N°1 January 2012

shareholder newsletter

A word from the CEO

Dear shareholders,

I am very pleased to address you, for the first time, through the CARMAT Shareholder Newsletter*. We want to make this Newsletter a means for a regular exchange of views and a medium rich in news and information to help you to follow the progress of our amazing project and to enable you to meet the men and women who are CARMAT's true assets.

In 2011, CARMAT achieved some substantial breakthroughs. We strengthened our management team, signed a major industrial agreement for the development of a portable console, finalised major preclinical tests with, in particular, conclusive haemocompatibility and sterility results. On a financial level, our capital increase was a success, reflecting your support and trust. All of these factors reinforce our project, the endgame of which is to market the world's most advanced artificial heart in order to give life and hope to patients.

2011 thus ended with a major event that rewarded all of our efforts: the favourable opinion of the Patient Protection Committee for the first clinical trial. As you know, this was one of the two necessary prerequisites to undertake the trial, the other being to obtain a favourable opinion from the *Agence Française de Sécurité Sanitaire des Produits* (AFSSAPS, the national agency responsible for health products). The file submitted in the spring was supplemented throughout the second half of the year as tests were carried out. Some tests are continuing, such as the lifespan of the complete system. Our regular and transparent progress reports vis-à-vis AFSSAPS enable us to anticipate their positive opinion that will allow us to proceed with the first clinical trial on a human being during the first half of 2012.

Of course all of us – and none more so than me – are impatient to see the results of over 20 years of work materialise at long last: all our teams are working flat-out to ensure that 2012 will see this first trial become a success. After the many years of research undertaken in this extraordinary project, our duty to you and to our future patients is first and foremost to take the necessary time to maximise the potential of the project's success.

On behalf of the CARMAT team, I would like to thank each and every shareholder, longstanding – notably Truffle Capital and EADS – and new, who has chosen to place their trust in us. I wish you a very happy New Year, and hope that you will enjoy reading this first Shareholder Newsletter. I look forward to addressing you through the second issue, with even more good news!

Marcello Conviti
CEO

** Readers are invited to consult the caution note included in the Company's press releases*

Contents

CARMAT IN FIGURES
(at 31/12/2011)

Number of employees
36, including 18 engineers, 4 Doctors of Science and 2 doctors

Surface area of premises
2,000 m², incl. white room of 250 m²

Number of patents
10

OSEO support
Already received:
€14.4m in subsidies
€3.7m in repayable loans

Still to be received:
€3.0m in subsidies
€10.8m in repayable loans

Funds raised on the market
€16m in 2010 via the IPO

€29.3m in 2011 via the capital increase with preferential subscription rights, €11m of it guaranteed by Truffle Capital

2011 key events

January	Henri Lachmann joins the CARMAT Board of Directors
February	Valérie Leroy appointed Director of Marketing and Investor Relations
May	Presentation of the promising anatomic compatibility study results
July	File submitted to AFSSAPS Signature of a partnership between CARMAT and BULL for the development of an apparatus for people with CARMAT artificial hearts
August	Substantial success of the rights issue with €29.3m raised, including the extension clause
October	Presentation of preclinical data to the 25th Annual Meeting of the Association for Cardiothoracic Surgery in Lisbon
November	Favourable opinion from the Patient Protection Committee

The clinician's point of view:
placing the patient first!

An interview with Professor Christian Latrémouille, Heart Surgeon at the Georges Pompidou European Hospital, Paris.

Dear Professor, could you briefly tell us about your collaboration with CARMAT: when did it begin and what activities have you participated in?

Prof. Latrémouille: I have had the pleasure and honour of working with Professor Carpentier for the last twenty years or so. I therefore participated with him in the very first trials on animals in the late 1990s. However, most clinical activity has taken place since 2008, on the definitive version. I notably carried out most of the experimental implants, which enabled implant tools to be developed. Furthermore, I collaborated in the development of the virtual implant model by validating the morphometric data permitting a patient's suitability in terms of anatomical compatibility to be verified. I also had the pleasure of being the Principal Investigator for the first clinical trials and, in this respect, I of course contributed to the study protocol that has just received the Patient Protection Committee's favourable opinion.

In your opinion, in what way is the CARMAT project different from other products or projects that already exist?

Prof. Latrémouille: This is the first intelligent prosthesis, the only one that continually analyses the patient's haemodynamic situation and adapts to it in almost real-time. It is also the only bioprosthetic heart, benefiting from all of Professor Carpentier's experience in biomaterials, to reduce the neurological risk associated with the formation of blood clots. Lastly, with the exception of the electric power supply, the entire apparatus will be contained within the thoracic cavity, which is fundamental for the patient's quality of life. If the product lives up to expectations, it will be a true definitive treatment: no such thing exists today.

Who will be "CARMAT patients"? Which patients would benefit the most?

Prof. Latrémouille: Every year, many patients on heart transplant waiting lists die from the lack of availability of a suitable heart. But this doesn't take into account all those, of which there are many more, who aren't even on those lists because of the number of non-eligibility criteria: medical antecedents, existing illnesses, and especially age, as the lack of a sufficient number of suitable hearts means that they are reserved in priority for younger patients. CARMAT's bioprosthetic heart could therefore be a solution for these tens of thousands of patients.

What are the main difficulties you anticipate during and after the procedure?

Prof. Latrémouille: The surgical technique itself is not that complicated. Because it's a prosthesis and not a graft, this is elective surgery – at a chosen time rather than a time defined by the availability of a donor – which enables the patient to be prepared and pressure on the teams to be reduced. The only difficulty lies in correctly positioning the heart in the thorax, but preoperative virtual simulation allows this difficulty to be well anticipated. We expect similar postoperative complications to any other major heart surgery, but the tests we have carried out have enhanced our confidence in the prosthesis, including during this critical phase.

The clinical trials foresee a first group of a small number of patients. What would you deem to be a good result for these first patients?

Prof. Latrémouille: For obvious ethical reasons, patients in this initial group will have an extremely negative prognosis and minimal life expectancy, even with the prosthesis: the risk incurred by testing the system has to be lower than the risk of not attempting it. Under these conditions, expectations are basic: to survive the operation without any major postoperative complications, confirm the prosthesis' performance and significantly improve certain essential functions (renal, hepatic, pulmonary and neurological) when they are damaged. Obtaining such a result will enable a second phase of trials to be envisaged on patients with a better prognosis for whom, beyond long-term survival, assessing the quality of life will be paramount: the objective is not to carry out a technological or surgical feat, but to give patients with little or no hope left a life that is truly worth living.

Integrator of technologies:
a demanding discipline

An interview with Patrick Coulombier, COO and Marc Grimmé, Technical Director

You both began your careers in aeronautics. Could you tell us when and in what circumstances you came onboard the CARMAT project?

MG: Back in 1996. I'd heard about the project, which I found totally fascinating. As soon as an opportunity arose, I joined the team: the opportunity to take part in an adventure such as this one doesn't come about twice in a lifetime…

PC: I was at Edinburgh airport in 2001 when I received a call from the General Secretary of MBDA* asking me to meet with him as soon as possible to talk about an atypical project. I had no idea back then just how exceptional the project was!

In your opinion, what are the main contributions the aeronautical industry can provide to a project such as CARMAT's?

MG: The methodology and standards behind its design and development are the same, just as rigorous. In fact many norms and standards applied to medical devices are inspired by aeronautics.

PC: In an aeroplane, there are three main lines of work: mechanics (fuselage, wings, cockpit), engines (reactors) and avionics (all the electronics). A methodology therefore has to be developed that enables multiple subcontractors to be managed, just like with the CARMAT heart project.

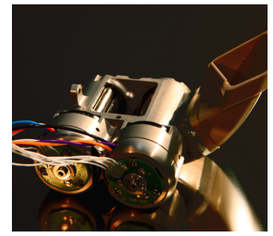
What is, for you, the most striking example?

PC: The most difficult technological challenge to meet was without doubt the one presented by the electrohydraulic converter, as we needed to develop a miniature electrohydraulic converter (< 3 cm long) capable of displacing the equivalent in litres of two Olympic swimming pools over 10 years without breaking down and using less energy than a CD burner.

MG: We therefore had to combine state-of-the-art expertise in modelling for the design with Phimeca and then qualify an industrial specialist in precision micromechanics – Vignal-Artru – and a specialist in tribology (the science of frictional effects and wear-and-tear) – HEF, and then get them to work in perfect harmony in accordance with our specifications.

PC: This is long-term iterative collaboration. We model a prototype, and then it undergoes endurance testing for friction and wear-and-tear, which leads to alterations in its design or its materials, which are then themselves prototyped, tested, etc.

MG: After a number of iterations, we ended up with the current definition. Thanks to these changes in material and reductions in friction, we now have a version that is not only much more robust, but that has also enabled us to reduce its energy consumption by three quarters.



Electrohydraulic converters

When did this development begin?

MG: The very first prototypes underwent endurance testing over a period of almost 10 years, and were still working when they were stopped in 2009. It was by analysing them and their successive improvements that we were able to obtain the current definition.

PC: The successive endurance tests carried out on each version make us very confident in the current definition's endurance tests, the results of which make up part of the technical file for the regulatory authorities. Indeed, as is only natural, even if the entire iterative testing process is taken into account in making their decision, the authorities will base themselves on the tests carried out on the version that will be implanted into humans.

**MBDA is an industrial group specialized in the field of aeronautics and defence. Its three major shareholders are EADS, BAE Systems and Finmeccanica.*

CE marking: a challenging procedure

by Joëlle Monnier-Roulé, Head of Quality

The CARMAT heart is an active implantable medical device (AIMD), and in this respect has to meet the requirements of directive 90/385/EEC in order to obtain CE Marking. This is a very demanding process, and CARMAT has already successfully passed the first stage thanks to its ISO 13485-9001 certification in July 2011. Indeed, CE marking, through a CE declaration of conformity, is based on a comprehensive audit of the quality system with an appraisal of all of the Company's processes and a focus on activities associated with the product. A comprehensive technical file then has to be put together incorporating, as well as its design elements, the risk management file and all verification and validation data – and notably the results of preclinical trials. The Company then has to undergo an audit by an independent notified body that will check the file and every process associated with the product and the organisation at CARMAT and, if necessary, at its subcontractors. Once this audit has been successfully completed, CARMAT will be able to obtain CE marking, which allows the product to be marketed throughout the European community.

Comprehensive audit of CARMAT's Quality System

- Design methodology
- Production (control of the environment process validation method, controls, etc.)
- Management of anomalies
- Identification and management of risks
- Sourcing (contracts, control and monitoring of subcontractors, audits, etc.)
- IT Systems
- Maintenance, Metrology
- Human Resources (skills, training, etc.)

➔ **ISO 13485-9001 certification obtained in July 2011, annual audit thereafter**

Compiling of the Technical File*

- **Product file** (design, choice and validation of materials, plans, labelling, notices, manuals, implant procedures, etc.)
- **Verification file** of the entire system, its constituents and components,
  - Biocompatibility tests
  - Bench tests (functional, endurance, etc.)
  - Electromagnetic compatibility tests
  - Validation of the sterilisation
  - Industrial validation – on the Company's site and at subcontractors
- **Risk management file**
  Failure mode, effects and criticality Analysis (FMECA), product and processes analysis
- **Validation file:** clinical trials

** The "Afssaps" file is part of this technical file*

Audit by an independent body

- **Analysis of the technical file**
- **Audit** of the organisation and of all processes associated with the product.
  - On the Company's site
  - At major subcontractors
- **Notice of conformity**

Declaration of European Conformity

CE

CARMAT and the stock market
at December 31st 2011

Share price (closing price): €83.84
Number of shares: 4,128,162
Free float: 24.2%

Name: CARMAT
Ticker: ALCAR
ISIN code: FR0010907956

ALCAR
LISTED
NYSE
ALTERNEXT.

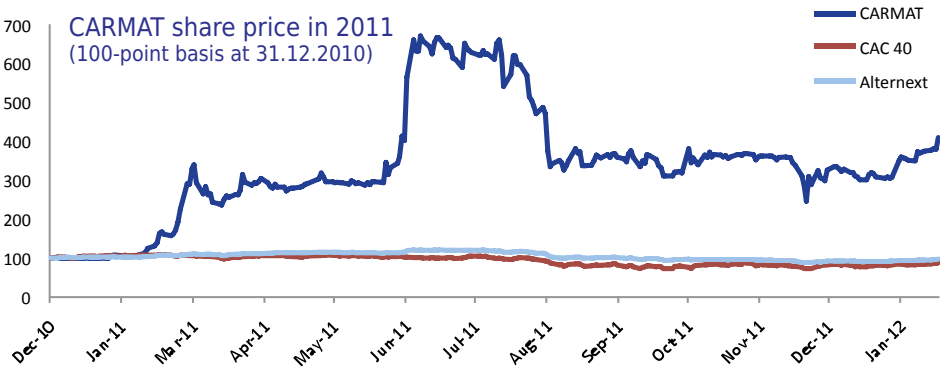
Best Alternext performance in 2011*

N° 1 market cap: **€346m**

Largest share price increase: **+207%**

Highest liquidity: **€382m** traded, or an average of 15,374 shares a day

**Alternext Allegra Finance study - January 2012*



Shareholders' questions

Like many small shareholders, I'm a little concerned about the AFSSAPS approval of your file, which was initially expected before the end of 2011. Are there some blocking issues?

In November 2011, CARMAT received a favourable opinion from the Patient Protection Committee, which is a major prerequisite for beginning the clinical trial process. The appraisal of the file by AFSSAPS (or its successor, ANSM), the second key stage, is currently in progress and will be finalised once the results of the endurance tests – which are generated in function of the time spent by the systems on our bench tests – have been transmitted. So far everything is progressing in line with expectations. We are confident that these tests will be validated, and we therefore hope to be able to begin, as planned, our first clinical trials during the first half of 2012.

What is the size of the CARMAT heart's potential market?

In Europe and the United States, over 20 million patients suffer from heart failure. CARMAT is aiming to market its artificial heart for patients suffering from class IV biventricular late-stage heart failure or from terminal acute heart failure following a massive heart attack. Taking into account criteria such as age or the respective anatomical compatibility of men and women, confirmed by the study presented at the Lyon congress in May 2011, this represents a potential of more than 100,000 compatible patients a year in developed countries. Assuming an average price of 160,000 euros for the CARMAT heart, the addressable market is estimated at 16 billion euros. The market share that CARMAT can anticipate will depend on various factors such as the result of clinical trials, sales coverage, the rate of adoption by the medical community and reimbursement conditions by country. It is therefore too early to give a specific figure in this respect.

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Financial Agenda

March 13th 2012
2011 annual results

September 17th 2012
2012 half-year results

CARMAT in the media

investir LE JOURNAL DES FINANCES
August 13th 2011
"Since its IPO in July 2010, the share price has more than quadrupled"

Le Revenu
September 9th 2011
"A revolutionary project and a fantastic industrial story"

L'USINE NOUVELLE
October 20th 2011
"CARMAT is a startup unlike any other. It is the result of the dream of a visionary, Professor Carpentier, who has been able to bring together the strengths of high-calibre industrialists, scientists and financiers."... "Almost 7,000 small shareholders have already come onboard the CARMAT dream."

Enjeux Les Echos
November 1st 2011
"Led for over twenty five years by its inventor, cardiologist Alain Carpentier, this small technological wonder is an exemplary illustration of an industrial project carried out the French way."

LA Recherche
January 1st 2012
"Today, this prosthetic heart is the only one in the world to use haemocompatible biological materials."

Réalisation Chêne Graphic