

# **BUILT TO LAST**

General Meeting Mai 11, 2022



### 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).

May 2022, CARMAT SA, France



## **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



Pascale d'Arbonneau Chief Financial Officer

- Over 25-year experience in Finance and in the health industries
- Previously VP-Finance at GSK
- Graduate of ESCP



Pr. Christian Latrémouille Director of Surgical Affairs

- Doctor of Medicine, specialised in Cardiac Surgery, University Professor at the University of Paris
- Previously cardiac surgeon at the Georges-Pompidou European Hospital



### **Board of directors**



**Pr Alain Carpentier** Honorary Chairman



Jean-Pierre Garnier Chairman

#### **Diversified and complementary board**

- 4 nationalities
- **8** independent directors
- **2** international experts in cardiology



Karl Hennessee Representative of Matra Defense







**André Muller** Independent Director



directors

Henri Lachmann Independent Director



**Dr Antonino Ligresti** Representative of Santé Holding SRL

Independent Director



**Dr Michael Mack** 



Independent Director





**Pierre Bastid** Independent Director



John B. Hernandez Independent Director





Florent Battistella Independent Director





# **Agenda**

- I. Bureau constitution
- II. Progress made by CARMAT in 2021
- III. Strategy and outlook
- IV. 2021 Financial report
- V. Statutory auditors' reports
- VI. Questions & answers
- VII. Voting on resolutions





### **Bureau constitution**

- Chairman: Jean-Pierre Garnier
- Secretary of the meeting: Pascale d'Arbonneau
- Appointment of Scrutineers
- Quorum update (OGM and EGM)





# **2021 Highlights**

Commercial launch in EU - 7 patients treated in 2021 First cohort of US Early Feasibility Study (EFS) completed - 3 patients Pivot study – 17 implants to date (indicative objective of 20) 5

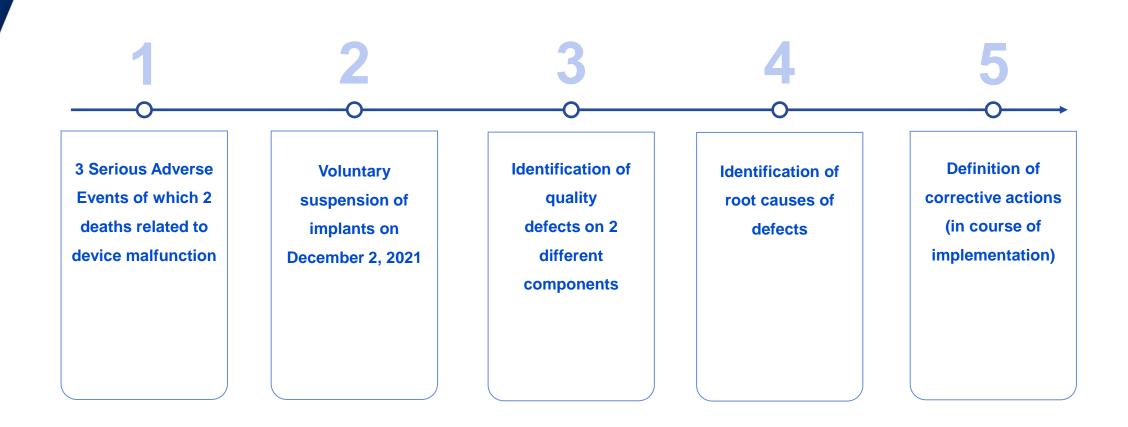
Manufacturing ramp up - 4 prosthesis a week in December

Voluntary suspension of implants due to quality issues





### **Situation**



 $-\sqrt{\sqrt{}}$ Swift and responsible action taken through the whole process



## **Next steps**



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

EFS. Green light to restart implants required from DEKRA (commercial), and ANSM / FDA (studies).





### **Vision and Mission**

#### **OUR VISION**

Aeson® to become the primary alternative to Heart Transplants

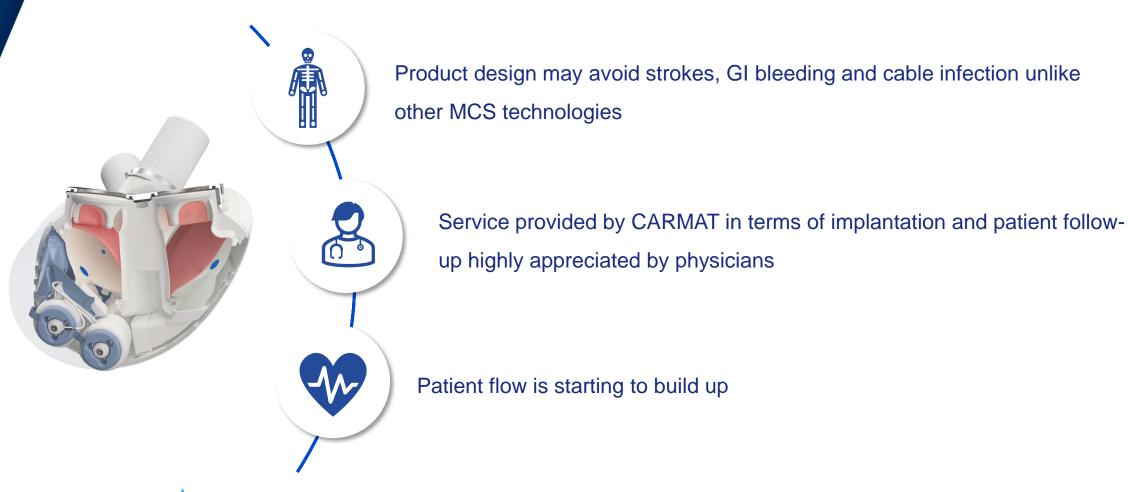


#### **OUR MISSION**

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







### Voice of the customer

QoL with Aeson is way better than that with LVADS"

We want to be the first to restart in Oct"

Dresden Centre

We are highly interested....we want to start"

We have at least 10 patients per year for Aeson"

Berlin Centre

Aeson can represent the future of MCS"
Hannover Centre

Thanks for the openness...we are confident for the restart"

Essen Centre

We want to restart ASAP as the patient not treated in December won't be able to survive very long"

Naples Centre

Other systems are not to be expected in the near future"

Bad Oeynhausen Centre



### The Aeson® Artificial Heart distinctive features



#### A PHYSIOLOGIC HEART REPLACEMENT THERAPY



- 1
- Biological blood-contacting surfaces
- Minimized shear-stress
  - → Acquired Hemocompatibility
  - → Low-intensity anticoagulation

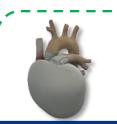
- 2 ) . .
- Biventricular, full pulsatility
  - Electro-hydraulic actuation
    - $\rightarrow$  Physiological flow
    - → Silent operation

- 3
- Pre-load triggered autoregulation of blood flow
  - → Activity-based output variation



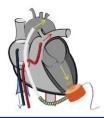
# **Aeson®'s unique competitive advantages**

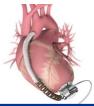
### 4 essential requirements to provide physiologic replacement without complications











	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 Stroke Gastrointestinal Driveling bleeding infection					
Aeson (n=15)*	20%	0%	0%	0%	
SynCardia**	41%	23%	20%	22%	
BIVAD***	n/a	7%	7%	7%	
LVAD****	14%	10%	25%	10%	



<sup>\*</sup> Data from the Pivotal study

<sup>\*</sup> 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

<sup>\*\*</sup> Lavee J et al., JHLT 2018;37:1399-1402. Arabia F et al., ATS 2018;105:548-56

<sup>\*\*\*</sup> 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

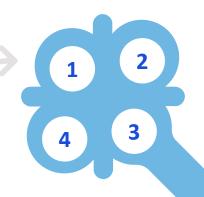
Requirement	Aeson®	Clinical Experience
Hemocompatible	<ul> <li>Minimal anticoagulation requirement</li> </ul>	<ul> <li>No stroke, no gastro-intestinal lesions/bleeding</li> </ul>
Physiologic blood flow	✓ Pulsatile, self-regulated blood flow	<ul> <li>Automatic response to different loading conditions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



## 2022 key objectives

### **Manufacturing**

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



#### **Financing**

- Fundraising of €40m in April 2022 extending financial visibility to March 2023
- Prepare for next financing

#### Commercial

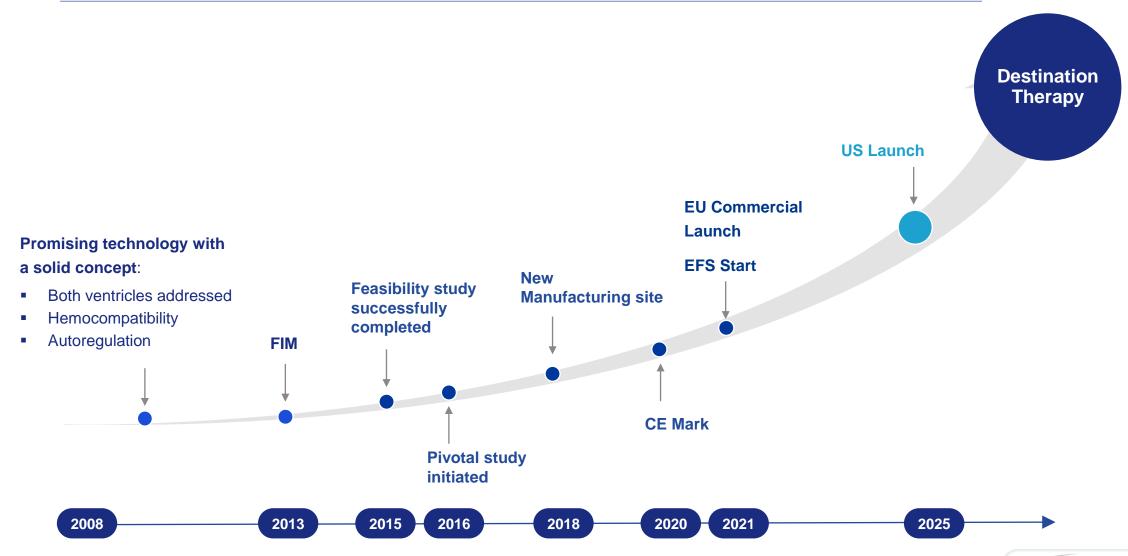
- Carry on training new centers
- Prepare for a strong restart
- Resume sales in October

#### **Clinical studies**

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



# **CARMAT – An accelerating path towards success**





### P&L

In €m	2021	2020
Sales	2.2	-
Operating Result	(60.4)	(36.4)
Financial Result	(3.3)	(2.5)
Non-recurring items	-	0.2
Research and Innovation tax credit	1.9	1.7
Net Result	(61.9)	(37.0)

- Sales of €2.2m (10 prostheses)
- Operating expenses impacted by a nonrecurring charge of €8m
  - 1. Structuring of production
  - 2. Strengthening the organisation in connection with the start of sales
  - 3. Non-recurring impact of €8m related to quality issues identified at year-end
- Increase in financial interests impact of the EIB loan
- Research and Innovation tax credit of €1.9m



# **Cash flow and position**

In m€	2021	2020
Cash and cash equivalents at beginning of year	36.0	55.5
Cash flow from operating activities	(60.2)	(43)
Cash flow from investment activities	(1.8)	(2.3)
Cash flow from financing activities	65.8	25.8
Cash and cash equivalents at end of year	39.2	36.0

- Cash-burn of €5 million per month
- Change in operating cash flow mainly due to production ramp-up
- Financing
  - 1. March 2021 fundraising (€56m)
  - 2. Drawdown of the third and final tranche (€10m) of the EIB loan
  - 3. Limited use of the Kepler-Cheuvreux flexible equity line (€3m)



# Funding: financial visibility until March 2023

Cash as 31.12.2021 €39m

Fundraising (April 2022)

Financial visibility extended to March 2023



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

#### Stock information as of 29.04.2022

Ticker: ALCAR

ISIN Code: FR0010907956

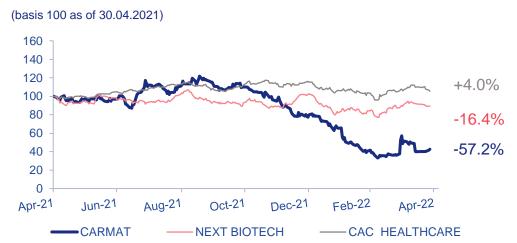
Industry: Health equipment and services

• **Share price**: 10.62 €

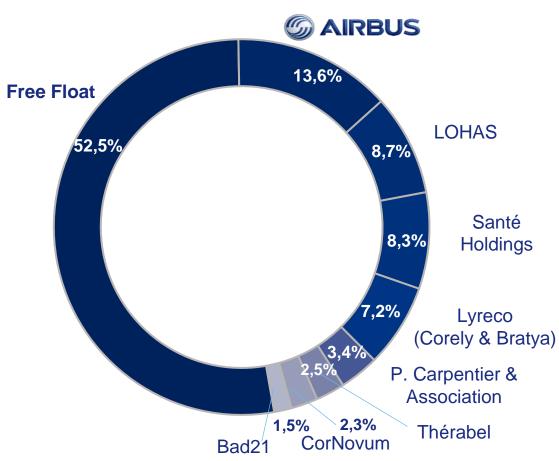
• Number of shares: 19,670,554

Market cap.: €209 m

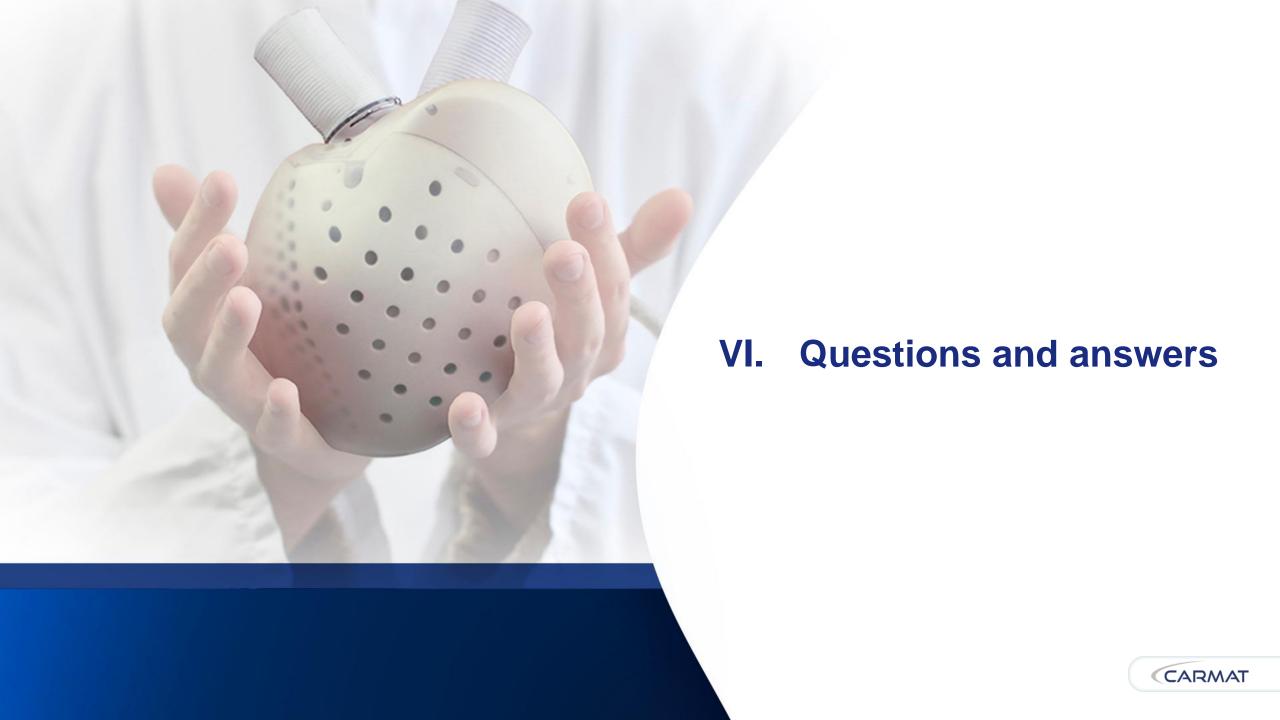
# Change in CARMAT share price vs. sector indexes (12 months)



#### Shareholding structure as of 15.04.2022









# **Ordinary resolutions (1/3)**

N°	Resolution	Adopted	Rejected
1	Approval of the annual accounts for the year ending 31 December 2021		
2	Discharge of the directors for the execution of their mandate during the past financial year		
3	Allocation of results for the year ending 31 December 2021		
4	Allocation of losses from the "retained earnings" account to the "share premium" account		
5	Review of agreements covered by Articles L. 225-38 et seq. of the French Commercial Code		
6	Renewal of the term of office of Mr Jean-Pierre Garnier (subject to the resolutive condition of the reduction of the directors' terms of office - as per resolution 24)		
7	Renewal of the term of office of Mr Jean-Luc Lemercier (subject to the resolutive condition of the reduction of the directors' term of office - as per resolution 24)		
8	Renewal of the term of office of Mr Michael Mack (subject to the resolutive condition of the reduction of the directors' term of office - as per resolution 24)		
9	Renewal of the term of office of Matra Défense (subject to the resolutive condition of the reduction of the term of office of the directors - as per resolution 24)		



# **Ordinary resolutions (2/3)**

N°	Resolution	Adopted	Rejected
10	<b>Renewal</b> of the director's mandate of Santé Holding S.R.L. (subject to the resolutive condition of the directors' mandate - according to resolution 24)		
11	<b>Acknowledgement</b> of the termination of the functions of all directors (subject to the condition precedent of the reduction of the director's mandate - according to resolution 24)		
12	<b>Appointment</b> of Matra Défense as director (subject to the condition precedent of the reduction of the director's mandate - according to resolution 24)		
13	<b>Appointment</b> of Mr David Coti as Director (subject to the condition precedent of the reduction of the Director's mandate - according to resolution 24)		
14	<b>Appointment</b> of Mr Pierre Bastid as Director (subject to the condition precedent of the reduction of the Director's mandate - according to resolution 24)		
15	<b>Appointment</b> of Mr Florent Battistella as director (subject to the condition precedent of the reduction of the director's term of office - according to resolution 24)		
16	Appointment of Mr Jean-Luc Lemercier as Director (subject to the condition precedent of the reduction of the Director's mandate - according to resolution 24)		
17	Appointment of Mr Michael Mack as Director (subject to the condition precedent of the reduction of the Director's mandate - according to resolution 24)		
18	<b>Appointment</b> of Mr John B. Hernandez as Director (subject to the condition precedent of the reduction of the Director's term of office - according to resolution 24)		



# **Ordinary resolutions (3/3)**

N°	Resolution	Adopted at	Rejected at
19	<b>Appointment</b> of Mr Stéphane Piat as director (subject to the condition precedent of the reduction of the director's mandate - according to resolution 24)		
20	<b>Appointment</b> of Mr André Muller as director (subject to the condition precedent of the reduction of the director's mandate - according to resolution 24)		
21	<b>Appointment</b> of Santé Holdings Srl as director (subject to the condition precedent of the reduction of the director's mandate - according to resolution 24)		
22	<b>Appointment</b> of Mr Jean-Pierre Garnier as director (subject to the condition precedent of the reduction of the Director's mandate - according to resolution 24)		
23	Authorisation for the Board of Directors to purchase the Company's own shares		



# **Extraordinary resolutions (1/3)**

N°	Resolution	Adopted	Rejected
24	Reduction of the term of office of directors from 6 years to 3 years		
25	Authorisation to the Board of Directors to reduce the share capital by cancelling treasury shares		
26	<b>Delegation</b> of authority to be granted to the Board of Directors to increase the capital by issuing ordinary shares and/or any securities, while maintaining the shareholders' preferential subscription rights		
27	<b>Delegation</b> of authority to be granted to the Board of Directors for the purpose of increasing the capital by issuing ordinary shares and/or any securities, with cancellation of the shareholders' preferential subscription right and public offering (apart from the offers referred to in paragraph 1° of Article L. 411-2 of the Monetary and Financial Code)		
28	<b>Delegation</b> of authority to be granted to the Board of Directors to increase the capital by issuing ordinary shares and/or any securities, with cancellation of the shareholders' preferential subscription right, to be issued within the framework of an offer referred to in paragraph 1° of Article L. 411-2 of the Monetary and Financial Code		
29	<b>Authorisation</b> to the Board, in the event of the issue of shares or any securities giving access to the share capital with cancellation of the shareholders' preferential subscription right, to set the issue price within the limit of 10% of the share capital and within the limits provided for by the general meeting		
30	<b>Delegation</b> of authority granted to the Board of Directors to increase the amount of each of the issues with or without preferential subscription rights that would be decided pursuant to the Twenty-sixth to Twenty-eighth resolutions above		



# **Extraordinary resolutions (2/3)**

N°	Resolution	Adopted at	Rejected at
31	<b>Delegation</b> of authority to the Board of Directors to decide on the issue of shares and/or securities, with cancellation of the shareholders' preferential subscription right in favour of a first category of beneficiaries (investors in the life sciences or technology sector)		
32	<b>Delegation</b> of authority to the Board of Directors to decide on the issue of shares and/or securities, with cancellation of the shareholders' preferential subscription right in favour of a second category of beneficiaries (strategic, commercial or financial partners)		
33	<b>Delegation</b> of authority to be granted to the Board of Directors for the purpose of increasing the capital by issuing ordinary shares or any other securities, with cancellation of the shareholders' preferential subscription right, in favour of a fourth category of persons meeting specific characteristics (credit institutions, investment services providers or members of an investment syndicate guaranteeing the realisation of the issue concerned)		
34	<b>Determination</b> of the overall amount of the delegations granted under the Twenty-sixth to Thirty-fifth resolutions Thirty-third resolution above		
35	<b>Delegation</b> of authority to be granted to the Board of Directors to increase the capital by issuing ordinary shares and/or 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 shareholders' preferential subscription right in favour of a third category of persons meeting specific characteristics in the context of an equity or bond financing facility		
36	<b>Delegation</b> of authority to be granted to the Board of Directors to increase the capital by incorporation of premiums, reserves, profits or others		



# **Extraordinary resolutions (3/3)**

N°	Resolution	Adopted at	Rejected at
37	<b>Delegation</b> of authority to be granted to the Board of Directors for the purpose of issuing share warrants in favour of (i) members and non-voting members of the Board of Directors of the Company 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 set up or which the Board of Directors may decide to set up. (ii) persons linked by a service or consultancy contract to the Company or one of its subsidiaries or (iii) members of any committee set up or to be set up by the Board of Directors who are not employees or executives of the Company or one of its subsidiaries		
38	Authorisation to the Board of Directors to proceed with the free allocation of existing shares or shares to be issued		
39	Authorisation to the Board to grant options to subscribe for or purchase shares of the Company		
40	<b>Amendment</b> of the terms of the Preference Shares 2020-01 and consequential amendment of paragraph 1 of Article 12.2. III of the Company's articles of association		
41	<b>Amendment</b> of the Articles of Association for the Company and the introduction of a new class of preference shares convertible into ordinary shares in Article 12.2 of the Articles of Association		
42	<b>Authorisation</b> granted to the Board of Directors to allocate free of charge preference shares convertible into ordinary shares "AGAP 2022" of the Company to the benefit of employees and/or corporate officers of the Company		
43	<b>Delegation</b> of powers to the Board of Directors to increase the share capital by issuing shares and securities giving access to the Company's capital for the benefit of employees participating in the company savings plan		



Their life. Your skills. Our technology.



Thank you for your attention!