



PRESS RELEASE

2014 Annual Results

- Operating expenses in line with the project's progress
- Cash position of €9.2 million at December 31, 2014
- The Company's development has been secured by the setting up of a contingent equity line in January 2015

Paris, February 11, 2015

CARMAT (FR0010907956, ALCAR), the designer and developer of the world's most advanced total artificial heart project, aiming to provide a therapeutic alternative for people suffering from end-stage heart failure, today announces its annual results for the year to December 31, 2014¹.

• 2014 annual results

In euros	31/12/2014	31/12/2013
Operating income		
- operating subsidies	10,000	2,873,627
- other operating income (reversal of provisions)	39,342	0
Total operating income	49,342	2,873,627
Operating expenses		
- other purchases and external expenses	14,030,567	13,376,375
- other operating expenses	5,887,783	5,613,876
Total operating expenses	19,918,350	18,990,251
Operating profit/loss	-19,869,008	-16,116,624
Financial profit/loss	-476,155	-323,611
Exceptional items	-127,078	25,219
Research Tax Credit	2,209,185	1,770,114
Net profit/loss	-18,263,056	-14,644,902

In 2014, CARMAT benefited from operating income of €49k, consisting of a reversal of provisions of €39k and an operating subsidy paid within the framework of a revitalization contract signed with Oracle France with the aim of supporting a structural action to accompany industrial SMEs in Vélizy-Villacoublay.

No revenue was recorded by the Company in 2014, with CARMAT's total artificial heart project still in its clinical development phase and yet to obtain CE marking, a prerequisite to marketing the product in Europe.

¹ Annual accounts were approved by the Board on February 10, 2015. Audit procedures relative to these accounts have been carried out. The auditor's report is currently being prepared.

Operating expenses totaled €19.9m over the year, a limited increase of 4.9% compared with 2013. This situation reflects a natural decrease in the level of R&D activity between the 1st and 2nd halves of 2014, insofar as the 1st half of 2014 saw a continuation of the efforts undertaken over the 2nd half of 2013 to industrialize the prosthesis and perfect the portable patient system:

In thousands of euros	2 nd half of 2013	1 st half of 2014	2 nd half of 2014
Operating expenses	10,350	10,743	9,175

Once a financial loss (-€476.2k), exceptional items (-€127.1k) and Research Tax Credit (€2,209.2k) are taken into account, the net loss was -€18.3m in 2014.

• Financial structure

At December 31, 2014, the Company had a cash position of €9.2m, versus €16.9m at December 31, 2013. It includes €5.3m in repayable advances received from Bpifrance for reaching milestone n°5 (see the press release of December 16, 2014), as well as net income of approximately €5.9m associated with drawdowns on the contingent equity line (equity warrants) during the year. These drawdowns resulted in the creation of 83,200 ordinary shares with a unit nominal value of €0.04 and to the payment of a net issuance premium of €5,922,626.

During 2015, CARMAT should receive €2.2m in Research Tax Credit recognized at December 31, 2014.

Furthermore, it is due to receive an additional €1.9m² in the form of subsidies and repayable advances within the framework of its master contract with Bpifrance.

Lastly, at the start of 2015, CARMAT secured its development by subscribing to a new contingent equity line with Kepler Cheuvreux. Consisting of 3 successive tranches of 12 months each, this equity line allows the Company to issue €20m of shares within the framework of the first tranche and €15m for each of the following two tranches under advantageous conditions for the Company and its shareholders, the discount being limited to 6% of the issuance price (see the press release of January 26, 2015).

All these financial resources will allow CARMAT to continue its clinical development and ensure the progress of its activities through to 2016.

• 2014 highlights

▪ **Completion of half of the first-in-man trial and finalization of the portable patient system**

Throughout 2014, the development teams continued their work on the portable patient system, with the functional prototype thus being finalized and validated at the end of the year. At the same time, the 1st half of the year was notably devoted to gathering and analyzing the data from the first implantation of the CARMAT heart and to implementing the necessary adjustments. During the 2nd half of the year, the Company was granted approval to resume the enrollment of patients within the framework of the first-in-man trial. The 2nd patient thus received a CARMAT heart in August, which allowed the Company to pass the halfway mark of this first-in-man trial by early September 2014 (see the press release of September 8, 2014).

▪ **Functional reorganization and strengthening of the management team**

A functional reorganization was carried out in March 2014 through the creation of three divisions to steer the various industrialization operations (Technical division, Production division and Industrial Development division). CARMAT also appointed Mr Eric Richez as Director of Business Development. His mission is to draw up the CARMAT system's market access strategy.

Altogether, the Company's workforce increased from 40 members of staff at December 31, 2013 to 47 at December 31, 2014.

² Balance still due within the framework of the master contract with Bpifrance for reaching the two final milestones, n° 6 and n° 7, consisting of €159,166 in subsidies and €1,741,218 in repayable advances.

▪ **Scientific conferences and awards**

CARMAT participated in a number of scientific conferences during the year in order to share its latest breakthroughs with international opinion leaders in the field of heart failure, notably at the 34th ISHLT (International Society for Heart & Lung Transplantation) annual meeting in San Diego, California in April 2014 and at the 28th EACTS (European Association for Cardio-Thoracic Surgery) Annual Meeting in Milan, Italy, in October 2014.

The technological and medical innovation the CARMAT artificial heart project represents was also rewarded by a number of awards:

- the "Mechatronics Award of the decade", received in June 2014 at the European Mechatronics Meeting (EMM) in Annecy;
- the "Prix d'honneur" honorary award from the *Microns d'Or* jury, received on September 23, 2014 at the Micronora international microtechnology trade fair in Besançon;
- the 2014 INPI Award in the "Patent" category, received on December 2, 2014.

• **Key events since the end of 2014**

▪ **2nd patient discharged from hospital, portable patient system now available**

The patient who was implanted with a CARMAT bioprosthetic heart at the Nantes University Hospital on August 5, 2014 was discharged home in early January 2015. This was made possible following the approval by the regulatory authorities of the inclusion of the portable power and alert system in the protocol of the ongoing feasibility study, thus making it accessible for all the patients taking part in this trial. This silent electric portable system is the lightest of any system currently available for powering a total artificial heart, and provides patients with mobility and autonomy in excellent conditions.

▪ **CARMAT project selected to benefit from the EUnetHTA SEED program³**

At the end of January, CARMAT announced that it has been chosen, along with 9 other European companies (7 in the drug field and 2 in the medical device field), to benefit from the EUnetHTA SEED project. Funded by the European Union within the framework of its Health Program, the aim of this project is to initiate preliminary dialogue between Health Technology Assessment agencies and developers of new health products that are currently in the development stage before receiving CE marking.

• **2015 outlook**

In 2015, CARMAT is planning to continue the necessary actions to obtain CE marking, and notably to:

- complete the ongoing first-in-man trial;
- carry out additional preclinical validations;
- undertake a second clinical trial on 20 to 25 patients in France and/or abroad.

The preclinical and clinical data thus collected will enable the Company to file a request for CE marking with the relevant authority following these activities. This request should be filed by the 2nd half of 2016 at the earliest, assuming the results are satisfactory and there are no delays enrolling patients in clinical trials.

Marcello Conviti, Chief Executive Officer of CARMAT, concludes: *"During 2014, we successfully achieved a number of major milestones regarding our project. Firstly, we began our first-in-man trial and rapidly received the authorization to resume its recruitment. At the same time, we adapted our organizational structure in accordance with the gradual scale-up of our activities. Furthermore, thanks to the commitment of our teams and our industrial partners, we were able to finalize the development of the portable patient system in 2014. Its validation by the regulatory authorities allowed it to be incorporated within the clinical protocol. The first discharge home was a historic moment for all of our teams, but also represented renewed hope for patients and their doctors. Lastly, the recent diversification of our sources of funding has provided us with greater flexibility and security for successfully addressing the next stages of our development."*



³ <http://www.eunetha.eu/seed>

About CARMAT: the world's most advanced total artificial heart project

A credible response to end-stage heart failure: CARMAT aims to eventually provide a response to a major public health issue associated with heart disease, the world's leading cause of death: chronic and acute heart failure. By pursuing the development of its total artificial heart, CARMAT intends to overcome the well-known shortfall in heart transplants for the tens of thousands of people suffering from irreversible end-stage heart failure, the most seriously affected of the 20 million patients with this progressive disease in Europe and the United States.

The result of combining two types of unique expertise: the medical expertise of Professor Carpentier, known throughout the world for inventing Carpentier-Edwards® heart valves, which are the most used in the world, and the technological expertise of Airbus Group, world aerospace leader.

Imitating the natural heart: given its size, the choice of structural materials and its innovative physiological functions, CARMAT's total artificial heart could, assuming the necessary clinical trials are successful, potentially benefit the lives of thousands of patients a year with no risk of rejection and with a good quality of life.

A project leader acknowledged at a European level: with the backing of the European Commission, CARMAT has been granted the largest subsidy ever given to an SME by Bpifrance; a total of €33 million.

Strongly committed, prestigious founders and shareholders: [Airbus Group](#), Professor [Alain Carpentier](#), the [Centre Chirurgical Marie Lannelongue](#), [Truffle Capital](#), a leading European venture capital firm, and the thousands of institutional and individual shareholders who have placed their trust in CARMAT.

For more information: www.carmatsa.com



Disclaimer

This press release and the information contained herein do not constitute an offer to sell or subscribe to, or a solicitation of an offer to buy or subscribe to, shares in CARMAT ("the Company") in any country. This press release contains forward-looking statements that relate to the Company's objectives. Such forward-looking statements are based solely on the current expectations and assumptions of the Company's management and involve risk and uncertainties. Potential risks and uncertainties include, without limitation, whether the Company will be successful in implementing its strategies, whether there will be continued growth in the relevant market and demand for the Company's products, new products or technological developments introduced by competitors, and risks associated with managing growth. The Company's objectives as mentioned in this press release may not be achieved for any of these reasons or due to other risks and uncertainties.

No guarantee can be given as to any of the events anticipated by the forward-looking statements, which are subject to inherent risks, including those described in the *Document de Référence* filed with the *Autorité des Marchés Financiers* under number D.14-0145 on March 17, 2014 and the *Note d'Opération* that was approved with visa no. 11-308 on July 11, 2011, changes in economic conditions, the financial markets or the markets in which CARMAT operates. In particular, no guarantee can be given concerning the Company's ability to finalize the development, validation and industrialization of the prosthesis and the equipment required for its use, to manufacture the prostheses, satisfy the requirements of the ANSM, enroll patients, obtain satisfactory clinical results, perform the clinical trials and tests required for CE marking and to obtain the CE mark. CARMAT products are currently exclusively used within the framework of clinical trials. They are not available outside these trials or for sale.



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