## CARMAT

### **BECAUSE WE DON'T BELIEVE THE FUTURE CAN WAIT FOR THE FUTURE**

Annual General Meeting May 12, 2021

Your skills.

Their life.



Our technology.

#### **Safe Harbor**

The following presentation and the information it contains do not constitute an offer to sell or subscribe, or the solicitation of an order to buy or subscribe, CARMAT shares in any country. This presentation may contain forward-looking statements about the Company's objectives. These forward-looking statements are based on the current estimates and expectations of the Company's management and are subject to risk factors and uncertainties such as the Company's ability to implement its strategy, the pace of development of the relevant market, changes in technology and in the competitive environment, and all risks associated with managing the Company's growth. The Company's objectives mentioned in this presentation may not be achieved due to these or other risk factors and uncertainties. No guarantee can be given as to any of the events anticipated by the forward-looking statements, which are subject to inherent risks, including those described in the Universal registration document filed with the Autorité des Marchés Financiers on February 24, 2021 under number D.21-0076 as well as changes in economic conditions, the financial markets or the markets in which CARMAT operates. In particular, no guarantee can be given concerning the Company's ability to finalize the development, validation and industrialization of the prosthesis and the equipment required for its use, to manufacture the prostheses, satisfy the requirements of competent authorities, enroll patients, obtain satisfactory clinical results, perform the clinical trials and achieve commercial objectives. Aeson® is an active implantable medical device commercially available in Europe ONLY, CARMAT SA., CE0344. The Aeson® TAH is intended to replace ventricles of 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 LVAD and are likely to undergo heart transplant in the 180 days following device implantation. The decision to implant and the surgical procedure must be executed by Health Care professionals trained by the manufacturer. Carefully read the documentation (clinician manual, patient manual & alarm booklet) for characteristics and information necessary for patient selection and good use (contraindications, precautions, side effects). In the USA, Aeson® is currently exclusively available within the framework of clinical trials.



#### **Speakers**



#### Jean-Pierre Garnier Chairman

- Over 40 years of experience in the pharmaceutical industry
- Board member of several biotech companies
- Previously Chairman of GSK (2000-2008)



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)



Pascale d'Arbonneau Chief Financial Officer

- Over 25-year experience in Finance
- Previously VP-Finance at GSK
- Graduate of ESCP

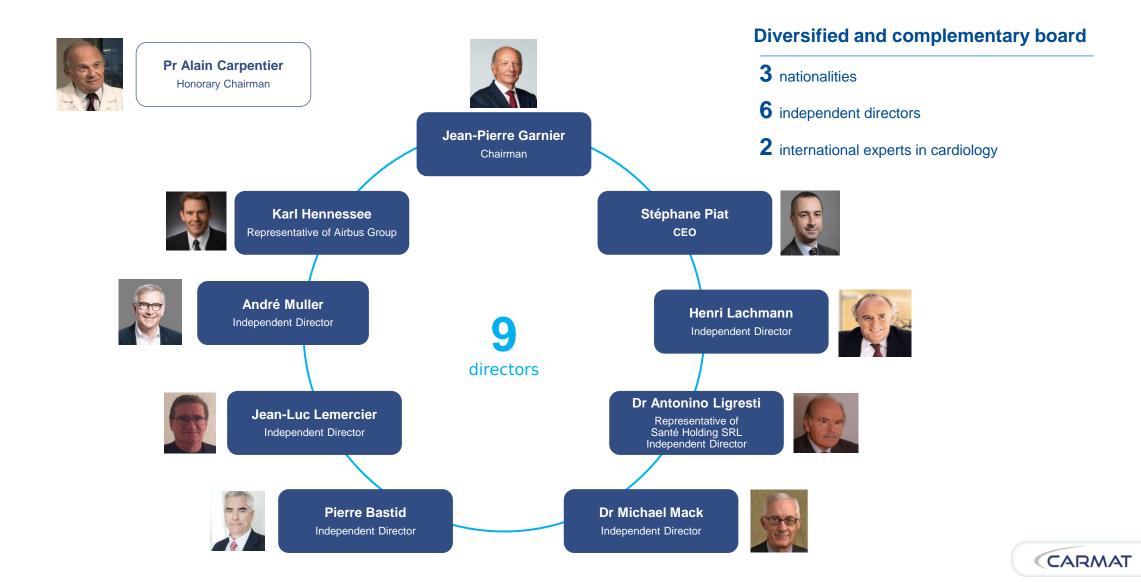


#### **Pr. Christian Latrémouille** Director of Surgical Affairs

- University Professor at the University of Paris
- Principal investigator of the CARMAT heart feasibility study
- Previously cardiac surgeon at the Georges-Pompidou European Hospital



#### **Board of directors**



## 3 new appointments to the Board of Directors proposed for approval by the meeting



#### Mr. Florent Battistella

- Engineer (INSA Toulouse), PhD in solid state physics (Paul Sabatier University of Toulouse)
- Previously CEO emerging countries at Converteam (acquired by General Electric in 2011)



#### Mr. David Coti

- Graduate in international business (ESSEC International and Plekhanov University in Moscow)
- Manager of family offices, including those of the Gaspard family (Bratya SPRL and Corely SPRL)



#### Mr. John B. Hernandez

- Doctor of Health Policy (Pardee RAND Graduate School, California).
- Clinical Director and Head of Clinical Research and Medico-economic Affairs at Google



#### Agenda

- I. Bureau constitution
- **II.** Progress made by CARMAT in 2020
- **III.** Strategy and outlook
- IV. 2020 Financial report
- V. Statutory auditors' reports
- **VI.** Questions & answers
- **VII.** Voting on resolutions





#### I. Bureau constitution



#### **Bureau constitution**

• Chairman: Jean-Pierre Garnier

• Secretary of the meeting: Pascale d'Arbonneau

- Scrutineers:
  - Laurent Kirsch
  - David Coti
- Quorum Update
  - Number of shares with voting rights: 15,349,739
  - Shareholders represented or voting by mail:
    - For ordinary resolutions: 7,809,738 shares; i.e. 9,748,305 votes
    - For the extraordinary resolutions: **7,261,738** shares; i.e. **8,652,305** votes
  - Quorum reached: 50.879% for the OGM and 49.519% for the EGM

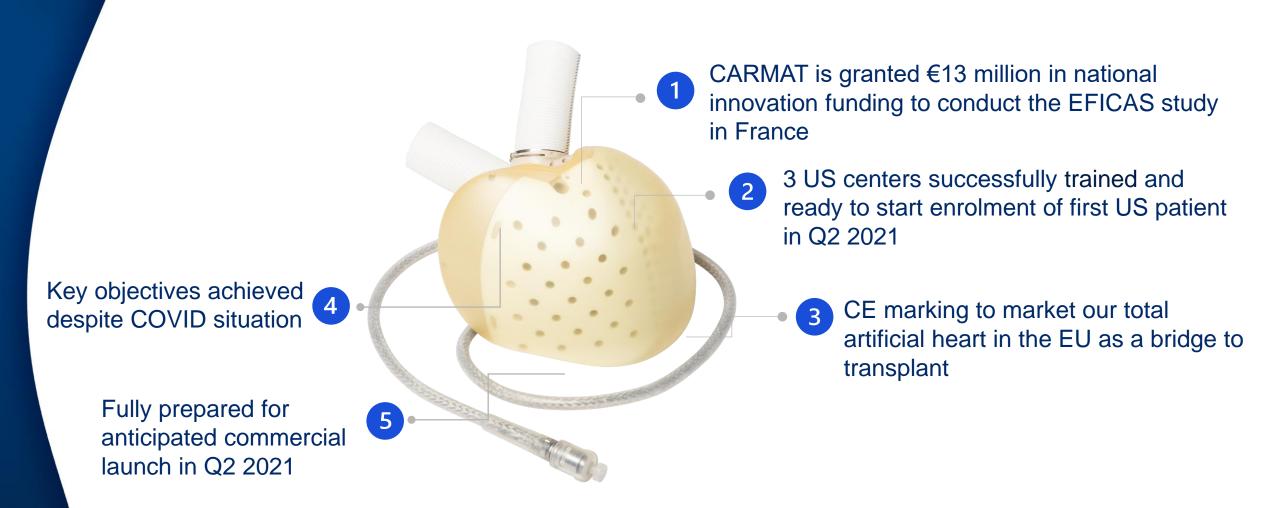




# II. Progress made by CARMAT in 2020



#### **2020 Highlights**







### **CE Mark Opportunity**



#### **CE Mark Milestone Achievement**



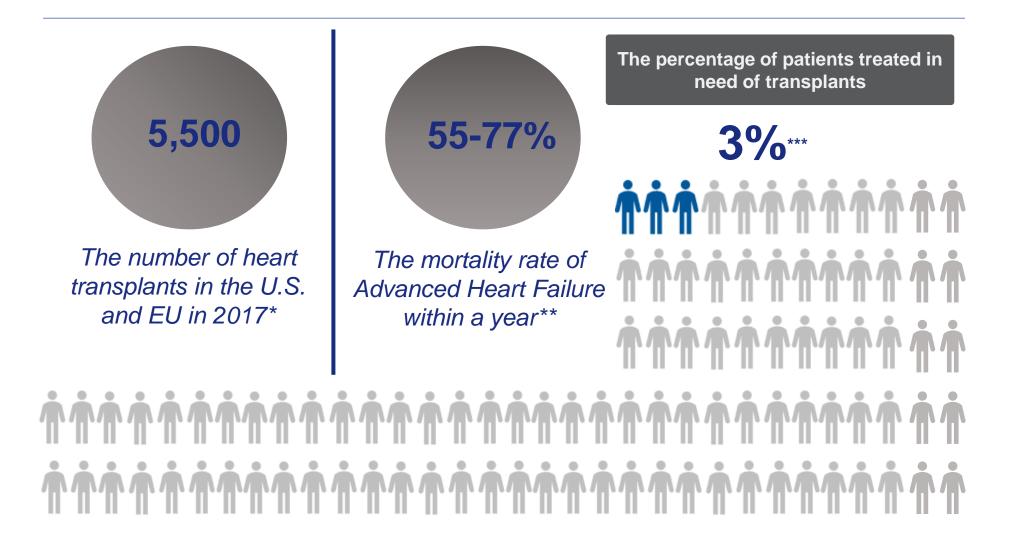
• CE marking granted to CARMAT's total artificial heart system as a bridge to transplant in patients suffering from end-stage biventricular heart failure (Intermacs Classes 1-4) who are not amenable to maximal medical therapy or the LVAD and who are likely to undergo heart transplant in the 180 days following implantation.

\*LVAD: Left Ventricular Assist Device

- Anticipate ramp-up of manufacturing activities and discussions with core target customers to achieve smooth commercial launch in Q2 2021
- CE mark allows CARMAT access to a larger pool of patients



### **Advanced Heart Failure**



\* Source: J Heart Lung Transplant 2019;38:1056-66

\*\* Source: Circ Heart Fail. 2009;2:320-324.

\*\*\* Source: GlobalData, CARMAT estimates



#### **Total Addressable Market**

A large waiting list not served

700 patients in active waiting list\* in Germany and 900 in France\*\* at the end of 2019

No strong alternative for patients not getting a heart transplant



Only 14 BVAD and 15 Syncardia performed in Germany in 2019, about the same in France \*\*\*

The BTT indication gives access in EU to a minimum of 2,000 patients per year

\* Source: statistics.eurotransplant.org: 9023P\_2019 \*\* Source: <u>https://rams.agence-biomedecine.fr</u> \*\*\* Source: ISHLT 2020 BVAD Virtual



#### **CARMAT's Unique Solution**

#### **Unparalleled Safety Profile**

Thanks to its technology, CARMAT is the only device which does not generate any of the following:



The CARMAT heart is a game changer for patients suffering with end-stage biventricular heart failure



\* Source: Clinical Evaluation Report



### **Clinical Developement**



#### **European Studies**

#### **Pivotal Study**

Objective: Safety & Performance data Sample size: Target 20 Enrollment: 15 patients to date Study Results: Support Clinical Evaluation Report for CE Marking

#### **EFICAS** in France

Objective: Safety & Performance data and Health Economics within BTT indication Sample size: 52 Enrollment: Starting date Q3 2021 Study Results: Drive product adoption, support value proposition and get French reimbursement

#### **PMCF (Post-Market Clinical Follow up)**

Objective: Device Safety & Performance data monitoring within BTT indication Sample size: Target 95 Enrollment: Starting date Q2 2021 Study Results: LT data (>1 year) to support indication extension for Destination Therapy



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

Objective

Sample size

**Enrollment** 

**Study Results** 

Safety and Performance data within BTT indication

• 10 ( 2 step-study; 3 + 7)

 3 Sites activated; enrollment expected to begin shortly

Support design of PIVOT study for FDA Approval



## **PIVOTAL Study Results from 15 patients to date**

The 6-months survival rate of the CARMAT TAH is superior to comparable therapy options.

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KG	-
K	Liff west(b)
Agri venos	SV/G pump

6-months Survival Rate			
CARMAT PIVOTAL (n=15)	73%		
CARMAT PIVOTAL BTT patients (n=9) 78%			
Syncardia*	54% - 62%		
BVAD**	46% - 68%		
LVAD***	90% - 92%		



\* 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 \*\*\* Strueber M et al. JACC 2011;57:1375–82. Netuka I et al., JACC 2015;66:2579–89



#### **Unparalleled Safety Profile**

The CARMAT TAH shows an outstanding 6-months safety profile, 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	
CARMAT	20%	0%	0%	0%	
SynCardia*	41%	23%	20%	22%	
BIVAD**	n/a	7%	7%	7%	
LVAD***	14%	10%	25%	10%	

\* 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

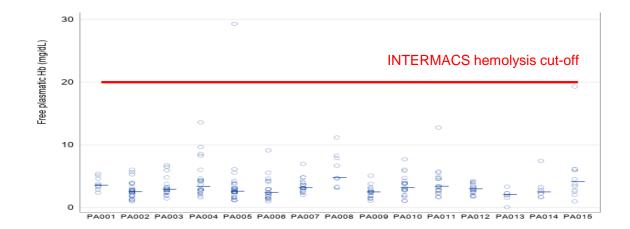
\*\*\* Mehra MR, et al., NEJM. 2019 Apr 25;380(17):1618-27. Strueber M et al. JACC 2011;57:1375-82. Netuka I et al., JACC 2015;66:2579-89



#### Hemocompatibility

The combination of biocompatible surfaces, low shear rates, absence of hemolysis and autoregulation provides a unique safety profile with low-level anticoagulation treatment.

Factors causing hemolysis	LVAD/BVAD	Syncardia	CARMAT
Shear stress	++	+++	-
Synthetic Material	+++	+++	+
Anti-platelet therapy*	Aspirin 81-325mg	81-325mg Dipyridamole 150mg	75-100mg
Anticoagulation therapy*	Coumadin (INR 2,0-3,0)	Coumadin (INR 2,0-3,0)	Prophylactic low molecular weight heparin
*Eur J Cardiothor Surg 2019;56:230-70			

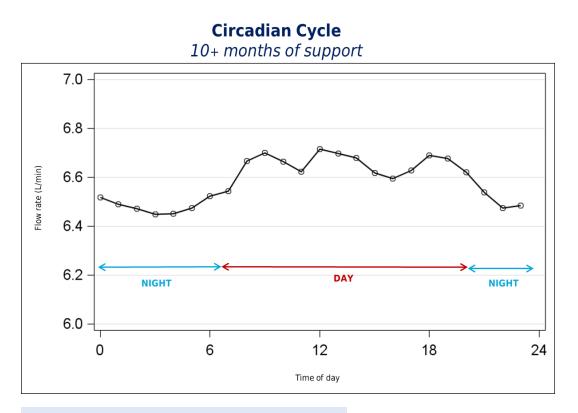


Hemolysis markers (plasma-free hemoglobin) are low in all CARMAT patients.



#### **Replicating the Function of a Human Heart**

The CARMAT TAH Autoregulation adapts appropriately to the physiological needs of patients in different daily situations\*.



\*Netuka, I et al., ASAIO J, 2021; in press



#### **Optimization of the Surgical Experience**



**100% success rate for the procedure** 



Length of surgery shortened with the benefit of experience



100% success rate for Heart transplantation following the CARMAT implantation



### **Overview of the Clinical Experience to Date**

• Operation

- Recovery times comparable to the norm for high-risk patients
- Physiological autoregulation of the prosthesis, adapting to the activity of the patient

#### Favorable safety profile

• No hemolysis, no stroke, no digestive system bleeding in the first cohort

#### • Follow-up

- 6-month survival rate among the first 15 patients: 73%
- Bridge to heart transplant performed with a 100% success rate
- Latest experience very positive with the Lille University Hospital





### **III. Strategy and Outlook**



### **Upcoming Developments**

1. Manufacturing

- 2. Clinical
- **3.** Commercialization

All strategic projects are progressing well



#### Manufacturing

- Increased reliability of prostheses following the implementation of new manufacturing processes
- Control of the processes allowing a better fluidity of the production and ramp-up
- Focus on suppliers to ensure production continuity



Goal is to be able to assemble 20 products a month by end of the year in order to support commercial demand and studies for 2022



### **Clinical planning**



#### **PIVOTAL Study**

- 15 patients enrolled to date
- Extremely encouraging data
- Completion of the study expected by Q1 2022



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

- 6 Centers selected
- 3 centers initiated
- First patients to be enrolled in Q2 2021



#### **EFICAS Study**

- 5 centers selected to date
- First patient to be treated in Q3 2021



#### **CARMAT Creates a New Product Category**



#### **From TAH – Total Artificial Heart**

#### To PHRT – Physiologic Heart Replacement Therapy.

Adding autoregulation\*\* and higher hemocompatibility\*\*\* to allow

AN ENHANCED QUALITY OF LIFE\*\*\*\*



\* Source: Richez U et al.; Hemocompatibility and safety of the CARMAT Total Artifical Heart hybrid membrane. Heliyon. 2019 Dec; 5(12): e02914. Published online 2019 Dec 8. doi: 10.1016/j.heliyon.2019.e02914 \*\* Source: Bizouarn P et al. ; Effects of pre-load variations on hemodynamic parameters with a pulsatile autoregulated artificial heart during the early post-operative period. J Heart Lung Transplant. 2018;37(1):161-3. \*\*\* Source: JACC 2017 Smadja, Bioprosthetic total artificial heart induces a profile of acquired hemocompatibility with membranes recellularization, July 2017:403-9 \*\*\*\* Source: Clinical Evaluation Report



### **Commercial Planning 2021**

• Focus commercially on Germany which represents 40%\* of the MCS\*\* market in EU5

Prospection extended to Italy and the Netherlands

\* Source: Global Data

\*\* Mechanical Circulatory Support

#### **Commercial Launch Preparation**

Accounts	Q2	Q3	Q4	Total
Trained	4	3	5	12
Open	1	5	6	12

First commercial sales in Q2 2021

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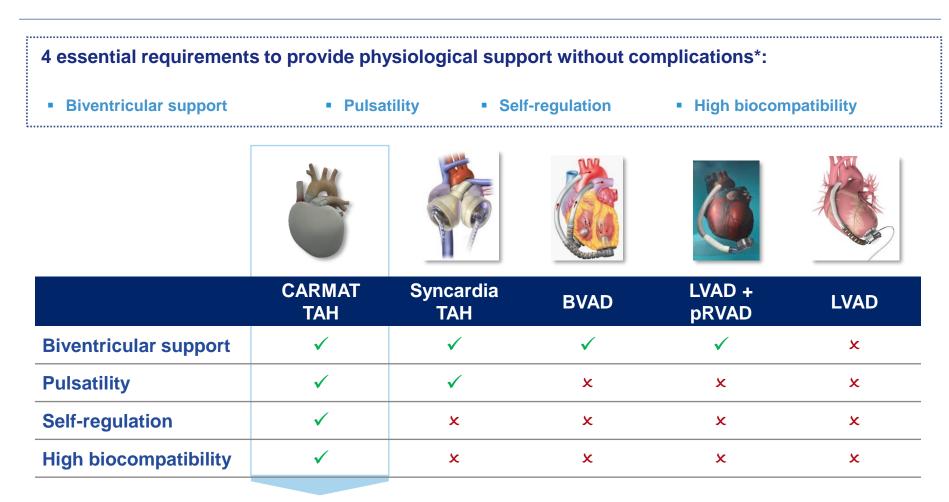
#### **Covid-19 Epidemic Impact on CARMAT**

	Manufacturing • Mild impact on suppliers
	PIVOTAL study Delayed because of suppliers
CORONAVIRUS	EFICAS study Limited delay because of suppliers
	EFS • Limited access to the US delaying start
	Commercialization • Training planning slightly delayed

Limited but increased impact compared to last year



### **CARMAT**, a Unique and Eagerly Awaited Solution



 The only system to offer real physiological support



### **CARMAT**, a New Opportunity in Cardiology



#### Large Market Opportunity

Over 100k patients in irreversible conditions at risk of death within weeks

#### First bioprosthetic physiological replacement heart

Credible therapeutic and economic alternative to transplant

2

3

#### **Clear market-access strategy**

- CE marking granted
- EFS undergoing
- KOL advocacy

## Short-term value creation milestones

- EFICAS start
- US EFS start
- First sales

#### Their life. Your skills. Our technology.

4

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### IV. Financial Report 2020



### **P&L: Operating expenses under control**

In €m	2020	2019
Sales	-	-
Operating Result	(36.4)	(42.4)
Financial Result	(2.5)	(1.8)
Non-recurring items	0.2	(0.1)
Research and Innovation tax credit	1.7	1.6
Net Result	(37.0)	(42.6)

- No sales in 2020 first sales expected in 2021
- Operating expenses under control :
  - 1. Production ramp-up
  - 2. Finalization of the commercial configuration of the artificial heart
  - 3. Preparation for commercialization in Europe
  - Continuation of clinical activities: pivotal study underway, preparation of EFS (United States) and EFICAS (France) studies
  - 5. Inventories recorded for the first time as assets on the balance sheet (net impact of €10 million)
- Increase in financial interests impact of the EIB loan
- Research and Innovation tax credit of €1.7m



### Cash position of €36m at 31.12.2020

In m€	2020	2019
Cash and cash equivalents at beginning of year	55.5	25.3
Cash flow from operating activities	(43.0)	(40.2)
Cash flow from investment activities	(2.3)	(0.6)
Cash flow from financing activities	25.8	71.1
Cash and cash equivalents at end of year	36.0	55.5

Cash-burn of €45 million (vs. €41 million in 2019)

■ Drawdown of 2<sup>nd</sup> tranche of EIB Ioan: +€10m

State-Guaranteed Loan: + 10 M€

■ Kepler-Cheuvreux equity line: +€5.8m



### Funding: financial visibility until mid-2022



Financial visibility until mid-2022 (without use of the Kepler line)

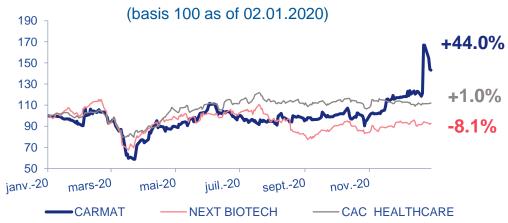


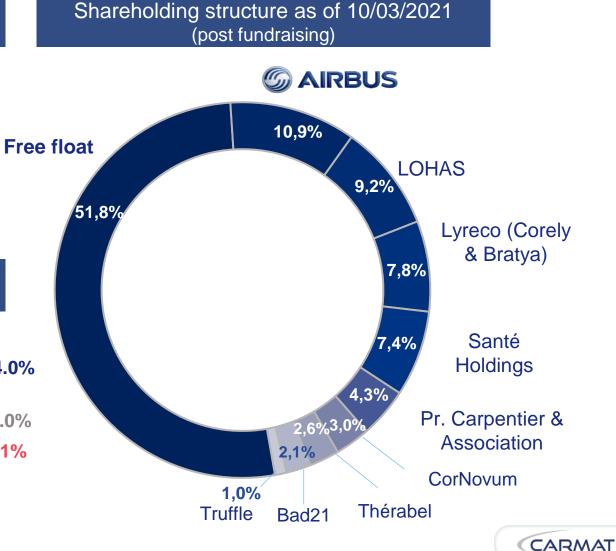
#### **CARMAT** and the stock market

#### Stock information as of 30.04.2021

- Ticker: ALCAR
- ISIN Code: FR0010907956
- Industry: Health equipment and services
- **Share price:** 25,45 €
- Number of shares: 15 353 452
- Market cap.: €391 m

### Change in CARMAT share price vs. sector indexes in 2020





### V. Statutory auditors' reports





### **VI.** Questions and answers





### **VII. Voting on resolutions**



### **Ordinary resolutions**

N°	Resolution	Adopted at	Rejected at
1	Approval of the annual accounts for the year ending December 31, 2020	100%	
2	Discharge of the directors for the performance of their duties during the past financial year	95.14%	
3	Allocation of results for the year ended December 31, 2020	100%	
4	Review of agreements covered by Articles L. 225-38 et seq. of the French Commercial Code	99.999%	
5	Appointment of a new director - Mr. David Coti	87.638%	
6	Appointment of a new director - Mr. John B. Hernandez	87.638%	
7	Appointment of a new director - Mr. Florent Battistella	87.638%	
8	Renewal of the mandate of PRICEWATERHOUSECOOPERS AUDIT as statutory auditor	91.834%	
9	Authorization for the Board of Directors to purchase the Company's own shares	98.482%	



### **Extraordinary resolutions (1/2)**

N°	Resolution	Adopted at	Rejected at
10	<b>Consultation of shareholders</b> , pursuant to Article L. 225-248 of the French Commercial Code, on the possible early dissolution of the Company following the recognition of accounting losses that reduce shareholders' equity to less than half the share capital	100%	
11	Authorization for the Board of Directors to reduce the share capital by cancelling treasury shares	98.293%	
12	<b>Delegation</b> to increase the capital by issuing ordinary shares and/or any other securities, with shareholders' pre-emptive rights maintained	98.293%	
13	<b>Delegation</b> to increase the capital by issuing ordinary shares and/or any other securities, without shareholders' pre-emptive rights and with a public offering	93.225%	
14	<b>Delegation</b> to increase the share capital by issuing ordinary shares and/or any other securities, without shareholders' pre- emptive rights, to be issued as part of an offer to qualified investors or a limited circle of investors as provided for in Article L. 411-2 of the Monetary and Financial Code	93.225%	
15	Authorization for the Board of Directors, in the event of the issue of shares or any other securities giving access to the capital with cancellation of the shareholders' preferential subscription rights, to set the issue price within the limit of 10% of the share capital and within the limits provided for by the General Meeting	94.387%	
16	<b>Delegation</b> to increase the amount of each of the issues with or without preferential subscription rights that would be decided under the 12th to 14th resolutions above	93.23%	
17	<b>Delegation</b> of authority to the Board of Directors to decide to issue shares and/or securities, without shareholders' pre- emptive rights, to investors in the life sciences and technologies sector	87.925%	
18	<b>Delegation</b> of authority to the Board of Directors to decide to issue shares and/or securities, without shareholders' pre- emptive rights, to strategic, commercial or financial partners	87.925%	

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### **Extraordinary resolutions(2/2)**

N°	Resolution	Adopted at	Rejected at
19	<b>Delegation</b> to increase the capital by issuing any securities that are equity securities giving access to other equity securities or giving the right to the allocation of debt securities, and/or securities giving access to equity securities, with cancellation of the pre-emptive right, to the benefit of a third category of persons in the context of an equity or bond financing facility	87.91%	
20	Determination of the total amount of the delegations granted under the 12th to 19th resolutions above	99.996%	
21	<b>Delegation</b> of authority to the Board of Directors to increase capital by incorporation of premiums, reserves, profits or other items	100%	
22	<b>Delegation</b> to issue warrants to (i) members and non-voting members of the Board of Directors in office on the date of allocation of the warrants who are not employees or executives of the Company or one of its subsidiaries, or (ii) persons linked by a service or consultancy contract to the Company or one of its subsidiaries, or (iii) members of any committee that has been or is to be set up and who are not employees or executives of the Company or one of its subsidiaries.	91.356%	
23	Authorization for the Board of Directors to grant existing or new shares at no cost	89.414%	
24	Amendment of article 14 of the articles of association "double voting rights"	100%	
25	<b>Amendment</b> to the terms of the AGAP 2019-01 and consequential amendment to paragraph 1 of Article 12.2. III of the Bylaws	92.988%	
26	<b>Delegation</b> of authority to the Board of Directors to increase the share capital by issuing shares and securities giving access to the capital to employees participating in the company savings plan		60.566%

CARMAT

Their life. Your skills. Our technology.



Thank you for your attention!