PRESS RELEASE

CARMAT reports its FY 2021 financial results and confirms its 2022 prospects

- Revenue of €2.2 million corresponding to the first sales of Aeson® hearts
- Aeson® implants expected to resume in October 2022
- Available financial resources providing financial visibility until July 2022
- Company actively exploring financing options beyond H1 2022

Paris, February 16, 2022 – 7 am CET

CARMAT (FR0010907956, ALCAR), the designer and developer of the world's most advanced total artificial heart, aiming to fulfill an unmet medical need by providing a therapeutic alternative to people suffering from end-stage biventricular heart failure, today announces its annual results for the year ending December 31, 2021[1] and confirms its development prospects for 2022.

Stéphane Piat, Chief Executive Officer of CARMAT, commented: *"2021 was marked by several tangible breakthroughs on the commercial, industrial and clinical fronts. First and foremost, we successfully launched our Aeson® artificial heart in Europe, thus generating CARMAT's first ever sales.*

At the same time, we began and completed in record time the enrollment of the first cohort of patients in the EFS[2] in the United States. This is the first step in the evaluation process that should enable us, in the next few years, to market Aeson® on the world's largest medical device market.

The clinical results obtained so far continue to demonstrate the Aeson® heart's superiority over other existing treatments addressing end-stage heart failure. The positive feedback from physicians who have already implanted our artificial heart, and the high level of interest in our therapy, clearly confirm our technology's potential. In all of the Company's departments, notably in production, we are putting in place the teams and fundamentals that are essential to our success and growth.

All these achievements give us great confidence in our ability to rapidly develop Aeson® sales as soon as implants resume in October and, in the longer term, in the Aeson® heart's potential to become the benchmark therapy for end-stage heart failure".

[1] Annual accounts were approved by the Board of Directors on February 14, 2022. Audit procedures relative to these accounts are currently being carried out.
[2] Early Feasibility Study

- **2021 annual results**

Simplified income statement (€ millions)	**2021**	**2020**
Sales	**2.2**	**0.0**
Operating loss	**-60.4**	**-36.4**
Financial loss	-3.3	-2.5
Non-recurring items	-	+0.2
Research and Innovation tax credit	+1.9	+1.7
Net loss	**-61.9**	**-37.0**

2021 annual revenues totaled €2.2 million. They correspond to the sale of 10 Aeson® systems, of which 7 on a commercial basis in Germany and Italy, and 3 within the framework of the EFS in the United States.

The operating loss of €60.4 million (€24.0 million greater than the previous year) is mainly driven by higher operating expenses as the Company has strengthened its organization, notably in manufacturing, to prepare for its commercial launch; and by non-recurring expenses of €8.1 million.

CARMAT indeed recorded a one-off expense of €8.1 million due to quality issues that affected some prostheses, which led the Company to suspend implants of its Aeson® artificial heart voluntarily and temporarily on December 2, 2021. This impact primarily consists of inventory write-offs.

Excluding this non-recurring item, operating loss was €52.3 million in 2021, compared to €36.4 million in the previous year, on a like-for-like basis.

In 2021, CARMAT devoted the majority of its efforts and resources to the following:

- On the commercial front: commercial launch of Aeson® in Europe in July (approaching and training hospitals, contractual negotiations, assistance with the reimbursement of the prosthesis, after-sales support).
- On the industrial front: further ramping-up of production and work to enhance the reliability of production processes at the Bois d'Arcy plant, in partnership with the Company's suppliers and subcontractors; intensification of actions to secure supplies and build up suitable inventory levels.
- On the clinical front: preparation, initiation and completion of the enrollment of the first cohort of 3 patients in the EFS in the United States; continuation of the PIVOTAL study in Europe with two more patients implanted; and preparation for the start of the EFICAS study in France (regulatory and administrative procedures, initiation of hospitals involved).
- On the R&D front: further continuous improvement of the Aeson® heart, preparation of the device's next configurations and assistance to production activities.

The net financial loss of €3.3 million, €0.8 million greater than in 2020, was due to the increase in loan interest charges associated with the evolution of the Company's debt level.

Taking into account the financial loss, and the Research Tax Credit of €1.9 million, the annual net loss was €61.9 million in 2021, compared to a loss of €37.0 million in 2020.

- **Financial structure**

As of December 31, 2021, the Company had a cash position of €39.2 million, an increase of €3.2 million vs last year, as shown below:

(€ millions)	**FY 2021**	**FY 2020**
Cash flow from operating activities	-60.2	-43.0
Cash flow from investment activities	-1.8	-2.3
Cash flow from financing activities	+65.1	+25.8
Change in cash position	**+3.2**	**-19.5**

Cash generated by financing activities includes:

- a capital increase of €55.7 million (gross amount) in March 2021;
- the drawdown, at end-October 2021, of the third and final €10 million tranche of the loan granted by the EIB;
- the use, for a total of €2.9 million, of the contingent equity line with Kepler Cheuvreux;
- the payment of the first tranche of €0.3 million of a total grant of €1.4 million obtained by the Company as part of the French Governmental "Industry recovery plan – Strategic sectors".

Net financial debt as of December 31, 2021 was €12.8 million, as shown below:

(€ millions)	**31.12.2021**
+ Long-term financial liabilities[3]	51.9
+ Short-term financial liabilities	0.1
- Cash position	-39.2
Net financial debt	12.8

The financial resources immediately available to CARMAT, consisting of the cash position of €39.2 million and the Research Tax Credit of €1.9 million[4], should enable the Company to fund its activities, according to its current business plan, until July 2022 without any additional funding.

Furthermore, the Company has the possibility of using the remaining balance (€13.3 million as of December 31, 2021) of the Kepler Cheuvreux contingent equity line, valid until March 27, 2022. Full use of this balance would extend CARMAT's financing horizon to September 2022. It is however not certain that the entire balance can be used before the term of this equity line.

CARMAT is actively exploring various financing options to secure the necessary funding to extend its activity beyond July 2022.

[3] Financial liabilities include the principal (€30m) and the interest due on the EIB loan, the principal (€10m) and interest due on the State-Guaranteed Loans and interest pertaining to the €14.5m repayable advance obtained from Bpifrance. The characteristics and conditions of the EIB loan and the Bpifrance repayable 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.

[4] This tax credit relates to 2021 and will be paid in 2022.

- **2021 highlights**

2021 was an important year for CARMAT, notably marked by the commercial launch and first sales of Aeson® in Europe, the initiation of the Early Feasibility Study (EFS) in the United States and the raising of €56 million via a capital increase.

However, on December 2, 2021 CARMAT took the decision to suspend implants of its artificial heart on a voluntarily and temporary basis following the identification of quality issues affecting some of its prostheses. At this stage, the Company plans to resume the implants in October 2022.

Commercialization of Aeson® in Europe

The CE marking granted in December 2020 with the "BTT" (Bridge To Transplant) indication allows CARMAT to commercialize its Aeson® artificial heart throughout the European Union and in a number of other countries that recognize this certification.

On July 19, 2021, the Company announced its first implant in a commercial setting, performed on July 15, 2021 at the Azienda Ospedaliera dei Colli hospital in Naples, Italy. This first sale was followed, between July and November, by 6 more in Germany and Italy (at hospitals in Kiel, Hanover, Dresden and Naples).

The Company is encouraged by the positive feedback it has received from the various hospitals that have implanted its Aeson® heart, emphasizing in particular the device's ease of use, patients' short recovery time following the operation, the quality of the support provided by CARMAT and the substantial number of patients who could benefit from Aeson®.

CARMAT's strategy in Europe will initially focus on Germany and Italy, before being gradually expanded to other countries.

Clinical studies

EFS in the United States

A first patient was implanted on July 12, 2021 within the framework of this study at Duke University Hospital, North Carolina. At the end of September, the enrollment of the first cohort of 3 patients (2 men and 1 woman) had already been completed at Duke and the University of Louisville. At the end of November, CARMAT – in accordance with the protocol of this study – submitted to the FDA a 60-day interim report on these first three patients.

The Company is intending to begin the enrollment of the second cohort of 7 patients as soon as the FDA gives it the go-ahead. 9 American hospitals have already been trained by CARMAT, and are therefore ready to enroll patients.

If the EFS is a success, it should be followed by a PIVOTAL study involving a few dozen patients, with a view to obtaining a PMA (Post-Market Approval) from the FDA allowing CARMAT to commercialize the Aeson® artificial heart in the United States.

PIVOTAL study in Europe

As of December 31, 2021, 17 patients had been enrolled within the framework of the PIVOTAL study (including 2 in 2021, in Prague and – for the first time – in the Dutch city of Utrecht). The study's positive interim results contributed to CARMAT being granted CE marking as a bridge to transplant in December 2020. The Company intends to continue enrollments in this study in order to achieve the initial indicative target of 20 patients in early 2023[5].

[5] The initial enrollment target for this study was 20 patients, a figure that could be revised up or down during the study. The primary endpoint of this study is 6-month survival with the CARMAT heart or a successful heart transplant within 6 months of the device being implanted. The granting of CE marking did not a priori require a specific number of implantations and/or a predetermined success rate. In accordance with good clinical practice and subject to regulatory obligations or special circumstances, CARMAT does not provide individual details of implantations or patients' condition. To date, 17 patients have been implanted within the framework of the study. Of the first 15 patients, 11 have successfully reached the study's primary endpoint (7 having survived for more than 6 months after receiving the CARMAT heart and 4 having had a successful heart transplant within 6 months of receiving the device), a success rate of over 73%.

EFICAS study in France

This study will allow CARMAT to collect both additional data on the efficacy and safety of its artificial heart and medico-economic data that can support its value proposition and the device's reimbursement, notably in France.

In early December 2021, following successful completion of all regulatory and operational steps, a first implant was scheduled but put on hold as the Company decided to suspend new implants. The Company is now intending to initiate this study in the fourth quarter of 2022 with the resumption of the implants.

Ramping up of production and further securing of supplies

In 2021, CARMAT continued – in close collaboration with its suppliers and subcontractors – to implement its plan to ramp up production and build up adequate inventory levels.

During the fourth quarter, the Company reached its target of assembling 4 prostheses a week at its Bois d'Arcy plant. CARMAT is also striving to build appropriate buffer stocks when its supply sources allow it to.

CARMAT is also working on the reliability and optimization of its supply chain, with the aim to ensure a high and constant level of quality and to reduce the production cost.

Production remains a key challenge, as the Company relies on many suppliers and subcontractors, not all of whom have the same ability to ramp up their capacity, and some of whom have less experience in the standards required within the medical sector.

The industrial headcount (including external resources) has increased to 83 as of December 31, 2021, compared to 61 at the end of 2020.

Strengthening of the Company's governance and organization

Three new directors, Florent Battistella, David Coti and John B. Hernandez, were appointed at the Annual Shareholders' Meeting of May 12, 2021, adding expertise in terms of industrialization, finance and market access.

Moreover, Professor Christian Latrémouille joined CARMAT's Management Team as Director of Surgical Affairs on February 1, 2021.

Lastly, in September 2021, Mr. Ivo Simundic was appointed Sales Director for the DACH region (Germany, Austria and Switzerland).

The Company had 160 employees as of December 31, 2021, an increase of 41 compared with end-2020.

Impact of the Covid-19 pandemic

Generally, the Covid-19 situation had a tangible negative impact on CARMAT in 2021, notably in H1.

In particular, the various travel restriction measures prevented some implants within the framework of the ongoing PIVOTAL study and delayed the first implants within the framework of the EFS in the United States, and the training and the first commercial sales in Europe. The Company also experienced supply issues that slowed the rate of prosthesis production and inventory build-up.

Despite the pandemic, the Company managed to maintain its activities, with an estimated impact on its calendar, limited to approximately one quarter.

CARMAT is continuing to closely monitor the Covid-19 situation in France and abroad, and – depending on developments – could have to reassess its impact and adjust the Company's prospects.

- **Outlook: implants expected to resume in October 2022**

CARMAT's primary objective for 2022 is to resume implants in October provided that all required authorizations from the relevant authorities are received and that necessary changes which need to be implemented in its supply chain allow for replenishment of its inventories. More specifically, in October 2022, the Company intends to:

- resume and develop sales of its artificial heart in Europe;
- continue the EFS in the USA with the start of the enrollment of the second cohort of 7 patients;
- initiate the EFICAS study in France.

CARMAT also aims to secure in H1 the necessary funding to finance its activities beyond July 2022.

CARMAT's vision is to make its Aeson® artificial heart the no. 1 alternative to a heart transplant. Despite the temporary suspension of Aeson® implants, the Company firmly believes that sales will rapidly pick up following the resumption of its implants, and also has confidence in the sturdiness of its business model and future trajectory.

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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.21-0076. 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).