PRESS RELEASE

CARMAT announces its 2022 annual results and confirms its 2023 objectives

- Gradual resumption in Aeson® implantations in line with progressive production ramp-up over the year 2023
- Cash position of €51 million as of December 31, 2022 and active exploration of financing options to extend cash runway beyond July 2023
- Confirmation of a sales target of €10 to €13 million in 2023

Paris, February 23, 2023 – 7 am CET

CARMAT (FR0010907956, ALCAR), designer and developer of Aeson®, the world's most advanced total artificial heart, aiming to provide a therapeutic alternative for people suffering from advanced biventricular heart failure, today announces its annual results for the year ending December 31, 2022[1] and confirms its 2023 objectives.

Stéphane Piat, Chief Executive Officer of CARMAT, said: "*Thanks to the efforts of the whole CARMAT team, we have achieved our main objective for 2022: resuming implantations of our Aeson® artificial heart in the fourth quarter, as previously announced.*

In order to address the strong interest of healthcare professionals in our therapy, we are confident in our ability to gradually increase our production volumes over the coming months, with an acceleration in the second half of the year, and initiate the commercial success of our artificial heart as early as 2023.

At the same time, we will deploy the EFICAS study in France, the largest clinical study ever initiated by the Company, which will enable us to confirm the efficacy and safety of our therapy, but also to collect essential medico-economic data for reimbursement, notably in France.

Furthermore, we carry-on working with the FDA to resume our Early Feasibility Study in the United States, a key step on the road to obtaining the marketing approval ('PMA') for Aeson® in this country.

We are also actively reviewing all funding options to extend our cash runway beyond July 2023, and *are confident in our ability to do so despite a challenging external environment.*

2023 will be a pivotal year to position Aeson® as the benchmark treatment for advanced heart failure".

[1] Annual accounts were approved by the Board of Directors on February 21, 2023. Audit procedures relative to these accounts are currently being carried out.

- **2022 annual results**

Simplified income statement (€ millions)	**2022**	**2021**
Sales	**0.3**	**2.2**
Operating loss	**-51.9**	**-60.4**
Financial loss	-3.8	-3.3
Non-recurring income	-	-
Research and Innovation tax credit	+2.1	+1.9
Net loss	**-53.7**	**-61.9**

2022 annual sales amount to €0.3 million, corresponding to the sale of 2 Aeson® artificial hearts since implantations resumed in November, the first on a commercial basis in Germany and the second within the framework of the EFICAS clinical study in France.

The operating loss was contained to €51.9 million in 2022, thanks to proactive cost control, compared to a loss of €60.4 million in 2021 that was impacted by a non-recurring expense of €8.1 million relating to quality issues.

In 2022, CARMAT focused its efforts and resources on the following:

On the industrial and quality front:

- definition and implementation of preventive and corrective actions in its supply chain to address the quality issues identified at the end of 2021;
- gradual resumption of its production of artificial hearts reflecting these changes;
- close collaboration with suppliers to increase production.

On the clinical and commercial front:

- obtention of the regulatory authorizations required to resume Aeson® implantations;
- continued training and education of hospitals and physicians.

Considering the financial loss (-€3.8 million), non-recurring items, and Research Tax Credit (+€2.1 million), the net loss amounts to €53.7 million in 2022, an €8.2 million improvement compared to 2021.

- **Financial structure**

As of December 31, 2022, the Company had a cash position of €51.4 million, up €12.2 million vs last year, as detailed below:

(€ millions)	**FY 2022**	**FY 2021**
Cash flow from operating activities	-54.4	-60.1
Cash flow from investment activities	-2.0	-1.8
Cash flow from financing activities	+68.6	+65.1
Change in the cash position	**+12.2**	**+3.2**

The cash generated by financing activities includes:

- 2 capital increases aimed at specialized and strategic investors, and retail investors (via the PrimaryBid platform), carried out in April and December 2022 for a gross amount of €40.5 million and €31.1 million respectively;

- €0.7 million from the use of the equity financing line put in place with Kepler Cheuvreux, which expired on March 27, 2022.

Net financial debt as of December 31, 2022 was €3.9 million, as detailed below:

(€ millions)	**31.12.2022**
+ Long-term financial liabilities[2]	52.7
+ Short-term financial liabilities	2.6
- Cash position	-51.4
Net financial debt	3.9

The financial resources immediately available to CARMAT, consisting of the cash position of €51.4 million should enable the Company to finance its activities, according to its current business plan, until July 2023 without any additional funding.

Furthermore, the company benefits from a research tax credit[3] of €2.1m. As a winner of the European Union's "EIC Accelerator" program, CARMAT also announced in December 2022, it had obtained a grant of €2.5 million and potential equity investments of €15 million. As the calendar of this funding is not confirmed at this stage, and the equity investments are not yet certain, these amounts have not been taken into account in the Company's financing horizon.

CARMAT is actively exploring various financing options to secure the necessary funding to extend its activities beyond July 2023 and remains confident to secure the resources required to continue its development.

[2] Financial liabilities include the principal (€30 million) and interests due on the EIB (European investment bank) loan, the principal (€10 million) and interests due on State-Guaranteed Loans, and interest relating to the €14.5 million conditional advance obtained from Bpifrance. The characteristics and conditions of the loans and the conditional advance are described in Section 3 of the Company's universal registration document. Long-term financial liabilities correspond to those with a maturity exceeding 12 months.
[3] This tax credit relates to 2022 - its perception is anticipated in September or October 2023.

- **2022 highlights**

Resumption in commercial implantations of Aeson®

From December 2021 and its decision to suspend all implants of its artificial heart on a voluntary and temporary basis, CARMAT focused on characterizing the identified quality issues. Corrective and preventive actions relative to each issue were then defined and implemented, both at the assembly plant in Bois-d'Arcy and, under CARMAT's supervision, by the relevant suppliers and subcontractors. Production, incorporating all these corrective and preventive actions, resumed at the end of the first quarter of 2022 and is gradually increasing since then.

Following the green light from the relevant authorities, the Company was – as anticipated – able to resume implants during the final quarter of 2022, with the first Aeson® implantation in a commercial setting being performed in a German hospital in November.

Initiation of the EFICAS clinical study in France

The first implantation of Aeson® within the framework of EFICAS was performed during the last week of December 2022 by Prof. André Vincentelli and his team at Lille Regional University Hospital.

In addition to the Lille hospital, five other medical centers are taking part in this prospective study: Pitié Salpêtrière University Hospital and Georges Pompidou European Hospital in Paris, Rennes University Hospital, Strasbourg University Hospital and Lyon University Hospital (*Hospices Civils de Lyon*).

The study will involve a total of 52 patients eligible for a heart transplant in France and will allow CARMAT to collect both additional data on efficacy and safety of its artificial heart and medico-economic data to support its value proposition for reimbursement, notably in France. The study's primary endpoint is survival for 180 days after implantation of the device without a debilitating stroke, or a successful heart transplant within 180 days of implantation.

As a reminder, CARMAT benefits from €13 million in funding from the French National Innovation Fund[4] to partially finance this study.

EFS study in the United States

During the second half of 2022, CARMAT also continued its discussions with the FDA (Food & Drug Administration) with a view to resuming Aeson® implants within the framework of the EFS (Early Feasibility Study) in the United States, which will involve a total of 10 patients[5]. The Company anticipates the completion of this study in 2023.

Changes in governance

The Annual General Meeting of May 11, 2022 approved the reduction of the term of office of the Company's directors from 6 to 3 years. As of the date of publication of this press release, the Board of Directors consists of 11 members, including 8 independent directors, whose term of office will expire at the Annual General Meeting that will be held in 2025 to approve the full year results ending December 31, 2024.

On December 21, 2022, Mr. Alexandre Conroy was appointed as Chairman of the Board of Directors in place of Mr. Jean-Pierre Garnier, who stood down for personal reasons.

[4] This funding will be gradually perceived as implantations are performed within the framework of this study.
[5] As a reminder, the protocol of the EFS study provides for the inclusion of a total of 10 patients eligible for a heart transplant. It is a phased study, with a first cohort of 3 patients followed by a second cohort of 7 patients. The first cohort of 3 patients was initiated and completed in the second half of 2021 and the 60-day report on these 3 patients has been submitted to the FDA, as provided for in the study's design. Enrollment of the second cohort's 7 patients will begin once the FDA gives its green-light.

Impact of the Covid-19 situation and the war in Ukraine

The Covid-19 pandemic had little impact on the Company's activity in 2022, apart from a few supply disruptions. Nevertheless, CARMAT keeps an eye on the evolution of the situation and could adjust its prospects accordingly.

Regarding the geopolitical situation in Ukraine, CARMAT has not seen any direct unfavorable impact on its activity, beyond inflation and the increase in energy prices and the costs of certain components and raw materials, that are however not significantly hampering its activity and results. The Company does not anticipate a bigger impact in 2023.

- **2023 Outlook**

In 2023, CARMAT aims to:

- develop Aeson® sales in Europe, with a target of 30 centers trained by the end of the year;
- continue implantations within the framework of the EFICAS study in France, in 6 centers;
- complete the EFS in the United States;
- increase its production capacity to 500 hearts annually by the end of the year, and
- secure the fundings required to continue its activity beyond July 2023.

CARMAT anticipates a gradual increase in the pace of its production in 2023, which should enable the Company to produce more than 100 artificial hearts and to generate revenue of around €10 to €13 million as it builds up its inventory of prostheses.

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About CARMAT

CARMAT is a French MedTech that designs, manufactures and markets the Aeson® artificial heart. The Company's ambition is to make Aeson® the first alternative to a heart transplant, and thus provide a therapeutic solution to people suffering from end-stage biventricular heart failure, who are facing a well-known shortfall in available human grafts. The world's first physiological artificial heart that is highly hemocompatible, pulsatile and self-regulated, Aeson® could save, every year, the lives of thousands of patients waiting for a heart transplant. The device offers patients quality of life and mobility thanks to its ergonomic and portable external power supply system that is continuously connected to the implanted prosthesis. Aeson® is commercially available as a bridge to transplant in the European Union and other countries that recognize CE marking. Aeson® is also currently being assessed within the framework of an Early Feasibility Study (EFS) in the United States. Founded in 2008, CARMAT is based in the Paris region, with its head offices located in Vélizy-Villacoublay and its production site in Bois-d'Arcy. The Company can rely on the talent and expertise of a multidisciplinary team of more than 200 highly specialized people. CARMAT is listed on the Euronext Growth market in Paris (Ticker: ALCAR / ISIN code: FR0010907956).

For more information, please go to www.carmatsa.com and follow us on LinkedIn.

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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. 22-0332. 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).