PRESS RELEASE

CARMAT announces its 2023 annual results and provides an update on its progress and prospects for 2024

- 2023 sales of €2.8 million, i.e. 17 Aeson® implants, including 11 in the last quarter
- 2024 sales forecast of around €14 million
- Active exploration of financing options to extend, in the short-term, the Company's financial horizon beyond May 2024.
- 12-month financing requirements estimated at around €45 million

Paris, April 24, 2024 – 7.00 am CEST

CARMAT (FR0010907956, ALCAR), designer and developer of the world's most advanced total artificial heart, aiming to provide a therapeutic alternative for people suffering from advanced biventricular heart failure (the "**Company**" or "**CARMAT**"), today reports its annual results for the year ending December 31, 2023, and provides an update on its progress and prospects for 2024.

The annual financial statements were approved by the Board of Directors on April 22, 2024, on a going concern basis. On April 30, 2024, the Company will publish its 2023 Universal Registration Document, including the annual financial report and the statutory auditor's report, whose audit procedures are being finalized.

Readers' attention is drawn to the fact that the Company's cash runway extends to mid-May 2024. Should the financings anticipated by the CARMAT not materialize by that date, the Company would then have to make significant adjustments to his annual financial statements.

Stéphane Piat, Chief Executive Officer of CARMAT, commented: *"In many respects, 2023 has been a structuring year for CARMAT, crowned in December by the symbolic milestone of 50 CARMAT heart implants since the start of our clinical experience, and by the opening of a second production building in Bois-d'Arcy.*

Backed by a first-class industrial tool, sized to support our growth, we can now look forward with confidence to the commercial deployment of our therapy. The momentum in Aeson® sales that began in the last quarter of 2023, with 11 implantations, has continued since the start of 2024, at an average rate of around 3 implants per month.

To date, we are on track with our targets for the training of additional hospitals, and implants as part of the EFICAS study. Our geographical deployment is continuing, and 25 of the 39 hospitals trained to commercial implants have already referred patients to CARMAT, confirming the medical community's strong interest in our therapy and its potential. All these advances enable us to anticipate a substantial gradual growth in our sales over the coming months, and revenue of around €14 million for 2024.

I would like to thank all our teams for their resilience, particularly over the past two challenging years. I would also like to express my gratitude to our shareholders, both historical and more recent, whose trust enables us to make progress towards our goal of making CARMAT a leading player in the treatment of advanced heart failure."

- **2023 annual results**

Simplified income statement (€ millions)	**2023**	**2022**
Revenue	**2.8**	**0.3**
Net operating expense	**-52.5**	**-51.9**
Net financial expense	-3.1	-3.8
Net non-recurring income	-	-
Research and innovation tax credit	+1.7	+2.1
Net loss	**-53.9**	**-53.7**

Revenues of €2.8 million corresponded to the sale of 17 Aeson® artificial hearts, including 7 in a commercial set-up in Germany and Italy, and 10 in the EFICAS clinical trial in France.

As a result of a tight cost control, the operating loss for the year was contained at €52.5 million, on par with that of 2022 (€51.9 million).

In 2023, CARMAT has dedicated most of its efforts and resources to:

- sales development, supported by the training of new hospitals (33 centers trained for commercial implants by December 31, 2023), and by preparations for the introduction of Aeson® in 8 additional countries;
- the extension of its Bois-d'Arcy manufacturing site, enabling it to reach a capacity of 500 hearts per year by early 2024;

  the acceleration of the EFICAS study in France (10 implantations in 2023, including 7 in the last quarter); and
- ongoing discussions with the FDA with a view to bringing Aeson® to the US market in 2027.

Taking into account net financial expense (-€3.1 million), non-recurring items and the research tax credit (+€1.7 million), the net loss for 2023 is €53.9 million, virtually unchanged from 2022.

- **Financial structure**

As of December 31, 2023, the Company's cash position stood at €8.0 million (versus €51.4 million at the end of 2022), reflecting the following cash flows:

(€ millions)	**2023**	**2022**
Cash flow from operating activities	-53.5	-54.4
Cash flow from investment activities	-4.9	-2.0
Cash flow from financing activities	+15.0	+68.6

Change in cash position	**-43.4**	**+12.2**

Cash flow from operating and investing activities in 2023 stood at -€58.4 million, up €2 million on 2022, due to higher industrial capital expenditure, associated with the extension of the Company's manufacturing capacity.

In terms of financing, in 2023 the Company received:

- €7 million as part of a private placement in October 2023 with 3 of the Company's core shareholders (Lohas, Sante Holdings and Therabel Invest);
- €5.8 million under the €13.2 million[1] mixed financing granted to CARMAT in April 2023 as part of the "France 2030" plan;
- €2.2 million under the €2.5 million grant awarded to CARMAT at the end of 2022 as a winner of the European Union's[2] "EIC Accelerator" program; and
- the second €0.7 million tranche of the total €1.4 million grant (known as "CAP23")[3] awarded to CARMAT under the "Plan de Relance pour l'industrie - Secteurs Stratégiques" call for projects.

In April 2023, CARMAT also made the first half-yearly repayment of €0.7 million due under its PGE (government-backed loan) contracted with BNP Paribas in 2020.

Net financial debt

As of December 31, 2023, taking into account the debt rescheduling agreement signed[4] in March 2024 with its financial creditors, CARMAT's net financial debt[5] was as follows:

(€ millions)	**31.12.2023**
+ Long-term financial liabilities	57.4
+ Short-term financial liabilities	0.2
- Cash and cash equivalents	-8.0
Net financial debt	49.6

This agreement, successfully negotiated by the Company with its three bank creditors (the European Investment Bank - "EIB", BNP Paribas - "BNPP", and Bpifrance - "BPI"), enables CARMAT to alleviate its short-term cash constraints, in particular by reducing the cash flows associated with repayment of the said loans by more than €30 million, compared with the initial schedules, over the period 2024-2025. As a result of this agreement, short-term financial liabilities at December 31, 2023 are limited to €0.2 million. Through the equitization[6] of the EIB loan, this agreement should also significantly limit cash flows linked to repayments over the 2026-2028 period.

Financing horizon

Given in particular the capital increase of €16.5 million (gross amount) carried out in January 2024,

[1] Mixed financing of €13.2 million, including a €7.9 million grant and a €5.3 million conditional advance, to be received in several instalments over the period 2023-2026, depending on the achievement of operational milestones.
[2] The final balance of this grant (€0.4 million) is expected in 2024.
[3] The final balance of this grant (€0.35 million) is expected in 2024.
[4] The financial debt rescheduling agreement entered into by the Company in March 2024, with the banks BNP Paribas and Bpifrance (for the PGEs) and with the European Investment Bank, is detailed in the Company's press release of March 22, 2024.
[5] Financial liabilities include the principal (€30 million) and interest due on the EIB (European Investment Bank) loan, the outstanding principal (€9.5 million) and interest due on the two state-guaranteed loans (PGE), as well as interest on the €14.5 million repayable advance obtained from Bpifrance, and on the €2.3 million repayable advance received in 2023 as part of the "France 2023 (Santé)" Plan. Long-term financial liabilities correspond to those with maturities in excess of 12 months. The characteristics and conditions of the loans (before the March 2024 rescheduling agreement) and the repayable advance from Bpifrance are described in Section 3 of the Company's 2022 universal registration document.
[6] For further details on equitization, please refer to the press release mentioned in note 4.

CARMAT's financial resources allow the Company, according to its current business plan, to finance its activities until mid-May 2024. The Company estimates its 12-month financing needs at around €45 million.

CARMAT is working very actively on initiatives aimed at strengthening its equity capital and cash position in the short term.

The Company thus anticipates a gradual extension of its financing horizon to 12 months, in several stages: a forthcoming capital increase, supported by historical shareholders, which should enable it to strengthen its cash position and thus pursue its activities beyond May 2024; then other additional initiatives (including one or more further capital increases) enabling it to further extend its financing horizon, bearing in mind that the expected growth in the Company's sales should strengthen CARMAT's attractiveness to investors, and thus facilitate the securing of new financing in the future. It should also be noted that the Company applies strict financial discipline, aimed at reducing its cash burn on operations and capital expenditure by around 20% between 2023 and 2024.

CARMAT is constantly pursuing an active investor relations policy, and seeking new financing (equity, public support or other types of financing) both in France and abroad. It believes it can count, to a certain extent, on the support of some of its key shareholders.

Based on these considerations, the going concern assumption was adopted by the Board of Directors, which approved the financial statements for 2023. However, there is no guarantee that the anticipated financing will be available. This creates a significant degree of uncertainty that could jeopardize the Company's ability to continue as a going concern and could lead to the Company being placed in receivership (“redressement judiciaire”) in the short to medium term.

- **2023 Highlights**

Milestone of 50 Aeson® implants since inception reached in 2023

Since the 1st implant in December 2013, CARMAT technology has been widely disseminated through clinical trials and then commercially: by December 31, 2023, 50 patients had benefited from the Aeson® heart since the Company's inception, in 8 different countries, bringing the cumulative experience to over 22 patient-years. By the end of 2023, 13 patients were living with the Aeson® device.

With strong support from leading cardiologists in Europe and the United States, Aeson® is gradually becoming a benchmark solution for transplant-eligible patients awaiting the availability of a human heart.

Early sales momentum

CARMAT's revenue of €2.8 million in 2023 corresponds to the sale of 17 Aeson® prostheses, including 11 in the last quarter, demonstrating a solid start to the sales momentum (with a rate of around one implant per week achieved in the last quarter), underpinned by CARMAT's ability to roll out its therapy on a large scale industrially and commercially.

It should be noted that sales of Aeson® were limited during the first half of 2023 by the low number of prostheses available over the period, due to supplier supply problems which delayed the ramp-up of production as initially planned by the Company. Production rates gradually returned to normal from the summer onwards.

By December 31, 2023, 33 hospitals in 11 different countries had been trained and were therefore ready to carry out Aeson® implants on a commercial basis.

Acceleration of the EFICAS study in France

The EFICAS study aims to gather additional data on the efficacy and safety of the Aeson® heart, as well as medico-economic data to support the device's value proposition and reimbursement. It is due to include 52 patients eligible for transplantation in France and should be completed in 2025.

10 patients were included in 2023 in this clinical study (in 6 different hospitals in Paris, Lille, Lyon, Le Plessis-Robinson and Montpellier), including 7 during the fourth quarter of the year, bringing the total number of inclusions in this study to 11 patients by December 31, 2023.

At the same date, 8 French hospitals[7] had already been trained for implantations within the framework of the study.

This is an essential study for the future marketing and reimbursement of Aeson® in France, but also to support the application for PMA (marketing authorization) in the United States, which the Company anticipates, at this stage, during the latter part of 2026.

As a reminder, CARMAT has received €13 million from the French national innovation[8] fund to partially finance this study.

Manufacturing capacity increased to 500 hearts per year

In 2023, CARMAT continued to invest in its industrial facilities, particularly with the opening of a second production building at Bois-d'Arcy, enabling it to increase its manufacturing capacity to 500 hearts per year from early 2024, corresponding to potential annual sales of around €100 million.

The Company has also continued to implement its multi-year roadmap aimed at strengthening its base of industrial suppliers and subcontractors, with a view to reinforcing continuity of supply and reducing Aeson®'s manufacturing cost.

Strengthening Aeson® reliability

In 2023, Aeson® continued to demonstrate a safety profile that clearly sets it apart from all other mechanical circulatory assistance systems: since its inception, Aeson® has not given rise to any gastrointestinal bleedings or disabling strokes.

At the end of the year, CARMAT also implemented a software enhancement for Aeson®, which significantly strengthens the safety profile of its device: from now on, for many potential malfunctions linked to the prosthesis's electronic components, the Aeson® software will automatically "correct" said faults by appropriately adapting the artificial heart's operation, so that the patient's support is not impacted.

Secured non-dilutive financing of €13 million as part of the "France 2030" plan

In April 2023, the Company was awarded a total of €13.2 million in blended financing (including €7.9 million in grants and €5.3 million in repayable advances) as part of the "France 2030" plan. The aim is to support the increase in annual production capacity of Aeson® artificial hearts to 1,000 per year within 5 years, and to reduce the production cost of the prosthesis. This financing is structured in tranches available according to the progress of the project over the period 2023-2026. A total of €5.8 million was perceived in 2023 by CARMAT.

Adapting governance

The Combined General Meeting of May 11, 2023 approved the appointment of Therabel Invest, represented by Mr. Laurent Kirsch, as a director of the Company, for a 3-year term. Mr. Laurent Kirsch brings to the Board his extensive experience of the healthcare industry, including at international level, as well as his financial expertise. At the date of publication of this press release, the Board of Directors, chaired by Alexandre Conroy, comprised 12 directors, 7 of whom were independent.

[7] AP-HP GHU Pitié Salpêtrière, Hôpital Européen Georges Pompidou, CHU de Rennes, CHU de Strasbourg, Hospices Civils de Lyon, CHRU de Lille, Hôpital Marie-Lannelongue and CHU de Montpellier.
[8] This funding is received as and when the sites are set up as part of the study.

- **Recent progress**[9]

Since the beginning of 2024, CARMAT has implanted 11 Aeson® hearts, at a rate of around 3 per month.

Strong momentum in EFICAS study implants

Sales momentum is particularly strong in the EFICAS study in France, with 8 implants since January 1, 2024, in 7 different hospitals, which is fully in line with the target of around 30 implantations by 2024.

To date, 19 implants have already been carried out since the start of the study, in which 10 centers are now taking part (two more than at the end of 2023: CHU Dijon-Bourgogne and CHU de Nantes), confirming the expected completion of the study in H1 2025, in line with the objective[10].

Ongoing commercial deployment

Since the beginning of the year, 6 new hospitals have been trained, bringing to 39 the number of centers able to carry out Aeson® commercial implants in 14 different countries. This confirms the Company's target of around fifty trained centers by the end of the year.

To date, of these 39 centers, 12 have already carried out at least one commercial implant of Aeson® and 25 have already referred patients for a potential implantation, confirming the strong interest of the medical community in the therapy.

3 commercial implants have been completed since January 1, 2024, including 2 in Germany and 1 for the first time in Poland, in April.

In addition to the three countries already commercially active (Germany, Italy and Poland), 5 others are now fully activated and ready to carry out implants (Switzerland, Austria, Slovenia, Greece and Israel). In 2024, the Company anticipates the activation of several other European countries, either through direct sales or through distributors with whom distribution contracts have already been signed or are in the process of being signed.

Based on these encouraging indicators, the Company anticipates a substantial gradual sales growth over the year, and revenue of around €14 million for 2024.

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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 circa 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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[9] Data as of April 23, 2024.
[10] As a reminder, the EFICAS study involves a total of 52 implantations of Aeson®.

Name: **CARMAT**
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Disclaimer

This press release and the information contained herein do not constitute an offer to sell or subscribe, nor a solicitation of an order to buy or subscribe to CARMAT shares in any country. This press release may contain forward-looking statements by the company regarding its objectives and prospects. These forward-looking statements are based on the current estimates and anticipations 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 CARMAT's production and sales, the pace and results of ongoing or planned clinical trials, technological evolution and competitive environment, regulatory changes, industrial risks, and all risks associated with the company's growth management. The company's objectives mentioned in this press release may not be achieved due to these elements or other risk factors and uncertainties.

Significant and specific risks of the company are those described in its universal registration document filed with the French Financial Markets Authority (*Autorité des marchés financiers* - the "**AMF**") under number D.23-0323 and in its amendment filed with the AMF on January 17, 2024 under number D.23-0323-A1. Readers' attention is particularly drawn to the fact that the company's current cash runway is limited to mid-May 2024. Readers and investors are also advised that other risks, unknown or not considered significant and specific, may or could exist.

Aeson® is an active implantable medical device commercially available in the European Union and other countries recognizing 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 for patients suffering from end-stage biventricular heart failure (INTERMACS classes 1-4) who cannot benefit from maximal medical therapy or a left ventricular assist device (LVAD) and who are likely to undergo a heart transplant within 180 days of implantation. 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 carefully read to understand the features of Aeson® and the information necessary for patient selection and proper use (contraindications, precautions, side effects). In the United States, Aeson® is currently exclusively available as part of an Early Feasibility Study approved by the Food & Drug Administration (FDA).