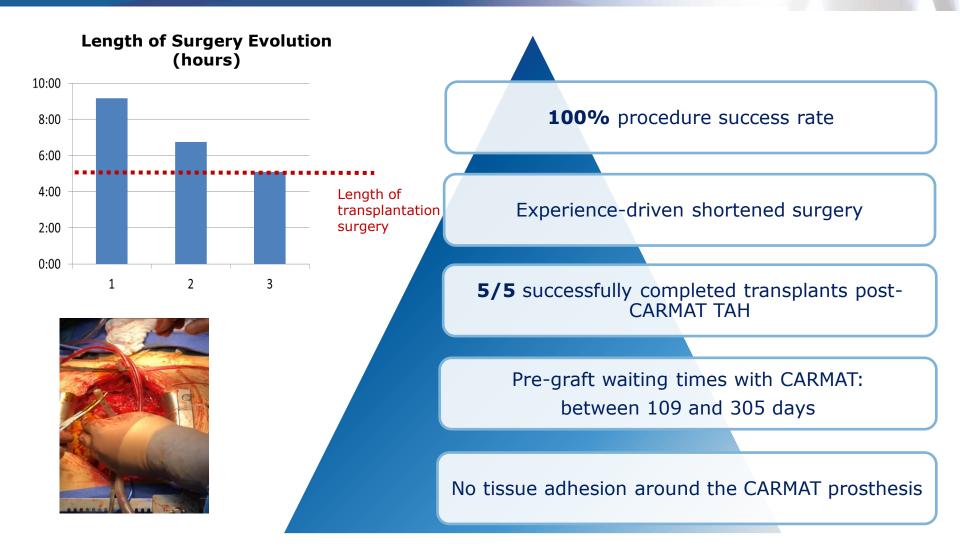
### **Circadian Cycle**

10+ months of support





## **Optimization of the Surgical Experience**





### **Improving Quality of Life**

### **CARMAT** device offers major quality of life improvements:

- Faster Recovery
- Greater mobility
- Regained physical independence
- Autonomy comparable to LVAD

Faster recovery with CARMAT TAH







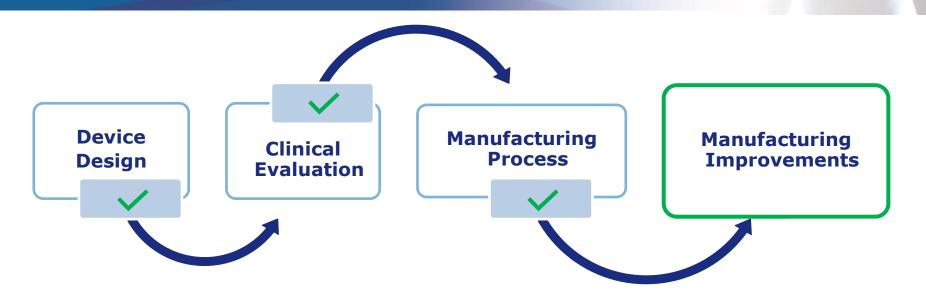


### Strategy and Outlook





## **Targeting Unmatched Support Horizon**



- Through its telemetry capacity the CARMAT device generates big data that drives continuous improvement
- Following analysis of the first cohort of the PIVOTAL study, multiple manufacturing process improvements have now been implemented
- This approach will be key to ultimately achieving the goal of providing a true destination therapy



### **U.S. Early Feasibility Study**



Study Objective: enroll first U.S. patients during 2H 2020



### **EFFICAS Study**

### **EFFICAS** in France



**Study Objective:** Complete study of 52 patients with collection of medicoeconomic data in France exclusively

### **Completed:**

- Forfait Innovation filed in Q4 2019
- Favorable HAS opinion received in February 2020

### **Outstanding:**

Working through budget negotiations





## **Upcoming Developments**





## Manufacturing & European Commercialization Updates

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### **Objective: to initiate commercial activities in the EU during 2021**

**Manufacturing** updates have increased reliability of the prostheses and allowed for better fluidity and continuity of production.



### Commercialization

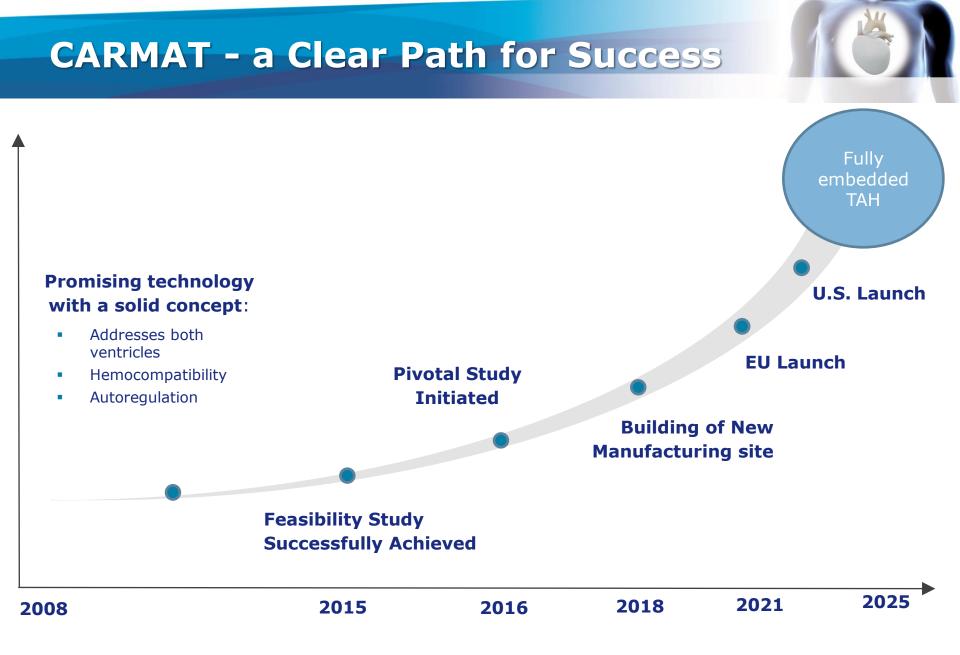
**CE Marking** 

Robust clinical file with 13 patients ongoing review of DEKRA on the technical dossier +

Start contract negotiations with German hospitals

Marketing











### **Financial Summary**





### **Financial Performance**

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€ millions FYE 31 Dec	2017	2018	2019
Revenue	€0.0	€0.0	€0.0
<b>Operating Profit</b>	(€31.0)	(€42.8)	(€42.4)
EBITDA	(€30.3)	(€41.8)	(€41.3)
Net Income	(€29.2)	(€41.7)	(€42.6)

- Prosthesis not yet marketed no sales in 2019
- Operating expenses addressed through European market access strategy:

- 1. Continuation of the CE marking process
- 2. FDA approval to start a feasibility study in the United States
- 3. Ensure the reliability of the production processes and preparation for the ramping up at the Bois-d'Arcy plant



## **Available Financing**





#### **CARMAT** currently has financial runway to 2H 2021 including completion of EU clinical developments and preparation for commercial activities.



### **Stock Market Performance**

#### **Public Market Overview**

Ticker: EPA: ALCAR

**ISIN Code:** FR0010907956

**Industry:** Health Equipment and Services

**Share Price:** €18.16

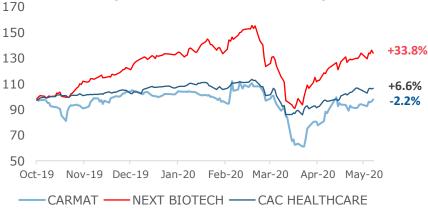
Shares Outstanding: 12,609,649

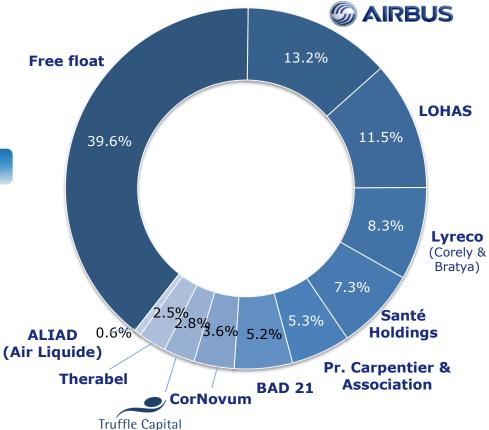
Market Cap.: €229.0m

Note: As of 2/01/20; Source: Bloomberg, Company Filings

#### CARMAT Share Price vs. Sector Indexes

(basis 100 as of 02.01.2020)







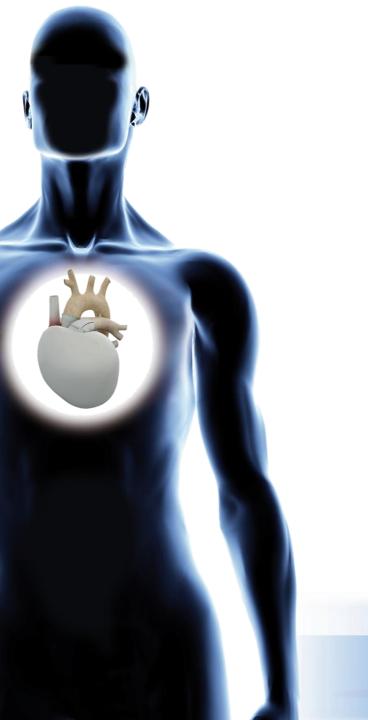




## Why Invest in CARMAT Today?

- Global technological breakthrough providing the first bioprosthetic heart based on physiological functions
- Credible solution to the problems associated with terminal biventricular heart failure, a condition steadily becoming more pervasive
- Significant clinical and technical progress to application submission and expected approval of CE mark in 2020
- Support from first-class industrial and financial partners, as well as leading players in cardiology
- Acceleration in CARMAT's transformation towards becoming an industry leading medical device company







# Thank You!