PRESS RELEASE

CARMAT publishes its 2024 half-year results and provides an update on its outlook

- Half-year sales of €3.3 million, exceeding 2023 full-year sales
- 20 implants of the Aeson® artificial heart performed in the first half of 2024
- 17% cash-burn[1] reduction compared to the first half of 2023
- 2024 anticipated annual sales of €8 to €12 million
- Other 2024 operational objectives on track
- Active exploration of financing options to extend in the near-term the Company's cash runway beyond the end of September 2024

Paris, September 6, 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 announces its results for the first half ending June 30, 2024[2], and provides an update on its progress and prospects.

Stéphane Piat, Chief Executive Officer of CARMAT, comments: *"The outcome of the first half of 2024 is very positive. With sales of €3.3 million, we have in just 6 months, exceeded our 2023 full-year sales. Achieving 20 Aeson® implants in the first half of the year is a very encouraging indicator for such an innovative device, which is still in its launch phase. In the second quarter of 2024, we performed twice as many implants as in the first quarter.*

But beyond these numbers, the feedback and numerous spontaneous testimonials from European physicians who have carried out Aeson® implants, speak for themselves and give us confidence in the progressive development of our truly unique therapy, which meets a real need and literally "gives life back to patients".

For the rest of the year, we anticipate a traction in implants, both in the EFICAS study and commercially, which should enable us to achieve annual sales of €8 to €12 million in 2024. In 2024, we therefore plan to multiply our revenue by 3 or 4 versus 2023.

In addition, we anticipate several key catalysts in 2025, including the publication of significant clinical results, which should confirm these expert testimonials, and thus objectify the safety and efficacy of our therapy. These results should play a key role in accelerating our growth. Finally, in 2025, we also anticipate resuming our PIVOTAL study in Europe, with patients not eligible for heart transplant, with a view to eventually obtaining the destination therapy indication that has always been and remains CARMAT's ultimate goal.

[1] Cash flow from operating and investing activities
[2] The interim financial statements were approved by the Board of Directors on September 5, 2024; The statutory auditor's limited review procedures are currently in progress. The 2024 half-year financial report is published today and can be consulted on the Company's website.

The development of a breakthrough therapy such as ours is necessarily an obstacle race. So far, we have overcome all hurdles, not without difficulty, but successfully. We therefore look forward to the next steps with confidence, resilience and the same winning spirit."

- **First-half 2024 earnings**

Abbreviated Income statement (in millions of euros)	**6 months ended June 30, 2024**	**6 months ended June 30, 2023**
Revenue	**3,3**	**0.6**
Net operating expense	**(25.4)**	**(25.9)**
Net financial expense	(1.7)	(1.7)
Net non-recurring income	0.1	-
Research and innovation tax credit	0.8	1.0
Net loss	**(26.2)**	**(26.7)**

CARMAT generated €3.3 million in revenue in the first half of 2024, corresponding to the sale of seven artificial hearts for commercial implants (in Germany, Italy and Poland) and 13 as part of the EFICAS clinical study in France.

In the first six months of the year, CARMAT's efforts and resources were predominantly focused on:

- deploying and developing its business in Europe;
- stepping up its EFICAS clinical study in France;
- continuing discussions with the FDA with a view to starting up the second cohort of its EFS (early feasibility study) in the United States;
- strengthening its financial structure.

The Company continued to keep tight control over its operating expenses, enabling it to slightly reduce its net operating expense to €25.4 million in the first half of 2024 (versus 2023).

After taking into account net financial expense of €1.7 million, net non-recurring income of €0.1 million and €0.8 million in income from the research tax credit, CARMAT ended the first half of 2024 with a net loss of €26.2 million (compared with a €26.7 million net loss in the first six months of 2023).

- **Cash and financial structure**

Cash position and cash runway

At June 30, 2024, the Company had €11.4 million in cash and cash equivalents, versus €8.0 million at December 31, 2023.

The variation over the first half 2024 can be analyzed as follows:

(in millions of euros)	**6 months ended June 30, 2024**	**6 months ended June 30, 2023**
Net cash used in operating activities	(25.7)	(30.7)
Net cash used in investing activities	(1.1)	(1.6)
Net cash from financing activities	30.3	4.7
Cash and cash equivalents at end of period	**3.4**	**(27.6)**

The cash burn used in operating and investing activities in the first half of 2024 decreased by 17% compared with that of the first half of 2023, in line with a planned trajectory that the Company is determined to continue during the rest of 2024 and in the coming years.

In the first half of 2024, Carmat obtained the following funds:

- an aggregate €32.5 million in proceeds from two capital increases (€16.5 million in January and €16.0 million in May); and
- €0.3 million corresponding to the final tranche of the total €1.4 million "CAP23" grant awarded to Carmat as a winner of the French government's "Industrial Recovery Plan - Strategic Sectors" call for projects.

In addition, on July 5, 2024, i.e., after the half-year close, CARMAT set up a flexible equity financing line with Vester Finance[3], involving the issue of up to 3,500,000 shares (corresponding to c. €8.2 million based on CARMAT's share price of €2.345 on June 30, 2024) over a 24-month period, with CARMAT immediately receiving €2.2 million.

In view of all of these factors[4], and based on its current business plan, CARMAT's confirmed financial resources should enable it to fund its business until end-September 2024. The Company is actively working on various financing options to secure in the very short-term, the financial resources it requires to continue as a going concern beyond that date[5]. The Company estimates its financing requirements over the next 12 months to be c. €45 million.

Net debt

On March 22, 2024, the Company reached an agreement with all of its lenders – the European Investment Bank (EIB), BNP Paribas (BNPP) and Bpifrance (BPI) – on new repayment terms for its bank loans[6].

Taking into account this agreement, CARMAT's net debt at June 30, 2024 was €47.1 million, breaking down as follows:

(in millions of euros)	**June 30, 2024**
+ Long-term financial liabilities (>12 months)	57.3
+ Short-term financial liabilities (<12 months)	1.2
- Cash and cash equivalents	(11.4)
(Net cash)/Net debt	**47.1**

Short-term financial liabilities comprise:

- €0.2 million in interest due on tranches 2 and 3 of the EIB loan; and
- an aggregate €1.0 million in principal and interest payments due on the government-guaranteed loans ("PGEs") taken out with BNPP and BPI.

[3] See the press release published by the Company on July 5, 2024 about this equity financing.
[4] Including the €2.2 million received in early July 2024 in connection with the Vester Finance equity financing line.
[5] See Section 4.2.1 for the factors underlying the going concern principle used by the Board of Directors.
[6] See the press release on the agreement published by the Company on March 22, 2024.

- **First-half 2024 highlights**

Marked acceleration in Sales

Twenty Aeson® implants were performed in the first half of 2024, versus respectively three and fourteen in the first half and in the second half of 2023. The rate of Aeson® implants reached four per month in the second quarter, doubling from two hearts per month in the first quarter.

In the first six months of 2024, CARMAT generated €3.3 million in revenue[7], which means that it has already exceeded its full-year revenue for 2023 (€2.8 million).

Sales were generated for the first time in Poland, bringing the number of countries in which CARMAT has a commercial activity to three (Germany, Italy and Poland). A total of nine hospitals carried out their first Aeson® implants in the first half of 2024 – four in Germany, three in France and two in Poland.

This very positive trend reflects the encouraging take-up of CARMAT's artificial heart therapy in Europe.

Very good momentum for the EFICAS clinical study

In the first six months of 2024, 13 Aeson® implants were performed as part of the EFICAS clinical study in France, corresponding to a rate of more than two implants per month.

This brought the total number of Aeson® implants performed under this study to 24 at June 30, 2024, paving the way for the completion, in the short-term, of half of the target number of patient recruitments, which represents 52 patients in total.

All of the French centers taking part in the study[8], a total of 10, had already referred patients, and nine of them had performed at least one implant.

As a reminder, EFICAS is the largest clinical study ever conducted by CARMAT and will allow the company to collect additional data on safety and performance of its Aeson® heart, as well as medico-economic data to support its value proposition. The Company anticipates publishing the study results in the last quarter of 2025.

This study is instrumental to report Aeson® clinical results scientifically on a significant sample size of patients, and thus facilitate the communication and dissemination of these results across the medical community.

In view of this, the Company believes that the publication will lead to a strong and sustained acceleration in the take-up of Aeson® artificial hearts in Europe.

EFICAS is a key study both for securing social security reimbursement of Aeson® in France and for supporting CARMAT's application for Premarket Approval (PMA) (marketing authorization in the United States issued by the FDA – Food & Drug Administration), which the Company expects to receive in 2027.

Continued international business development

Europe and Middle East

In the first half of 2024, CARMAT trained nine new hospitals to perform Aeson® commercial implants, expanding its network to 42 centers in 14 different countries[9]. The Company is therefore well on track to meet its target of 50 trained hospitals by the end of 2024.

Out of these 42 centers, three-quarters were active in first-half 2024, i.e., they had already submitted patient files to Carmat to assess their eligibility for implantation.

[7] Including €1.1m in the first quarter and €2.2m in the second quarter.
[8] 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, CHU de Montpellier, CHU de Nantes and CHU de Dijon.
[9] Germany, Italy, Poland, Switzerland, Israel, Slovenia, Saudi Arabia, Serbia, Croatia, Austria, Denmark, Netherlands, Czech Republic and Greece.

In addition, five countries in Europe (Switzerland, Austria, Slovenia, Croatia and Greece) and one in the Middle East (Israel) were activated and therefore ready to perform implants. The Company plans to activate more countries in Europe in the second half of the year.

United States

Discussions with the FDA (the U.S. Food & Drug Administration) continued during the period, with a view to commencing the second cohort of seven patients in the EFS[10].

Based on all of the information available, the Company expects this to happen in Q1 2025, and still foresees the commercial launch of Aeson® in the United States taking place during the second half of 2027.

Production ramp-up

Thanks to its expanded production capacity, with a second production facility coming on stream at its Bois-d'Arcy site at the end of 2023, as well as its growing supplier base and the experience it has built up over the last few years, the Company had a continuous production output in the first half of 2024, enabling it to meet demand without any difficulties, while keeping up an inventory level of more than 20 Aeson® hearts.

CARMAT intends to continue to implement its industrial roadmap aimed at continuously improving its production processes, securing its supplies, gradually reducing the production cost for its artificial heart, and aligning its capacity development with demand.

Changes in the Company's governance

On June 24, 2024, Pierre Bastid, having served on the Company's Board as a director since 2018, was appointed as Chairman of the Board of Directors, replacing Alexandre Conroy, who resigned for personal reasons.

A seasoned industrialist and entrepreneur, Pierre Bastid has subscribed for shares in each of the capital increases carried out by the Company since 2016 and holds 13.1% of CARMAT's share capital[11] via the Lohas and Les Bastidons entities.

CARMAT's Board has now 10 directors, including five independent directors.

- **Strategy and outlook**

2024 Objectives

For the second half of 2024, the Company forecasts a sales trend which would reach a yearly turnover within a range of €8 million to €12 million, to be compared with revenue of around €14 million previously communicated. This forecast reflects a better understanding of the market access dynamics and seasonality, as well as two summer months during which the level of surgical activity remained limited across Europe.

Regarding the other key objectives for 2024, the Company confirms it is on track to achieve them by the end of the year, namely:

- a patient recruitment rate of around 75% in the EFICAS clinical study,
- c. fifty centers trained for commercial implants,
- a c. 20% reduction in cash burn (operations and investments) versus 2023,
- filing to resume the EFS study (United States).

[10] The first cohort of seven patients was finalized in the second half of 2021.
[11] At June 30, 2024.

Key catalysts anticipated in 2025 to support short and medium-term development

In 2025, the Company anticipates four key drivers to support its short and medium-term development:

- Q1 2025: initiation of the second cohort of patients in the EFS study in the United States,
- H1 2025: publication in a scientific journal of the Aeson® clinical results for patients previously under "ECLS[12]",
- H2 2025: resumption of the PIVOTAL study in Europe for a cohort of patients not eligible for heart transplant, to target the "Destination Therapy" indication,
- Q4 2025: publication of the results of the EFICAS study (52 patients).

In the short term, continued development in Europe supported by scientific publications

With over 70 patients having received an implant since Aeson® was created, CARMAT has built up substantial clinical experience. This testifies to the technology's unique performance and safety profile, particularly given that the Company tends to treat patients at an increasingly severe stage of the disease.

In the coming months, the Company intends to carry-on with the gradual spread of its therapy across Europe, in the bridge-to-transplant indication for which Aeson® is currently approved, by building on this clinical experience, but also on the growing reputation of Aeson®, supported in particular by a ripple effect between centers, and spontaneous positive communication by physicians and hospitals performing implants.

Aeson® sales' growth should then accelerate significantly following the publication of Aeson® clinical results in patients previously under ECLS, anticipated in Q1 2025, and EFICAS study results in Q4 2025.

In the medium term, heading towards the US market and the Destination Therapy

In the medium term, the Company continues to target access to the US market, as well as the Destination Therapy (DT) indication (or so called "permanent implant"), which would allow patients to remain under Aeson® support with no subsequent heart transplant. In terms of addressable market, the Destination Therapy represents one of the biggest opportunities in cardiology.

The anticipated launch, in Q1 2025, of the second cohort of patients in the US EFS study, and the expected resumption in H2 2025 of the European PIVOTAL study with a cohort of patients not eligible for heart transplant, are important milestones to ultimately get Aeson® approved for this strategic indication.

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[12] ECLS = Extra-Corporal Life Support

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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This press release may contain forward-looking statements about the Company's objectives and prospects. 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, including those described in its universal registration document filed with the Autorité des Marchés Financiers (AMF) under number D.24-0374 and available on CARMAT's website, as updated in the Company's 2024 half-year financial report published today.

Readers' attention is particularly drawn to the fact that the Company's current financing horizon is limited to the end of September 2024 and that, given its financing requirements and outstanding dilutive instruments, the Company's shareholders are likely to experience significant dilution of their stake in the Company in the short term. The Company is also subject to other risks 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, changes in technology and the competitive environment, regulatory developments, industrial risks and all risks associated with managing the Company's growth. The forward-looking statements contained in this press release may not be achieved due to these or other unknown risk factors and uncertainties, or factors which the Company does not currently consider material and specific.

Aeson® is an active implantable medical device commercially available in the European Union and other CE-marked countries. The Aeson® total artificial heart is intended to replace the ventricles of the native heart and is indicated as a bridge to transplantation in patients with 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 benefit from heart transplantation within 180 days of implantation. The implant decision and surgical procedure must be carried out by healthcare professionals trained by the manufacturer. The documentation (clinician's manual, patient's manual and alarm booklet) must be read carefully to learn about the characteristics of Aeson® and the information required for patient selection and proper use (contraindications, precautions, side effects) of Aeson®. In the United States, Aeson® is currently available exclusively as part of a feasibility clinical trial approved by the Food & Drug Administration (FDA).