PRESS RELEASE

CARMAT delivers a solid FY 2024 with 42 implants of its Aeson® artificial heart and anticipates continued strong momentum in 2025

- Over 90 patients have received the Aeson® artificial heart since the first implant in 2013, including 42 in 2024.
- 2024 Sales of €7 million (a 2.5-fold increase vs 2023).
- Cash burn reduced by over 20% vs 2023.
- 50 hospitals trained in Aeson® implants internationally[1].
- Successful first "Aeson® User Meeting" and increasing engagement from trained hospitals, supporting the anticipation of a strong implants momentum in 2025.
- CARMAT expects to at least double its sales in 2025.

Webinar in English tonight at 8 pm CET.
To participate, please register by clicking on this link

Paris, January 8, 2025 – 5:45 pm CET

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**"), announces its 2024 annual sales[2] and provides an update on its development outlook.

Stéphane Piat, Chief Executive Officer of CARMAT, stated: *"With 42 implants of our Aeson® artificial heart and €7 million in sales, i.e. 2.5 times higher than in 2023, we delivered a very solid commercial performance in 2024, while reducing our cash burn by over 20%.*

All our operational indicators are trending positively, reflecting increasing interest and growing adoption of our therapy by hospitals: 60 centers are now trained on Aeson®, including 50 internationally for commercial implants, 43% of them have already performed at least one implant, and among those, six have performed at least four implants. In 2024, Aeson® was sold in four European countries, namely Germany, Italy, Spain, and Poland - and, of course, in France as part of the EFICAS study.

[1] Excluding the United States, where 9 hospitals are trained as part of the EFS (Early Feasibility Study) clinical trial, and France, where 10 centers are taking part in the EFICAS study.
[2] Unaudited data.

The first "User Meeting" we organized in November 2024, which brought together nearly 100 experts in cardiology to share their experience with Aeson®, was a tremendous success. It should prompt many European hospitals to either take the step of performing a first implant of our artificial heart or integrate it more broadly into their clinical practice.

All this, combined with the strong momentum in our EFICAS study in France, makes us optimistic about the future trajectory of our implants, and allows us to anticipate doubling our sales in 2025, at the very least.

A well-structured supply chain, calibrated to meet the demand, distribution agreements already in place in nine countries, a "field" team providing best-in-class support to hospitals, and key scientific publications on Aeson® outcomes planned in 2025, will support this momentum. We are therefore very well-positioned to continue and accelerate our development in the coming months and progressively establish Aeson® as a benchmark in the treatment of advanced heart failure."

Strong commercial performance in 2024 with 42 Aeson® implants and sales multiplied by 2.5

The Company's 2024 sales amount to €7 million, corresponding to the sale of 42 Aeson® hearts, including 17 in a commercial set-up (in Germany, Italy, Spain, and Poland) and 25 as part of the EFICAS clinical study in France.

This performance represents a 2.5-fold increase in Aeson® implants and sales vs 2023.

CARMAT's activity showed strong momentum throughout the year, with a monthly average number of implants of 3.5, rising to nearly 5 over the last four months of the year.

Continued strong recruitment momentum in the EFICAS study

By the end of 2024, nearly 70% of the planned recruitments in this study had been completed.

CARMAT anticipates completing EFICAS enrolment (i.e. a total of 52 patients) in the first half of 2025, paving the way for the publication of its results[3] at the end of 2025.

As a reminder, the EFICAS study is the largest study ever initiated by CARMAT. It is key to facilitate a broader commercial deployment of Aeson® ("evidence-based medicine") and obtain its reimbursement in France; and in order to secure the authorization to market Aeson® in the United States ("PMA"), which the Company anticipates in 2027-2028[4].

The EFICAS study is currently being conducted in 10 hospitals in France[5], among which 2 have already performed 7 implants each, demonstrating a high level of satisfaction with the therapy among healthcare professionals.

Increasing number and activity by hospitals trained in Aeson® implants

At the end of 2024, 60 hospitals were trained in Aeson® implants, including:

- 50 for commercial[6] implants in Europe, Israel and Saudi Arabia (+17 vs 2023),
- 10 in France as part of the EFICAS study (+2 vs 2023).

Among these trained centers[7]:

- 43% have performed at least one Aeson® implant (compared to 30% at end-2023),
- 27% have already performed several implants (compared to 15% at end-2023), and
- 6 hospitals have performed 4 or more implants.

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[3] Results on 52 patients. The primary endpoint of the study is support with Aeson® at 6 months or transplantation within 6 months, without disabling stroke.
[4] Subject in particular to the successful completion of the EFS study in the United States, second cohort of which is planned in 2025.
[5] 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.
[6] Of which 21 in Germany, 9 in Italy, 4 in Poland, 2 in Spain, 2 in Switzerland, 2 in Saudi Arabia and 1 in Israel.
[7] Cumulative data.

The positive evolution of these indicators reflects the growing interest of hospitals in Aeson®, as well as their increasing inclination, once trained, to carry out a first implant and then to adopt the therapy by performing additional ones.

CARMAT anticipates the acceleration of this trend, as supported by the results of a survey conducted by the Company among the 41 hospitals represented at the first "Aeson® European User Meeting[8]" in late November 2024, indicating that 100% of them intend to perform at least one implant in 2025, with 70% planning to perform several implants.

Further geographical expansion

In 2024, Aeson® implants were performed in 5 countries (+2 vs 2023), namely Germany, Italy, Spain, and Poland in a commercial set-up, and France as part of the EFICAS study.

In Europe, Germany is the largest market targeted commercially by CARMAT. The Company also aims to establish significant recurring activity in its three other active countries (Italy, Spain and Poland), and to initiate commercial implants in additional countries in Europe and the Middle East, where centers are already trained.

To this end, distribution contracts are in place to facilitate future sales in 9 countries (Poland, Switzerland, Greece, Israel, Slovenia, Croatia, Bosnia, Serbia, and North Macedonia).

CARMAT will continue to rely on a hybrid commercial approach, combining direct sales in certain countries, and support from distributors in others, when this latter model is deemed more appropriate.

Strong added-value services provided to hospitals in terms of clinical support and funding of the therapy

Building on a commercial and clinical organization scaled to support the growth in implants, CARMAT provides hospitals with best-in-class training, clinical support before, during, and after implantation, and also assist them in securing funding or reimbursement for the therapy.

During the fourth quarter of 2024, CARMAT's "field" team was able to successfully support four implants in a single week, and two implants in a single day.

All commercial implants of Aeson® have been appropriately funded, either through standard public and/or private reimbursement mechanisms specific to each country or region, or through specific funding dedicated to innovation.

Reduction of more than 20% in cash burn[9] associated to operations and investment

In line with its objective, CARMAT reduced its operating and investment cash burn by more than 20% in 2024 compared to 2023, achieving an average monthly cash burn of less than €3.8 million during the year.

The Company intends to carry-on with this reduction in 2025 and beyond.

Outlook

Based on these promising results and indicators, as well as feedback gathered during the first "Aeson® European User Meeting", CARMAT anticipates significant growth in Aeson® implants in 2025, driven particularly by the combined effect of more trained hospitals taking the step of performing their first implant, and an increase in the average number of implants by centers having a recurring activity.

The Company believes that this momentum will be further strengthened by the publication, in the first quarter of 2025, of the results of the clinical experience with Aeson® in patients previously supported by ECMO[10], and later in the year, by the results of the EFICAS study.

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[8] For further details, please refer to the press release issued by the Company on November 26, 2024.
[9] Unaudited data.
[10] ECMO = Extracorporeal Membrane Oxygenation.

CARMAT therefore expects to, at least, double its sales in 2025 compared to 2024.

As an indication, the Company estimates that its financial breakeven can be achieved with circa 500 Aeson® implants per year. This threshold is expected to be reached within a few years, based on approximately 100 Aeson® "implanting" centers in Europe and the Middle East, performing, on average, 5 implants a year.

The Company also continues to aim for the destination therapy indication, which would enable patients to remain on long-term Aeson® support without a subsequent heart transplant, as well as for the commercial launch of Aeson® in the United States.

To this end, the Company plans, in 2025, to conduct the second cohort of patients in its EFS[11] study in the United States, and to initiate a clinical study dedicated to patients not eligible for a heart transplant, in Europe, in order to gain clinical experience in destination therapy.

Based on its confirmed financial resources, CARMAT can fund its activities until February 2025 and estimates its 12-month financial needs in the range of €40 to €45 million. The Company is working very actively to secure, in the short-term, additional financial resources to extend its cash runway beyond February.

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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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[11] EFS – Early Feasibility Study

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This press release 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 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, as updated by an amendment to the 2023 universal registration document filed with the AMF on 17 September 2024 under number D. 24-0374-A01 (together the '2023 Universal Registration Document'), and available on CARMAT's website.

Readers' attention is particularly drawn to the fact that the Company's current financing horizon is limited to February 2025 and that, given its financing requirements and the dilutive instruments in circulation, 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, technological developments, changes in 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 as a result of these factors or other unknown risks and uncertainties or factors that the Company does not currently consider material and specific.

Aeson® is an active implantable medical device commercially available in the European Union and other countries recognising the CE mark. 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 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 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'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 only available as part of a feasibility clinical trial approved by the Food & Drug Administration (FDA).