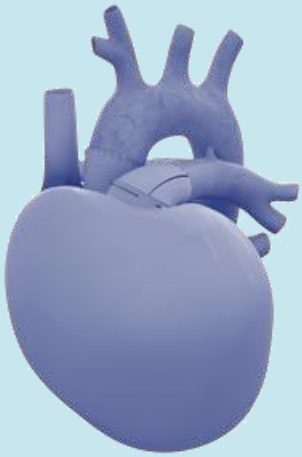
DOCUMENT DE REFERENCE

UNAPPROVED

ENGLISH

TRANSLATION

2011



CARMAT

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A Public limited company with share capital of 165.527.80 €
Registered Address: 36, avenue de l'Europe
Immeuble l'Etendard Énergie III
78140 Vélizy Villacoublay
Versailles Trade and Companies' Register 504 937 905

DOCUMENT DE RÉFÉRENCE 2011

Under the general regulations, and in particular Article 212-13, the Financial Markets Authority registered **the original French-language version of this "Document de Référence"** on September 12, 2012 under number R.12-044. **The issuing party drew up the original French-language version of the "Document de Référence"**, and its signatories are liable for its content.

Pursuant to the provisions of Article L. 621-8-1-I of the Financial and Monetary Code, registration took place after the AMF had established that **the original French-language version of the "Document de Référence"** was complete and understandable, and that the information it contains was coherent. It does not imply that the AMF has authenticated the accounting and financial information presented.

This document incorporates by reference:

- The "Document de Base" registered by the Financial Markets Authority on the May 21th, 2010 under the number I.10-037 (the "**Document de Base**")
- The document of reference 2010 registered by the Financial Markets Authority the 27th of April 2011 under the number R.11-017 (The "Document de Référence 2010")

Copies of **the original French-language version of this "Document de Référence"** as well as copies of this **UNAPPROVED ENGLISH TRANSLATION** are available free of charge from the CARMAT head office at 36 avenue de l'Europe – Immeuble l'Etendard Energy III – 78140 Vélizy Villacoublay. **The original French-language version of this "Document de Référence"** can also be consulted on the CARMAT website (www.carmatsas.com) and on the website of the Financial Markets Authority (www.amf-france.org).

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GENERAL REMARKS

In this “Document de Référence”, the terms “CARMAT” or the "Company" shall mean the company, CARMAT.

This “Document de Référence” contains information on the Company’s objectives and its avenues for development. This information is sometimes identified by the use of the future or the conditional, and terms that refer to the future, such as “consider”, “envisage” “think” “have as an objective”, “expect”, “intend”, “must”, “aspire”, “estimate”, “believe”, “wish” “can” or, where appropriate, the negative form of these verbs, or any other variation or similar terminology. The reader’s attention is drawn to the fact that these objectives and avenues for development depend on circumstances or events which may or may not occur.

These objectives and avenues for development are not historical data and must not be interpreted as guarantees that the events and data set out will occur, that the hypotheses will be verified or that the objectives will be achieved. By their very nature, the objectives and avenues for development in this “Document de Référence” could be affected by known and unknown risks, or by uncertainties linked specifically to the regulatory, economic, financial and competitive environment or by other factors which could lead to the Company’s future results, performances and achievements being significantly different from the objectives that have been formulated or suggested here. In particular, these factors may include the factors set out in Chapter 4, “Risk Factors”, of this “Document de Référence”. It is therefore possible that these objectives and avenues of development may not be implemented, and the statements or information in this “Document de Référence” may turn out to be erroneous. As such, the Company will not be required, under any circumstances, to provide updates, subject, that is, to the applicable regulations, and in particular the General Regulations for the Financial Markets Authority.

This “Document de Référence” also contains information relating to the Company’s activity, as well as the market and industry in which it operates. This information specifically comes from studies carried out by internal and external sources (analysts’ reports, specialist studies, sector publications and any information published by market research companies and public bodies and corporations). The Company considers that this information presents a faithful picture of the market and the industry in which it operates, and it faithfully reflects its competitive position. However, although this information is considered to be reliable, it has not been verified by an independent expert, and the Company cannot guarantee that a third party using different methods to gather, analyze or calculate data on the markets would obtain the same results.

Investors are invited to consider carefully the risk factors described in Chapter 4 “Risk Factors” in this “Document de Référence” before deciding to invest. If some or all of the risks materialize, this could have a negative impact on the Company’s activity, its position, its financial performance or its objectives. Moreover, other risks which have yet to be identified or which are not deemed significant by the Company, may have the same negative effect, and investors may lose all or part of their investment.

The drawings, images, graphics used in this “Document de Référence” are meant for illustrative purposes only and do not represent any form of pledge on the behalf of CARMAT.

To assist the reader’s understanding, this “Document de Référence” has a glossary attached. Words containing an “*” when they first appear can be found in this glossary.

A summary table listing the sources referenced in this “Document de Référence” is present at the end of this “Document de Référence”

1 AUTHOR

1.1 AUTHOR OF THE DOCUMENT DE RÉFÉRENCE

Mr Marcello Conviti, Chief Executive Officer of CARMAT.

1.2 DECLARATION OF THE AUTHOR OF THE DOCUMENT DE RÉFÉRENCE

"Having taken all reasonable steps to verify the contents of this “Document de Référence”, I affirm that the information contained therein is accurate to the best of my knowledge, and that no material information has been omitted.

I have obtained a completion letter from the Statutory Auditors, in which they state that they have verified the information concerning the financial situation and the accounts set out in this “Document de Référence”, and that they have read the entire “Document de Référence”".

The historical financial information for the year ending 31 December 2011 set out in this “Document de Référence” was the subject of the auditors’ report which appears in paragraph 20.3 of said “Document de Référence”, and which contains no observations.

The historical financial information selected by the Company and listed in this “Document de Référence” is, except when it is specifically noted otherwise, taken from accounts closed on December 31th, 2011, and when referrring to older data, to the document of references 2010, which is registered by the Financial Markets Authority on April 27th 2011 under the number R.11-017 and to the document de base, registered by the Financial Markets Authority on May 21 2010 under the number I. 10-037. This information is subject to the same auditors’ reports appearing in paragraph 20.3.1 of this “Document de Référence”; one of which contains an observation relative to *to the financial situation of the company* in December 2009 and *the measures announced by the management to enable the company to pursue its operations as described in* the *the appendix to the 2009 annual accounts*.

Mr Marcello Conviti
Chief Executive of CARMAT

2 AUDITORS

2.1 STATUTORY AUDITORS

PricewaterhouseCoopers Audit, member of the Regional Auditors' Association of Versailles
Represented by Mr Pierre Riou
63, rue de Villiers – 92200 Neuilly-sur-Seine
Date of commencement of duties: appointed when the undertaking was incorporated on 25 June 2008,
Duration of current term: Six financial periods from the date the Company was incorporated,
Date current term expires: at the end of the general shareholders' meeting to approve the accounts for the year ending 31 December 2014

Ms Lison Chouraki, member of the Regional Auditors' Association of Versailles
53, avenue Hoche – 75008 Paris
Date of commencement of duties: 16 October 2008,
Duration of current term: Six financial periods from 16 October 2008,
Date current term expires: at the end of the general shareholders' meeting to approve the accounts for the year ending 31 December 2014.

2.2 ALTERNATE AUDITORS

Mr Etienne Boris, member of the Regional Auditors' Association of Versailles
63, rue de Villiers – 92200 Neuilly-sur-Seine
Date of commencement of duties: appointed when the undertaking was incorporated on 25 June 2008,
Duration of current term: Six financial periods from the date the Company was incorporated,
Date current term expires: at the end of the general shareholders' meeting to approve the accounts for the year ending 31 December 2014

Ms Soulika Benzaquen, member of the Regional Auditors' Association of Paris
5, rue de Prony – 75017 Paris
Date of commencement of duties: 16 October 2008,
Duration of current term: Six financial periods from 16 October 2008,
Date current term expires: at the end of the general shareholders' meeting to approve the accounts for the year ending 31 December 2014

2.3 STATUTORY AUDITORS WHO RESIGNED, WHO WERE DISMISSED OR WHO WERE NOT REINSTATED

Since their appointment, none of the statutory auditors or their substitutes was dismissed from their positions, nor have any resigned.

2.4 AUDITOR'S FEES

	PricewaterhouseCoopers Audit				Lison Chouraki			
In Euros	2011	%	2010	%	2011	%	2010	%
Auditing, certification, examination of individual accounts - Issuer	45 200	95,76	45 930	95,83	25 075	92.61	25 500	92,73
Other activities and services directly linked to the auditing task	2 000	4,24	2 000	4,17	2 000	7,39	2 000	7,27
Total	47 200	100	47 930	100	27 075	100	27 500	100

3 SELECTED FINANCIAL INFORMATION

The Company was created on 25 June 2008. It completed its first financial year on 31 December 2009, for which the audited accounts cover the first 19 months of the Company's existence. Since then, the Company has completed two financial accounts covering each 12 months, which terminated on 31 December 2010 and 31 December 2011. The auditors certified those financial accounts.

The data below is taken from the capital balance, the profit and loss account and the cash flow table in the accounts for the years ending 31 December 2011, December 31th 2010 and 31 December 2009, drawn up in accordance with French accounting standards.

Consolidated Balance Sheet	*12 month*	*12 month*	*19 month*
ASSETS (in Euros)	31/12/2011	31/12/2010	31/12/2009
Net Capital Expenditure	3 147 942	3 582 600	3 243 191
Including intangible assets	234 707	324 112	431 219
Including tangible assets	2 448 058	2 832 276	2 733 869
Including financial assets	465 178	426 212	78 104
Current Assets	34 278 141	17 465 088	2 808 532
Including cash and cash equivalents.	29 369 693	11 415 823	712 837
TOTAL ASSETS	37 426 083	21 047 688	6 051 723

LIABILITIES (in Euros)	31/12/2011	31/12/2010	31/12/2009
Equity	26 890 919	13 474 075	3 527 996
Other owned funds	3 743 141	2 018 892	546 304
Provision for risk and charges	35 660	18 357	4 500
Debt	6 756 362	5 536 364	1 972 923
Including financial debt	217 066	78 096	12 219
Including operation debt	6 539 296	5 355 111	1 960 704
TOTAL LIABILITIES	37 426 083	21 047 688	6 051 723

Consolidated Income statement	*12 month*	*12 month*	*19 month*
(in Euros)	31/12/2011	31/12/2010	31/12/2009
Revenue	0	0	0
Operating aid	6 051 177	5 048 697	4 822 638
Operating charge	22 192 807	15 530 940	10 806 620
Operating Result	- 16 091 054	- 10 482 243	- 5 983 982
Financial Result	97 271	- 20 807	77 636
Current Result before tax	- 15 993 783	- 10 503 050	- 5 906 346
Extraordinary results	37 234	16 066	0
Research Tax Credit	- 2 515 527	- 2 750 499	- 1 184 342
Net Result	- 13 441 022	- 7 736 485	- 4 722 004

Consolidated Cash Flow	*12 month*	*12 month*	*19 month*
(in Euros)	31/12/2011	31/12/2010	31/12/2009
Net Result	- 13 441 022	- 7 736 485	- 4 722 004
Capacity of Self-Financing	-11 927 757	- 6 495 140	- 4 016 003
Operating Cash flow	- 9 705 912	- 6 951 146	- 4 676 580
Investment Cash Flow	-1 061 303	- 1 566 896	- 2 459 106
Financial Operation Cash Flow	28 721 085	19 221 028	7 848 523
Change in cash	17 953 870	10 702 986	712 837
Initial cash	11 415 823	712 837	-
Final Cash	29 369 693	11 415 823	712 837

4 RISK FACTORS

Investors are invited to take into consideration all the information appearing in this "Document de Référence", including the risk factors described in this chapter. When preparing this "Document de Référence", the Company carried out a review of the risks which might have an unfavourable impact on its activity, its financial situation or its capacity to achieve its objectives, and it considers that there are no other significant risks than those presented.

4.1 RISKS RELATING TO THE COMPANIES' ACTIVITY

4.1.1 Risks of failure or delays in the development of the total artificial heart

CARMAT is developing an orthotopic* and biprosthetic* artificial heart that is fully implantable, as well as its electricity supply system and its remote monitoring system.

This innovating system aims to treat an often-fatal disease and furthermore, aims to answer a real medical need, so far unmet.

The development plan for the total artificial heart is broken down into three phases:

- A phase for the preparation of clinical investigations consisting of examining, designing and manufacturing CARMAT total artificial heart systems for implantation into humans, and carrying out a number of tests necessary to obtain approval for an Authorization for Clinical Trials (**ACT)** from the French regulatory body (**l'ANSM)** [*1]
- A clinical trials phase including a feasibility trial and a pivotal trial ;
- A development phase which is aimed at finalizing the system definition and its *in vitro* and clinical validation file. This third phase will proceed in parallel with the clinical trials

This structuring makes it possible to obtain clinical validation data as quickly as possible, and also to validate the different technical choices for the CARMAT total artificial heart (anatomy – miniaturization, physiology - self-adjustment, haemocompatibility*, reliability) or to provide feedback with the same responsiveness on the design.

The artificial heart project was presented to the French safety agency for health products ("**AFSSAPS**")* in 2004, 2007, 2008, 2009 and 2010. The reception was favorable because, thus far, there is no alternative to such a device on the market, and because the methodology used - a product of the aeronautics and aerospace industries - should open the way for more modern developments in the area of complex medical devices. Regular meetings are organized between CARMAT and AFSSAPS in order to review the progress made in developing the total artificial heart.

In the framework of their mission to support innovation, the AFSSAPS offers a specific procedure to submit applications preemptively to the official demand for the Authorization of a Clinical Trial (ACT). This procedure allows for additional information to be submitted as it becomes available. The advantages of such a procedure lie in significantly reduced delays in comparison to those normally needed in order to obtain the authorization when submitting the official demand of ACT.

Such a procedure was begun in the spring of 2011. Additional information was added, notably in February 2012. There have been regular meetings and correspondences with the AFSSAPS to oversee the progress in developing the total artificial heart.

The human clinical validation will start once approvals have been obtained from the Committee for the Protection of Individuals * ("**CPP**") and "l'Agence Nationale de Sécurité du Médicament et des produits de santé* (**"ANSM")**[1]. Approval from the CCP was obtained on November 28th 2011. The decision of the ANSM will be made after the complete report of pre-clinical trials is filed, which is the final stage for the completion and official submission for an ACT.

Any failure or delay in developing the total artificial heart during the validation phases for commencing the clinical trials and during the clinical trials, or any delay in obtaining approvals from the CPP or AFSSAPS could have a significant, unfavorable impact on the Company's activity, its performance, its financial situation and its prospects.

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1 French Law n° 2011-2012 of 29 December 2011 regarding the reinforcement of health security for drugs and health products, and Decree No. 2012-597 of 27 April 2012 specify the organization of the National Security Agency of Drugs and Health Products (ANSM) that the legislature has established in place of the French Agency for Health Products (AFSSAPS). In this document, the acronym AFSSAPS is therefore used only when referring to events prior to the decree.

4.1.2 Risks involved with dependence on the total artificial heart

As at the date of registration of this "Document de Référence", the Company is dependent on the development and commercial success of its total artificial heart. The development of this complex bioprosthesis required significant investments from the Company in terms of time and financial resources, as well as the involvement of highly qualified staff, and this requirement will continue until the product is put on the market.

CARMAT's future success and its capacity to generate revenue will depend on the technical and commercial success of this medical device, and specifically on a number of conjectural factors, such as:

- The success of the clinical programs for the total artificial heart;
- Obtaining the CE Conformity Marking in the European Union and the Pre-Market Approval* ("**PMA**") from the Food and Drug Administration ("**FDA**") in the United States.
- The success of the commercial launch; and
- The acceptance of the total artificial heart by the medical community, and more particularly by cardiologists and cardiac surgeons, as well as third party payers (e.g. social security systems).

If CARMAT does not manage to develop and market its total artificial heart, there could be a significant impact on the Company's activity, its prospects, its financial situation, its performance and its development.

4.1.3 Risks relating to competition

- CARMAT's potential competition is composed as followed:
- On one hand, from total artificial hearts – marketed or still in development – and from BIVentricular assist Device, which are somewhat substitutable to the heart developed by CARMAT.
- On the other hand, and to a lesser degree, from Right/ Left Ventricular assist Device (RVAD/ LVAD) which are less substitutable as they only support one ventricle.
- .
- A detailed analysis of the competition is made at section 6.4.2 Technologies and market players.

To this day, and to the Company's knowledge, no other existing device, or project for creation of such, uses or, involves the use of, biological material or of self-regulation via multiple integrated sensors. These two characteristics are the core of the technological innovation embodied by the CARMAT heart.

Nonetheless, the medical device market is a very competitive environment and is subject to frequent and rapid evolutions. The Company competes with other larger corporations, some having more industrial and commercial experience and disposing of greater resources. Consequently, the Company cannot, in any way, warrant that its project will:

- Obtain the necessary regulatory approvals and will be marketed faster than its competitors;
- Be competitive to other products developed, or being developed, which may prove to be cheaper, safer or more efficient;
- Adapt rapidly to conjectural technological evolutions and scientific discoveries;
- Be accepted by doctors and patient alike instead of the existing traditional treatments, and;
- Be indeed competitive with regards to other concurrent products to treat the same pathologies.

It is likely that new developments will occur within the medical device industrial sector and within public and private research institutes. Notwithstanding the development of safer, cheaper or more efficient products than that made by CARMAT, the Company cannot warrant that its competitor would not be able to industrialize and commercialize their products more efficiently. The Company cannot, therefore, exclude the possibility that companies or public organizations, which are currently in competition with the aforementioned, would merge or create partnerships or other types of alliances between them and would consequently become more aggressive competitors. Furthermore, rapid technological development by competitors could render the Company's product obsolete before it entered into a profitable stage where the fees invested in research, commercialization, and development could be reimbursed.

Even if the Company's product was to be commercialized successfully, it could take time for its qualities to be recognized on the markets and this would result in the Company's inability to balance its operating cost with its revenues. In order to have its product recognized faster than those already existing, the Company will have to concede serious efforts in both marketing and investment. To this date, and as long as the product remains in development, the Company has taken no significant marketing initiative.

Lastly, the contracts signed between CARMAT and its employees do not carry non-compete clauses. The company, therefore, does not benefit from any of the advantages which such clauses provide, albeit, the maintaining of key personnel loyalty is ensured through the attribution of shares in the Company's equity.

4.1.4 Risks of a commercial failure

If the Company is successful in obtaining the CE Conformity Marking in the European Union and the PMA from the FDA in the United States for the CARMAT total artificial heart, thus enabling it to market its total artificial heart, it

might need time to secure the backing of the medical community, especially cardiologists, cardiac surgeons and healthcare payors.

-
- Market adoption of the total artificial heart depends on a number of factors, of which:

- The medical profession's perception of the therapeutic benefit of the total artificial heart;
- The number of establishments likely to carry out these artificial heart implant operations;
- The process and the quality of the training of cardiac surgeons who need to master a new surgical technique;
- The cost of the treatment;
- The policies for reimbursing governments and other third parties;
- The effective implementation of a publication strategy; and
- The support of recognized experts.

Poor market penetration resulting from one of these factors could have a significant, unfavorable impact on the Company, its prospects, its financial situation, its performance and its development.

Nevertheless, because CARMAT total artificial heart project responds to a growing global public health problem, which to this date has not had a satisfactory response, and because CARMAT works in collaboration with eminent cardiac surgeons on its ex-vivo* trials, the Company considers this risk to be limited.

4.1.5 Dependence risks relating to current and future strategic partnerships and collaborations

- In order to develop and market its total artificial heart, CARMAT, as project leader, has benefited from exceptional aid from the French agency for supporting SMEs and VSEs (OSEO Innovation) in the sum of 33 million Euros as part of the strategic industrial innovation program ("ISI") (see Chapter 22 "Important Contracts". It is also collaborating with the following four partners:

- DEDIENNE SANTE in the preparation of implantable PEEK* parts;
- PAXITECH in the development of a portable fuel cell*;
- VIGNAL ARTRU INDUSTRIE to develop the motor pump group;
- HEF R&D for the approval qualification of the motor pump group.

As the Company is not involved in producing the different components of the total artificial heart, and has no vocation to be, but does bring them together in order to create and market this complex bioprosthesis itself, it could be dependent on these partners. Indeed the Company cannot control the amount or the timetable of the resources that its existing or future partners will devote to the total artificial heart. It is possible that these partners fail to fulfill their obligations as the Company expects. That is why the Company may be faced with operational delays, which could have a significant, unfavorable impact on the Company's activity, its performance, its financial situation and its prospects. However, under the OSEO Innovation contract, each partner has undertaken the necessary steps to make the project to develop a total artificial heart and its components a success.

Additionally, since the Company was set up, CARMAT has always collaborated with reputable teams of cardiac surgeons, and in light of the clinical trials on humans it has formed close ties with three transplantation centers in France: the Georges Pompidou European Hospital in Paris, the Marie Lannelongue Surgical Centre in Plessis-Robinson, near Paris, the Laënnec Hospital in Nantes.

If the first implants of total artificial hearts are successful, the Company might become dependent on these French transplantation centers and their cardiac surgery teams. This could slow down the general acceptance of the artificial heart and the transfer of acquired skills and the surgical procedure during the first clinical trials in other transplantation centers and, as a result, it could have negative consequences on the Company's expansion and development.

In order to limit this risk, the Company has already identified other transplantation centers in the United Kingdom, Germany, Spain and Italy which might have an interest in artificial heart implantations.

4.1.6 Risks connected with a slowdown in the Company's efforts to train cardiac surgeons

In order to ensure the success of the Company's marketing efforts, it is essential that a sufficient number of cardiac surgeons are trained and that they have at their disposal the necessary instructions to implant the total artificial heart.

This training process could turn out to be longer than predicted and thus affect the progress of the Company's sales. If they are not adequately trained, the surgeons are at risk of carrying out inappropriate operations or surgical procedures that could result in the patient's death. This type of situation may undermine the image of the Company and indeed it could lead to legal proceedings being brought against it. All these consequences could have an unfavorable impact on the widespread expansion of the use of the total artificial heart and the Company's activity in general.

The Company considers that its methods for training surgeons comply with the FDA regulations and the relevant legislation in European countries in which it will initially market the total artificial heart. However, these methods for surgeons' training may be subject to specific local regulations governing relations between the manufacture of medical devices and health professionals. Thus in France, the training programs are subject to the prior opinion of the French medical association (l'Ordre des Médecins*) issued at the request of the manufacturer of the medical devices.

In addition, every competent authority, such as the FDA in the United States and ANSM in France, may:

- decide that the training is seen as publicity for unauthorized usage;
- order the Company to modify its training program;
- order the suspension of the training by the Company; or
- where a breach in regulations constitutes a criminal offence, report this fact to the State Prosecutor or any other competent body in this field with a view to commencing legal proceedings against the manufacturer.

However, given the innovative character of the CARMAT total artificial heart for patients and cardiac surgeons, the Company considers these risks to be limited.

4.1.7 Risks connected with outsourcing the manufacture of the components of the total artificial heart

The Company integrates different components in order to create the total artificial heart, while the actual manufacturing of most components is outsourced to different suppliers. CARMAT's capacity to market its total artificial heart depends in part on its capacity to obtain, from its suppliers, components that have been manufactured in strict compliance with the regulatory provisions and established protocols, in a profitable manner and in the quantities requested.

-
- It is not possible for the Company to control the amount or the timetable of resources that its suppliers will devote to the total artificial heart. In addition, problems might arise during the manufacturing process for different reasons, such as equipment failure, breach of specific protocols and procedures, or problems with the supply of raw materials.
-
- Problems arising during the production phase could cause delays in the supply of components, which could have the following consequences:

- An increase in costs;
- A fall in sales;
- A deterioration in relations with the clients;
- Delays and costs of identifying the cause of the problem;
- The Company becoming liable when the problems are not discovered before the product's commercialization;
- Delays in the manufacturing of the necessary prostheses for the pre-clinical trials, clinical trials or commercialization.

If relations with its suppliers break down or deteriorate, the Company might be unable to form new relationships with other suppliers in commercially acceptable conditions, or even at all, which could damage its ability to produce, develop and market its total artificial heart successfully.

-
- Moreover, the dependence on third party manufacturers creates additional risks, which the Company would not have if it produced the components itself, namely:

- Non-compliance of the components manufactured by third parties with regulatory provisions and quality control;
- Breach of the agreements with the Company by third parties; and
- Termination or non-renewal of these agreements for reasons outside the Company's control.

If it turns out that products manufactured by third parties do not comply with the regulatory provisions, sanctions could be imposed on the Company. These sanctions might include fines, injunctions, claims for damages, the refusal of regulatory authorities to allow clinical trials or to grant it the CE Conformity Marking or the PMA for its total artificial heart, the suspension or withdrawal of authorizations, the revocation of licenses, the seizure or recall of its products, operational restrictions and criminal prosecutions. All these measures could have a negative impact on its activity.

If the Company changes its product manufacturers, it would be required to revalidate the manufacturing process and procedures in accordance with current regulations. This revalidation could be costly and time consuming, and it could require the attention of the Company's most qualified staff. If the revalidation were to be refused, the Company could be forced to find another supplier, and this could delay the production, development and marketing of the total artificial heart and increase its manufacturing cost.

These events could have a significant unfavorable impact on the Company, its prospects, its financial situation, its performance and its development.

4.1.8 Risks connected with the supply and the increase in the costs of raw materials

Given the extent of the wide range of different materials (PEEK, polyurethanes, expanded PTFE and silicone oil), biological products (chemically treated animal pericardium*) and electronic and electromechanical components, which are necessary for the manufacture of the total artificial heart, as well as its electricity supply system and its remote monitoring system, the Company is dependent on a large number of suppliers and sub-contractors for the procurement of these items.

Even if the Company endeavors to formalize long term contractual relations with its strategic suppliers and sub-contractors, the procurement of any one of these materials, products or components could be reduced or interrupted. If that were the case, the Company might not be able to find other suppliers of materials, biological products, electronic and electromechanical components of acceptable quality in appropriate volumes and at an acceptable cost. If its principal suppliers or sub-contractors defaulted, or if its procurement of products, materials, or components was reduced or interrupted, the Company might not be able to continue to develop its total artificial heart for the purposes of the clinical trials, and then to produce and market its total artificial heart in time and competitively.

These materials, products and components are subject to extremely strict specifications, comprising a demanding manufacturing process and rigorous tests. Delays in manufacturing these materials, products or components by the suppliers or sub-contractors could affect the Company's capacity to carry out its clinical trials and to market its total artificial heart, as well as its electrical energy supply and its remote monitoring system, profitably and within reasonable time limits.

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- Although the Company has always sought to develop sources of procurement from several suppliers and sub-contractors so as to reduce the risks referred to above, CARMAT is still dependent on a single supplier for the provision of the following items:

- Long term implantable PEEK and other implantable polyurethanes,
- Implantable expanded PTFE; and
- Carpentier-Edwards® biological heart valves for which CARMAT concluded an agreement on 5 November 2010 with EDWARDS LIFESCIENCES (see Chapter 22 "Important Contracts").

Faced with a recurring surcharge experienced by certain suppliers from the new technologies sector, CARMAT now intends to accelerate the search for secondary supply sources for the prosthesis and the external subsets' most critical parts in order to ensure reliable supplies and thus ensure sufficient production capacities. This selection must be conducted in line with strict criteria for the quality, skills and production facilities of the suppliers. Consequently, CARMAT must launch surplus products, validate the industrial processes and verify that the products obtained are identical to those from its first supply source. In some cases, CARMAT will probably have to integrate certain outsourced processes vertically.

If the Company were to encounter difficulties in the supply of these materials, biological products or electronic or electromechanical components, and if it were unable to respect the sub-contracting agreements, enter into new agreements or obtain the materials or biological products needed to develop and manufacture its total artificial heart ,as well as its electrical energy supply system and remote monitoring system, in the future, its activity, prospects, financial situation, performance and development could be significantly impacted.

In time, during the marketing phase of the total artificial heart, the Company's gross margin could be affected by fluctuations in the market prices of raw materials, such as animal pericardium, long term implantable PEEK and other implantable polyurethanes, expanded PTFE and biological valves; these are difficult to predict or control and might have an unfavorable impact on the financial situation, performance and prospects of the Company.

4.1.9 Risks connected with the lack of sales resources and means of distribution

So far the Company does not have a marketing structure designed to support its future activity following the sale of the total artificial heart, nor does it have its own resources in terms of sales.

In order to ensure the success of the sales of the total artificial heart on a large scale, the Company will have to adapt its structure, develop itself at an international level, develop a distribution network and recruit dedicated, qualified teams. To this end, the Company has recruited Mrs. Valérie Leroy as marketing and investment relations director. Studies are currently being undertaken to recruit staff and to adapt CARMAT's organizational structure.

However, if the Company did not manage to put such a structure in place, or if there were delays in organizing marketing and distribution measures or the recruitment of a qualified sales team, this could have an unfavorable impact on the Company's activity, its prospects, its financial situation, its performance and its development.

4.1.10 Risks connected with growth management

The Company expects to grow significantly and to extend its field of activity to designing and producing medical devices, other than the total artificial heart. It will therefore need to adapt its organizational structure and implement new skills, recruit personnel and extend its operational capacities; this will significantly mobilize its internal resources.

- To this end, the Company will have to:

- Train, manage and hold on to a growing number of qualified staff;
- Make allowances for expenses connected with this growth and associated financing needs;
- Anticipate demand for its products and the revenues they might generate; and
- Increase the capacity of its existing operational, financial and management computer systems.

The Company's inability to manage growth or unexpected difficulties encountered during its expansion could have a significant, unfavorable impact on its activity, its performance, its financial situation and its prospects. However, as regards its growth at an international level, the Company has established a scientific committee to accompany it in all the development phases of the total artificial heart (see paragraph 16.3.3 "Medical and Scientific Committees").

4.1.11 Risks relating to the need to keep, attract and retain key personnel and scientific advisors

The Company's success depends largely on the work and expertise of the members of the board of directors and key scientific personnel, in particular Professor Alain Carpentier, Scientific Director, Marcello Conviti, Chief Executive, Patrick Coulombier, Assistant Chief Executive, Petrus Jansen, Medical Director and Marc Grimmé, Technical Director. So far the Company has not taken out any so-called "key man" insurance (an insurance policy to cover permanent incapacity/death) and the loss of their skills might affect the Company's capacity to attain its goals.

Although the Company has for several years conducted management and knowledge transfer programs, thereby creating an independent know-how base of individuals, the simultaneous departure of several important employees in its executive or its research and development activities could affect the Company's capacity to attain its goals.

Furthermore, the Company will need to recruit new executives and qualified scientific personnel in order to develop its activities as and when it expands into the areas which require more skills, such as manufacturing, marketing and regulatory affairs.

The Company is competing with other companies, research bodies and academic institutions in order to recruit and retain highly qualified scientific, technical and management personnel. As this competition is very intense, the Company may not be able to attract or retain key personnel in conditions that are acceptable from an economic point of view.

The Company's inability to attract and retain these key personnel might prevent it from attaining its objective overall, and that could have a significant, unfavorable impact on its activity, its performance, its financial situation and its prospects.

In order to motivate and retain the loyalty of the directors and employees who were present in the Company during CARMAT's first year, the Company put in place share option schemes ("**BSA**") and start-up share option schemes ("**BCE**")(see paragraph 17.2 "Shareholdings and share option schemes held by members of management and supervisory bodies"), and it created a remunerations committee made up of Jean-Claude Cadudal and Philippe Pouletty.

4.2 REGULATORY AND LEGAL RISKS

4.2.1 Risks connected with an increasingly stringent regulatory environment

Research and development work, pre-clinical studies, clinical studies and the manufacture and marketing of medical devices are strictly supervised and governed by numerous legislative or regulatory provisions, in particular those relating to health and safety, and they are subject to controls by competent administrative bodies, notably the ANSM.

The regulations on medical devices which CARMAT is subject to are complex, and they are becoming increasingly stricter. The regulations of the FDA in the United States and Directive 90/385 EEC of 20 June 1990, as amended by Directive 2007/47/CEE of 5 September 2007 relating to active implantable medical devices, for the countries of the European Union, which were transposed into the Public Health Code in France, and similar laws and regulations in other countries in the world govern numerous aspects of medical devices, notably:

- Design, development and manufacture of products;
- Product testing and clinical trials carried out on humans;

- Product storage;
- Marketing of products, including advertising and promotion;
- Approvals and market authorizations;
- Procedures for storing data; and
- Supervision, after products are put on the market and reporting deaths.

The direct or indirect costs associated with complying with current regulations, obligations or directives may rise. Notably, a revision of Directive 2007/47/CEE is expected in the Fall of 2012.

Furthermore, data from pre-clinical and clinical trials can produce divergent interpretations, which could delay or restrict the scope of the regulatory authorization, or force the Company to repeat trials in order for them to meet the requirements of the different regulators. The regulatory requirements and processes vary significantly from one country to another, and so the Company or its partners might not be able to obtain authorization in every country concerned in good time. Changes to the regulations during the development of the total artificial heart and its regulatory review can lead to delays or the authorization being refused.

In Europe, the United States and in other countries, the regulations may:

- delay and/or significantly increase the cost of developing, testing, manufacturing and marketing the Company's total artificial heart;-
- limit the indications for which CARMAT would be authorized to market its total artificial heart;
- impose new, stricter requirements to suspend authorization of the total artificial heart, or put a stop to clinical trials;

Any breach of the compliance obligations can lead to sanctions, including fines, injunctions, civil sanctions, refusal of the CE Conformity Marking or PMA, delays, suspension or withdrawal of the authorizations, the seizure or recall of products, restriction on use or criminal prosecutions. Individually these could significantly increase the costs borne by the Company, delay the development and marketing of its total artificial heart, and thus have a significant unfavorable impact on its activity, its performance, its financial situation and its prospects.

4.2.2 Specific risks connected with pre-clinical studies and clinical trials

The Company is currently in the phase of preparing for clinical investigations and studies on test beds recreating the bloodstream and mimicking human activity (activity, rest and sleep cycle), and tests on the hemocompatability of the CARMAT bioprosthesis are currently being conducted (see paragraph 6.3.3 "Development processes and clinical trials of the total artificial heart")

In addition CARMAT commenced the industrial assembly of the first two prostheses of the CARMAT total artificial heart in its clean room in November 2010. The next key stage in the development of the CARMAT total artificial heart will be implantation in a human being. The CARMAT bioprosthesis would first have to be evaluated on patients that cannot benefit from any other therapy and whose condition is life threatening, then, depending on the results, on patients with a better prognosis. CARMAT would then have to produce news series of implantable models for clinical trials.

This human clinical evaluation could begin once the approval of the ANSM has been obtained and all the development data has been evaluated by the competent regulatory authorities.

These regulatory authorities could put a stop to the clinical trials or require additional preclinical testing, if the data submitted was not produced in accordance with the applicable regulations, or if they consider that the comparison between the benefits expected from the product and its potential risks is not enough to justify the trial.

It should be noted that the Company could decide to, or indeed the regulatory bodies could demand that the Company suspend or put an end to the clinical trials if the patients were exposed to unexpected, serious risks. Deaths and other undesirable events connected with the trials might occur and therefore cause delays or interrupt that trial and consequently prevent the Company from pursuing the development of its total artificial heart in the targeted direction or even in other directions.

The Company's inability to carry out and complete these pre-clinical and clinical trials successfully could have a significant, unfavorable impact on its activity, its prospects, its financial situation, its performance and its development. In order to limit these risks, the Company set up two scientific committees, one of which is a medical committee, with the aim of preparing these clinical trials, (see paragraph 16.3.3 "Medical and Scientific Committees").

Clinical and pre-clinical trials are costly. If the results of these trials are not satisfactory or conclusive, the Company may be required to choose between abandoning its program, resulting in the loss of the corresponding investment in time and money, or continuing, with no guarantee that the additional expenses incurred will lead to a successful outcome.

4.2.3 Specific risks connected with obtaining the CE Conformity Marking and the agreement of the FDA to market the CARMAT total artificial heart

The total artificial heart will be used initially for research purposes under the regulatory status of "Investigation Use Only" (IUO) as part of the clinical trials. However, in order to be able to market its total artificial heart in countries of the European Union, the Company will have to obtain the CE Conformity Marking. (see paragraph 6.4.1 for the procedure to obtain the CE Conformity Marking .)

Similarly, the Company will be obliged to obtain the agreement of the FDA in the United States and the agreement of the regulatory authorities in other counties where the Company wishes to begin marketing its total artificial heart.

Each regulatory body may impose its own conditions, refuse to grant authorization or require additional data before granting its authorization to put the product on the market, even if that authorization had already been granted by other comparable bodies. (See paragraph 4.2.1 Risks connected with an increasingly stringent regulatory environment).

The process of obtaining regulatory authorizations is long and onerous, and the precise date of granting the authorization to place a medical device on the market is difficult to predict. Every delay or failure by the Company to obtain authorization to place the artificial heart on the market could have a significant unfavorable impact on its activity, its performance, its financial situation and its prospects.

4.2.4 Risks connected with being liable for the products

Cardiac surgery involves significant risks of serious complications that can have mortal consequences. The clinical trials and marketing of the total artificial heart involve a risk of incurring the manufacturer's liability for defective goods. If CARMAT were faced with a liability claim for defective goods, and if it did not manage to defend that claim successfully, its liability could be significant.

So far the Company has not entered the phases for the clinical trial and marketing of the total artificial heart, and so it has not taken out insurance for the clinical trial phase, as is required under France's Huriet Law of 20 December 1988, or insurance for defective product liability. However, the Company has already negotiated with a first rate insurer to insure against these risks and will dispose of a suitable amount of coverage, as required by the current regulations, at an acceptable cost as soon as the approval of the ANSM is granted.

However, the Company cannot guarantee that its insurance cover will be sufficient to respond to liability actions that might be brought against it. If CARMAT's liability were called into question, and it was not able to obtain and maintain appropriate insurance cover at an acceptable cost, or to protect itself in any way against liability actions arising out of defective products, this would have a serious impact on the marketing of the total artificial heart and more generally it would damage its reputation, its activities, its performance, its financial situation and its prospects.

4.2.5 Risks connected with uncertain protection of patents and other intellectual property rights

It is important for the success of the Company's activity that it is able to obtain, maintain and ensure respect for its patents, and other intellectual property rights, and thus protect its technologies against possible unlawful use by third parties. However, the patents and other intellectual property rights may only offer limited protection and may not prevent the unlawful use of the technologies belonging to CARMAT. In particular, the unauthorized exploitation of the Companies' technologies by third parties may lead to the loss of CARMAT's competitive advantage.

The efforts made by CARMAT to protect its technologies might not be successful for various reasons. Indeed, we cannot discount the fact that:

- The patents granted might be contested or held to be invalid, or that the Company cannot ensure that they are respected;
- The patents for which applications are being considered, including certain important patents in several jurisdictions, might not be granted;
- The extent of the protection conferred by a patent might be insufficient to provide effective protection from competitors;
- Its products will not infringe, or will not be accused of infringing patents belonging to third parties; or
- Third parties might claim rights over patents or other intellectual property rights owned by the Company.

The grant of a patent does not guarantee its validity or its enforceability, and third parties may call into question these two features. The granting and enforceability of a patent in the area of medical devices are highly uncertain and raise complex legal and scientific questions. Until now, no uniform global policy has emerged on the content of patents granted in the area of medical devices and the scope of the claims allowed. It may be that legal action is necessary to ensure respect for intellectual property rights, to protect commercial secrets or to determine the validity and scope of the Company's intellectual property rights. Any dispute could result in significant expenditure. It could also distract the management team from its priorities and reduce profits, and it might not provide the protection sought by the

Company. Competitors may successfully contest patents granted before a court or as part of other proceedings, which might have the effect of reducing the scope of the Company's patents. Furthermore, patents may be successfully infringed or bypassed as a result of innovations.

There is great disparity in the laws of the different countries where the Company has registered or is protecting its intellectual property rights. These differences might prevent the Company from satisfactorily protecting its technologies in one or more countries or from ensuring the same level of protection in the different countries.

If one of these factors concerning one of the patents or intellectual property rights occurs, it could have an unfavorable impact on the activity, prospects, financial situation, performance and development of the Company.

Bearing in mind the key importance of patents in its sector of activity, the Company has commissioned a study by a firm of specialists to confirm that it has freedom of exploitation, both in the United States and in Europe, for American and European patents with claims over every apparatus, system and method pertaining to the total artificial heart. According to the conclusions of the study, the Company's patents do not infringe the American and European patents highlighted in the research carried out.

In addition, CARMAT implements a policy of applying for patents at an early stage in order to optimize their priority rights.

4.2.6 Risks connected with the inability to protect the confidentiality of Company information and its know-how

The Company may be required to provide public or private bodies with information in order to conduct certain tests for the purposes of researching or validating its commercial projects. The Company also relies on its own technologies, methods, processes, know-how and data that are not patented and which it considers to be industrial and technical secrets. In both cases, their protection is specifically insured by confidentiality agreements between the Company and its employees, consultants and third parties. It cannot be excluded that these agreements or other methods of protecting commercial and technical secrets will not ensure the protection sought, or are not respected, or that the Company may not have an appropriate response to such breaches, or that its commercial and technical secrets are divulged to potential competitors or developed independently by third parties.

If one or more of these risks materialized, this could have a significant, unfavorable impact on the Company, its performance, its financial situation and its prospects.

4.2.7 Risks connected with pricing and changes in reimbursement policies for medical devices

The Company's capacity to make sufficient profits on the sale of the total artificial heart will depend in part on the level of costs assumed by the public health authorities, private health insurance, healthcare management organizations and other organizations.

If patients were not sufficiently reimbursed for the cost of the total artificial heart and the costs connected with the implant surgery, CARMAT could see sales volumes of the total artificial heart being unfavorably affected.

Governments and other third party payers are engaged in a drive to contain health costs by limiting both the cover and the amount of the reimbursement for new therapeutic developments. The Company expects increasing and constant changes from the draft legislation aimed at imposing government controls. If these proposals or reforms are adopted, this could have a significant negative impact on the Company's activity and the level of its revenue.

Moreover, governments and other third party payers are intervening more and more against medical and pharmaceutical sector undertakings on the pricing of products and medical services. There is a great deal of uncertainty over the reimbursement status of these new healthcare products and the possibility that the healthcare authorities or third party payers will assume enough of the cost. This could have a significant negative impact on the Company's activity and level of revenue.

As CARMAT aims to market the total artificial heart worldwide, particularly in the United States, its acceptance by the total artificial heart market will also depend in part on the mode of reimbursement being used in the systems for paying healthcare expenses in the countries in question.

CARMAT's failure to obtain adequate funding for the total artificial heart in countries where the Company wishes to expand would have a negative impact on its acceptance by the market in the country where these applications for funding have failed.

CARMAT is not able to anticipate how much funding there might be or the level of reimbursement for its products, as this is normally decided by the payers. Any funding levels or any changes to the funding and the resulting situation could have significant, unfavorable effects on the activities, prospects, financial situation, performance and development of the Company.

However, as the CARMAT total artificial heart responds to a global public health need, namely advanced heart failure, which so far does not have a satisfactory response, and as the price of the total artificial heart and the associated costs are calibrated so that they are close to those of a heart transplant (all the pre- and post operative costs and those of the transplantation itself – see paragraph 6.4 “Market and Strategies”), the Company considers these risks to be limited. Furthermore, the development of the CARMAT system and in particular the portable external part of the system which could allow the patient to be discharged more rapidly from the hospital to return home, and which could improve the patient’s quality of life, must allow for a reduction in the direct and indirect costs for the health systems.

4.2.8 Risks connected with changes to the tax on medical devices

The manufacturers of medical devices (including those implanted in full or in part in the human body) who place their products on the French market must pay the tax set out in Article L.5211-5-2 of the Public Health Code if their annual turnover before tax in relation to the sale of these products is equal to or greater than 763 000 €

This tax is for 0.25% of the total annual turnover before taxes made on medical devices, and before 31 March each year the Company must file a tax return along with payment to the AFSSAPS accounting officer. If no return is filed within the time limit set or if the return is inaccurate, the AFFSAPS can carry out its own assessment which will result in a fine of 10% being imposed for filing a late return or 50% for failing to file a return or filing an inadequate return. If the tax is not paid, the outstanding portion, including any penalties imposed, is increased by 10%.

The introduction of these taxes in other countries or their increase could have a significant, unfavorable impact on the activity, performance, financial situation and prospects of the Company.

4.2.9 Risks relating to hygiene, safety, technical installations and the environment

In light of the search for non-thrombogenic material, CARMAT decided to follow a path originally opened by Professor Alain Carpentier’s work with biological valves using chemically treated animal pericardium to avoid rejection by the body. In designing the total artificial heart, the Company is subject to chemical and biological risks preventing it from putting in place prevention measures and measures to protect operators and to manage waste in line with current regulations on the environment and those governing the use, storage, handling and disposal of hazardous materials. The Company is compliant with these regulations.

If the Company did not comply with the regulations, it would be subject to fines, and it may have to suspend all or part of its activities. Compliance with legislation relating to the environment and health and safety produces additional costs, and it could require the company to incur significant expenses in order to comply with future legislation and regulations on the environment in the relevant jurisdictions. Complying with environmental legislation and regulations could mean that the Company has to buy equipment, adapt its installations and more generally incur other sizeable expenses.

If one or more of these risks materialized, this could have a significant, unfavorable impact on the activity, prospects, financial situation, performance and development of the Company.

4.2.10 Risks connected with the loss of status of Young Innovative Enterprise

CARMAT opted for the status of Young Innovative Enterprise (“**JEI**”) in September 2008. On 8 July 2009, the Fiscal Services Directorate for the administrative district of Yvelines gave a favorable opinion on the company’s application for the title of JEI.

The status of JEI is intended to provide significant support to young enterprises which are very active in research and development by ensuring they benefit from exemptions from employers’ social security contributions.

In this way JEIs enjoy exemptions from employers’ social security contributions for researchers, technicians, research and development project managers, lawyers responsible for ensuring industrial protection and drawing up technology agreements connected with the project and personnel responsible for carrying out pre-competitive tests. This exemption is also open to company representatives in relation to the general social security system.

The French Parliament voted to amend the provisions relating to the status of JEI through Article 78 of the Finances Act 2011, so as to place a cap on the provision for social security contributions by JEI employers and to make them regressive by introducing:

- A gross monthly salary cap per person, set at 4.5 times the French minimum wage (or 6,142.50 € in 2011);
- An annual cap on eligible contributions per establishment, set at three times the annual cap for social security, or 106 056 € for 2011;
- A progressive reduction in the exemptions over the course of the life of the company. The new exemption provision provides that on the basis of the exemption figure which the establishment could claim, the exemption rate will be 100% of this figure from the first to the fourth year, and then it will be progressively reduced over the following four years – 75%, 50%, 30% and 10%, respectively – before it expires.

This reform represents a cost overrun for CARMAT of 0.5 million Euros for the year 2011 and 3 million Euros overall for the years 2011 to 2015, the eighth and final year in which CARMAT can benefit from the JEI status.

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- In order to benefit from JEI status, the company must comply with the following five conditions:

it must be an undertaking within the European Union, which in the financial year or tax period for which it wishes to benefit from the JEI status must employ fewer than 250 people, and have a turnover of less than 50 million Euros or have a total capital of less than 43 million Euros;

- At the end of each financial year, it must have incurred research expenses representing at least 15% of the tax deductible charges for that same year (these research expenses are calculated on the basis of the expenses used for the research tax credit);
- It must be less than eight years old;
- It must not have been created as part of a concentration, restructuring or extension of a pre-existing activity or the recommencement of such an activity within the meaning of Article 44 sexies, III of the General Tax Code;
- It must be independent within the meaning of Article 44 sexies-0 A of the General Tax Code, that is, at leas50% must be continuously owned by:
  - Individuals; or
  - A company that fulfils the same conditions and whose capital is at least 50% owned by individuals; or
  - Venture capital companies, risk investment funds, regional development companies, venture capital financial companies, or single member risk investment companies, provided the JEI and these companies are not dependent on each other; or
  - Foundations or non-profit science associations, or by a company with the status of a young innovative company which carries on research and development projects; or
  - Public research and teaching institutions or their affiliates;

This condition as to the ownership of capital must be complied with throughout the financial period for which the undertaking in question wishes to benefit from the special status.

If the Company loses JEI status for failing to comply with one of the above conditions, this could have an unfavorable effect on the performance, the financial situation and the prospects of the Company

4.3 FINANCIAL RISKS

4.3.1 History of operational losses – Risks connected with forecasted losses

The Company was created in 2008. On 31 December 2010, the accumulated losses (including losses carried forward) reached 25 899 511 €. This loss comes from research costs and the costs of developing the CARMAT total artificial heart; these charges cannot be recognized as intangible assets under French accounting rules.

The Company is expected to experience new, more significant operational losses in the course of the next few years, particularly in view of:

- the completion of research and clinical trials in Europe and then the United States on the total artificial heart in order to obtain marketing authorizations;
- costs connected with marketing the CARMAT total artificial heart;
- the expansion of its portfolio of products through the future implementation of projects to develop new breakthrough medical devices using skills and know-how developed by CARMAT for the total artificial heart.

As at the date of registration of this “Document de Référence”, the total artificial heart has not produced any operational revenue. The Company’s profitability will be dependent on the results of its clinical trials and the marketing of the total artificial heart, which would commence as soon as the Company is granted the CE Conformity Marking. The Company considers that the only sources of financing to be generated before the total artificial heart is marketed will come from funds raised on the NYSE Euronext’s Alternext market in Paris, state grants, research tax credits (CIR) and, to a lesser extent, income from cash investments and current financial instruments which enable it to deal with short and long term liquidity risks (see paragraph 4.4.2 “Liquidity Risks”). .

The cash-flow position as of December 31st 2011 – including the funds resulting from the share capital increase with preferential subscription rights carried out in August 2011, the completion of the next key stage of the OSEO Innovation program and the 2010 CIR rebate – will enable the Company to meet its needs until December 2013. Thereafter, additional financing will be needed to enable the Company to finance the commercialization of the total artificial heart, particularly through capital increases.

The increase in these expenses, particularly in the event of an absence or rupture of revenue sources could have a significant, unfavorable impact on the Company, its performance, its financial situation and its prospects.

4.3.2 Unreliable capital resources and unreliable additional funding

The Company made significant investments into research and development since it began its operations in 2008, and this has produced an operating loss of 5 983 982 €, 10 482 243 € and 16 091 054 € for the years ending respectively December 31st 2009, December 31st 2010 and December 31st 2011.

Overall, the monetary cost of developing the total artificial heart is expected to be in the order of 80 million € for the Company. This will be financed

- First by subsidies and repayable advances from the OSEO Innovation program (see Chapter 22 "Important Contracts"), the subsidies from the Yvelines General District Council already paid, research tax credits with an estimated total of 41 million Euros, (excluding reimbursement of the research tax credit to come);
- Then by increases in capital for a total gross sum of around 41 million Euros. This figure includes funds raised when the Company's shares were floated on the NYSE-Euronext's Alternext market in Paris in July 2010 for a total sum of 14.2 million Euros and the proceeds from the fundraising carried out as part of the capital increase with preferential subscription rights on the Alternext market of NYSE-Euronext Paris in August 2011 for a net 26.7 million Euros.

The aforementioned funds should enable the Company to finalize the development of the total artificial heart, and to perform the clinical trials needed to submit an application for the Conformity Marking ; scheduled, to date, at the end of 2013.

Its future capital needs will depend on a number of factors, such as:

- higher costs and slower progress than had been expected for its program to develop the total artificial heart;
- higher costs and longer delays than had been expected in obtaining regulatory authorizations, including the preparation time for the application files submitted to the regulatory authorities;
- the costs of preparing, lodging, defending and maintaining patents and other intellectual property rights; and
- new opportunities to develop new promising products or acquire new technologies, products or companies.

The Company anticipates that in the near future it will have capital needs to commence marketing the total artificial heart as soon as the CE Conformity Marking has been granted. At this development stage, because the Company cannot fund its own growth, it will have to look for other financing sources, in particular through new increases in capital, which could come to a total of around 30 million Euros in order to assure the new marketing structure and industrial operating costs.

It may be that the Company cannot raise sufficient funds within acceptable conditions, or even that it cannot raise funds at all when it needs to. If the necessary funds are not available, the Company may have to:

- Delay or scale down its development program;
- Cut staff;
- Obtain funds through partnership agreements which could force it to give up rights over certain technologies, rights which it would not have given up in different circumstances;
- Grant licenses or conclude collaboration agreements that might be less attractive than those which it would have been possible to obtain in different circumstances; or
- Consider hiving off assets, or even approaching another company.

If one or more of these risks materialized, this could have a significant, unfavorable impact on the Company, its performance, its financial situation and its prospects, as well as the situation of its shareholders.

4.3.3 Dilution risk connected with issuing shares giving immediate or long term access to the Company's capital

As part of its policy on motivating its executives and employees, the Company has since its creation allocated or issued BCEs and BSAs. The Company could in the future allocate or issue new instruments giving access to its common stock.

As at the date of registration of this "Document de Référence", the use of all the instruments allocated by the Company giving access to its common stock meant that 334.100 new shares were subscribed to, representing a total of 8,07% of the common stock. The use of instruments giving access to floating capital and all new allocations or issuances would lead to a significant dilution for the shareholders.

4.3.4 Risks connected with state subsidies and research tax credits

In the event that the Company were to breach the contractual conditions in the agreements for subsidies and repayable advances concluded with OSEO Innovation for an overall sum of 31.9 million Euros (see Chapter 22 "Important Contracts"), it would not receive the proposed aid.

If the Company were to breach the contractual conditions concluded with OSE Innovation, it could be required to repay the sums advanced. These situations could deprive the Company of the financial means to complete its research and development. Indeed, the Company will not necessarily have the additional financial means available or the time to replace these financial resources with others.

Furthermore, in order to finance its activities, the Company also opted for the research tax credit ("**CIR**") for the years 2009, 2010 and 2011. This mechanism involves offering a tax credit to undertakings which invest significantly in research and development.

The research expense eligible for the CIR specifically includes wages and salaries, services sub-contracted to approved research organizations (public or private) and intellectual property costs.

The CIR for the year 2011 was recorded in the entry "Tax on profits" in the profit and loss accounts, and it appears in the entry "Other liabilities". The profit and loss account for the period shows a CIR in the sum of 2 515 527 €, made up of 2 566 103 € for the CIR for the period 1 January 2011 to 31 December 2011 and -50 576 for the adjustment of the CIR for the year 2010 by comparing the amount recorded at year end 2010 (2 819 267 €) and the amount repaid by the tax authorities (2 768 691 €). In July 2012 the liability for the CIR 2011 was cashed-in for an amount of 2 558 614 €, very close to the December 2011 forecasted amount.

The CIR is an important source of finances which could be called into question by a change to the regulations or by the tax authorities raising an objection even though the Company is compliant with the documentation requirements and those on the eligibility of expenses.

4.4 MARKET RISKS

4.4.1 Interest rate risks

The Company's financial debts are made up of a repayable advance provided by OSEO Innovation in the sum of 3 743 141 € for the year ending 31 December 2011. This repayable advance carries contractual interest at the rate of 5.59%. Accrued interest at year end came to 217 066 € (see Chapter 22 "Important Contracts").

The total amount of marketable securities listed in the balance sheet amounted to 10 039 822 €. They correspond to certificates of deposit amounting to 10 000 000 €; it concerns five contracts signed in October 2011 and expiring on October 25, 2012. Corresponding accrued interest were recorded at the end of year and amounted to 39 822 €. These contracts are negotiable at any time on the market. The redemption price is thus established based on the conditions of the monetary market of the moment.

Treasury instruments correspond to the term accounts for 17 000 000 € and it concerns twenty-nine contracts signed in October 2011 and with initial maturities on January 25, 2012 (5 000 000 €), to April 25 2012 (2 000 000 €), to 25 July 2012 (4 000 000 €, or eight contracts for 500 000 €, closed in advance during the first half of 2012) and October 25, 2012 (6 000 000 €, corresponding to twelve contracts of 500 000 €, which closed a contract in advance during the first half of 2012). Corresponding accrued interest were recorded at the end of the year amounting to 66 499 €.

These investments do not pose a significant risk to the invested capital

4.4.2 Liquidity risks

The Company's growth is financed by strengthening its own funds through increases in common stock or convertible bonds.

At the date of registration of this "Document de Référence", the Company has no banking debts, and it is therefore not exposed to any liquidity risks from the enforcement of clauses on the early repayment of bank loans.

Furthermore, bearing in mind the Company's historic deficit situation, explained by the fact that it is still in the development phase during which it is incurring expenditure on research and development without earning a regular income, the Company is at risk in terms of its liquidity.

However, when the accounts for the year ending 31 December 2010 were approved, it was assumed that it would continue its operations:

- Particularly in the light of its liquidity levels (liquid assets, cash instruments and investment securities) readily available as at 31 December 2011 of 29 369 693 €;
- Subsidies (3 033 000 € paid on 3 January 2011) and repayable advances (10 764 000 € yet to be received) under the OSEO Innovation program concluded in 2009.

The Company will be able to meet its needs until January 2012 in light of the following:

- Available cash as at 31 December 2011 in the sum of 29 369 693 €;

- The payment on 3 January 2011 of OSEO-ISI subsidies amounting to 2 874 000 € connected with key stage 4 as per the addenda to the framework contracts which and beneficiary of the CARMAT project signed in June 2011 (see paragraph 6.3.3 “Process and stages of development of the total artificial heart” and see chapter 22 “Important Contracts”) ;
- The payment of OSEO-ISI subsidies to the CARMAT project for maximum sums respectively of 3 772 000 € and 5 251 000 € in May after completion of key stages 4 and 5 of the OSEO-ISI program as per the addenda to the framework contracts which and beneficiary of the CARMAT project signed in June 2011 (see paragraph 6.3.3 “Process and stages of development of the total artificial heart” and see chapter 22 “Important Contracts”) ;
- The reimbursement of the 2011 CIR in the sum of 2 558 000 € planned for July 2012.

After that, additional financing will be needed so the Company can continue to finance the development of the total artificial heart, in particular through future increases in capital. These could come to a total of 30 million euros until the product is marketed.

These funds will be used, notably:

- To finance the training of additional implant centers - beyond the centers already trained for the feasibility study
- To develop and run a direct or indirect sales force, and to provide technical support to clinical and implant centers and their patients
- To carry out further clinical activity such as implant registries, or comparative economic studies - at the request of regulatory authorities or voluntarily for purposes of marketing
- To implement improvements to the systems or to pursue reimbursement for the total artificial, its external systems and its ancillary services in various countries.
- To ramp up industrial production, notably by securing new procurement sources for critical components and by setting up additional production capacities..

4.4.3 Currency exchange risks

- To this date, the Company assumes no currency exchange risks on its purchases. CARMAT estimates that:
- 0.3% of its purchases are in American or Canadian dollars;
- 0.005% of its purchases are in European currencies other than the euro, of which 7% are in Swiss francs.

The future exposition of the Company to this exchange risk will essentially depend on the currency in which it will make its revenue and assumes most if not all of its operating costs. The importance of this risk will depend on the countries in which the Company will carry out its developmental procedures, the marketing of the total artificial heart and other product which it may develop, as well as the currency in which it will have to pay its operating costs.

If the Company is capable of developing its industrial and commercial activities in countries outside of the Euro zone, it is probable that it will realize and support, respectively, a higher income and upkeep in other currency. The Company will then consider the most pertinent method to manage its exchange risk.

4.4.4 Share Risks

As at the date of registration of this “Document de Référence”, the Company does not have any shareholdings in any third party listed companies and consequently it is not exposed to a risk over shares

The Company has contracted with an independent provider in financial service, in 2010, a liquidity contract, the object of which is to favor the liquidity of the transactions and the regularity of CARMAT securities prices without hampering the normal functioning of the market and not misleading others. As such, the Company has made available to the provider the amount of 300 000 €. The treasury shares acquired through the implementation of this liquidity contract are included in financial assets for their purchase price. Where appropriate, a valuation allowance is recorded by reference to the average official trading value of the last month before the market closes (see paragraph 3.2.4 Financial assets of the notes on the accounts of the 2011 paragraph 20.1).

4.4.5 Risks relating to the Company’s share price evolution and stock value on the financial markets.

During its initial public offering (IPO) in July 2012, the introduction price of the CARMAT share was set at 18.75 € representing a market capitalization of 71.3 M €.

As at the date of registration of this Document de Référence”, the share price is 131.10 €, thus a 599% increase, representing a market capitalization value of 541 M€. Between these two dates, the stock value has strongly fluctuated, as show by the graph to the right.

CARMAT's share price has fluctuated according to the investors' perception of the realization or not, or of the delay in realizing, key scientific or regulatory stages, by the Company, concerning the development of the total artificial heart. Any delay or failure in the realization of new scientific or regulatory key stages could have a negative effect on the Company's stock price and market capitalization.

4.5 INSURANCE AND COVER FOR RISKS

As at the date of registration of this 'Document de Référence', the Company is confident to have a suitable insurance coverage, for the principal risks that can be insured, adapted to the nature of its activities with guarantee amounts deemed compatible with those required by its activity. .

The Company having not yet entered its clinical trials phase for its total artificial heart as at the date of registration of this Document de Référence", the Company has not yet subscribed to a specific insurance complying with the Loi Huriet of December 20th 1988. It has, however, negotiated the terms of such insurance with a first grade insurance company in light of subscribing to such insurance as soon as the approval by the ANSM will allow for the clinical trials to begin. The terms for said insurance are detailed in the table thereafter:

The Company does not foresee any particular difficulties in maintaining the levels of insurance coverage described below, within the limits of the conditions of the market. The Company has subscribed to several insurance policies, of which the essentials are described in the table thereafter:

Risks covered	Insurer	Guarantee amounts	Excess per claim
Professional Liability - All personal injuries, damage to property and financial losses combined	Allianz	 1 500 000 € per annum	 1 500 €
Operating Liability - Losses not arising out of harm to the environment. - - All combined loss or damage, but not exceeding the - following loss and damage : - - Damage to property and consequential financial - losses, except for theft by servants - - Consequential financial losses - - Damage to property entrusted to others - Losses arising out of accidental harm to the environment - - All combined loss or damage - - Harm to servants - - Personal injuries and ancillary damage to property	Allianz	 10 000 000 € per claim 7 000 000 € per claim 30 000 € per claim 1 000 000 € per claim 1 000 000 € per claim 1 500 000 € per claim 1 500 000 € per claim	 1 500 € 1 500 € 1 500 € 1 500 € 1 500 €
Professional Liability for Company Directors and Officers	Allianz	10 000 000 € per annum	
Individual Accident Insurance - Professional assignments throughout the world (risks of civil or foreign war and similar risks): strikes, riots, popular uprisings, sabotage, insurrections, sedition, invasion, attacks, acts of terrorism, kidnap or hostage taking) **Individual Accident Insurance** - Assistance with repatriation/medical expenses	 Ace Europe Mondial Assistance	 Maximum limit 90 Social Security monthly limits	 10%
Indemnity Insurance: Insured capital - Direct loss or damage - - Damages to property, contents and fixtures Additional expenses - - Additional operating costs - - Indemnity period **Damage to property insurance** - - Direct loss or damage: - - - Materiel everywhere - - Natural events excluding natural disasters - - Land transport - - Machinery breakdown - - Electrical damage - - Automatic guarantee on investments - - Related expenses and losses - - Claims from neighbors and third parties, claims from - tenants, loss of peaceful enjoyment, loss of rents, - liability of the owner or bailee - - Theft and damage to real or personal property arising - out of a theft or an attempted theft - - Additional operating costs: - - Additional operating costs including - Wages and salaries - Indemnity periods	Allianz	 8 000 000 € 5 000 000 € 12 month Limited to 13 000 00 € per claim, subject to the following limitation: 1 500 000 € per claim 2 000 000 € per claim 500 000 € per claim 2 000 000 € per claim 2 000 000 per claim 500 000 € per claim 1 000 000 € per claim 5 000 000 € per claim 500 000 € per claim 5 000 000 € per claim 3 500 000 € per claim 12 months	 All damages : 5 000 € Except : Plate-glass breakage : 1 000 € Theft : 1 000 € Natural Disaster Legal Excess All loss or damages : 5 days Natural Disaster Legal Excess
Vehicle fleet – Road Traffic Liability - personal injury: - damage to property and financial losses arising out of damage to property:	Allianz	 Unlimited €100 000 000 per claim	
Civil Liability [(1)] *« Clinical trials for the evaluation of the Total Artificial Heart CARMAT »*	*Allianz*	*1 000 000 € per victim* *Limited to :* - *6 000 000 € per research protocol* - *10 000 000 € for the totality of claims presented during one year of insurance for several research protocols*	
[(1)] Will be subscribed to at the effective start of clinical trials			

4.6 SPECIAL CIRCUMSTANCES AND DISPUTES

There are no administrative, judicial or arbitration proceedings, including any proceedings the Company is aware of, which are pending or which are being threatened, and which are capable of having or which in the course of the last 12 months have had a significant impact on the financial situation or the profitability of the company and/or group

5 INFORMATION CONCERNING THE ISSUER

5.1 HISTORY AND DEVELOPMENT OF THE COMPANY

The Company CARMAT and its project of a total bioprosthetic artificial heart is the fruit of the collaboration between a world class medical team – that of Professor Alain Carpentier – and a high technology company, Matra. The total artificial heart project began in 1988 with Professor Alain Carpentier's filing for several patents for his work with the CETIM (Technical Center of Mechanical Industries).

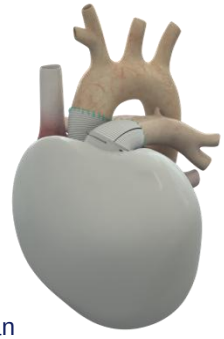
The bioprosthesis is born of a meeting, in the early 90s, between Professor Alain Carpentier and Jean–Luc Lagardère, then President of Matra. The result was a very close and active cooperative since 1993 with the aim to conceive a total bioprosthetic artificial heart including the left and right ventricle, the different sensors and the whole of the electronics integrated in one unique implantable device. At the heart of this partnership, Professor Alain Carpentier brought forth all his knowledge on bioprosthetic heart valves and the use of chemicals to treat biological tissues of animal origins which he developed (Carpentier–Edwards valves®). For its part, Matra brought forth its experience in embedded systems and their constraints (reliability, severe environments, mass and volume) allowing thusly the engineers to work on the concept with the help of simulations, models and test benches.

The objective is to create an artificial heart as physiologically compatible as possible, which could notably:

- Offer a bioprosthetic interface for the blood as to reduce major thromboembolic complications encountered by prior project; and
- Procure to the patient, an immediate response adapted to his or her metabolic needs in terms of flow and heart rate.

In 2001, the project saw a renewed impulse with the first successful animal implants of a prototype in calves. These implantations shed some light on the road ahead and the efforts still needed but confirmed the feasibility of concept. A team composed of a dozen of complementary experts (system conception, biocompatible materials, particular polymers, integrated technologies, and electronics) was then set up. This team worked in close cooperation with the medical team under the supervision of Professor Alain Carpentier in the research labs for transplants and prostheses at the Université Pierre et Marie Curie and at the Hôpital Européen Georges Pompidou to optimize the prosthesis.

The collaboration of these two multidisciplinary teams, coming on one side from a medical background and on the other side from the aeronautics and space programs backgrounds, allowed to achieve considerable progress leading to, most notably, the miniaturization of the integrated system in volume, energy consumption, mass and to the biocompatibility with the human body through the development of biomaterials and unique procedures (see paragraph 6.3.2 "Innovations and competitive advantages of CARMAT's total artificial heart).



A large number of processes were patented, including the architecture, the hybrid membrane which is both impermeable and haemocompatible, the locking interface device (connecting to the patient's atria through an interface device allowing for an easy stitching, on which the prosthesis will be connected), the pump, or even the physiological auto-regulating system.

Thus, after fifteen years of research and development, a new prototype weighing 900g (compared to the 1200g of the old prototype conceived 4 years earlier) and completely optimized (savings in volume, mass and energy consumption of approx. 25%) allowed in June 2008 the creation of the company CARMAT.

Its objective is to finalize the development of a bioprosthetic artificial heart with a lifespan equivalent to that of a donor graft and at a global cost inferior to a cardiac transplant, and to implement the post-market industrial and marketing strategies.

The company CARMAT has, to this date, devoted the entirety of its activity to the research and development of the total bioprosthetic artificial heart and has not yet generated any revenue. To finance its project, the company has benefited from:

- In September 2008, an capital increase of 7 250 000 € (5 000 000 invested by the funds managed by Truffle Capital, 2 250 000 million by Matra Défense and the Professor Alain Carpentier);
- In September 2008, an amount of 33 000 000 € of subsidies and repayable advances granted by
- OSEO Innovation in connection with the Industrial Strategic Innovation program, which is the largest aid ever given to a Young Innovative Company by this body (see Chapter 22 "Major contracts");
- In June 2009, a subsidy for 1 500 000 € given by the Conseil Général des Yvelines;
- In February 2010, an capital increase of 950 000 € by the funds managed by Truffle Capital;
- In May 2010, an issue of convertible bonds for 2 000 000 € underwritten by the funds managed by Truffle Capital and converted at the time of the stock market flotation of CARMAT on the Alternext Paris market of NYSE Euronext Paris;
- In July 2010, in connection with the stock market flotation by public offering of the company on the Alternext Paris market of NYSE-Euronext.
- In August 2011, a capital increase with preferential rights issue for 29 300 000 € on the Alternext Paris of NYSE-Euronext

The Company aims to start clinical trials for its total artificial heart in 2012, subject to the ANSM approval, and to prepare for commercial launch at the end of 2013, subject to obtaining the CE Conformity Marking .

5.1.1 Registered Name

The Company's registered name is: **"CARMAT"**

5.1.2 Place and number of the Company's registration

The Company is registered at the Versailles Trade and Companies' Register under number 504 937 905.

5.1.3 Date of incorporation and term

The Company was incorporated on 25 June 2008 and registered on 30 June 2008 for a term of 99 years, subject to any extension or early dissolution.

5.1.4 Registered address, legal form and applicable law

The Company's registered office is located at 36, avenue de l'Europe – Immeuble l'Etendard Energy III – 78140 Vélizy Villacoublay.

The Company is a public limited company under French law with a Board of Directors, and it is governed by the provisions of Book II of the French Commercial Code.

5.1.5 Important events in the development of the Company's activities

1988	First patent on the total artificial heart filed by Professor Carpentier
1993	Collaborative partnership with Jean-Luc Lagardère, Chief Executive of Matra, to create the total artificial heart
2000	Creation of the first prototype of the total artificial heart (1900 grams) Industrial approval of concepts
2001	First successful animal transplantation Creation of dedicated full time project team within the EADS Group
2004	Creation of the second prototype of the total artificial heart (1200 grams)
2004-2008	Optimization of the volume, weight and energy consumption of the total artificial heart
2008	Creation of CARMAT SAS from Matra Défense (EADS Group) and Prof. Alain Carpentier Contribution in kind (patents, licenses, software, equipment, etc.) to CARMAT SAS by the Carpentier Foundation ("Association Recherche Scientifique de la Fondation Alain Carpentier") and the EADS Group (via its subsidiary Matra Défense) Grant to CARMAT SAS and its partners of a sum of 33 million Euros in subsidies and repayable advances by OSEO Innovation as part of the strategic industrial innovation scheme, the largest ever granted to a young innovative enterprise by OSEO Innovation Increase in the CARMAT SAS common stock in the sum of 7.25 million Euros, including issue premium (5 million invested by Truffle Capital and 2.25 million by Matra Defense and Professor Alain Carpentier)
2009	Grant of a subsidy of 1.5 million Euros to CARMAT SAS by the General District Council of Yvelines Authorization from the European Commission for the grant of 33 million Euros in favor of the CARMAT SAS research and development program Appointment of Marcello Conviti as Managing Director of CARMAT SAS Opening of the CARMAT SAS clean room* by Valérie Pécresse, Minister of Higher Education and Research Completion of the modeling and optimization of the artificial heart (900 grams) in readiness for the assembly and implantation phase for the pre-clinical trials

2010	Increase in the CARMAT SAS own capital by the sum of 0.95 million Euros from funds managed by Truffle Capital Transformation of Company into a plc Issue of convertible bonds for a sum of 2 million Euros and paid up BSA-OC from three Truffle Capital Funds converted or exercised when CARMAT SAS was floated on the NYSE-Euronext's Alternext market in Paris CARMAT granted the status of "Innovation Enterprise" for the Mutual Funds for Investment in Innovation (FCPI) by OSEO Innovation Increase in capital by the sum of 16 million Euros, including issue premium, to coincide with the floating of CARMAT on the NYSE-Euronext's Alternext market Conclusion of an agreement with Edwards Lifesciences, the world leader in the cardiac valves sector and in hemodynamic monitoring, for the use of Carpentier-Edwards biological cardiac valves in the CARMAT total artificial heart Industrial assembly of the first two prostheses of the CARMAT total artificial heart in the clean room Henri Lachmann joins the CARMAT Board of Directors
2011	Payment of 3.8 million Euros in state aid first for the completion of key stage no. 2 of the OSEO ISI program in the sum of 3.5 million Euros and receipt of 300 000 Euros from the total balance of 1.5 million Euros in aid granted as part of the R&D program set up by the Yvelines local authority CARMAT is listed on the NYSE Alternext OSEO Innovation index Appointment of Valerie Leroy as Director of Marketing and Investor Relations Presentation of promising test results for the physiologic compatibility. CARMAT submit its preliminary file to the AFSSAPS. CARMAT and BULL announce the development of a device destined to the bearers of the CARMAT artificial heart. CARMAT is certified ISO 13485:2003 and ISO 9001:2008, which validates its quality management system. Launch of a €25.5m rights issue with preferential subscription rights Great success of the rights issue , subscribed for €29.3M, extension clause included. CARMAT présente des donnés précliniques d'hémocompatibilité au 25ème congrès annuel de l'Association Européenne de Chirurgie Cardio-Thoracique CARMAT presents some CARMAT presents pre-clinical data on haemocompatibility at the 25th Annual Meeting of the European Association for Cardio-Thoracic Surgery Favorable opinion from the CPP (Patient Protection Committee)
2012	CARMAT publishes its first Shareholder Newsletter Important shareholder participation at the General Assembly, Q&A session for which minutes are published. Recertification audit for ISO 13485:2003 and ISO 9001:2008 passed CARMAT laureate of the European Mediscience Awards in the Best Technology category. Further elements added to the ANSM file, notably the results of the implants on animals and the intermediate results on the durability tests. Confirmation of a shift in the test calendar and, consequently, in the calendar concerning the first implantations; due mostly to delays related to the industrial validation procedures with our contractors.

5.2 INVESTMENTS

5.2.1 Principal investments made in the last two fiscal years

Over the 12 month accounting period to 31 December 2010, the Company incurred investment expenses of around 1 million Euros corresponding to:

- Technical installations, material and industrial tools, for 698 516 € and corresponding to the invoice of the clean room and the invoice of technical units received during the period (spectrometer, sterilizer, test benches for pressure sensors, endurance tests and motor pump groups, insulator, HIL simulator[2]);
- intangible fixed assets amounting to 81 266 € for the purchase of licenses and the set up of a part of the software Product Lifecycle Management (PLM)
- General facilities, fixtures and fittings, for 177 705,50 € corresponding to the development of additional office space taken during the year (including 32 049.50 € of deposit)
- Office supplies as well as computer equipment amounting to 32 352 €

Over the 12 month accounting period to 31 December 2011, the Company incurred investment expenses of around 902 961 € corresponding to:

- Tangible fixed assets, amounting to 100 363 €, mainly in respect of work relating to the office premises, and the acquisition of computer equipment and furniture;
- Tangible fixed assets under construction, amounting to 802 598 €, corresponding to the acquisition of test benches for subsets and for the prosthesis, approved but not yet in service at the date of year end.

5.2.2 Principal investments underway and method of financing

Tangible fixed assets under construction at the end of fiscal year 2011 reflect the acquisition of test benches for subsets and the prosthesis. These acquisitions represent a total of 802 598 €, received as at 31 December 2011.

These investments are financed by the Company's cash account, which include the proceeds from the IPO of the Company on the Alternext market of NYSE-Euronext Paris conducted July 12, 2010, the proceeds of the rights issue with preferential subscription rights on the market Alternext of NYSE-Euronext Paris conducted August 10, 2011, and grants and repayable advances from OSEO Innovation.

5.2.3 Principal future investments

The most significant investments in the short term future will be the acquisition of a "Entreprise Ressource Planning" software for 250 000 € and the acquisition of a calibration bench of the pressure sensors for 350 000 €.

[2] Hanson B.M. Hardware-in-the-loop-simulation of the cardiovascular system, with assist device testing application, Medical Engineering & Physics 29 (2007) 367–374 - A real time simulator that makes the computers believe they are navigating the actual system (Hardware in the Loop test principle).

6 OVERVIEW OF THE COMPANY'S ACTIVITIES

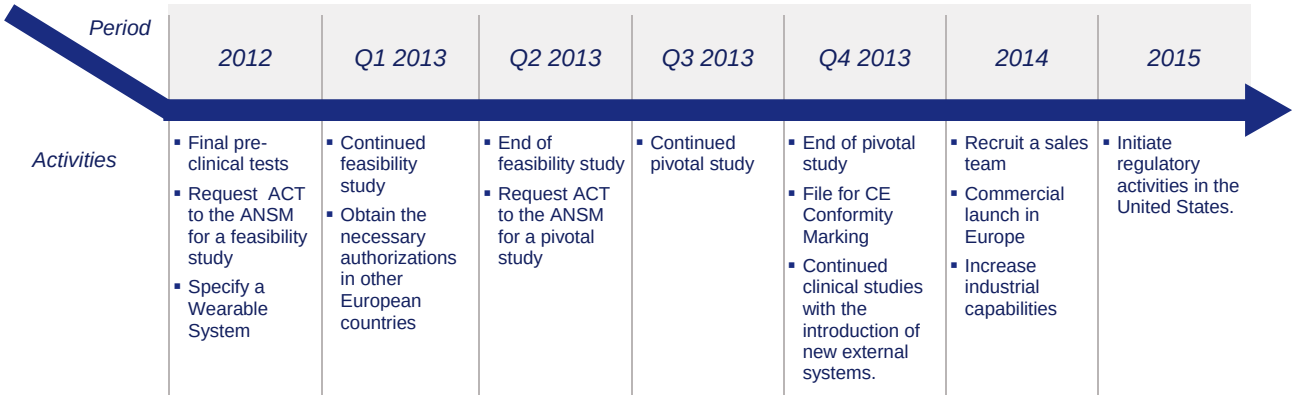
6.1 GENERAL OVERVIEW

Founded in 2008, after 15 year of research, CARMAT develops an orthotopic, bioprosthetic, self-regulated and implantable **total artificial heart**, as well as its energy source and its remote monitoring control interface.

The Company has, thus far, dedicated the whole of its activity and resources towards research and development for the total artificial heart project and has not yet generated any turnover. The fundraisers realized, the existing equity and the expected financial aids, notably those from OSEO or from CIR, should allow for the artificial heart project to be financed until its term.

However, some important scientific and regulatory steps, described mainly in the calendar below as well as in paragraphs 6.4.6, 22.1.6, 22.1.7 and 22.1.8, must still be successfully passed. When necessary, a new fundraising will have to be organized to raise an estimated cumulated sum of 30M € for the industrialization and commercialization, at the soonest in 2014.

As at the date of registration of this Document de Référence", the provisional calendar of the project is as followed:



The reading is also invited to refer to chapters 4.3.1 (Historic of operating loss – risks linked to operating loss) 4.3.2 (Uncertain resources in capital and uncertain complementary finances) and 4.3.3 (Dilution risk connected with issuing shares giving immediate or long term access to the Company's capital)

The name CARMAT is born of the meeting, in the early 90s, between Professor Alain Carpentier and Jean-Luc Lagardère, former President of Matra. The result was a very close and active cooperation since 1993 with the aim to conceive a total bioprosthetic artificial heart.

This unique partnership regroups:

- Professor Alain Carpentier's 30 years of experience of,[3] the father of modern cardiac valve surgery. The Professor has developed the procedures for chemically treating biological tissues of animal origins which allowed him to create the biological heart valves most often used throughout the world today (Carpentier-Edwards valves®). Furthermore, based on his belief that a device must always be associated with a repeatable procedure, he also developed the surgical techniques for mitral repair, used throughout the world today.
- Matra's experience in portable medical devises and their constraints (weaknesses, constraining environments, mass and volumes) enabling the engineers to work on the concept with the help of simulations, models and test benches.

The Company's objective is to answer a public health need on a global scale through the development of a long term treatment for end-stage heart failure. This is a severe disease, as it is degenerative, often fatal and with a steadily increasing prevalence rates in developed countries. The total artificial heart is designed to provide a long term therapeutic solution to patients with advanced biventricular heart failure, ineligible for a transplant, having exhausted all possible drug and with no satisfactory alternative currently available.

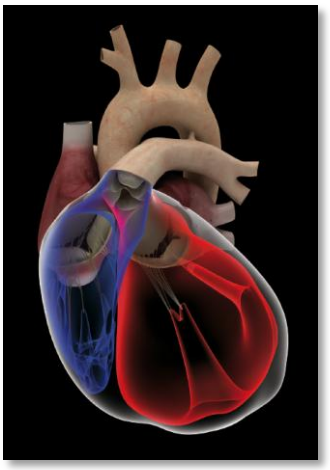
3 Carpentier A. Cardiac valve surgery--the "French correction". J Thorac Cardiovasc Surg. 1983 Sep;86(3):323-37.

6.2 HEART FAILURE

6.2.1 Pathologies and Etiologies*

Heart failure occurs when the myocardium (heart muscle) cannot maintain its essential function as the body's "blood pump" and provides an insufficient cardiac output to meet the metabolic needs of the organism. When the failure reaches the left ventricle, it is called left ventricular failure, when it reaches the right ventricle, ones talks of right ventricular failure, when failure reaches both ventricles - right and left - it is called total or biventricular heart failure. The two main causes of heart failure are coronary heart disease * (myocardial infarction *) for about 40% of cases and high blood pressure * for about 44% of cases

- In the myocardial infarction, a plate of fat or a blood clot forms in an artery of the heart called the coronary and the blood flow is interrupted at this level. The portion of heart muscle that receives more blood is more oxygenated (ischemia*). It is destroyed and replaced by a scar. If this part is important, the heart muscle weakens and the heart tends to expand; this expansion, secondary to the elevated pressure within the heart, will in turn deteriorate the healthy part of the heart and the heart failure will worsen over time.
- In high blood pressure (hypertension), resistance to blood flow increases in arteries. The heart must fight against this resistance. Like any muscle subjected to increased effort, it will first increase in thickness (hypertrophy *). If hypertension is not treated properly, the heart may dilate; its force of contraction will then gradually decrease and heart failure will develop; this heart failure is often compounded by the propensity of hypertensive hearts to develop infarcts.



Dilated ventricle

The ventricle most frequently affected is the left ventricle. The right ventricular failure is most often the result of pressure overload of the right ventricle; i.e. of pulmonary hypertension. But the main cause of pulmonary hypertension is left ventricle failure[4]. This is why heart failure progresses frequently from the left ventricle to the right ventricle. Up to 30% of patients with left ventricular heart failure treated with a left ventricular assist device develop right ventricular heart failure. [5,6]

The most common complications are as follows.

- Arrhythmias: the heart must pump faster to ensure the same rate despite its expansion; serious ventricular arrhythmias may then develop, up to cardiac arrest;
- Thromboembolic events (clotting): if a clot moves up to the brain, it creates a stroke*, with dramatic consequences and often disabling.
- And renal failure; kidneys being organs very sensitive to pressure changes induced by a failing heart pump.

Being a progressive disease, the prognosis is poor: less than 50% survive 5 years after diagnosis[7], over 40% die in the year following the first hospitalization.[8] Practitioners distinguish the severity of the failure by measuring the extent of disability using the NYHA (New York Heart Association) based on symptoms and with 4 classes.

NYHA	Class I	Class II	Class III	Class IV
Symptoms	No symptoms	Fatigue, palpitations, shortness of breath after a sustained effort	Symptoms and unease at the slightest effort	Symptomatic even while resting
Activity	No limitations	Modest limitations	Important limitations	Impossible to perform any activity, permanent bed-rest.

Class III is considered a critical threshold: [9]

4 Voelkel NF et al. Right Ventricular Function and Failure : Report of a National Heart, Lung, and Blood Institute Working Group on Cellular and Molecular Mechanisms of Right Heart Failure. Circulation. 2006;114:1883-1891

5 Dang NC, et al. Right heart failure after left ventricular assist device implantation in patients with chronic congestive heart failure. J Heart Lung Transplant 2006;25:1-6.

6 Boyle AJ, et al. Predictors of poor RV function following LVAD implantation. J Heart Lung Transplant 2003;22:S205

7 Blackledge HM et al. Prognosis for patients newly admitted to hospital with heart failure: survival trends in 12 220 index admissions in Leicestershire 1993–2001. Heart 2003; 89:615–620.

8 Stewart S et al. . More 'malignant' than cancer? Five-year survival following a first admission for heart failure. Eur J Heart Fail 2001;3:315–322.

- For the patient, as it marks the transition between an almost normal life and a greatly reduced activity, often involving a dependency;
- Clinically, this means more aggressive therapies, drug dependency, and early Class IV repeated hospitalizations;
- For society, this represents an explosion of costs, especially due to hospitalization: a patient in class IV is costing the community up to 15 times more than a patient in class II. [10]

Patients with class III and IV represent between 20 and 35% of the total, Class IV up to 5%, of heart failure patients. [11]

CARMAT's total artificial heart will initially be addressed to patients with terminal heart failure – the most advanced form of the disease, for which the one-year mortality is estimated between 60 and 94%.[12] Depending on the benefits demonstrated by clinical studies, it could then be offered to patients with a better prognosis.

6.2.2 Epidemiology, prevalence and incidence

The prevalence of heart failure is rising sharply in developed countries, affecting about 2% of the general population[13,14]; i.e. about 15 million Europeans[15,16]. Moreover the prevalence increases sharply with age. A French epidemiology study has shown that it can reach up to 12% for patients over 60 years old.[17]

There are over 5.8 million people with heart failure in the United States, with an annual incidence* superior to 550 000 new patients each year. According to a study published by the *American Heart Association* in February 2010, the prevalence of heart failure in the United States is expected to grow 25% between 2010 and 2030. [18]

This changing epidemiology is due to an aging of the population, but also, in the case of advanced heart failure, to the improvement of the survival rate after myocardial infarction and to recent advances in drug therapy, such as beta blockers* and diuretics*.[19]

Paradoxically, these advances contribute to the increased prevalence of chronic heart failure and reduce the possibility of heart transplantation because they delay the age of iterative decompensation and therefore the one at which patients reach an advanced, chronic and irreversible stage, affecting both ventricles, in addition to the many indications of emergency transplant following an acute myocardial infarction in the absence of compatible donor.

6.2.3 Economic stakes

Heart failure constitutes a real public health issue that is expected to grow in western countries, where the cost of heart failure is now the largest of all chronic diseases.

The total cost of heart failure is estimated at 44.5 billion dollars for the United States in 2015 and 97 billion in 2030. [20] 12 to 15 million consultations per year and 6.5 million days of hospitalizations are attributed to it. [21] According to a study published by the *American Heart Association* in February 2011, the direct treatment costs (medical costs) of patients is expected to grow 215% within the U.S. population (and even more amongst those above 65 years) and indirect costs (lost productivity) by 80% between 2010 and 2030. [22]

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9 Launois R et al. Coût de la sévérité de la maladie; le cas de l'insuffisance cardiaque. Journal d'Économie Médicale, 1990, T. 8, n° 7-8, p. 395-412.

10 Kulbertus HE et al. What has long-term medical treatment to offer and what does it cost. Eur Heart J 1987 (suppl F) 26-28

11 Agence Nationale d'Accréditation et d'Évaluation en Santé – Évaluation de l'assistance ventriculaire en attente ou en alternative à la transplantation cardiaque – Avril 2001.

12 Gorodeski, Chu, Reese, et al. Prognosis on chronic dobutamine or milrinone infusions for stage D heart failure.Circ Heart Fail. 2:320-24, 2009.

13 Cowie MR, et al. *The epidemiology of heart failure*. Eur Heart J 1997;18:208–225.

14 Davies MK et al. *Prevalence of left ventricular systolic dysfunction and heart failure in the Echographic Heart of England Screening Study: a population based study*. Lancet 2001;358:439–444.

15 Remme WJ et al. *Public awareness of heart failure in Europe: first results from SHAPE.* Eur Heart J 2005; 26:2413–2421.

16 McMurray JJ et al. ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012. Eur Heart J 2012;33:1787–1847 (nombre incluant les 51 pays adhérents de la Société Européenne de Cardiologie).

17 Saudubray T et al. Prévalence et prise en charge de l'insuffisance cardiaque en France : enquête nationale auprès des médecins généralistes du réseau Sentinelles La revue de médecine interne 26 (2005) 845–850

18 Heidenreich PA et al. Forecasting the future of cardiovascular disease in the United States: a policy statement from the American Heart Association. Circulation. 2011 Mar 1;123(8):933-44

19 *Évaluation de l'assistance ventriculaire en attente ou en alternative à la transplantation cardiaque.* Rapport de l'ANAES (Agence Nationale d'Accréditation et d'Évaluation de Santé) – Avril 2001 – E.

20 *Heart Disease and Stroke Statistics* – American Heart Association 2012.

21 Hunt SA et al. ACC/AHA 2005 Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult : A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation. 2005;112:e154-e235

22 *Heart Disease and Stroke Statistics* – American Heart Association 210

The direct cost of advanced chronic heart failure in France was around 1.5 billion Euros[23] (3.3 billion Euros for the class of long-term illness involving severe cardiovascular diseases - ALD 5) in 2010 and involved more than 670 000 people. In a statement released May 7, 2010 to mark the European Day for Heart Failure, the French Society of Cardiology and the French Federation of Cardiology recalled some figures:

- In France there are more than 100 000 new cases annually;
- 10% of these patients were hospitalized (it should be noted that the average length of stay exceeds 10 days and that the rate of re-hospitalization within six months is 20%);
- In 2008, heart failure was the primary diagnosis of 195,800 hospital stays in France, where the daily cost of hospitalization in intensive care in cardiology was over 2 000 €.

Overall, heart failure is responsible for about 2.5% of the total health expenditures in Western countries; hospital expenditures representing alone 70% of the total cost of the pathology. [24] Because of repeated hospitalizations, class IV chronic heart failure represents between 61% and 92% of the total cost of heart failure. [25]

6.2.4 Available treatments

It should be noted this disease is not curable once in its chronic phase and current treatments are aimed solely at reducing symptoms. Treatments change as the disease progresses.

Drugs

In class I and II, the treatment is essentially drug-based[26]. Depending on the severity and symptoms, it combines:
- Anticoagulants and anti-platelet agents* to prevent blood clots;
- Angiotensin-converting enzymes* to reduce vascular resistance;
- Beta-blockers, which reduce the rate and cardiac output to decrease blood pressure;
- Diuretics to remove excess fluid and therefore relieve the burden of the heart and prevent pulmonary edema;
- Vasodilators that relax blood vessels to increase blood flow and oxygen supply to the heart without increasing its work;
- Etc....

The complexity of the treatment and the need for frequent adjustments lead to a fairly low patient-compliance regarding the drug intake protocol: 40% of patients do not follow their treatment in a consistent manner after 3 months. [27]

Devices

From Class III onwards, surgical options, such as the implantation of supporting medical devices, are considered:

- Mono or biventricular pacemakers to prevent arrhythmias;
- Implantable defibrillators to treat ventricular tachycardia and prevent sudden death;
- Left ventricular reconstruction;
- Restrictive mitral annuloplasty;
- Mechanical circulatory support systems, implantable or not, and artificial hearts.

Most of these options aim to recover the heart's natural function. For example, biventricular pacemakers are designed to rehabilitate the ventricles by synchronizing their contractions. The restrictive mitral annuloplasty is designed to retrain the left ventricle by influencing its geometry. However, if these approaches relieve some patients temporarily, they face significant difficulties in selecting appropriate patients[28] and in technical implementation[29], both of which restrict their adoption; additionally, they do not prevent the progression of the disease.

The mechanical circulatory support systems are what could be considered the closest, in function and indication, to the CARMAT artificial heart. Their characteristics and their evolution are detailed in paragraph 6.4.2. "Technologies and market players"

In the most advanced stage of disease, positive inotropes* are generally introduced. These are drugs, administered intravenously in the hospital setting that increase the contractility of the heart, and allow, at least temporarily, to

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23 Régime général de l'Assurance Maladie – Mis à jour en 2012 – http://www.ameli.fr/l-assurance-maladie/statistiques-et-publications/données -statistiques/affection-de-longue-durée-ald

24 McMurray JJ, Stewart S. Epidemiology, aetiology, and prognosis of heart failure. Heart 2000;83:596–602.

25 Clinical and cost effectiveness of LVAD for end stage heart failure – Health Technology Assessment NHS – 2005.

26 American Heart Association – Heart Failure Medications - http://www.heart.org/HEARTORG/Conditions/HeartFailure/PreventionTreatmentofHeartFailure/ Heart-Failure-Medications_UCM_306342_Article.jsp

27 Benner JS, et al. Long-term persistence in use of statin therapy in elderly patients. JAMA. 2002;288:455-61.

28 Strickberger SA et al. Patient Selection for Cardiac Resynchronization Therapy, Circulation. 2005; 111: 2146-2150

29 Marwick TH. Restrictive Annuloplasty for Ischemic Mitral RegurgitationToo Little or Too Much. J Am Coll Cardiol. 2008;51(17):1702-1703.

resolve critical situations of low cardiac output in episodes of acute decompensated heart failure* or cardiogenic shock*. Dependence on inotropes mark the terminal phase of heart failure with a mean survival of $3^{1/2}$ months.[30]

Transplantation

Indeed heart failure, in its end-stage form, has only one possible treatment which is the replacement of failing ventricles by transplantation of a healthy heart; that is to say of a donor heart.

Professor Christian Barnard performed the first heart transplant in South Africa December 3, 1967. The first transplanted patients, with rare exceptions, did not survive more than a few weeks, mainly due to acute rejection (when the host's immune system responds against the implant considering it as a foreign biological body). Several important advances have improved patient survival since:

- Preservation of donor hearts with cold perfusion, enabling graft procurement away from the place of transplantation;
- Endomyocardial biopsy for early diagnosis of acute rejection: a probe is inserted in a large vessel under fluoroscopic guidance and local anesthesia and advanced into the right ventricle, allowing to sample a small piece which is examined microscopically;
- Last but not least, the advent of cyclosporine, an immunosuppressive agent whose therapeutic use* helped develop the field of organ transplantation by preventing acute rejection from the early 1980's.

Today, the survival of heart transplant patients is slightly above 50% at 10 years.[31] However, survival after 1 year has progressed very little over the past 20 years.

The hopes founded on this treatment continue to stumble on major issues that limit its generalization. Actually, when comparing a very conservative estimate of about 400 000 patients in end-stage heart failure class IV (a mere 2% of the total number of patients with heart failure of all classes in Europe and the U.S. that is to say more than 20 million people) to a very optimistic estimate of about 4,000 heart transplants performed in the same area in 2010 (see paragraph 6.4.1 Market Numbers), there is a considerable gap in treatment.

The first reason lies in the very strict eligibility criteria, for both the donor and the patient. Notably, the donor[32] must be under the age of 61 years, brain-dead, not a carrier of certain viruses such as HIV or hepatitis B and C, not addicted to any drugs or suffering cancer, and of course not suffering from any other heart disease. This limits the possibility of donations mostly to deaths due to trauma (including traffic casualties, steadily decreasing). In France in 2010, only 376 hearts have been collected and 356 implanted.[33]

Given this shortage of transplants, the recipient's eligibility criteria are more stringent[34] to ensure the greatest chance of success with each transplant. Blood types must be identical, the weight and size equivalents. Irreversible pulmonary hypertension, active infection or cancers are definitive exclusion criteria. Other exclusion criteria comprise diabetes, advanced pulmonary or liver disease, renal failure or morbid obesity. A psychological evaluation is always performed to ensure that the patient understands and agrees to comply with complex medication for life. Patients with psychiatric disorders or addiction to alcohol or drugs are not considered.

The age of the patient, which must be less than 65 years, is particularly discriminating. The grafts are in fact reserved to the youngest patients, while the vast majority of patients with chronic heart failure have over 60 years or suffer from comorbidities, making them ineligible.

Therefore, the number of transplants is stable or declining in all developed countries for over 10 years, while the prevalence of heart failure has increased dramatically.

Waiting lists for heart transplantation therefore do not reflect the need for treatment, but simply the number of patients satisfying all eligibility criteria, including age. The low penetration of heart transplantation as treatment of choice for terminal stage heart failure is illustrated in the following table.

	France (1)	United States (2)	Germany (3)	United Kingdom (4)
Transplantations	356	1853	341	92
Patient Waiting list	283	2668	992	130
Population (5)	65 436 552	311 591 900	81 726 000	62 641 000

30 Hershberger RE et al. Care processes and clinical outcomes of continuous outpatient support with inotropes (COSI) in patients with refractory endstage heart failure. J Card Fail. 2003;9(3):180–7.

31 Stehlik J et al. The Registry of the International Society for Heart and Lung Transplantation: Twenty-eighth Adult Heart Transplant Report. J Heart Lung Transplant 2011;30:1078-1094.

32 Latrémouille C., Jouan J. Transplantation cardiaque. EMC - ©Elsevier, Techniques chirurgicales - Thorax, 42-748, 2006.

33 Agence de Biomédecine - Synthèse nationale de prélèvement et de greffe 2010 et annexe au bilan 2010.

34 Mehra MR et al. Listing Criteria for Heart Transplantation: International Society for Heart and Lung Transplantation Guidelines for the Care of Cardiac Transplant Candidates. J Heart Lung Transplant 2006;25:1024 – 42

Patients with Terminal HF (6)	26 000	124 000	32 000	25 000

(1) 2010 – Agence de Biomédecine
(2) 2009 - Organ Procurement and Transplantation Network – Scientific Registry of Transplant Recipients
(3) 2011 – Eurotransplant statistics
(4) Avril 2010 / Mars 2011 – NHS Organ Donation Annual Report
(5) Banque Mondiale 2011
(6) In the absence of reference epidemiology data, cautious estimate based on a 2% prevalence of heart failure in the general population, of which 2% are in the end stage of the disease. Please also refer to paragraph 6.4.1.

The limits of transplantation also appear in the difficulties to support transplanted patients and in the associated adverse events, either within the graft itself or induced by the immunosuppressant therapy. Thus, five years after heart transplantation, 95% of patients suffer from hypertension, 81% from hyperlipidemia and 32% from diabetes. In addition, 25% to 50% develop coronary disease of the grafted heart, and 33% suffer from chronic renal failure [35].

Heart transplantation is a major surgery associated with a very high cost. The Milliman institute publishes every three years a detailed report[36] on the cost estimates of organ transplantation in the United States. With regard to heart transplantation, the findings for 2011 show a cost of 997,700 dollars, including 30 days pre-transplant and 180 days post-transplant and distributed as follows (in U.S. $):

30 days pre-transplantation	Procurement	Admission	Procedure	180 days post-transplantation	Immuno-suppressants and other treatments	**Total**
42 200	80 400	634 300	67 700	137 800	30 300	997 700

It is difficult to make international comparisons given that healthcare systems are very different and that available figures cover heterogeneous periods before and after transplant.

For example, France uses today – since the transition to the T2A in 2008 – a lump sum system covering cross-cutting activities to the removal and transplantation, in addition to ad-hoc reimbursement for procedures, with amounts ranging from one to four depending on the severity and complexity of the case[37], However, there is no national annual summary of the cost. As an illustration, lump sums and maximum reimbursement are as follows (in Euros):

2011	**Lump sum**	**per patient**
Annual lump sum for coordination of procurement (at least 10 grafts)	403 731	
Annual lump sum for transplantation (for 10 transplants)	32 088	
Transplant		10 304
Procedure		56 532
Immune response and rejection		29 913

These amounts do not cover expenses usually borne by the Social Security, such as hospitalization with daily rates of up to 2 000 € in intensive care unit, or cardiac medications, or costs as postoperative functional rehabilitation units, examinations, immunosuppressant therapy or other acute complications.

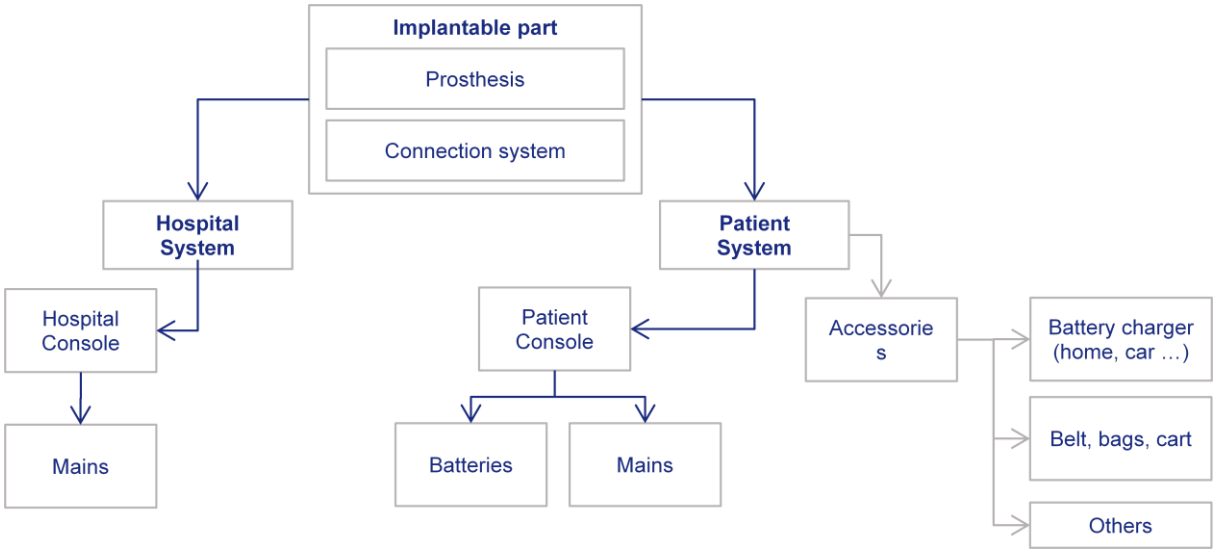
The objective of CARMAT is to propose an immediately available alternative to heart transplantation, at a lower total pre-and postoperative cost, with equivalent survival rates and reduced complications. The projected price of a CARMAT system is between € 140 000 and € 160 000 and is expected to provide an attractive economic alternative, to the extent that some very significant costs such as repeated hospitalizations while awaiting transplantation or immunosuppressive therapy will be avoided.

35 Lindenfeld JA et al. Drug Therapy in the Heart Transplant Recipient. Circulation.2005; 111: 113-117
36 Milliman Report 2011 - Table 2 : Estimated U.S Average 2011 Billed Charges Per Transplant
37 Agence de Biomédecine 2011 – Modalités de financement des activités de procréation, embryologie et génétique humaine, et de prélèvement et greffe d'organes.

6.3 CARMAT: THE FIRST BIOPROSTHETIC ARTIFICIAL HEART PROJET

6.3.1 Description of CARMAT's bioprosthetic artificial heart project

The system consists of some implantable parts – the total artificial heart – of systems that enable the patient to return home and a hospital system allowing for the complete parameterization of the prosthesis and for patient monitoring.



Source Carmat – The complete system project

6.3.1.1 The prosthesis

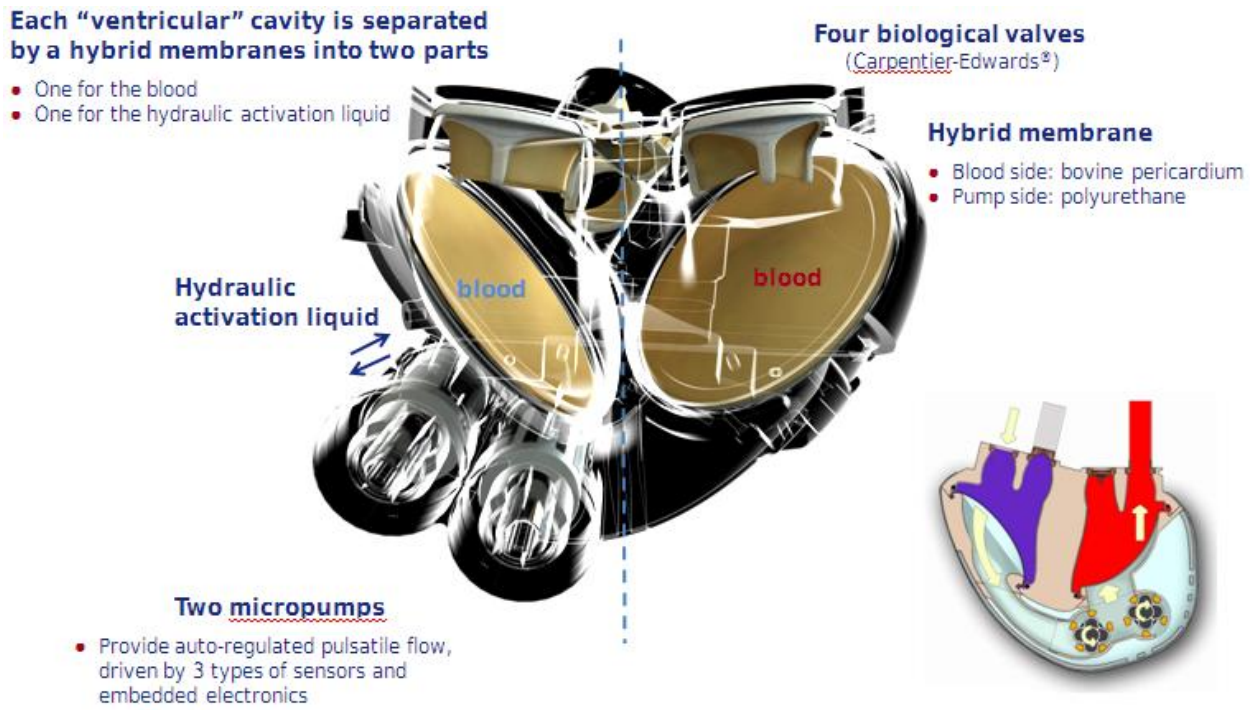
The implantable part comprises the heart prosthesis and its electrical connection to the power supply, either through batteries or the mains.

The prosthesis will mimic the natural functioning of the heart by using hydraulic actuation. A liquid is used as an intermediary to push the blood. The heart rate is divided into two stages, diastole* when the ventricles fill with blood, and systole* during the ejection of blood into the pulmonary artery and the aorta.

The prosthesis consists of two ventricles, right and left, each separated into two volumes, one for the blood and one for the intermediary fluid, by a flexible membrane hybrid. This membrane mimics the viscoelastic nature of the heart muscle and acts in the same manner on the blood, pushing it during contraction.

A motor pump group – comprising two miniature pumps - moves the intermediary fluid in the ventricles thereby generating systole or by reversing the direction of rotation to the outer bag during diastole. An electronic device regulates the operation of the prosthesis according to the needs of patients, based on information provided by the sensors and processed by a microprocessor. A flexible outer bag contains the intermediary fluid and beats with the heart rate.

The fitting of the internal components of the artificial heart has been subject to continuous optimization over the recent years. The engineers have endeavored to position the different sub-components of the prosthesis in their utmost ideal place to maintain an important ventricular volume and allow a for adequate blood flow without having to artificially increase the heart rate (see paragraph 6.3.2 "Innovations and competitive advantages of CARMAT's total artificial heart project).



Source CARMAT – Inner setting of the bioprosthetic artificial heart project components

The prosthesis is then connected to the patient's atria through an interface allowing for an easy suture on which the prosthesis is then 'clicked into place'

Additionally, a number of implanting tools destined for the procedure were developed alongside the surgeons to facilitate the procedure, reduce the operating ischemia timeframe and consequently, minimize the inherent complications carried by a prolonged extracorporeal circulation.

6.3.1.2 The electronic connection

The supply of electric power from the monitoring console or from the batteries to the prosthesis will be achieved percutaneous for the early clinical trials. This solution has the merit to be clinically proven since it is already used by the vast majority of the implanted ventricular assist systems currently available. However, the percutaneous cable represents a serious risk of infection and the Company is currently studying several innovative technologies as alternatives to further add to the competitive advantages of the product.

In 2011, feasibility studies on a power supply system by way of a plug behind the ear did not lead to satisfying conclusions. This technology was hence put on hold for the moment and other promising alternative are being tested, with the aim of entering clinical trials by the end of 2013.

6.3.1.3 Hospital support console

The Hospital Support Console – already available – will only used by qualified personnel in hospitals where implants and follow up will be performed.

It starts up the prosthesis during the implantation, works as a power supply during the stay in the hospital and monitors and configures the prosthesis during periodic hospital follow-ups.

It can import monitoring data from the patient systems and, in the long term, it would interface with the physician's computer to receive and analyze patient data transferred wirelessly.

It offers to surgeons detailed functions for the analysis of the prosthesis' behavior and of the physiological parameters measured.

Source CARMAT – Hospital Monitoring Console (HMC)

6.3.1.4 Patient system

The ergonomics of the systems that the patient carries home strongly influences his quality of life as they grant him the necessary mobility and autonomy for as close to normal a lifestyle as possible.

The Company is currently developing two generations of systems:

- A portable system on a carry-on cart, comfortable and silent, allowing for 4 to 6 hours of power supply: this first system is already available and can be used as soon as the patient leaves the hospital after the first clinical phase in order to allow discharge in comfortable conditions.
- Another portable system is already specified, much lighter and enabling a significantly increased mobility. This evolved system is currently being developed. It could enter a clinical trial phase after the initial CE Conformity Marking has been granted.

6.3.1.5 Batteries

-
- The first generation of batteries (Lithium-ion) will offer autonomy of 4 to 6 hours:
- The second generation, at the core of the research conducted with the company PaxiTech, will enable the patients not to worry about frequent battery replacement as they would provide an autonomy superior to 12 hours and weigh less than 3 kilos.

The use of a fuel cell battery as a power source would be a first in the medical domain. It should offer an original solution involving the use of hydrogen produced on demand and optimize patient's safety while being very ergonomic (useful width: 2mm). The first operational prototypes of this fuel cell battery should be available towards the end of 2012 to be tested in the aforementioned portable system.

Other external devices such as battery charger, means of connecting to electrical power outlets at home or charging the batteries from the car outlets, bags or belts for the transport or for assuring the protection of the system during the shower are all being considered. All the systems components are designed with the patient's safety in mind, for an increased quality of life at home and to ensure a maximum amount of mobility in their daily activity.

The patient systems – including the batteries – constitute an important part of the development efforts carried out at CARMAT. Indeed, they are key to the quality of life of the patient and therefore to the adoption of the CARMAT heart by the market. Furthermore, they may provide healthcare systems with a reduction of direct and indirect costs by promoting a rapid discharge from the hospital, thus creating a favorable cost/benefit ratio when filing for reimbursement.

6.3.2 Innovations and competitive advantages of CARMAT's artificial heart project

Historically, the research on the total artificial heart began in the United States in 1963 under the supervision of Congress. However, all the research efforts on implantable artificial hearts have rapidly encountered problems linked with haemocompatibility, self-regulation of the heart to the physiological needs of the patient, miniaturization, autonomy and long-term reliability.

The challenges offered by Professor Carpentier to Matra engineers were many:

- Conceiving a prosthesis minimizing the risks of thrombosis, the major problem met by all other projects (see paragraph 6.4.2 "Technologies and market players");
- Developing an automatism enabling a self-regulation of the prosthesis reproducing the behavior of a natural heart, without the need for the patient or the clinician to intervene;
- Integrating all the necessary elements for a physiological operation of the prosthesis, in a mass and a volume compatible with the thoracic space available in the majority of patients;
- Optimizing the reliability and the durability of the prosthesis, as they are essential characteristics for a life - supporting implantable device, to obtain a lifespan as long as that of a real heart transplant;
- Providing the patient with autonomy and mobility as close as possible to those of normal life conditions;
- Lastly, ensure that the implantation procedure of the heart can be completed without any difficulties by any cardiac surgical team.

Several innovations and multiples competitive advantages have emerged from the answers the CARMAT team brought to Professor Carpentier's challenges.

6.3.2.1 Haemocompatibility:

The only artificial heart where all areas in contact with blood will be made from compatible biological material to reduce the thromboembolic risk

All implants and assist devices in contact with blood pose the main problem of their haemocompatibility. They must not cause the destruction of red blood cells (haemolysis*) or activate the coagulation cascade*, thereby promoting the formation of a clot blocking a blood vessel can cause a pulmonary embolism or a stroke.

Issues occur when the following factors are insufficiently taken into account:

- Haemodynamic conditions, respect for the blood flow, which should avoid stasis (abnormal blood stagnation and accumulation) or the "tearing" of blood cells (shear stress);
- Surface quality and toxicity of materials in direct contact with the blood. These materials can be of various chemical compositions but their surface must be either, perfectly smooth and hydrophobic to generate no adhesion at all, or made of a micro-porous structure to ensure satisfactory adhesion of biological tissue proteins.

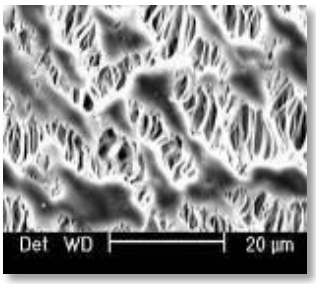
CARMAT's total artificial heart project brings creative solutions to this major obstacle in developing a type of actuation of the blood flow compatible with physiological blood pressures, by an optimized design of the ventricular cavities, and by using only synthetic or biological microporous biomaterials allowing for continuous protein recovery and adhesion for all surfaces in direct contact with blood.

Research for non-thrombogenic implantable materials, essential for the final performance of a system, is a quest that many manufacturers have pursued without success, particularly in the field of ventricular assistance. CARMAT's total artificial heart project followed the path opened by the original principles of haemocompatibility demonstrated by the research on the Carpentier-Edwards biological valves, designed by Professor Alain Carpentier. These valves have accumulated a proven clinical experience of 30 years, with more than one million patients implanted up to 25 years.[38,39] These biological valves, unlike mechanical valves, greatly reduce or even eliminate in some cases, the anticoagulant therapy especially burdensome for these patients.

An agreement with an original maturity of one year automatically renewable each year, was signed on November 5, 2010 between CARMAT and Edwards Lifesciences, a global leader in the science of heart valves and hemodynamic monitoring, for use and provision of biological heart valves Carpentier-Edwards® in the total artificial heart project.

Biosynthetic membrane

Carpentier-Edwards® pericardium valve



Microporous PTFE of a ventricle

Atria interface

Source: CARMAT – Haemocompatible materials

Four Carpentier-Edwards pericardial valves will be used in each total artificial heart. Interfaces for connecting to the atria remnants are also made of treated bovine pericardium on the blood side. Also, only the face covered with pericardium of the hybrid ventricular biosynthetic membranes is in contact with blood. Thus all components that will interact with the blood are made of biological haemocompatible materials. This is a significant differentiation with all other projects of artificial hearts, using mechanical valves.

The development and characterization of microporous materials is based on the experience of significant key corporate partners such as the Laboratoire de Recherches Biochirurgicales (Broussais Hospital and Georges Pompidou European Hospital) who developed the biological tissues and their treatment and FRK (Foundation of Cardiac Surgery Development in Poland), expert in the manufacture of implantable polyurethane parts.

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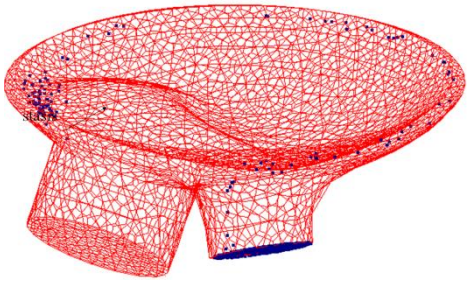
[38] Ayegnon KG, et la. A 25-year experience with Carpentier-Edwards Perimount in the mitral position. Asian Cardiovasc Thorac Ann. 2011 Feb;19(1):14-9

[39] Aupart MR et al. Perimount pericardial bioprosthesis for aortic calcified stenosis: 18-year experience with 1133 patients. J Heart Valve Dis. 2006 Nov;15(6):768-75; discussion 775-6.

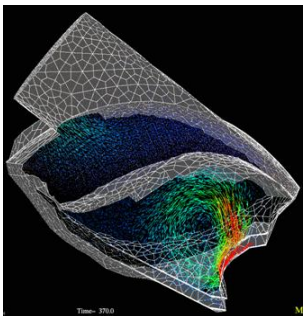
The development of large biosynthetic materials, such as the ventricular membranes and atrial interfaces already represents a significant advance in the history of implantable materials.

As part of the preparation for clinical trials and prior to submitting the application with the ANSM in order to gain approval for setting up early clinical trials, tests for the resistance to calcification, haemocompatibility and to demonstrate the suitability for implantation of CARMAT's bioprosthetic heart have been performed and published.[40] The conclusions of these studies are presented in paragraph 6.3.3 "Processes and stages of development of total artificial heart project."

Haemodynamics, studied through various models, has been validated with digital simulations. These studies have permitted i) to avoid shear stress and stasis, ii) to ensure a thorough "washing" of the entire ventricle at each cycle, and iii) to evaluate the optimal movement of the membrane.



Stasis detection



Intra ventricular hemodynamic simulations

Source : CARMAT- Digital simulations

6.3.2.2 Auto-regulation

The first intelligent artificial heart that will respond immediately and automatically to the metabolic needs of the patient..

To improve the quality of life of patients, the CARMAT total artificial heart project will be designed to continuously analyze the hemodynamic situation of the patient and adapts in real time.

For example, if a patient climbs stairs, the cardiac output of the artificial heart will increase, as it would have happened with a natural heart. If he lies down to sleep, the heart will slow down to ensure a comfortable sleep. Similarly, the total artificial heart project responds to pathological situations such as hemorrhage, using proprietary algorithms to reproduce the behavior would have had a natural heart in the same circumstances.

This automatic response to patients' physiological needs comes from the design of a bioprosthetic artificial heart as faithful as possible to the natural physiology of the heart, through a combination of CARMAT teams and medical teams led by Professor Alain Carpentier.

Thus, the flow of the artificial heart project will be pulsating*, as is that of the natural heart, and hemodynamic regulation is based on Starling's law which governs the functioning of the human heart. Under this law, changes in cardiac output arise primarily from changes in venous return (preload) but are also sensitive to the influence of arterial pressure (after-load).

The artificial heart project also will simulate the natural behavior of the heart to stimuli from the nervous system especially in the maintenance of aortic pressure to ensure continuous satisfactory perfusion to organs and in particular cerebral areas.

Unlike other research projects on the total artificial heart, which offer little or no adaptation to the needs of the patient, medical self-regulation CARMAT's bioprosthesis reproduces physiological functioning by implementing:

- A unique algorithm that replicates the viscoelastic properties of the heart muscle which is deformed under the effect of pressure in terms of its initial elongation in accordance with Starling's law;
- An algorithm simulating the operation of the heart in response to changes in peripheral resistance, themselves dependent on nervous system. Analysis of aortic pressures adapt the heart rate;
- An algorithm using information provided by an inclinometer 3D (position sensor) to identify changes in the patient's posture and manage these transitions with respect to the physiology and the patient's comfort.

The control system was developed in two stages:

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[40] Jansen P, van Oeveren W, Capel A, Carpentier A. In vitro haemocompatibility of a novel bioprosthetic total artificial heart. Eur J Cardiothorac Surg. 2012 Jun;41(6):e166-72.

- First based on computer simulations to model the artificial heart and its environment, that is to say, the patient's bloodstream, posture and activity. These simulations were designed to be as representative as possible and helped to generate test cases;
- Then in the laboratory by placing the prosthesis on a hydraulic test bench specially designed for this purpose that recreates the circuit of blood (haemodynamics) and simulates human activity (cycles of rest, activity, sleep).

6.3.2.3 Miniaturization

A cardiac bioprosthesis that is optimized and anatomically compatible with the majority of the patients.

In the absence of embedded auto-regulation, other projects of artificial hearts have tried to circumvent the issue with the use of external controllers or by using portable extracorporeal devices. These bulky devices, often reserved to medical staff in the hospital setting do not allow an acceptable quality of life for the patient.

Benefiting from advances in the miniaturization of electronics, research projects are now trying to design hearts integrated with more controls and adaptation. The intra-thoracic space being limited by anatomy, this integration is often achieved at the expense of ventricular volume, forcing devices to accelerate the heart rate to provide a physiological blood flow.

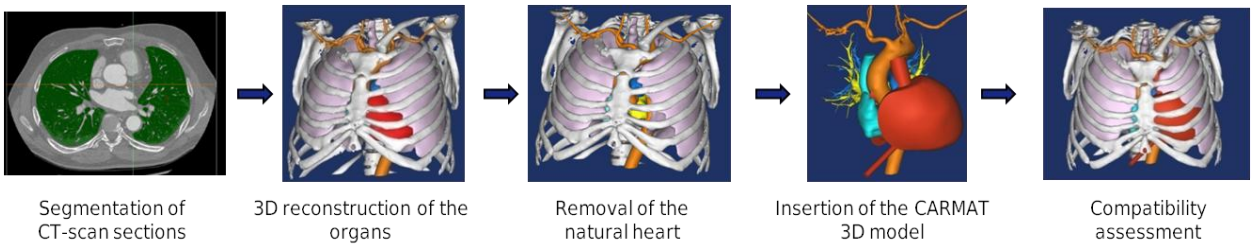
The shape of CARMAT artificial heart project, similar to that of a human heart, has been fully optimized for the anatomy of the human thorax, in order to satisfy the greatest number of patients while maintaining a physiological ventricular volume, by using all available space around the reserved blood volumes.

The anatomical shape has been studied taking into account several criteria such as its total volume, the ventricular volume, its interface with the aorta*, the pulmonary artery*, and atria*. A reduction in the size at the expense of the ventricular volume would not have been physiological, as the operating frequency should have been increased to achieve the same blood flow.

In order to respect the constraint of a high ventricular volume, while maintaining a strong reliability of the embedded elements, CARMAT undertook significant miniaturization efforts for all subsets involved in its activation: motor-pump, electronic and control sensors. The optimization of the final form was first conducted by using a means of CT imaging combined with 3D image fusion mechanisms, which were used to verify the anatomic compatibility of CARMAT's total artificial heart project, and second by performing ex vivo* implantations.

An advanced virtual pre-implantation system has been developed, based on a sophisticated three-dimensional simulation, which allows for, in a virtual and completely non-invasive setting, removing the natural heart and implanting the prosthesis to verify its anatomical compatibility within a given patient.

A validation of this model was performed in silico* by a study based on more than 100 chest CT images of patients with cardiac disease, and confirmed by ex vivo testing of 15 chest. This study aimed to validate the compliance of the prosthesis to the average chest size, the feasibility of connecting to large vessels, and lack of contact with the diaphragm. According to this study in collaboration with the University Hospital of Nantes, the total artificial heart project would be compatible with 86% of the chest of men and 14% of women studied[41].



Source CARMAT – 3D Virtual Implantation simulator

6.3.2.4 Power and autonomy

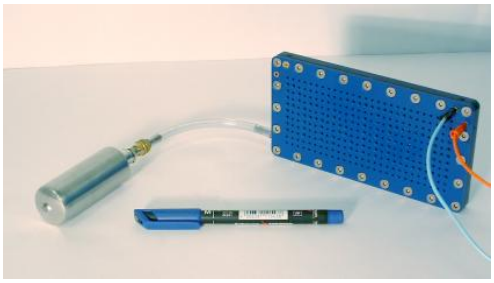
The first medical use of a fuel cell battery

Experience gained with ventricular assist devices has unveiled the limits of current power supply technologies. These systems use different technologies of rechargeable batteries (Nickel Metal Hydride, Lithium Ion,). The autonomy offered is 4 to 6 hours only, raising patients' anxiety at each battery change. In addition, a number of difficulties come thwart the direct use of these equipments (levels and types of power supply, obsolescence of technologies used,

41 Informations présentées au 64ème congrès de la Société Française de Chirurgie Thoracique et Cardio-Vasculaire (SFCTCV) à Lyon, les 26 et 27 Mai 2011.

weight considerations ...). Progress is being made every year but they do not allow for very significant improvements in the short term. These traditional means will therefore only be used in early versions of CARMAT systems.

To be able to have a manufacturable innovative technology from the time of the CE Conformity Marking of its artificial heart, CARMAT develops in partnership with PaxiTech – a start-up spun off the Nuclear Energy French Agency (CEA) – a fuel cell battery which would not present the problems of hydrogen storage and replenishment which are traditionally encountered in fuel cells. Such a battery could offer the patient at least a 12-hour autonomy, for a maximum weight of 3 kg, significantly improving their quality of life.



Source: PaxiTech – portable fuel cell battery

Moreover, percutaneous energy transfer, through the skin via wiring, creates risks of infection on the long term if used outside a sterile environment. The rate of infection of the percutaneous wire is superior to 20% in ventricular assist devices reported long-term experience. [42] (See paragraph 6.4.2 Technologies and market players)

The Company accelerated its research efforts in both these areas since September 2011, in order to improve patients' quality of life and reduce the risk of driveline infection.

6.3.2.5 Reliability

The first artificial heart project tested to the standards of the space industry in the 21st century.

CARMAT bioprosthetic total artificial heart project is based on high-end technologies incorporating diverse materials and components, implanted in the human body. The reliability of such a system is critical when aiming to become a real alternative to transplantation. The total artificial heart project should ultimately ensure a durability allowing the same survival as heart transplant, ie. a 50% survival rate at ten years post-implant.

Few devices, that are continuously operating, have comparable lifetimes, without specific maintenance activities. An artificial satellite in orbit tens of thousands of miles from Earth has to offer this type of performance. That is why the same test methodology was applied to the CARMAT artificial heart project.

The aim of the endurance tests for the bioprosthetic is 5 years, representing about 230 million beats. The lifetime is estimated from mathematical models used in aerospace and electronic parts for the endurance test for electromechanical or mechanical moving parts.

However, one should distinguish the duration of the endurance tests on benches from the real sustainability of a given device. Test time corresponds to minimum regulatory requirements (CE or FDA guidance) that are generally 5 years, in real time or with an acceleration factor. The actual performance can be much longer (refer to the durability of heart valves that can exceed 25 years) and can be established only by clinical experience. The actual performance of the CARMAT artificial heart project will be established only after accumulation of clinical data in real time. Furthermore, the durability of a device does not predict the survival of the patient if it, for example, leads to direct or indirect complications.

Endurance tests benches reproduce the conditions under which the device will operate when used in the patient's body.

[42] Zierer A. Late-onset driveline infections: the Achilles' heel of prolonged left ventricular assist device support. Ann Thorac Surg. 2007 Aug;84(2):515-20.

Source CARMAT – Endurance test room for the complete systems, allowing for up to 12 simultaneous tests

For some of these tests, it is possible to use an acceleration factor by increasing the frequency of solicitations, although this is subject to remaining consistent with the profile of future use. For example, a heart can be tested up to an accelerated frequency which remains within the physiological limits of a natural heart.

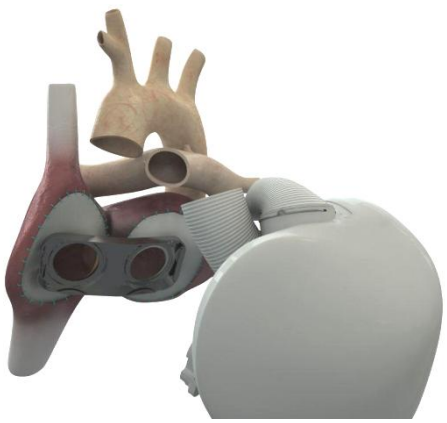
Iterative testing conducted for many years were used to optimize product design, highlighting the possible failure modes and implementing solutions addressing these weaknesses. Regarding the hydraulic pump, the results show a continued improvement in its design with no visible wear after 4 years of testing the latest generation while the first generation showed signs of wear after 3 months. In addition, 22 pumps were tested over periods ranging from 2 years to 6.7 years, with an average of 4.3 years, with no measured loss of performance. Moreover, the polyurethane membrane was tested over a period of 5.6 years without wear and the biosynthetic membrane over a period of 1.8 years without biological or mechanical alteration.

As part of preparation for clinical trials and prior to submitting the application for the ANSM for the permission to set up clinical trials, new functional tests, computer software, environmental and endurance tests were conducted on custom benches. Endurance tests are continuing. Preliminary findings of these tests are presented in paragraph 6.3.3 "Processes and stage of development of total artificial heart project."

6.3.2.6 Implantability
A simple, replicable procedure for any surgical team

An implantable device can be a valid therapeutic option only if implantation is simple and replicable. Under the direction of Professor Carpentier, CARMAT teams have therefore worked closely with several surgeons, anesthesiologists, perfusionists and operating room nurses to design and develop a procedure that any cardiac surgery team can perform in good conditions even an emergency.

In particular, an original interface with the patient's atria was developed, which allows the surgeon to have much more room to work, and a better alignment of the prosthesis. Therefore, the procedure is considerably accelerated and facilitated. The implantation time must indeed be as brief as possible if one is to limit the neurological risks of prolonged cardiopulmonary bypass.



Source CARMAT – Rapid connection interface to the atria

Once this interface is sutured to the atria, the prosthesis can be simply “clicked” onto it. This interface comprises a hybrid material whose face in contact with blood is treated bovine pericardium, thus respecting the philosophy of haemocompatibility of the prosthesis.

Many ancillary implantation tools have also been developed in collaboration with medical teams.

6.3.3 Process and development stage of CARMAT’S artificial heart project

The development plan for the total artificial heart consists of three phases:

1. a preparation phase of the clinical investigations in humans which consist in studying, designing and manufacturing systems of implantable total artificial heart, and in performing all the tests and validations necessary to obtain a Authorization of Clinical Trials by the ANSM;

2. a clinical trial validation phase including a feasibility study and a pivot study;

3. a development phase which aims to complete the definition of the device and its clinical and in-vitro validation file for the application to the CE Conformity Marking. This third phase will run in parallel to the clinical trials.

This planning provides clinical validation data as quickly as possible, and enables CARMAT to validate in real time distinctive technical choices of the project (haemocompatibility, physiology, self-adaptation, anatomy, miniaturization, reliability) or to retroact with the same reactivity on the design.

This development plan was approved by OSEO Innovation in the contract signed in 2009, and modified by an amendment in 2011 (see paragraph 22 Important Contracts). The key stages of the OSEO development plan correspond to the stages of this development plan. (Refer to paragraph 22 Important Contracts). This plan was also presented to AFSSAPS in 2004 and its principle validated when the application was submitted for pre-submission in 2011 (see paragraph 6.4.5 Regulatory Strategy).

6.3.3.1 Preparation

The preparation phase is based on an initial definition of the CARMAT system. For reasons of robustness, this definition includes:

- A long term clinical-grade implantable bioprosthesis ;
- A wired intra-extra corporeal connection ;
- An external power supply ;
- An alarm module ;
- A wired connection to an external power supply and data storage device (console).

A first step was to conduct the study and the detailed design of the system and its subsets. This step in particular helped move from a prototyping stage performed during feasibility studies to the definition of an implantable system. Research conducted included notably the following:

- Study of the system architecture and development of its specifications ;
- Technological studies on methods of obtaining the haemocompatible surfaces (ventricular membrane coating, atrial connection interface, ventricles shape) ;
- Studies of mechanical assemblies: fitting of the motor pump on the prosthesis body, locking the prosthesis body on the atrial interface, adhesives used for binding the outer bag on the prosthesis body, …) ;
- Integration study: Exploring ways to purge the prosthesis from air and to ensure its sterilization.
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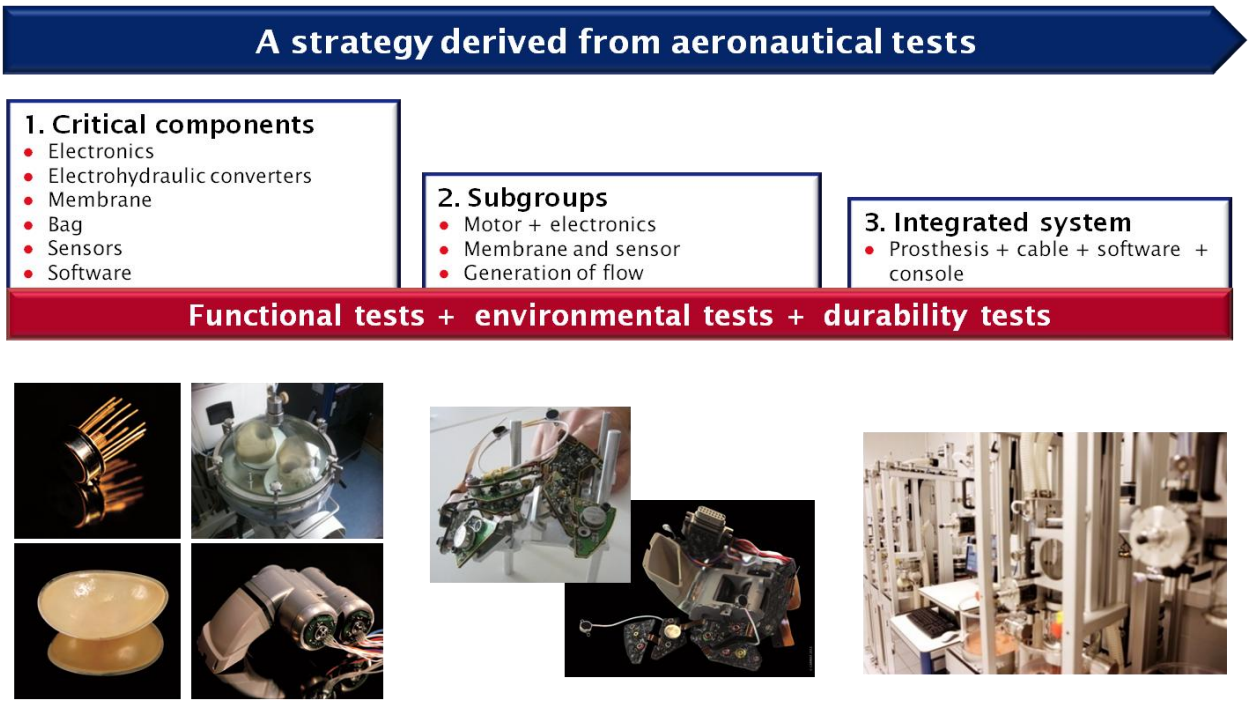
The second step consisted in the development of the different subsets, their qualifications and system integration. Twenty systems were manufactured to, first conduct in vitro tests, and then to conduct endurance tests and qualification tests on test benches recreating the bloodstream and replicating human activity (rest , activity, and sleep cycles).

The final step is the manufacturing of the systems needed to initiate clinical trials.

For the purpose of this phase of preparation for clinical investigations, the Company has built a clean room for integration and conducted a Bayesian approach of intensive preclinical testing, illustrated and detailed hereafter.



Source CARMAT – Pre-clinical test strategy

Biocompatibility testing

The prosthesis uses hybrid materials in the ventricular cavities and on the atrial interface. These materials are one of the key differentiating features of the CARMAT system. In addition to demonstrating their long-term physico-chemical stability in vitro, the Company chose to demonstrate their good capabilities in long-term implantation through their resistance to calcification and good haemocompatibility.

- **Calcification testing**

With the expertise of Professor Alain Carpentier, CARMAT has conducted several tests to identify the level of calcium in the fixed tissue 1 month after subcutaneous implantation in 12 day old Wistar rats.[43] More than 500 rats were implanted with four discs of 8 mm diameter in supine position (more than 2000 records) and explanted after 1 month. An assay of calcium was carried out. The results for the hybrid material (polyurethane disks –pericardium), corresponding to the hybrid material used in CARMAT ventricular biosynthetic membrane – are comparable to those of bovine pericardium alone, the material used in clinically proven bioprosthetic valves. The hybrid material of the Company therefore should not present a higher calcification risk than already approved materials.

- **Haemocompatibility testing**

The micro-textured coating of the pericardium of the hybrid membrane and the waterproof ePTFE were put in direct contact with human whole blood* to characterize their action on blood activation. All blood characterizations were based on the recommendations of ISO 10993-4: 2009.[44] A negative control (PVC coated with heparin) and a positive control (silicone) were used as references.

Initial results showed that the materials used by the Company do not affect the blood count and do not generate haemolysis. Slight platelet activation and a very low level of inflammation were observed. They remained consistent with the Company's expectations in terms of a low bioactivity of its proprietary materials. This may allow a reduced long-term anticoagulant therapy. The analysis of the scanning electron microscopy images showed the non-thrombogenic effect of the materials.

The study of the biocompatibility of the materials used by CARMAT in direct contact with biological tissues is now complete and was published in a scientific journal.[45] The company now has a strong confidence vis-à-vis the haemocompatibility of its materials.

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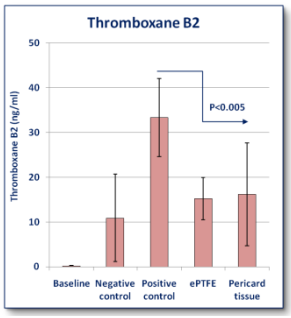
43 Golomb et al. American journal of Pathology, 1987, vol 127, n°1, p. 122-130.

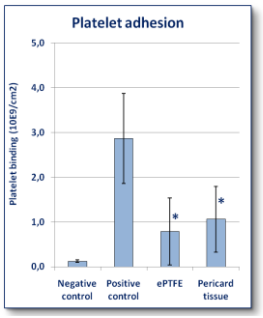
44 Seyfert et al. Biomolecular Engineering, 2002, n°19, p. 91-96.

45 Jansen P, van Oeveren W, Capel A, Carpentier A. In vitro haemocompatibility of a novel bioprosthetic total artificial heart. Eur J Cardiothorac Surg. 2012 Jun;41(6):e166-72.

Atrial connection interface

Hybrid Biomembrane





Coagulation factors*

Source CARMAT – Résultats d'hémocompatibilité des interfaces biologiques hybrides

- **Hemodynamic biocompatibility**

The objective of this test was to verify that the risk of haemolysis and thrombosis in the device is as small as possible. Studies have shown that medical devices were causing unnatural blood platelet activation resulting in thrombus formation.[46] Haemolysis and thrombosis are two phenomena caused in part by a too high shear rate of blood cells.

CARMAT limited the materials interacting with blood to bovine pericardium and ePTFE which are known to be biocompatible. The inflow and outflow grafts as well as the ventricles have been designed to maximize blood flow through the device as to minimize contact and risk of thrombosis. The pericardial tissue covering the atrial interface provides continuity to the inflow valves.

Verification of technical requirements - Tests on test benches

All tests on benches have been conducted in a constant effort to take into account the constraints of each element in the system as to increase the overall quality of the device. Hence, manufacturing constraints have been taken into account in the design phase of the prosthesis.

The strategy of testing conducted by CARMAT was to specify the critical elements of its system in order to study them independently and then combine these components and test the overall system to achieve a sufficiently high level of confidence for its device. Thus, the Company has implemented a comprehensive program of testing for its device and specified sub-components: motor pump, hybrid membrane, sensors, electronics and software in four major categories of tests:

• Functional Testing

They are based on the demonstration of the product's performance

a) Pump unit

Pumps consist of a motor and two concentric gears.

A first series of tests is performed on a pneumatic test bench which allows for rotating the gears of the motor while applying a negligible but precise friction torque to achieve very precise measurements of performance. The test bench has two main functions: (i) drive CARMAT motor to measure its electrical performance and (ii) exercise a precise friction torque to measure the mechanical performance of the engine.

Another test bench is dedicated to the measure of the pump's performance. It consists of a tank filled with silicone oil maintained at 40 ° C, which reproduces the environment in which the equipment is functioning normally and a collector equipped with a limiter section connected to the outflow grafts for simulating the hydraulic pressure.

b) Hybrid membrane and compliance bag*

The main performance to be tested in these two elements is their compliance and impermeability to silicone oil and physiological fluids. Measurements were performed on a special bench and using a control system based on contactless video tracking to verify compliance of the components and their integration. The compliance of the hybrid membrane is perfectly in line with expected performance. The volume of bag deployment is also consistent with the requirements.

To assess the permeability of the bag and the membrane, samples taken from the manufactured products were placed in environments representative of the interface of the clinical trial configuration, with silicone oil and a

[46] Danny Bluestein, Research approaches for studying flow-induced thromboembolic complications in blood recirculating devices, Department of Biomedical Engineering, New York University at Stony Brook, 2004 Sep;1(1):65-80.

physiologic liquid at 40 ° C. After 1 month and 3 months, samples were analyzed with a Raman microscope to measure the penetration of silicone oil in the material thickness. The results concluded that the two components were impermeable.

c) Electronics

Simulations were conducted to verify the safety factors of the functions performed by the electronics and to ensure that components are properly sized to be free of stress which may reduce their life expectancy. A thermal study was also conducted to verify that the electronic components operate at temperatures compatible with their specifications. All electronic components have been evaluated.

Tests were performed on prototype electronics in order to verify that all functions were operating at room temperature. These tests are performed by downloading test software in the microprocessor. It performs measurements, stimulates the functions of the electronic component and communicates with a human-machine interface that indicates the test result or action.

Pressure measurement is calibrated and tested using a bench that reproduces the pressure ranges to which the circuits will be submitted. This test is performed in temperature.

d) Prosthesis Tests

The major functions of the prosthesis are evaluated by coupling the various components:

- The control of pumps: basic function that manages the flow of the actuator fluid to move the charged membrane for the blood to circulate.
- The verification of this function is performed by coupling a pump unit, the electronics and software modules in charge of steering engines. The software transmits to the motor, through the electronics, a command representative of the prosthesis' flow.
- The measurements verify the accuracy of the control for the pumps as well as the power consumption of the electronics and any disturbance generated by the engines on the electronics. The results are also compared with performance on previous versions of prosthesis.
- The results are consistent with the specification requirements. The improvement of the new sensors that detect the position of the rotary engine and the enslavement of the electrical current of the motors, have not only reduced consumption, but also made the pump controls more robust to variations in voltage.
- The detection of the membrane via ultrasounds: function contributing to precisely measure the volume of blood contained in the ventricles.
- This function is verified by connecting a motor pump unit, a membrane, an electronic device equipped with and ultrasonic sensor and the software modules responsible for controlling the motors and for emitting and detecting ultrasound signals.
- The initial tests carried out in static mode make it possible to check that the membrane is detected by the electronics even when it is inclined at the maximum angle relative to the axis of the sensor.
- These tests are reproduced in dynamic mode until reaching a membrane displacement speed equivalent to the maximum flow rate in the prosthesis. The software transmits to the motor pump unit, via the electronics, a command representative of the flow in the prosthesis. The membrane then moves in the same way it will in the prosthesis. The information received from the ultrasonic electronic module make it possible to check that the position of the membrane remains detectable while in operation
- The final stage consists in verifying that membrane detection is functional when all the components are integrated into the prosthesis, and in particular that there is no interaction between the membrane detection in the two ventricles. These tests were being performed on a complete prosthesis.
- Medical regulation: function allowing for the adjustment of the blow flow to the patient's needs.
- The first version of this algorithm, which automatically adjusts the flow through the prosthesis, has been tested on a hydraulic test-bench. To do this, a previous generation of prosthesis integrating the new pump principle with which the current prototypes are fitted was used. Testing software that integrates medical regulation has been developed to activate this prototype. The prosthesis is connected to the test-bench and this is adjusted so as to obtain an average flow rate of 6 l/min. The variations in the flow rate through the prosthesis and the variation in the arterial and pulmonary pressures according to the filling of the test-bench characterized by the systemic pressure can then be observed.
- These preliminary static tests have shown the capacity of the prosthesis to adjust its flow rate automatically from 4 to over 9 l/min. They also serve to demonstrate that the prosthesis can cope with situations of pulmonary arterial hypertension by maintaining the flow rate despite very high pulmonary pressures. An adjustment of the algorithm to the architecture of the prostheses destined for clinical trials is under investigation. This test-bench allows for more complex dynamic scenarios to be introduced, such as the

transition from decubitus to orthostatic position, which will make it possible to validate all the performance parameters of the CARMAT system.

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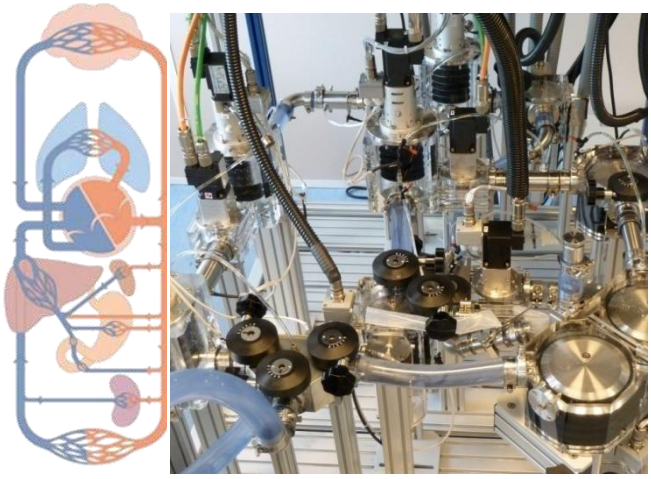


Source CARMAT – Advanced haemodynamics test bench

- **Software tests**

They follow a particular logic in accordance with the EN 62304 standard, based on testing at increasing levels of integration and verifying the records of design and specification.

The process of software verification is an integral part of the software lifecycle; its aim is to detect and act on errors that might have crept in during the course of development of the software associated with the prosthesis.

Such verification processes have two additional objectives: (i) to demonstrate that the prosthesis software meets the requirements set out in the specification and design documentation, and (ii) to eliminate errors that could lead to unacceptable failures and to demonstrate with a high degree of confidence that these errors have been eliminated. There are three main verification phases: unit tests, verifications of the design, as well as verifications of the specification. According to Standard EN 62304, all the requirements contained in the specifications and designs must be tested or verified. The tests verifying the conception are completed; those validating the compliances with the abovementioned norms are being finalized.

- **Environmental tests**

They are based on the verification that the products support and do not influence abnormally the ranges of temperature, pressure and vibration as well as the magnetic and electrical fields in which they are subject to evolve. Performances specifically involving certain equipments are verified as soon as possible, such as the correct operation of equipment according to the ambient temperature, variations in the temperature and in the electrical fields generated by the equipment itself.

After these unit checks have been carried out, the conformity of the complete system has also been verified.

a) Motor pump unit

On a chemical level, all the adhesives and coatings used in the manufacture of the pumps have been evaluated by aging in the actuation liquid kept at temperature.

On a mechanical level, vibration testing of the motor pump units is currently under way. The test-bench intended for this test is connected to the pump and reproduces the load represented by the actuation liquid.

b) Hybrid membrane and compliance bag

Aging tests on the materials used for the bag and the hybrid membrane have been passed with success. The anticipated durability of the biological materials should be equivalent to that of biological valves.

c) Electronics

The entire electronic assembly is covered with a coating. Ageing tests on this coating, which is immersed in silicone oil at temperature, have demonstrated the product's stability. The requirements relating to the complete lifecycle have been verified.

d) Prosthesis

The prosthesis has undergone several environmental-type tests: thermal tests, electromagnetic testing and vibration tests.

At this stage of the project, the initial electromagnetic tests were carried out on prototypes of the previous generation in terms of irradiation and susceptibility. These have made it possible to fulfill the manufacturing requirements for the electronic cards.

e) System

Tests on the system environment are going to consist essentially in verifying that requirements as regards electromagnetic environments and electrical safety are complied with. These tests were concluded successfully.

- **Integration process validation and verification testing**

The integration process of the prosthesis is intrinsically innovative as there are no known biocompatible implantable regulated prosthesis on the market today and no known affiliated industrial sector. The Company must therefore, for each component, part, and subassembly, step by step and contractor by contractor, establish a detailed description of the steps of manufacturing for each component, control procedure, part or final subassembly, the procedure of “first article” at CARMAT, the process and instruction manuals for acceptance into the clean room etc., as well as the whole of the documentation required by the Quality Assurance System of the Company and ISO requirements, at CARMAT as well as at its contractors’ facilities.

In the development and pre-series stage, the volumes are not sufficient to justify setting up an automated or robotic assembly line. Several tasks are therefore manual, with all the variances this implies. The Company has therefore adopted a very strict protocol for its tests: each component must have absolute compliance with this protocol. The setting up of the process has required severe efforts, including an analytical approach enabling to correct any error or imperfection as they appeared, even when it implied a prolongation of the duration of some tests.

- **Endurance Tests**

These tests perform the verification of the reliability requirements for the prosthesis

CARMAT has performed initial verification of the reliability of the various components of the system, the central element being the prosthesis. The moving parts (pumps, membrane, pouch) have undergone specific testing, as have the sensors which are subject to mechanical stress: pressure sensors equipped with a silicon membrane and ultrasonic sensors made of piezoelectric components. They are tested on test-benches reproducing the environment in which the components normally have to work, and also reproducing the actual interface with the parts of the prosthesis with which they are related. It is possible to speed up the tests for these constituents to obtain endurance results more speedily and thus reinforce the reliability of the prosthesis itself.

13 new test-benches are currently set up for the purpose, notably, of conducting endurance tests and of simulating the patient’s entire lifecycle with, for example, typical daily scenarios. These test-benches also comprise hemodynamic test-benches developed for performance testing.

These sophisticated digital benches are custom-designed and made specifically for the CARMAT bioprosthesis. They have indeed represented a "project within the project." Much proprietary know-how has been acquired during their development.

Given the demonstrated inadequacy of the animal model for prostheses designed for the human physiology such as the CARMAT bioprosthetic heart (see next paragraph, Ex-vivo and in-vivo tests), the development of these means of tests inspired by the aerospace industry is an additional first to be put to the credit of CARMAT for the medical device industry.

To allow the first phase of clinical trials, the ANSM requires that five systems have accumulated four months of continuous operation without any failure. Subsequently, five other systems will be installed on these banks, bringing the total to 10 systems in on-going endurance testing. These systems will be tested continuously until failure, with a goal of one failure maximum at one year on the 10 systems.

As stated in a communiqué released on 26 July 2012, interim results of endurance tests have been filed with the ANSM, with one of the systems having already exceeded five months of continuous operation.

The advancement of preclinical in-vitro testing to date is as follows:

AFSSAPS criteria/ISO standards	Progress*
Components and sub-assemblies	
Haemocompatibility biomembrane & ePTFE in-vivo	
Biostability bag in-vitro	
Biostability biomembranes, atrial interface & bag in-vivo	
Endurance biomembranes	
Endurance bag	
Endurance ultrasound sensors	
Endurance pressure sensors	
Endurance electrohydraulic converter	
Prosthesis and system	
Production environment (clean room)	
Anatomical compatibility in-silico	
Biocompatibility of integration process	
Software (feasibility trial version)	
Functions (response to activity, safety, real-life scenarios)	
Endurance complete system	

Source: CARMAT- Synthesis of the pre-clinical tests progress

All of the preclinical testing and validation testing has represented a considerable effort for the Company, its partners and suppliers over the last 12 months, in a context of total innovation, not only technological, but regulatory (no precedent in France) and industrial (procedures and integration methods being new, with no existing industrial sector).

Some tests have proved to more consuming in prostheses than expected. In other cases, it was not possible to parallelize tests, or to reuse the same prosthesis for successive testing.

The need for a greater number of test prostheses has resulted in the production of double the number originally planned for preclinical trials. This considerable workload increase, in the context of establishing an innovative integration process, has resulted in shifts in CARMAT's planning as well as in its partners and suppliers' planning. As a result, a number of tests were not completed on the dates specified in the original schedule due to a lack of available test prostheses.

A strict test sequence must be observed, in particular to ensure that all prostheses are tested within the same definition of product and at the same level of validation, in accordance with ISO standards and CE Conformity Marking requirements. The endurance tests of the complete system are the last of this sequence and their start has thus been subject to accumulated delays to receive parts and subassemblies, manufacture additional prostheses and finalize preceding tests in the sequence.

To date, the tests have produced satisfactory results. Between the publication of the previous Document de Référence and the date of registration of this "Document de Référence", the following activities were performed:

Prosthesis manufacture: 19 prostheses of clinical quality and four prostheses intended only for benches were made for the benefit of the various tests, in vitro and in vivo.

Animal Testing: A campaign was conducted in order to train surgical teams (3 teams) to the operative procedure and the set up of the prosthesis.

Finalization of the pre-qualification testing of the system

Filing of pre-submissions No. 1 and 2 with AFSSAPS / ANSM and CPP approval: questions were asked by AFSSAPS / ANSM experts, to which CARMAT had to provide written responses, supported by formal meetings.

Environmental testing of the prosthesis: thermal and vibration testing to supplement electromagnetic compatibility testing achieved previously. The prosthesis has shown excellent performance in these tests.

Finalization of wear testing on the GMP, membrane, bag and ultrasonic sensors based on the clinical definition: the durations specified by the ANSM (formerly AFSSAPS) have been reached without encountering any mechanical failure.

Qualification testing of GMP subcomponents and electronics: the motor pump and electronic prosthesis successfully underwent all planned qualifying events.

Finalization of biocompatibility tests: blood compatibility tests have shown excellent results proving the validity of the use of micro-porous materials for parts in contact with blood. Further testing of biostability and biocompatibility of the manufacturing process were added to these technical justifications.

Software development of the prosthesis according to standard 62304: Development of the final software to replace the software model used for functional testing has been divided into two parts: one software for the hospital phase and additional comprehensive software for discharge home. The hospital software has been validated in parallel with the finalization of the software-only cycle. The "home" software will be downloadable on the implanted prosthesis.

End of the development and qualification of external parts: definitions of cables, external routing module and hospital monitoring console were improved from a performance and ergonomics standpoint. The software of the hospital console followed the V development cycle of the EN 62304 standard. These different subsets were environmentally qualified.

Documentation: all the manuals included in the documentation plan have been produced and published: the instructions for use, the virtual implant procedure manual, the operator's manual, the implantation manual, the explantation manual and the patient manual.

Endurance tests: implementation of test benches reproducing the lifecycle of the prosthesis.

Tests ex-vivo et in-vivo

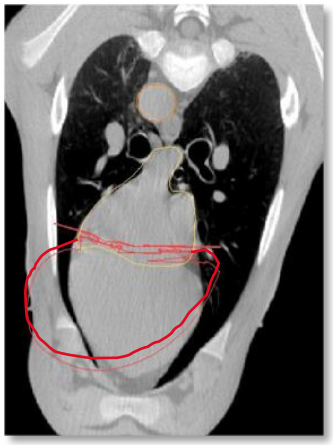
Between 2010 and 2011, the Company conducted 15 ex-vivo implantations, in order to assess the anatomical compatibility, to develop ancillary implantation tools and to fine-tune the surgical procedure.

With regards to in-vivo testing, the animal model, widely used in medical devices evaluation, does not lend itself to an artificial heart project designed for a human thorax and self-regulated on the physiological needs of man.

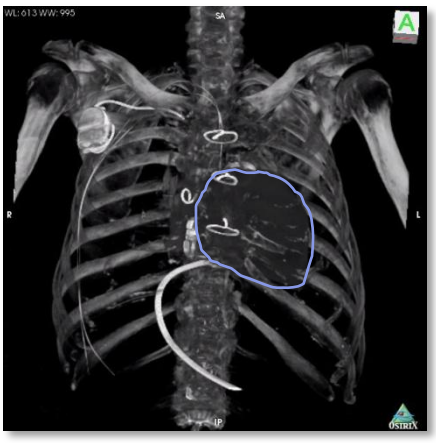
Indeed, the only usable model in terms of size, weight and thoracic capacity – when excluding primates for ethical reasons – is the calf. However, a calf weighs 40 kg at birth, but 300 kg at 6 months and up to 500 kg at 10 months. It is therefore not possible to test on the long-term a prosthesis designed for human physiology. CARMAT's artificial heart project would not be capable to perfuse a 500 kg organism.

Moreover, it is not possible to test on a calf the pressure changes related to standing, and therefore the perfusion of the human brain. Functional assessment of the sensors present in CARMAT artificial heart project and their associated algorithms is not possible.

The calf's chest is concave (V-shaped), unlike the human thorax which rather ovoid, the position of the great vessels is different, which makes implantation difficult and may negatively influence the results.



Calf thorax, in red the position that the prosthesis should occupy In a human thorax



Human thorax, in blue the anatomical position of the prosthesis

Source CARMAT – Experimental implantations, in-vivo and ex-vivo

Finally, results obtained in an animal model do not predict results in humans as there are too many differences (physiology, anatomy, and especially blood factors ...). A U.S. artificial heart project successfully completed 14 implantations in the animal with a one month survival before moving to human clinical validation. This success turned into failure in humans, with 9 strokes on the first 14 patients. [47]

Therefore CARMAT chose a strategy of exhaustive in-vitro testing to evaluate endurance and haemocompatibility.

However, animal testing is a valuable procedural training tool. In addition to preclinical testing for the Health Authority, CARMAT therefore conducted between September 2011 and June 2012 the implantation of his artificial heart in several calves. The purpose of these implantations was to verify the proper functioning of the prosthesis in vivo and to validate the surgical technique.

These short-term implantations were performed under a strict protocol on calves with a size and weight consistent with the prosthesis capacities. An experiment on an animal of 120 kilos, has been extended for 24 hours entirely satisfactorily. Each of the three surgical teams selected for the first clinical phase of the project participated in the implantations.

The results correspond to the objectives of the protocol: start-up and correct operation of the prostheses, achieving physiological pressure curves and blood flow.

Professor Christian Latrémouille, cardiac surgeon at the Georges Pompidou European Hospital and principal clinical investigator, participated in all the implantations and made the following comment in the Company's Newsletter on July 26, 2012: "*The average time of surgical implantation is only 2h40, comparable to a transplantation, despite the constraints imposed by the anatomy of the chest of a calf, very different from that of the human thorax for which the prosthesis was designed. In all cases, the prosthesis took over from the cardiopulmonary bypass as planned and helped to correct and maintain the metabolic situation of the animals. These data are essential for the later stages and the clinical phase.* "

6.3.3.2 Human Clinical Validation

- **Necessary authorizations**

In France, two authorizations are required in order to initiate clinical trials.

- The approval of the Comité de Protection des Personnes (CPP, i.e. Ethics Committee)
- The Authorization for Clinical Trials (ACT) from the ANSM

The approval of the CCP (Ile-de-France III, approval n°2925) was granted on November 28th 2011 and is relevant to the ethical aspects of the research protocol and the patient's consent. The approval of the CCP is valid on a national level for all the French medical institutions that will participate in the CARMAT artificial heart project trials.

The human clinical validation will be able to start after obtaining the ACT of the ANSM. This latter will be based on an analysis of the file containing the pre-clinical test results and an evaluation of a favorable risk/benefits ratio for the patient considered, by independent ANSM experts.

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- The development of CARMAT's bioprosthetic total artificial heart has benefited from the ANSM's innovation fostering procedure; that latter being authorized for medical devices regarded as highly innovative in:
- Treating an otherwise fatal disease; and
- Meeting a real and otherwise unmet medical need.

Through the « ANSM pre-submission procedure of certain clinical trials » CARMAT is assured to be able to prepare commercialization of its heart in the best delays.[48] This procedure allows for the completion of the final demand as data becomes available in order to reduce the normal delays. (see paragraph 6.4.5.1 Regulatory Strategy – Europe)

- **Training of the hospital facilities**

-
- CARMAT initiated, at the end of 2011, an intensive training and certification program with three transplantation centers in France in order to conduct the clinical trials:
- Hôpital Européen Georges Pompidou, Paris (Pr Latrémouille)
- Hôpital Marie Lannelongue, Le Plessis Robinson (Pr Darteville et Dr Nottin)
- Hôpital Laënnec, Nantes (Pr Duveau)

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47 FDA Panel review Summary of Safety and Probable Benefit - H040006 - AbioCor® Implantable Replacement Heart. http://www.accessdata.fda.gov/cdrh_docs/pdf4/H040006b.pdf

48 Association Nationale de Sécurité du Médicament et des produits de santé (ANSM). Procédure de pré-soumission à l'ANSM de certains essais cliniques à l'attention des promoteurs d'essais cliniques portant sur des dispositifs médicaux et dispositifs médicaux de diagnostic in vitro (21/05/2012)

These three teams, as well as the members of the Scientific Committee, have already greatly contributed to the development – specifically to the development of the ancillary tools, the anatomical compatibility models and medical auto-regulation – of the artificial heart project, to the animal study protocol and in reviewing the patient recruitment protocol. Under the supervision of Pr Carpentier, this collaboration has ensured the transfer and dissemination of the acquired knowledge to create and nurture a favorable clinical environment for the acceptation of the device once commercialized.

This very complete and interactive training includes:

- Theoretical training:
  - Presentation of the CARMAT system in a demonstration room
  - Operation of the CARMAT prosthesis
  - Visual and theoretical training on the Hospital Monitoring Console
  - Presentation of the virtual implantation system
  - Training on the implantation procedure: conditions and selection of patients, preparing the prosthesis , surgical procedure and accessories.
  - Training on patient management and follow-up.
- Practical training
  - Hospital console operation for prosthesis management on a training bench and review of the documentation
  - Start to finish animal implants in order to validate the theory.
  - Hospital console operation for patient management
  - Device explantation procedures.

The collaborative design of training procedure is rich in information for both the medical teams and CARMAT, since it identifies the expectations of the clinical teams that will be its clients.

- **Clinical investigation plan**

- The clinical trials will be conducted in two stages:
- A feasibility study, the objective of which would be to verify the safety and the correct functioning of the principal features. (4 patients)

The feasibility study will be conducted in the three transplantation centers mentioned above. The Medical Committee of the Company, composed of Professor Christian Latrémouille, Professor Daniel Duveau, Doctor Rémi Nottin and Professor Alain Carpentier, is in charge of validating the patient's profile and the clinical protocols.

Under condition of obtaining the ANSM approval, the protocol already approved by the CPP defines the following criteria as an acceptable patient profile (see paragraph 6.2 'Heart Failure' for a further evaluation of the risks at stake):

- Age ≥ 18 years old
- Irreversible biventricular hear failure, which can only be treated through transplantation but is not eligible.
- Functional status of the patient evaluated with the NYHA at Class IV
- Ejection fraction of the left ventricle < 30% and cardiac index ≤ 2.0 L/ min/ m²
- Already under optimal medical treatment and dependant on continuous intravenous inotropes
- No strokes in the past month, or septicemia or blood clotting pathologies
- No short term life threatening cancer
- No psychiatric disorders which would impede the respect of the procedure or the monitoring of the CARMAT system

This humanitarian indication concerns patient with severe cardiogenic choc for which the vital prognostic is engaged on the very short term, from a few hours to a few days. The procedure includes extensive monitoring while at the hospital and monthly thereafter.

- A pivotal study for the purpose of validating the safety and performance variables of the system and to obtain CE marking (up to 22 patients).

Under condition of satisfactory results during the feasibility study, the pivotal study protocol could include patients with a better prognostic.

In order to establish a European network of trained cardiac surgeons prior to commercialization, CARMAT will broaden the pivotal study to other European centers, especially in Germany where the number of potential patients is important as the frequency of severe cardiovascular pathologies is approximately 50% higher than in France and as there is known reimbursement possibilities for innovations. The Company has already identified suitable centers in Germany, the United Kingdom, Spain and Italy that would be interested by the implantation of CARMAT's artificial heart within the scope of clinical trials.

The broadening of the pivotal study to European centers will require for the Company to localize all the needed training and documentation for physicians, patients and hospitals and will require, as early as the first quarter of 2013, to obtain legal authorizations to conduct clinical trials in each country, as well as approval from local ethics committees. In total, a minimum of 22 patients should be implanted with CARMAT's total artificial heart for the clinical validation necessary for the filling of a demand of the CE Conformity Marking.

In the event of successful clinical trials, and under condition of no unproductive delays, particularly in the rhythm at which patients will be recruited, the Company should be able to file for CE Conformity Marking at the end of 2013. The Company expects to perform further clinical trials in the United States in order to obtain the authorization from the FDA to sell CARMAT's total artificial heart on the American territory. These clinical trials could start from the first quarter of 2015 with an objective to gain approval for commercialization as soon as late 2016.

- **Communication of the first clinical trial results.**

CARMAT's scientific committee will perform the initial analysis prior to any communication of the clinical trial results and will collectively exercise sovereign power on the communication of trials results, with regards to the ethical considerations owed to the patients and their families.

It will furthermore decide as to the publication of studies relevant to these results in specialized scientific journals.

6.3.3.3 Development

This phase will immediately follow the feasibility study of the clinical trials. It aims to complete the definition of the system and its in vitro and clinical validation file in order to file for CE Conformity Marking.

This third phase will be performed in parallel with the pivotal study and will include:

- The aforementioned pivotal study ;
- Further endurance tests on 10 systems, the 5 systems tested in order to gain ANSM approval and an additional 5 systems that will be produced and set up on test benches. These systems will be tested continuously until failure; with an maximum failure of 1 at 1 year in the 10 systems
- Potential modifications of the CARMAT system resulting from the clinical experience gained through the feasibility study and the ongoing pivotal study, particularly with regards to the procedure, the ancillary tools, the software, the packaging, the ergonomics or the documentation meant for physicians and patients.
- A study for localizing the documentation – for regulatory purposes as well as for patients – in order to expand, outside of France, the clinical trials, for CE Conformity Marking and lastly, the commercialization.
- A study of potential improvements to the production tools in order to increase production, particularly with regards to securing procurement via the development of secondary sources and rationalization of the integration process.
- Lastly, the design and development of new accessories or new functions allowing for additional competitive advantages such as an innovative connection to the prosthesis in order to limit the risks of infection, a portable system integrating the fuel cell batteries, and a remote monitoring system.

Some of these developments are already underway, notably their design and specification phase.

6.4 MARKET AND STRATEGIES

6.4.1 Market numbers

CARMAT seeks to market a bioprosthetic total artificial heart for patients with terminal heart failure in NYHA class IV, either chronic or following an acute myocardial infarction, as a 'destination therapy', as opposed to the 'bridge to transplant' indication, that is to say awaiting for a donor graft (see paragraph 6.4.2 Technologies and market players).

Chronic heart failure affects approximately 15 million patients in Europe[49] and 5.8 million patients in the United States,[50] a total of approximately 20.8 million patients in this geographical area.

If one refers to the approved indications obtained by similar devices, as well as criteria for inclusion and exclusion in the currently proposed clinical trial protocols by CARMAT to the regulatory authorities (see paragraph 6.3.3.2 Validation of clinical trials), the bioprosthetic total artificial heart would be appropriate, at least, for patients with chronic end-stage heart failure or acute end-stage heart failure, aged under 70, who cannot be transplanted, are not suffering from cancer reducing their life expectancy to less than 6 months, dependent on inotropic drugs and with impaired biventricular function or mono-ventricular with risks of contamination of the other ventricle.

Considering that:

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[49] ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2008. European Heart Journal (2008) 29, 2388–2442 (sur les 900 millions d'habitants des 51 pays adhérents de la Société Européenne de Cardiologie)

[50] Heart Disease and Stroke Statistics – 2010 Update at a glance – American Heart Association and American Stroke Association

- 2.3% of these patients reach, each year, the terminal stage of the disease – marked by the first hospitalization – thus a rough estimate of 475 000 patients. [51]
- 38% of this population is aged under 70, hence a target population of about 180 000 patients. [52]
- Around 12 000 eligible patients will be transplanted - or are on a waiting list; [53]
- 67%[54] of these patients do not have risks of contamination to the right ventricle; and
- The anatomical compatibility of CARMAT heart for men and women is 86% of men and 14% of women respectively (see paragraph 6.3.2.3 Miniaturization)

Then, the number of potential patients with end-stage chronic heart failure Class IV would be around 24 000 patients in Europe and the United States.

Besides, *acute myocardial infarction*[55] constitutes an important source of patients who need cardiac substitutes.

In France, around 100 000 patient suffer a myocardial infarct each year. Of those hospitalized, 7% die within the first month.[56] Myocardial infarction affects 925 000 patients each year in the United States.[57] Its incidence varies depending on the sex (less in women) and location most notably due to the type of diet present in a chosen area. The incidence rate can be as high as 8% in Finland and as low as 0.75% in Japan.

In total, considering an average incidence rate of 2% in Europe and the United States[58] – a cumulative population of 1 070 millions – the annual number of myocardial infarcts can be estimated to be around 2 140 000.[59]

7%[55] to 18%[60] of patient suffering from acute myocardial infract die within 30 days. At this stage, the physician's only available therapy is emergency cardiac transplant as the native heart can no longer assume its pump function.

Considering a average estimate of 12% (which corresponds to the mortality rate after 30 days in the United States[61]) there are then over 250 000 people who die each year after an acute myocardial infarction episode.

This sub-group of the population consists of critical patients and is CARMAT's secondary market.

Hence, considering that:
- The average incidence is 2%, thus 2.14 millions of patients in Europe and in the United States[62].
- 12% of patient die within 30 days, for lack of available transplantable hearts[63];
- 65% of these patients are under 70[64] ;
- Over two thirds of the patients are men[65,66];
- The anatomical compatibility of CARMAT heart is of 86% for men and 14% for women (see paragraph 6.3.2.3 Miniaturization) ;

Consequently, the number of potential patients with life-threatening acute myocardial infarction would exceed 100 000.

The market estimates of the total artificial heart can hence be estimated at around 125 000 prosthesis in cases of chronic terminal heart failure of NYHA Class IV and of irreversible acute heart failure due to myocardial infarction for men and women given their respective anatomies in Europe and the U.S. (see the methodological note at the bottom of the following page)

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51 Jhund PS et al. Long-term trends in first hospitalization for heart failure and subsequent survival between 1986 and 2003: a population study of 5.1 million people. Circulation 2009;119:515–523.

52 Jhund PS et al. ibid.

53 Purshouse K et al. Is There a Crisis in Heart Transplantation? Reflection over 10 Years. Open Journal of Organ Transplant Surgery, 2012, 2, 1-4

54 Baumwol J. Right heart failure and "failure to thrive" after left ventricular assist device: clinical predictors and outcomes. J Heart Lung Transplant. 2011 Aug;30(8):888-95. Epub 2011 Apr 29.

55 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012 - European Heart Journal (2012) 33, 1787–1847

56 Site de la Haute Autorité de la Santé - La HAS s'attaque à l'infarctus du myocarde – Mai 2007.

57 Heart Disease and Stroke Statistics – 2010 Update at a glance – American Heart Association and American Stroke Association.

58 Yeh RW et al. Population Trends in the Incidence and Outcomes of Acute Myocardial Infarction. N Engl J Med 2010; 362:2155-2165

59 Perspectives de la population mondiale - Révision de 2006, Organisation des Nations unies - Département des affaires économiques et sociales, 2007,

60 Roger VL. Epidemiology of myocardial infarction. Med Clin North Am. 2007 July; 91(4): 537–ix

61 http://www.cdc.gov/dhdsp/atlas/2010_heart_atlas/docs/Executive_Summary.pdf - page 16

62 Yeh RW et al. Ibid

63 http://www.cdc.gov/dhdsp/atlas/2010_heart_atlas/docs/Executive_Summary.pdf - page 16

64 Roger VL. Ibid

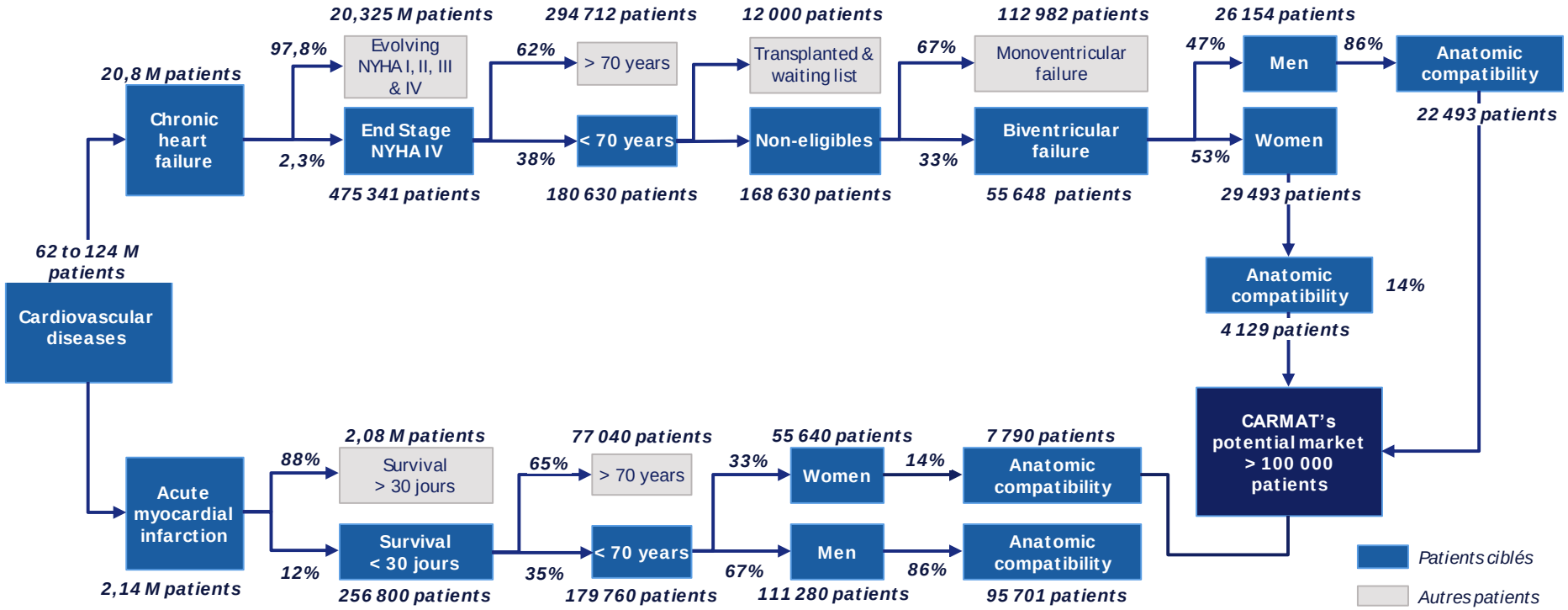
65 Lundblad D et al. Gender differences in trends of acute myocardial infarction events: The Northern Sweden MONICA study 1985 – 2004. BMC Cardiovascular Disorders 2008, 8:17

66 Vaccarino V et al. Sex Differences in Mortality After Acute Myocardial Infarction Changes From 1994 to 2006. Arch Intern Med. 2009;169(19):1767-1774.

On a purely prospective basis, one can expect that, in years to come, the incidence of irreversible acute myocardial infarction will decrease, and that the rate of chronic heart failure will, consequently, increase; as mentioned in paragraph 6.2.1 Pathologies and Etiologies of Heart Failure.

These estimates are summarized in the illustration thereafter.

NUMBER OF POTENTIAL PATIENTS IN EUROPE[67] AND IN THE UNITED STATES



Source CARMAT – Potential market for CARMAT's total artificial heart

METHODOLOGICAL NOTE

Estimates based on detailed hypotheses, referenced in the two previous pages. The Company strives to update these numbers on a yearly basis according to relevant scientific publications, and to reduce the number of references as to reduce the bias induced by aggregating heterogeneous populations or differing methodologies. Nonetheless, there exists no referenced official epidemiological data for the geographical zones targeted. In light of that, the studied populations can differ from those defined as CARMAT's potential indications. For example, available data are usually stra tified by age at around 65 than 75 years old, against a maximum age of 70 for CARMAT's heart indication. The Company has in this case established a prudent estimate based of demographic data of the considered population. Furthermore, it has not been possible to find published references of the proportion of patients suffering from terminal cancer (with a estimated lifespan of under 6 months) within the population of patient already suffering from end-stage heart failure. This exclusion criterion has therefore not been accounted for. The Company estimates however that this flaw does not impact the abovementioned estimates in a significant manner. The abovementioned data is given on a purely illustrative basis and does not constitute, in any way, a binding commitment of the Company regarding the size of the market at the market release date of the CARMAT heart or on any forecast of potential revenues.

[67] 51 countries members of the European Cardiology Society, including Eastern Europe, Russia and the Gulf countries.

6.4.2 Technologies and market players

Heart transplant, especially in light of the lack of donors, can only be performed in patients in Class IV end-stage heart failure (see paragraph 6.2.4 Available treatments). Alternative medical devices exist – often regrouped under the term mechanical circulatory support.

The major market players are Thoratec® and HeartWare® in the ventricular assist device market segment and Syncardia in the artificial heart market segment.

These devices apply to two different indications:

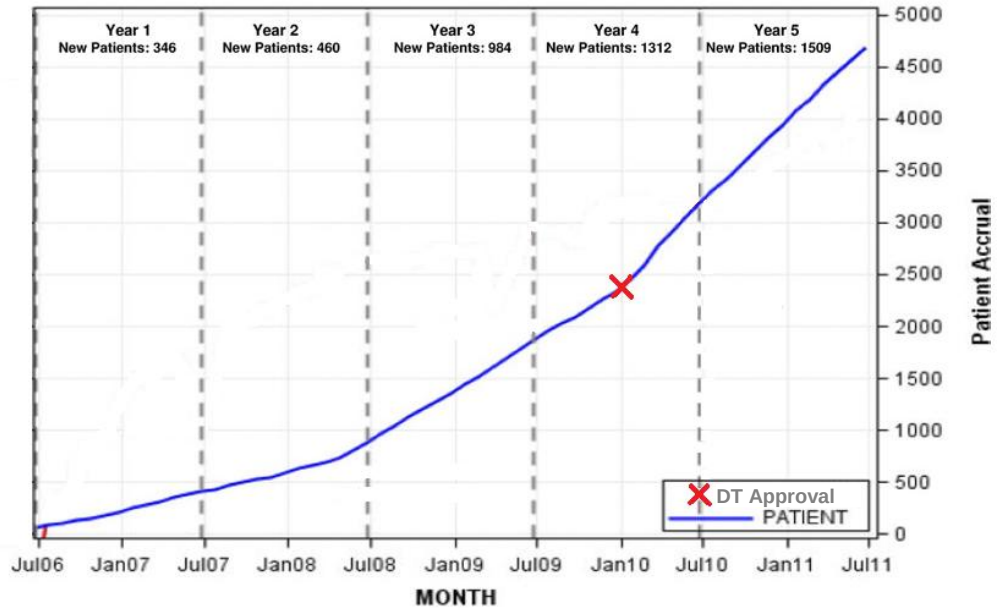
- While **awaiting transplant** (referred to as *Bridge to Transplant: BTT)*

  The device is implanted temporarily in eligible patients to substitute the heart functions until a suitable donor is found or until the patient's condition improves enough to tolerate heavy surgery. Given the thromboembolic events rate and risks of infection of the available devices, these were most often used for short term treatment. They were also limited by their cost – the implantation fees being in addition to the transplantation fees.

- As a **definitive treatment** (referred to as *Destination Therapy: DT)*

  This indication was, until recently, reserved to a very limited number of patients; often ineligible for transplantation or not wanting a transplant. However, due to the disease raising prevalence and the lack of donors, a number of patients with temporary implants become in fact destination therapy patients.

  Additionally, since the first approbation of the FDA in 2010 of this indication for the Heartmate® II, it has considerably developed in Northern America as well as in European countries such as Germany. Since then, Heartware® has begun a clinical study in the U.S. to obtain this indication and the company Syncardia has been granted in 2012 by the FDA the designation of humanitarian device destined as a first line treatment to destination therapy. (See paragraph 6.4.2.2 Orthotopic total artificial hearts)



Source – Adapted from the Interagency Register of Circulatory Assist Systems (INTERMACS[68])

NB: Devices intended as *Bridge to Recovery: BTR* are not mentioned here. Actually, their purpose and their technology are very different. They can only provide a limited assistance (2L/min versus 9L/ min for the CARMAT heart) for a very limited time (from a few hours to a few days) and are meant only for patients with temporary ventricular deterioration who need a temporary hemodynamic support, e.g. after surgery or a post-traumatic hemorrhage.

Given the advantages expected from the many innovations of CARMAT's bioprosthetic artificial heart project, and more precisely, those aimed at a long term treatment with reduced complications, CARMAT wishes to target this

[68] Kirklin JK et al. The Fourth INTERMACS Annual Report. J Heart Lung Transplant 2012;31:117–26 (North American Registry INTERMACS. The European EUROMACS registry is being created).

latter indication, steadily increasing, and which represents today over 34% of the indications for a mechanical circulatory assistance in the North American Registry.[67]

The aim of *Destination Therapy* is to offer a system providing the patient with true quality of life. That is, a reasonable autonomy and the possibility to be discharged home, ideally with a professional and a social life. This means lowering the NYHA status by at least 2 classes (NYHA Class II), without major adverse events.

Devices for this indication can then be classified in two distinct categories.

6.4.2.1 Ventricular Assist Devices (VAD)

These devices are too often, wrongly, described by the media as artificial hearts.

However, as their name tells, these devices are implanted in parallel to the native heart to assist it, supplement its blood flow as to satisfy the metabolic needs, but they do not replace the heart or the ventricles. The historical leader in this category is the Company Thoratec®, with the Heartmate II®, its major challenger being the company Heartware®.

This type of devices can in theory assist the left ventricle (*Left Ventricular Assist Device – LVAD)* or the right ventricle (*Right Ventricular Assist Device – RVAD)* or both. In case of the latter, they are called biventricular assist devices (BiVAD). To this date, there are no implantable devices approved for the right ventricle or a biventricular application, all devices having been designed for the left ventricle.

Nevertheless, wider use of these left ventricular assist devices has led to an increase in the need for BiVAD. Indeed, right heart failure is often a major consequence of a left ventricular assist device usage. The indication for a RVAD, after already having implanted a LVAD, represents up to 37% of cases.[69]

Methods for evaluating the risk are currently being developed to identify patients who would benefit from a BiVAD at an early stage, since it has been demonstrated that an earlier implantation results in a significant increase in survival rate in comparison to an implant done at a later stage. This could contribute to a higher use of biventricular devices like that of CARMAT, as a first line treatment.

Miniature devices, such as rotating centrifugal pumps being fixed on the ventricles, are conceptually attractive. However, there remain numerous obstacles to their practical use as definitive treatment of biventricular diagnoses.

These non-pulsating, miniature devices, such as the HVAD® of the company Heartware®, were designed to assist the cardiac functions but not to replace them. There are therefore limitations in terms of blood flow. The blood flow generated by the centrifugal pumps of these LVADs is specific to the geometry of each device, to the rotation speed per minute of the pump and to the differential pressure between the pump's input (ventricular pressure) and the pump's output (aortic pressure).

The blood pressures are very different in the right heart. On the left side, the blood must perfuse all the organs: the brain higher up as well as the distal extremities of limbs, away from the pump. On the right side however, it "simply" needs to send blood to the neighboring lungs to be re-oxygenated. The primary design of a LVAD, with centrifugal pumps and constant blood flow, would need to be heavily modified if it were to be used as a RVAD.

To our knowledge, no manufacturer of implantable left ventricular assist device with centrifugal or axial pump has submitted a file for approval as a right ventricular assist device.[70]

A few LVAD with centrifugal pumps and constant blood flow have been experimentally tested in BiVAD applications.[71] Very few publications exist on the matter. However, all the existing ones highlight the initial design as for the left side as their primary flaw: currently "the right pump, in a circuit mimicking normal pulmonary resistance, would pump more volume than the left and that would result in pulmonary edema."[72]

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[69] Potapov EV, et al. Tricuspid incompetence and geometry of the right ventricle as predictors of right ventricular function after implantation of a left ventricular assist device. J Heart Lung Transplant 2008;27:1275–81.
Dang NC, et al. Right heart failure after left ventricular assist device implantation in patients with chronic congestive heart failure. J Heart Lung Transplant 2006;25:1-6.
Klotz S, et al. Pre-operative prediction of post–VAD implant mortality using easily accessible clinical parameters. J Heart Lung Transplant 2010;29:45-52.
Boyle AJ, et al. Predictors of poor RV function following LVAD implantation. J Heart Lung Transplant 2003;22:S205.

[70] HeartWare® Stockholder update – Janauary 2010: http://phx.corporate-ir.net/External.File?item= UGFyZW50SUQ9MjYyMjF8Q2hpbGRJRD0tMXxUeXBlPTM=&t= 1

[71] Hetzer R et al. Long-term biventricular support with the HeartWare implantable continuous flow pump. J Heart Lung Transplant 2010;29:822-4.

[72] Loforte A et al. Biventricular support with the HeartWare implantable continuous flow pump: An additional contribution. J Heart Lung Transplant 2010;29:1443-4.

The alternatives for solving such problems are:

- A reduction of the pump's speed to match the recommended values, which could cause a thrombosis of the pump or rotor instability[71]. This option must therefore be forgone as it goes against the core principle of the pump.
- The reduction in diameter of the outflow conduit, which would provoke an increase in the total resistance of the pump and would allow for the necessary amount to be pumped, all the while staying within the speed limitation of the pump.

However, in patients with a high vascular pulmonary resistance, and in particular when the condition is irreversible, the reduction should be less. Therefore, an adaptable shrinking of the conduct is desirable[71].

A recently published animal study concluded that, "for biventricular support, the adjusting of the device's right blood flow through the adjustment of the pump's rotation speed is limited, even when using an outflow conduit with a reduced diameter." [73]

How does one realize these adjustments, how to make them dynamic and automatic, in short auto-regulated? No answer has yet been brought to these questions. They are nonetheless essential for the patients, as their long term hemodynamic stability cannot be guaranteed. CARMAT's artificial heart project proposes exactly this type of auto-regulation.

In BiVADs, each device is controlled independently by two portable controllers. Lack of communication between the two controllers severely limits the synchronization between the two implanted devices with regards to physiological demands. The need to wear two controllers and two battery packs also obviously further limits the quality of life of the patient.

To this day, the majority of ventricular assist devices with rotating pumps have fixed rotation speeds which can only be modified by healthcare personnel possessing the access codes. The lack of synchronization therefore interferes with the patient recovery as well as the management of the device (consuming skilled medical resources to reset device parameters).

Furthermore, the fixed flow pumps are generally set up at low rotation speeds to enable the native left ventricle to create left ventricle pressure and therefore a pulsating flow. However, in most high risk patients for whom a BiVAD is indicated, the diseased native ventricle is not able any longer to generate a left ventricular pressure. In these patients, hepatic and renal functions are often already compromised and the long term effects of a non-pulsating flow on end organs have not been studied.

Finally, through the use of two systems, one right and one left, there are necessarily 2 percutaneous drivelines, which significantly increase the risks of infections, already high with a unique system.[74]

The limitations are hence inherent to the initial design of these left ventricular assist devices. They remain an attractive solution for temporary left ventricular assistance, but this is a completely different indication than the one targeted by CARMAT.

The physiological auto-regulation of CARMAT's project should answer the need of synchronization between the pulmonary and the systemic circulation. An immediate response to physiological changes is a critical element for the rehabilitation of the high risk group of patients in biventricular heart failure.

While assist devices support the heart pumping function, the diseased organ is still deteriorating progressively. Long-term experience shows that in 38% of the cases there is a regurgitation of the native aortic valve[75] and severe ventricular arrhythmias in 31% of cases, both of which occur in the midterm[76]. The difficulties often require other costly and high-risk procedures such as implanting a replacement valve or a defibrillator. These complications do not, of course, exist in the event of a total replacement to the native heart. They can however be fatal to patient and often lead to the need for emergency transplantation or to the implantation of a device such as CARMAT's one.

No device, designed originally for a short term implantation, while awaiting a donor graft, has yet developed efficient long-term solutions to prevent the complications of implanting thrombogenic materials.

Metals and polymers, except if their design or their nature induces surface proteinization, such as the ePTFE and the bovine pericardium used exclusively by CARMAT for all the surfaces in contact with blood, are thrombogenic:

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[73] Meyer AL et al. Biventricular Implantation of the HeartWare HVAD in an Animal Study. 2011 Annual Meeting and Scientific Sessions, The International Society for Heart and Lung Transplantation http://www.abstracts2view.com/ishlt/

[74] Zierer A. Late-onset driveline infections: the Achilles' heel of prolonged left ventricular assist device support. Ann Thorac Surg. 2007 Aug;84(2):515-20.

[75] Toda K et al. Late aortic insufficiency related to poor prognosis during left ventricular assist device support Ann Thorac Surg. 2011 Sep;92(3):929-34.

[76] Brenyo A et al. Risk of mortality for ventricular arrhythmia in ambulatory LVAD patients. J Cardiovasc Electrophysiol. 2012 May;23(5):515-20.

they activate the coagulation cascade and therefore create blood clots, which can potentially migrate in dangerous areas such as the brain – with a risk of stroke (in up to 20% of patients[77]) – or the lungs, at the risk of pulmonary embolism.

In order to limit these complications, these devices require a heavy anticoagulation treatment for life (blood-thinners). This treatment is alienating, complex and unstable. Furthermore it creates additional complications inherent to the treatment[78]: if the blood is too thin, one risks severe hemorrhage, and if it is too thick, there is a risk of clotting and a risk of stroke.

CARMAT's bioprosthetic artificial heart project is therefore the only device designed to limit the thromboembolic risks by using biological, hybrid and synthetic materials with a proven long term clinical haemocompatibility. Even if anticoagulation is needed, it would be limited in its intensity and the constraints it would impose on the patient; it could furthermore be temporarily interrupted with more ease if necessary.

Overall, these devices target patient different from those CARMAT wish to target and are barely substitutable. Nonetheless, VADs enable a great number of patients to benefit from a temporary or long term alternative to transplantation. Their usage growth is important and has created a medical and scientific community dedicated to the problems of circulatory assistance – which will be an ideal environment for the first clinical, then commercial steps of CARMAT's bioprosthetic artificial heart project. Their success or difficulties have also arisen the interest of the financial community – particularly in North America – which constitutes another point of interest for CARMAT. The stock performance of some VADs companies has been quite interesting and successful.

6.4.2.2 Total Artificial Heart: TAH

Akin to a transplantation procedure, these devices replace both failing ventricles, by implanting in the exact same location (orthotopic replacement) two ventricular volumes and one system to maintain the blood flow. CARMAT's bioprosthetic artificial heart project belongs to this category.

The only total artificial heart currently marketed in Europe and in the United Stated belongs to the eponym private equity company Syncardia[79].

This device was designed in the 1970s and implanted for the first time in 1982 – under the name Jarvik 7. The patient survived 112 days. In 1985, a patient reaches for the first time the transplantation stage after having survived 9 days with the artificial heart. In 1990, the FDA shuts down the company Symbion, Inc., who owned the rights and licenses of the Jarvik 7 and stops the clinical study in progress (IDE*) because of its noncompliance with regulatory requirements. The technology then migrates to a university center in Arizona under the name of CardioWest™. A new clinical study begins in 1992 in the United States that will last 10 years and will result in FDA approval in 2004 in a bridge to transplant indication. The device obtains CE Conformity Marking in 2005. Meanwhile, a new private equity firm, Syncardia Systems, Inc., is created in 2001 to prepare and then take over the commercialization phase. Syncardia announced the 1'000th implantation of its heart in February 2012, 19 years after the first implantation in 1982. The North American registry INTERMACS recorded 99 commercialized implants (studies aside) between 2006 and 2011. [80]

It is therefore an artificial heart with a design initiated over 40 years ago. Its function rests on a pneumatic actuation. Internal polyurethane diaphragms are activated with compressed air generated by a compressor, electrically powered. Two percutaneous lines, each 7 feet long, connect the device to the external compressor.

Up to the CE Conformity Marking of a first portable compressor in 2006, all patients had to stay at the hospital, connected to a large compressor and controller – often called "Big Blue" by care teams – until their transplantation. In the FDA study (available on the company's website), the average waiting time before transplant was 79 days, with a maximum of 411 days and a survival rate of 50% at 48 weeks. The first generation portable compressor is not available in the United States, and the clinical study (IDE) of the second generation – the Freedom™ portable driver – is still on-going, despite having received CE Conformity Marking in 2010. All American patients, except those in the clinical study for the Freedom™ portable driver, still have to stay at the hospital to await their transplant, which implies heavy costs.

Despite a relatively short implantation period (79 days on average), the rate of complications[81] – particularly infectious (69.5% of 95 patients), hemorrhagic (44%) and thromboembolic (22%) – is high, probably for the same reasons as those detailed in the prior paragraph regarding VADs (design and materials).

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77 Backes D et al. Cerebrovascular complications of left ventricular assist devices. Eur J Cardiothorac Surg (2012). doi: 10.1093/ejcts/ezs320.

78 Rossi M et al. What is the optimal anticoagulation in patients with a left ventricular assist device? Interact CardioVasc Thorac Surg(2012)doi: 10.1093/icvts/ivs297.

79 www.syncardia.com – l'ensemble des informations concernant Syncardia sont tirées de leur site internet, sauf mention spécifique.

80 Kirklin JK et al. The Fourth INTERMACS Annual Report. J Heart Lung Transplant 2012;31:117–26 (Registre nord-américain, le registre EUROMACS est en cours de création).

81 FDA (2004) – Summary of Safety and Effectiveness Data – PO30011 – disponible sur le site de la société ou sur celui de la FDA.

Syncardia recently announced record sales in the first quarter of 2012 (being a privately-held company; they do not have to communicate actual numbers). The explanation lies most likely in the availability of the portable system – commercialized in Europe and in on-going clinical studies in the United States – enabling patients to await their transplantation at home. This contributes firstly to their quality of life and secondly to significantly reduced costs to the healthcare system. Furthermore, Syncardia has obtained in March 2012 the Humanitarian Use Device (HUD) designation allowing to apply for the corresponding exemption (the Humanitarian Device Exemption: HDE) and if granted, to commercialize up to 4'000 devices per year in the United States.

CARMAT can only welcome the regulatory or commercial successes of other marker players. Indeed, they keep the scientific and financial communities interested and highlight CARMAT's competitive advantages, basically paving the way for CARMAT's project.

In comparison to transplantation, the respective advantages and drawbacks of current devices are summarized in the table below. [82]

-

	Transplantation	Assist systems and artificial hearts
Pros	- State of the art destination therapy - Normal physical activity is possible - Favorable long-term prognosis	- Immediate availability - Planned intervention - Good level of physical activity

Cons	- Lack of donors
	- Risks of rejection
	- Transplanted organs subject to pathologies
	- Risks of coronary disease of the transplanted heart
	- Risks relative to immunosuppressant therapy
	- Renal failure
	- Neoplasm (cancer)
	- Susceptible to infection
	- Diabetes
	- Hypertension
		- Complete dependence on the device
		- Autonomy dependant on a power source
		- Infection through the percutaneous driveline
		- Risks related to anticoagulation:
		  - Major hemorrhage
		  - Stroke
		
		Regarding Assist devices:
		- Severe cardiac arrhythmias
		- Aortic regurgitation

Through the use of state of the art technologies, such as biological or haemocompatible materials to limit the risks associated with anticoagulation, or fuel cell batteries to increase patient autonomy and quality of life, CARMAT aims to sensibly reduce the majority of drawbacks and to offer a real alternative to transplantation.

NB: Abiomed®'s artificial heart Abiocor® is no longer detailed in this "Document de Référence". Indeed, despite the device obtaining an HDE from the FDA in 2006, no implant has been made since 2009 and the company has since then entirely reoriented its strategy towards Bridge to Recovery therapies with a system called Impella®. The presentations recently made to investors, available on their website, do not mention either the product or its market. Therefore CARMAT no longer considers Abiomed® to be part of market players of TAH or long term Assist Devices. Similarly, other projects – essentially university driven – do not seem to have evolved since the last "Document de Référence". The reader is hence invited to refer to the previous 'documents de base' of the Company for these historical information, as well as to paragraph 4.1.3 'Risks related to competition'.

6.4.3 Commercial Strategy

The Company will be able to commercialize its product in all European countries once it has been granted CE Conformity Marking. To this date, the Company seeks to proceed with this commercialization through a direct sales force in the main European countries, at least in a first phase.

This choice is driven by two factors:

- The need for technical and clinical support that the Company will provide in the initial phase
- A concentric market strategy which will consist in focusing first on core targets – the most active cardiac transplant institutions (at least 20 transplants per year) – then on less active centers, then on institutions that have a heart failure team but no license to transplant, and lastly all cardiac surgery institutions.

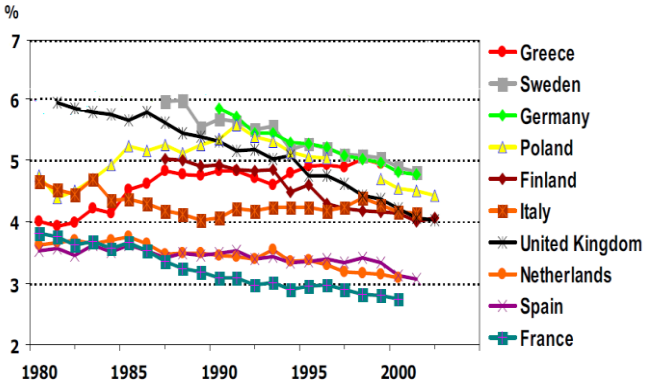
This approach should enable progressive investments. Indeed, given the very limited number of valid donors, the number of truly active cardiac transplantation institutions – that is, institutions that fully use their agreement to transplant and realize a sufficient amount of transplant to justify the upkeep of trained and available surgical teams – is also very limited; less than a dozen in each major country. For example only 8 institutions in Germany

[82] Adapté de Strüber M et al. The Current Status of Heart Transplantation and the Development of "Artificial Heart Systems". Dtsch Arztebl Int 2009; 106(28–29): 471–7

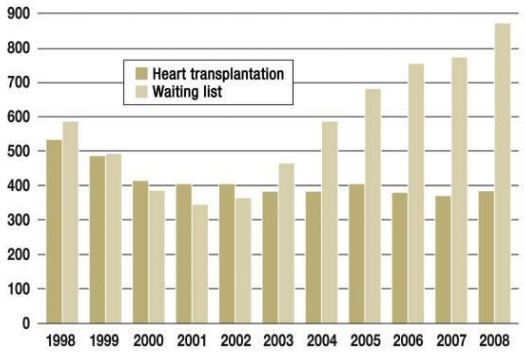
(out of 79 cardiac surgery institutions), 7 in France (out of 64 institutions) and 2 in the United Kingdom realize over 20 transplantations per year.

The Company considers therefore that, to target these centers of excellence, a direct sales force is the most appropriate answer.

The order in which the different European countries will be approached will depend on the prevalence of cardiovascular diseases, the size of the institutions, and the reimbursement procedures available for innovation. Germany comes first given those three criteria.



Death rate of cardiovascular diseases (Europe)[83]



Transplantation and waiting list – Germany [84]

In 2011, for a population 25% greater to France's and a prevalence of cardiovascular disease almost twice as high, Germany[85] realized less cardiac transplant than in France (341 vs. 356) and had a waiting list three times as big (991 vs. 283).

It is in fact the country with the greatest experience in Assist Devices (even ahead of the U.S. where innovative devices are generally approved much later than in Europe), it hosts the largest European centers in terms of volume and offers established reimbursement procedures for innovation.

In Germany, a patient in need of transplantation is automatically given the choice between a transplant and an implant, fully aware of the fact that an implant automatically withdraws them from the emergency transplant list. Nevertheless, it has been shown that choosing a device, if it is not a last minute decision once the patient's condition is already very deteriorated, gives the patient the same survival rate than with a transplant.[86,87]

Italy is also an attractive market for these three criteria, despite a lack of centralized decisions (approval granted on a regional basis).

Establishing centers of excellence with strong capacities in the selected countries as early as the clinical phase enables a rationalization of clinical and commercial resources, the development of "advocates" and training facilities, and then, to prospect indirect forms of distribution for other countries.

The development of a commercial approach for the American market is, at this stage, premature, but would most likely require an association.

The price objective remains between 140 000 and 160 000 €. This price range is in line with current practice and the level of reimbursement of available devices; for example, an implantable LVAD costs today in Europe between 60 000 and 110 000 €. The CARMAT system consists not only in an implantable prosthesis, but also in external equipments and pre and post-operation services, providing adjustment variables to adapt to the different volumes and reimbursement pathway of each institution or market.

It is worth noting that an absence of reimbursement does not mean an absence of sales or revenue. Indeed, many hospitals command their own budgets to finance innovation and several schemes to finance innovation in the pre-reimbursement phase exist in some countries.

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83 Adapté de : European Heart Network – Cardiovascular statistics 2008 - http://www.ehnheart.org/cvd-statistics.html.

84 Traduit de Strüber M et al. The current status of heart transplantation and the development of "artificial heart systems". Dtsch Arztebl Int. 2009;106(28-29):471–477.

85 Eurotransplant (registre des dons d'organes et transplantations pour l'Allemagne, la Belgique, les Pays-Bas, l'Autriche, la Croatie et la Slovénie). http://www.eurotransplant.org/cms/mediaobject.php?file=Year-Statistics-20113.pdf

86 Komoda T et al. Influence of new Eurotransplant heart allocation policy on outcome of heart transplant J Heart Lung Transplant. 2008 Oct;27(10):1108-14.

87 Beyersdorf F. Heart Transplant and Artificial Heart Systems. Dtsch Arztebl Int. 2009 July; 106(28-29): 469–470.

Reimbursement pathways differ in each country. The sales team will therefore be composed on one hand of clinical specialists to secure the training and adoption by the medico-surgical community, and on the other hand, of specialists in reimbursement and negotiation with hospital groups or private and public insurers.

6.4.4 Industrial Strategy

The industrialization phase, which will begin after the first series of clinical trials, will consist in the setting up of means of production for CARMAT and its subcontractors.

6.4.4.1 The choice of an integration model

Through the strength of its experimented R&D department, the Company specifies and designs all the components of the CARMAT heart project, including its external elements, as well as all its ancillary tools, packaging, systems and processes to validate the project (test benches) and to produce its components, sub-components and complete device (clean room). CARMAT has acquired strong intellectual property concerning all these elements. Nevertheless, given the important number of specialties and skills involved in each component and sub-component of the device, it is impossible to develop and further less manufacture them all internally.

For example, the Company has not developed and manufactured pressure sensors but use a precise and recent miniature model used in aeronautics. It has however developed the characterization procedure of these sensors, as well as specified the electronics and the software source code which allows for its use within the prosthesis. This electronics is also subcontracted, the manufacturing of electronic circuits requiring significant volumes of manufacturing in order to amortize the cost of manufacturing equipment, volumes which the Company would never reach based solely on the manufacture of the artificial heart.

The Company has therefore adopted an integration model: it specifies and designs, but entrusts manufacturing of the components to specialized subcontractors, recognized in their domain of activity and selected through rigorous tenders; these components are then integrated in the Company's white room.

CARMAT integrates the components and sub-components provided by a large number of vendors and sub-contractors, all very unlike with regards to their size, their methodology and their area of expertise. As such, CARMAT works with over 80 vendors for the implantable part of the system.

The challenge for a young enterprise like CARMAT is to federate around the same project companies with different origins and methods – some being established multinational corporations, contractors for the aerospace industry, others being tiny companies with very specialized and valuable skills –, while maintaining the same qualified methods and processes and within the framework of the same common and drastic guidelines required by medical device regulatory bodies. This coordination touches on many aspects such as technical specifications, logistics and above all quality control. Significant efforts have been made by the Company to validate and qualify these contractors, such that each one of them conforms to the very high standards of quality required for active implantable medical devices.

The operating mode of CARMAT, its methodologies and its integration processes are therefore identical to that of a large corporation in managing a project as complex as that of a total bioprosthetic heart. The creation of this new industrial network constitutes an accomplishment as such, creating added value for CARMAT as well as for the industry in general.

Additionally – and as announced in July 2011 at the time of the capital increase – the Company has actively pursued a strategy to develop secondary sources for supplies, particularly for the transformation of critical raw materials or the procurement of key components. To initiate a secondary source implies to select a new contractor, to help him manufacture its first components, and then to qualify them so that each part, whatever the providing source, is strictly identical, including the documentation accompanying it to warrant traceability.

It is an important but mandatory effort to reduce the dependence of the Company with regards to its contractors, and to anticipate the industrialization phase.

6.4.4.2 The internalized production and production capabilities

However, the Company has internalized the manufacturing of all biosynthetic materials used in the prosthesis (ventricular membrane, coating of the ventricles, and connection interface to the atrium) as they constitute the core of CARMAT's technology and intellectual property.

CARMAT's clean room is entirely operational. It is separated in two distinct zones, one at ISO Class 5 level used for the manufacturing and sterilization of the biosynthetic and ventricular internal components, the other at ISO Class 7 level where the other components, essentially subcontracted, are assembled around the sterile "heart of the heart".

The manufacturing, integration and sterilization of the prosthesis are thus achieved in a controlled environment by trained and qualified specialists. Over twenty prostheses have been manufactured for the needs of the pre-clinical

trials. For each planned patient implantation, two prostheses have to be made available to the hospital in case of an emergency, a technical issue or a procedural mishap such as an accidental de-sterilization.

The Company aims to produce around forty devices in 2013, and to reach a production pace of forty devices per month in 2017. The maximum production capacity in the Company's current clean room is approx. 200 prostheses per year. Additional manufacturing capabilities will have to be considered for larger production volumes.

6.4.4.3 The major partners

In the framework of OSEO Innovation financing conditions (see paragraph 22 'Important Contracts'), the total artificial heart project was organized with CARMAT as its main driver and four other partners in complementary R&D sectors, allowing thusly to initiate the development of a high end technological network in the medical device sector:

- DEDIENNE SANTE is a SME, specialized company dealing with the design, manufacturing, marketing and distribution of surgical implants, particularly in the orthotopic sector. Within CARMAT total artificial heart project, DEDIENNE SANTE develops the biocompatible PEEK components constituting the structural parts of the prosthesis. This development is done in an environment dedicated to CARMAT so as to avoid any contamination coming from non-implantable materials.
- HEF R&D is a branch of the HEF group, specialized in surface engineering and it the creator of numerous treatments and coating for non-corroding surfaces. Within CARMAT total artificial heart project, HEF R&D is in charge of motor pump unit qualification, which represents a sensitive part of the prosthesis.
- PAXITECH is a technological spin off of the CEA (Nuclear Energy Agency), created in September 2003, whom objective is to produce and market portable fuel cell batteries as well as the components of fuel cell batteries, in a large output range. Within CARMAT total artificial heart project, PAXITECH develops a fuel cell battery that could be used as an external power source and which would grant an autonomy of over 12 hours to the patient. PAXITECH has also designed the integration of the fuel cell battery with the hydrogen container such that it became a suitable alternative to the portable batteries.
- Strong from an experience spanning over 50 years (company created in 1959), VIGNAL ARTRU INDUSTRIES ("VIA – Pack'Aero group") is a SME specialized company that creates high precision mechanical micro-systems. In the CARMAT project, VAI produces the electro-hydraulic converters, composed of two micro-pumps and one duct. VAI is in charge of the integration of these groups, the different characterization and break-in runs as well as of "first-article" files of the electro-hydraulic converters.

6.4.5 Regulatory strategy

6.4.5.1 European background

The development process as detailed in paragraph 6.3.3 was presented to the AFSSAPS in 2004, 2007, 2008, 2009 and 2010. This process was approved given that there is no alternative to this day for CARMAT's device and that the methodology used, coming from space and aeronautics programs, paves the way for innovative development methods for complex medical devices.

Regular meetings were held, organized between CARMAT and the AFSSAPS, then later the ANSM in order to study the development progress of the total artificial heart. In addition to these meetings, CARMAT filed its pre-submission file to the AFSSAPS/ANSM in the spring of 2011 and has since then been regularly adding data to as it became available, particularly in February and July 2012. At the end of the pre-clinical trials required by the ANSM, CARMAT will be able to formally file for an ACT in France (Authorization for Clinical Trials; see paragraph 6.3.3.2 Human Clinical Validation) for a feasibility study on 4 patients. Should the results of this feasibility trial be deemed satisfactory, CARMAT will file with the ANSM a second request for an ACT for a pivotal study that would also include European institutions. (See paragraph 6.3.3.2 'Human Clinical Validation').

The CARMAT heart is an active implantable medical device (AIMD) and must, therefore, satisfy the Essential Requirements of the 90/385/CEE directive in order to obtain the CE Conformity Marking. This is a rigorous process, of which CARMAT has already achieved the first step with its ISO 13485-9001 certification. The yearly audit of re-certification has also been successful in May 2012.

The Essential Requirements mentioned in the different directives applicable to medical devices are described in relatively general terms in order to include a large spectrum of technologies. The manufacturers must review each Essential Requirement to determine if it applies to the device, and then identify the harmonized European norm which allows demonstrating the conformity to that Essential Requirement. The obligation to be conform with the Essential Requirement must be the priority of the manufacturer to ensure that all necessary measures were taken so that the device does not compromise the safety and health of the patients, of the users and, if applicable, of other individuals once it is installed, maintained and used correctly, in line with its intended use, providing that the

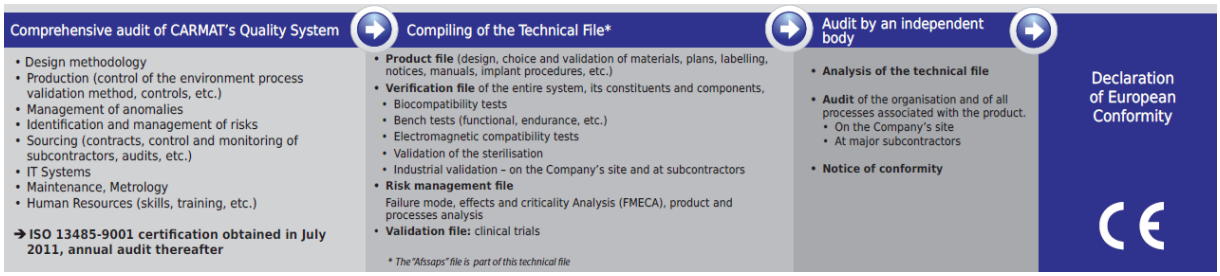
known risks related to its use stay within the boundaries of what is deemed acceptable given the benefits the device brings to the patient.

Conformity to the Essential Requirements must be considered as much as an objective (the respect of the patient health and safety) as a mean to achieve the objective.

According to European directives, each step for the CE Conformity Marking process must consider, in addition to the safety and intended use of the device, other aspects such as design or characteristics of the manufacturing process, electro-magnetic compatibility, mechanical, thermal and electrical risks or the function measurement or the labeling.

The CE Conformity Marking through CE conformity declaration relies on the extensive audit of the qualified device with an evaluation of all the procedures of the Company and a focus on the activities linked to the product. An exhaustive technical file is built, including – beyond the design history file – the detailed reporting on risk management activities and the verification and validation files - particularly the clinical validation. Then, the Company will be audited by an independent body that will verify the technical file and all the procedures relating to the device and the organization at CARMAT and, if need be, at its contractors. Once this audit is passed successfully, CARMAT will be granted the CE Conformity Marking which authorizes the commercialization of the product in all of Europe. Some member states have set up additional conditions with regards to notification of market availability or registration with local bodies.

Providing that clinical trials outcomes are satisfactory and that no issue arises, particularly in the patient recruitment pace, the file for the CE Conformity Marking on the total artificial heart project could be submitted at the end of 2013. The validation process usually takes between 6 weeks and 3 months. This process is summarized in the illustration shown below:



Source CARMAT – CE Conformity Marking process (Shareholder Newsletter n°1 – January 2012)

6.4.5.2 US regulatory requirements

The marketing of CARMAT heart in the United States is subject to obtaining a PMA (Pre-Market Approval) delivered by the FDA (Food and Drug Administration). Before filing for a PMA with the FDA, CARMAT will first need to complement its existing clinical data with data from a larger clinical study. Performing such study in the US is subject to obtaining an IDE (Investigational Device Exemption) from the FDA, based notably, on the audit of all existing pre-clinical data (technical tests, animal tests, etc…) and on all existing clinical data collected in other countries.

To avoid spreading itself too thin during the important phase of the product launch in Europe, the Company has so far planned to wait one year after the European market launch before the initiation of regulatory activities in the U.S.

This expected benefits of this careful strategy are to be able to include most clinical data generated in Europe to the FDA file (all selected European centers are FDA-compliant) and to self-finance, at least in part, this new regulatory effort.

6.4.6 Innovation Strategies – application of know-how

CARMAT is a young company that is just 4 years old, but it already owns, thanks to its key staff's historical involvement in the TAH project, an exceptional and unique cross-domain know-how which stems from 15 years of collaborative R&D between medical teams and engineering teams, to create new biomaterials and high-end technologies applied to the total artificial heart project.

The operation mode of CARMAT, its methodologies and its integration processes are therefore identical to that of a large corporation in managing a project as complex as that of a total bioprosthetic heart.

Professor Alain Carpentier's medical contribution enabled the Company to establish a solid experience and know-how with regards to the human physiology, the development of a complex bioprosthesis, the simulation of vascular circulation and the design of haemocompatible materials.

EADS' contribution, particularly its experience gained in satellites manufacturing, has been materialized by the high technical expertise in computer science and embedded electronics of CARMAT's team. Through the use of miniaturized control and information processing systems, the Company has set up reliable measuring and detection tools for anomalies, to ensure the correct functioning of CARMAT's bioprosthesis.

Beyond the initial contributions from the medical or spatial sectors, the Company was able to create true team work between very different talents and competencies that were never associated before in such a complex project, and to share their knowledge and experience.

Once the artificial project is completed, this unique ability to create synergies between the industrial and medical world, may enable CARMAT to develop new bioprostheses with physiological auto-adaptive regulation features to replace or complement other human organs..

Several proprietary devices derived from the research already realized by CARMAT and from its own patents, particularly regarding haemocompatible materials, could also be developed. Devices derived from already filed patents, especially with regards to digital simulation and ancillary implantation tools, could lead to commercial ventures or to royalties. Proprietary services could also be commercialized.

However, the Company does not intend to allocate any resource to such potential applications before the total artificial heart project is completed. Nevertheless, it pursues an aggressive policy for the protection of its intellectual property (see paragraph 11 Research and Development, Patents and Licenses) and performs an on-going technological watch regarding technologies and methods corresponding to its activity.

As at the date of registration of this "Document de Référence", the provisional project calendar is as followed:

Periode	*2012*	*1st quarter 2013*	*2nd quarter 2013*	*3rd quarter 2013*	*4th quarter 2013*	*2014*	*2015*
Activities	▪ Final pre-clinical tests ▪ Request ACT to the ANSM for a feasibility study ▪ Specify a Wearable System	▪ Continued feasibility study ▪ Obtain the necessary authorizations in other European countries	▪ End of feasibility study ▪ Request ACT to the ANSM for a pivotal study	▪ Continued pivotal study	▪ End of pivotal study ▪ File for CE Conformity Marking ▪ Continued clinical studies with the introduction of new external systems.	▪ Recruit a sales team ▪ Commercial launch in Europe ▪ Increase industrial capabilities	▪ Initiate regulatory activities in the United States.

This calendar is based on the Company's best estimate to this date. However, in a context of constant innovation, elements could appear after the publication of this "Document de Référence", which could influence this calendar in a positive or in a negative way. The reader is invited to refer to paragraph 4 Risk Factors, for an informed assessment of this calendar, as well as to the regular press releases of the Company on the project's progress.

7 ORGANISATION CHART

7.1 ORGANISATION OF THE GROUP

The Company is not part of a group.

7.2 SUBSIDIARIES AND SHAREHOLDINGS

The Company has no subsidiaries or shareholdings.

8 PROPERTY, PLANT AND EQUIPEMENT

8.1 SIGNIFICANT EXISTING OR PLANNED TANGIBLE FIXED ASSETS

The Company engages its activities in premises that it leases on the basis of a lease agreement concluded in accordance with market prices and conditions with companies which have no direct or indirect ties to Company directors. CARMAT does not own any real estate.

Société titulaire du bail	Address	Nature of the premises	Surface area	Lease start date	Lease expiry date	Rent 2011 (including charges)
CARMAT	36, avenue de l'Europe Immeuble l'Étendard Energy III 78140 Vélizy Villacoublay	Business premises	1053 m²	1/02/2009	31/01/2018	273 927,21 €
CARMAT*	34, avenue de l'Europe Immeuble l'Étendard Energy III 78140 Vélizy Villacoublay	Business premises	342 m²	01/07/2009	30/06/2011	55 965,84€
CARMAT*	36, avenue de l'Europe Immeuble l'Étendard Energy III 78140 Vélizy Villacoublay	Business premises	595 m²	01/10/2010	30/09/2019	136 695,54 €
CARMAT*	36, avenue de l'Europe Immeuble l'Étendard Energy III 78140 Vélizy Villacoublay	Business premises	595 m²	01/07/2011	31/03/2013	37 597,89 €

The Company considers that it has dedicated premises which should allow it to meet the envisaged growth of the Company and its staff in the short and medium-term.

8.2 ENVIROMENTAL ISSUES

In developing the bioprosthetic total artificial heart, the Company is subject to chemical and biological risks (particularly due to the use of chemically-treated animal pericardium) which forces it to implement preventive and protective measures for its operators and for waste management in accordance with the regulations in force, with regard to safety and the environment, governing the use, storage, handling and disposal of hazardous materials. The Company complies with these regulations.

9 REVIEW OF THE COMPANY'S FINANCIAL SITUATION AND PERFORMANCE

This chapter is devoted to the presentation of CARMAT's earnings and financial situation for its first three financial years. The first financial year, covering a 19-month period, ended on December 31st 2009, the second financial year covering a 12-month period ended on December 31st 2010 and the third financial year covering a 12-month period ended on December 31st 2011. The Company has no subsidiaries and consequently does not prepare consolidated accounts but simply company financial statements in accordance with French standards.

It is suggested that you read this chapter with a view to the whole of this "Document de Référence".

In particular, you are invited to read the description of the Company's business activity as presented in Chapter 6, Overview of the Company's Activities of this "Document de Référence". Similarly, it is suggested that you consult the financial statements for the period ended 31 December 2011, of which the annex forms an integral part, which are presented in Chapter 20, Financial information concerning the Company's assets and liabilities, financial position and earnings in this "Document de Référence".

9.1 CARMAT'S MAIN EXPENSES AND REVENUES

Established in June 2008, CARMAT is a research and development company which aims to develop a fully implantable orthotopic and bioprosthetic artificial heart equipped with an electrical power supply system and a remote diagnostic system.

Through its objective to treat an illness which has a fatal outcome, the Company could also provide a solution to a public health need with major socio-economic implications for which no treatment exists to date.

The activity of the Company, which has enjoyed the status of 'Jeune Entreprise Innovante' (Young Innovative Enterprise) since 2008, has focused uniquely on the development of the total artificial heart to date, which can be divided into three phases:

- a preparation phase comprising the research, design and manufacture of CARMAT total artificial heart systems ;
- a tuning phase to complete the qualification and validation ;
- a human clinical validation phase, in parallel with the necessary validation activities to obtain the CE Conformity Marking.

Whilst the Company was established in June 2008, its operating activity only concretely started from the fourth quarter of 2008 following:

- the contribution in kind of intangible (patents) and tangible assets by Matra Défense (EADS Group) and the *Association Recherche Scientifique de la Fondation Alain Carpentier* (Alain Carpentier Foundation Scientific Research Association), with respect to which a contributions auditor (Commissaire aux Apports) has prepared a report, concluding with the fact that '*the value of contributions in kind, which amounts to € 960 000, has not been overvalued and that consequently, the value of the contribution in kind is at least equal to the capital increase of the company receiving the contribution, CARMAT SAS, plus the contribution premium'* ; and
- the arrival of the first employees, formerly employees of the EADS Group where they were working on the total artificial heart project.

The CARMAT financial statements have been prepared in accordance with the provisions of the Commercial Code (Articles L123-12 to L123-28) and the general rules for preparation and presentation of annual accounts (PCG 99-03 as modified by the regulations subsequently issued by the Accounting Rules Committee).

9.1.1 Operating income

Since its creation, the company has been in a research and development phase and has not had any sales. No marketing is envisaged in the short term. The program has been financed by company equity resulting from funds secured from the main shareholders (Matra Défense (EADS Group), the Scientific Research Association of the Alain Carpentier Foundation and the funds managed by Truffle Capital), research subsidies and repayable advances granted, as well as funds raised at the time of the stock market listing and capital increases.

During the financial year ending on 31 December 2011, operating income grew by 20.9% to 6 101 753 €, exclusively represented by:

- Operating subsidies of 6 051 177 € ;
- The release of provisions amounting to 50 576 €.

During the financial year ending on 31 December 2010, operating income grew by 4.7% to 5 048 697 € exclusively represented by subsidies:

- a subsidy of 4 297 697 € from OSEO Innovation, covering expenditure over the period 1 January until 31 October 2010, for a net sum of 3 090 110 € and the share of the subsidy collected on 3 January 2011 and

corresponding to expense incurred in the period 1 November to 31 December 2010, of 1 207 587 €, shown in the assets under accrued income as at 31 December 2010 ;
- a subsidy of 750 000 € corresponding to the balance of the subsidy granted by the Yvelines Departmental Council to the company, 450 000 € of which were received in the financial year ending 31 December 2010 and 300 000 € on 4 February 2011. Since all the research expense had been incurred as at 31 December 2010, the entire subsidy is recognized in the result for the 2010 financial year ;
- sundry subsidies received of 1 000 €.

During its initial trading period of 19 months ending on 31 December 2009, overall operating income received (4 822 638 €) was broken down as follows:

- a subsidy of 4 072 638 € granted by OESO Innovation in connection with a multiannual agreement over 5 years ;
- a subsidy of 750 000 € granted by the Yvelines Departmental Council.

9.1.2 Operating expenses

During the 2011 year, operating expenses amounted to 22 192 807 €, compared with 15 530 940 € in the previous period (an increase of 43.7%), essentially for the research costs of the Company, accounted for under expenses for the period.

These research activities involved expenses in three main areas:

- Purchases (other than raw materials) and external expenditure of 16 276 476 € compared with 11 190 896 € for the previous period;
- Wages and salaries of 4 156 960 € compared with 2 946 472 € for the previous period;
- Depreciation of fixed assets acquired for the research and development phase amounting to 1 496 234 € compared with 1 227 259 € for the previous period.

The operating result for the 2011 period is -16 091 054 €, compared with -10 482 243 € for the previous period.

9.1.3 Financial results

The financial result corresponds mainly to the return on the various marketable securities (certificates of deposit) and financial instruments (time deposit accounts), with a deduction being made for interest accruing on the repayable advances made by OSEO Innovation in connection with the financing of the research activities of the company. In 2011, the financial result was positive at 97 271 €, compared with a loss of -20 807 € in the previous period and with a gain of 77 636 € in 2009.

9.1.4 Result for the period

The company opted for Research Tax Credit (CIR) for the 2009 and 2011 calendar year. This option was retained for the 2011 financial year. The CIR system consists of allowing a tax credit to companies making significant investments in research and development. Research expenditure eligible for CIR includes in particular wages and salaries, consumables, sub-contract service provision by approved research bodies (public or private) and intellectual property costs.

CIR is accounted for in the income statement for the period for the amount of 2 515 527 € and is breakdown as follows:

- 2 566 103 € by way of CIR for the period from 01/01/2011 to 31/12/2011 compared with 2 819 267 € in 2010 ;
- -50 576 € for regularization of the CIR for the 2010 year, from a comparison between the amount accounted for as at the close of the 2009 financial year (2 819 267 €) and the amount actually reimbursed by the tax authorities (2 768 691 €).

After accounting for an exceptional result of 37 234 € and for a CIR of -2 515 527 €, the loss for the 2011 financial year was -13 441 022 €, an increase of 73% on the loss for the previous period ending on 31 December 2011 (7 736 485 €). The loss of the period ending on 31 December 2009 was 4 722 004 €.

9.2 MAIN ITEMS OF THE CARMAT BALANCE SHEET

9.2.1 Main asset items

As of December 31 2011, the balance sheet total of the Company was 37 426 083 € compared to 21 047 688 € in December 31 2010 and 6 051 723 € in December 31 2009.

Fixed assets of 3 147 942 € (compared to 3 582 600 € in December 31st 2010) corresponded essentially to:

- Tangible fixed assets (2 448 058 €) : technical plant, equipment, measurement and special tooling, clean room, grey room and office fixtures and fittings, etc., necessary for the preparation for clinical trials described above ;
- Intangible fixed assets (234 707 €): patents, licenses and software.

The remaining 34 278 141 € corresponded mainly to:

- Tax credits (4 120 628 €): mainly CIR 2011 (2 556 103 €) and VAT input or refundable tax (1 541 479 €) ;
- Advances and payment on account (486 860 €) ;
- Treasury and marketable securities (29 369 693 €).

During the 2011 period, the balance sheet total was multiplied by 1.8 to amount to 37 426 083 €.

Fixed assets remained stable, with the increase in assets under construction (476 583 € en 2011 compared to 231 682 in 2010) being offset by the fall in the technical plant, equipment, measurement and special tooling items (1 262 724 € en 2011 compared to 1 849 680 previously).

Current assets doubled to 34 278 141 € in December 31st 2011 (compared to 17 465 088 € for the previous period).

9.2.2 Main liabilities items

Out of the 6 051 723 € of the balance sheet total in December 31st 2009, equity represented 3 527 996 € broken down as follows:

- 8 250 000 € of capital and issue premiums as a result of the three increases in capital carried out on June 28th, September 30th and October 1st 2008:
  - 40 000 € by way of an increase in capital by cash contribution at the time the company was set up on 28 June 2008 (€ 20 000 from Matra Défense (EADS Group) and 20 000 from Professor Alain Carpentier);
  - 960 000 € by way of an increase in capital through contribution in kind, on 30 September 2008, of tangible and intangible fixed assets by Matra Défense (EADS Group) and the Scientific Research Association of the Alain Carpentier Foundation;
  - 7 250 000 € by way of an increase in capital by cash contribution on 1 October 2008 (5 M€ from the funds managed by Truffle Capital and 2.25 M€ from Matra Défense (EADS Group) and Professor Alain Carpentier).
- A loss for the period ending on 31 December 2009 of 4 722 004 €.

This equity was essentially supplemented by the following:

- 546 304 € of conditional repayable advances granted by OSEO Innovation, and
- 1 960 703 € of accounts payable (suppliers, tax and social security, buildings).

As at December 31 2010, the balance sheet total of the company was 21 047 688 €, some 3.5 times that of 2009. This total is comprised mainly of:

- 25 932 563 € of capital and issue premiums following the seven increases in capital carried out during the 2010 financial year, 14 187 621 € of which were raised at the time of the stock market listing of the company in July 2010 (please refer to section 10 “Cash and capital”);
- -12 458 489 € of losses for 2010 and losses brought forward;
- 2 018 892 € of repayable advances made by OSEO Innovation;
- 4 186 770 € of trade accounts payable and related payables.

As at December 31 2011, the balance sheet total of the company was 37 426 083 €, 1.8 times that of 2010. This total is comprised mainly of:

- 52 790 430 € of capital and issue premiums, of which 26 669 533 € as a result of the increase in capital with preferential subscription rights carried out by the Company in August 2011 on Alternext Nyse-Euronext Paris (please refer to Chapter 10 “Cash and Capital”) ;
- -25 899 510 € of losses for 2011 and losses brought forward ;
- 3 743 141 € of repayable advances made by OSEO Innovation;
- 4 992 835 € of trade accounts payable and related payables.

10 CASH AND CAPITAL

10.1 DETAILS OF COMPANY CAPITAL

Data in Euros	December, 31 2011	December, 31 2010	December, 31 2009 [1]
Equity	26 890 919	13 474 075	3 527 996
Other equity – conditional advances	3 743 141	2 018 892	546 304
Gross financial debt	217 066	78 096	12 219
Cash and Cash equivalent [2]	29 369 693	11 415 823	712 837
Net financial debt	- 29 152 627	-11 337 727	-700 618
Net financial debt as proportion of equity	N/A	N/A	N/A

[1] Period of 19 months
[2] Cash comprises:

- Marketable securities shown in the balance sheet with a value of 10 039 822 € as of December, 31 2011 corresponding to French monetary unit trusts for 10 000 000 € and certificates of deposit, maturing in October 2011, which generated 39 822 € of interest accounted for at the close;
- Cash instruments corresponding to time deposit accounts with a total value of € 17 000 000 maturing on 25 January 2012 (5 000 000 €), 25 April 2012 (2 000 000 €), 25 July 2012 (4 000 000 €) and 25 October 2012 (6 000 000 €). The interest generated at the end of the period amounted to 66 499 €. ;
- Cash on hand or at the bank is entered at face value (€ 2 263 372).

Since the end of the financial year to 31 December 2011, no significant even has affected the Company's equity or the low level of risk associated with the investments of the cash.

The assumption that the business is a going concern was made by the Chairman taking into account in particular the following points:

- the liquidity level, cash instruments and investment securities as at 31 December 2011, totalling EUR 29 369 693;
- payment of subsidies (EUR 3 033 000) and refundable advances (EUR 10 764 000) remaining to be paid between now and 2013 under the OSEO aid programme signed in 2009.

10.2 CASH FLOW

Please refer to section 5.2 "Investments" and paragraph 20 "Financial information on the assets, the financial position and the results of the company" of this "Document de Référence".

10.3 BORROWING CONDITIONS AND FINANCING STRUCTURE

10.3.1 Bank debts

To date the company has financed its investments from equity or quasi-equity resulting from the raising of capital on successive occasions from the shareholders, subsidies and repayable advances granted by OSEO Innovation (please refer to section 22 "Important contracts") and the Yvelines Departmental Council and increases in capital carried out in connection with the listing of the company on the Alternext Paris market of NYSE-Euronext (increase in capital with a gross value of € 14.2 million; supplementary issue option included) and the share capital increase with preferential subscription rights on the Alternext Paris of NYSE-Euronext in August 2011 amounting to 26.7 million Euros (net premium included).

Consequently, the company does not have any financial resources of a banking kind, bearing in mind the particular nature of its activities, with the loans and financial debts shown in the balance sheet as at the end of 2011 corresponding mainly to interest accruing on repayable advances.

Schedule of payables	Gross Sum	1 year or less	1 to 5 years	More than 5 years
Sundry loans and financial debts	217 066		217 066	
Accounts payable and related payables	4 992 835	4 992 835		
Staff and related payables	665 324	665 324		
Social security and other social bodies	492 560	492 560		
Other taxes and related payables	1 532	1 532		
Liabilities secured to property and related liabilities	380 547	380 547		
Group and associates				
Other debts	6 498	6 498		
Total	**6 756 362**	**6 539 296**	**217 066**	

10.3.2 Leasing debts

None.

10.3.3 Convertible bonds

Bonds totaling € 2 000 000 issued by decision of the Extraordinary General Meeting of the company on 7 May 2010, were converted automatically into new ordinary shares in the company on the date of the first listing of the company's shares on the Alternext Paris market of NYSE-Euronext.

No bond issue by the company was in existence as at the date of registration of this "Document de Référence".

10.3.4 Other means of financing

During the year ending on 31 December 2011 and as at the date of registration of this "Document de Référence", the company was in a research and development phase and did not have any sales. Finance for the program was provided by:

- The increase in equity of the Company resulting mainly from the raising of funds on the Alternext Paris market of NYSE-Euronext in August 2011, with preferential subscription rights.
  - The exercise of 786 BCE-2009-2 resulting in a capital increase, dated April 28, 2011, amounting to 786 €, bringing the capital from 153 114.44 to 153 900. 44 €, by issuing 19,650 common shares with a nominal value of 0.04 euro each, issued at a price of 8 €, with a premium of 7.96 € per share. The share premium is accordingly found to rise from 25,779,449 € to 25,935,863 €.
  - The exercise of 95 BCE-2009-2 resulting in a capital increase, dated June 19, 2011, amounting to 95 €, bringing the capital from 153 900.44 to 153 995. 44 €, by issuing 2 375 common shares with a nominal value of 0.04 euro each, issued at a price of 8 €, with a premium of 7.96 € per share. The share premium is accordingly found to raise from 25 935 863 € to 25 954 768 €
  - The Company completed a new increase in capital with preferential subscription rights decided by the Board of Directors on July 11, 2011 on delegation of authority from the Joint General Assembly of April 28, 2011. The subscription period ran from July 13 to 29, 2011. This resulted in a capital increase amounting to € 11 068.36, together with a gross premium of € 29 320 085.64, representing gross emission products amounting to 29 331 154 €. This capital increase led to the creation of 276 709 new shares with a nominal value of € 0.04, in addition to the 3 849 886 existing ordinary shares, bringing the capital from € 153 995.44 to 165 063.80 €. Given the costs associated with the operation, amounting to 2,661,621 €, which are deducted from the premium under the preferential method of accounting, the net premium resulting from this capital increase is 26,658,465 €.

- The exercise of 48 BCE-2009-2 resulting in a capital increase, dated September 26, 2011, amounting to 48 €, bringing the capital from 165 063,80 to 165 111,80 €, by issuing 1 200 common shares with a nominal value of 0.04 euro each, issued at a price of 8 €, with a premium of 7.96 € per share. The share premium is accordingly found to raise from 52 615 766 € to 52 625 318 €
- The exercise of 118 BCE-2009-2 resulting in a capital increase, dated March 8, 2011, amounting to 118 €, to bringing the capital to 165 111,80 €, by issuing 2 950 common shares with a nominal value of 0.04 euro each, issued at a price of 8 €, with a premium of 7.96 € per share. The share premium is accordingly found to raise from 52 625 318 € to 52 648 800 €
- The exercise of 298 BCE-2009-2 resulting in a capital increase, dated June 27, 2011, amounting to 298 €, to bringing the capital from 165.229,80 to 165.527,80 €, by issuing 7 450 common shares with a nominal value of 0.04 euro each, issued at a price of 8 €, with a premium of 7.96 € per share. The share premium is accordingly found to raise from 52 648 800 € to 52 708 102 €

- Conditional advances and subsidies granted:
  - Repayable advances received from OSEO Innovation totaling 1 724 249 €. The total value at the close of the period of repayable advances increased accordingly from € 2 018 892 to 3 743 141 €. These repayable advances are interest-bearing at the contracted rate of 5.59%. Accrued interest at the end of the financial year was € 217 066 € ;
  - a subsidy totaling 6 039 510 € granted by OSEO Innovation in connection with a multiannual agreement over 5 years,

10.4 RESTRICTIONS ON THE USE OF CAPITAL THAT HAVE HAD OR COULD HAVE A MARKED INFLUENCE, DIRECTLY OR INDIRECTLY, ON THE ISSUER

None.

10.5 ANTICIPATED SOURCES OF FINANCE

The OSEO Innovation agreement provides for the payment of a total sum of EUR 17.4 M by way of subsidies, of which approximately 3 032 793 € remained to be received as at 31 December 2010 up until 2013.

It provides for payment of a total sum of € 14 507 324 by way of repayable advances, of which € 10 764 169 remain to be paid between December 31 2011 and the end of the project.

The company also opted for the Research Tax Credit for 2011 period. This option was retained for the 2010 financial year and first subscribed to in 2009. The Research Tax Credit pertaining to the 2011 financial year was accounted for under the ‘Income taxes’ item of the income statement and appears under the ‘Other debtors’ item of the balance sheet. The income statement for the period shows a Research Tax Credit for a sum of 2 515 527 €, broken down as follows:

- 2 566 103 € for the period from 01/01/2011 to 31/12/2011 compared to 2 819 267 € for 2010
- -50 576 € for regularization of the Research Tax Credit for the 2010 year, from a comparison between the amount accounted for as at the close of the 2010 financial year (2 819 267 €) and the amount reimbursed by the tax authorities (2 768 691 €).

The Research Tax Credit for the 2011 year of 2 566 103 € accounted for as at the close of the 2011 financial year has almost entirely been accepted by the fiscal administration (2 558 614 €) and reimbursed in July 2012.

11 RESEARCH AND DEVELOPMENT, PATENTS AND LICENCES

11.1 RESEARCHA ND DEVELOPMENT

Please refer to paragraph 6.3.3 Development process and clinical trials of the total artificial heart project and 6.4.6 Innovation strategies – application of knowhow of this "Document de Référence". Please also refer to note 5.2 of the annex to the Company financial statements for the year ending December 31, 2011 in paragraph 20.1.1 Company accounts of CARMAT as at 31 December 2011 according to French standards

11.2 INTELLECTUAL PROPERTY

Patents and other intellectual property rights are of fundamental importance in the medical devices sector. Accordingly, CARMAT regularly files patent applications to protect its innovations.

11.2.1 Patents

The CARMAT portfolio of patents is made up of ten patents held in its own name, classified in two categories, firstly patents associated with the architecture of the total artificial heart project and secondly patents linked to the haemocompatible materials and subassemblies of the prosthesis.

These patents are detailed below:

Title	Geographical area	Application/publication number	Date filed	Status
"Prothèse cardiaque implantable à chambres ventriculaires indépendantes" (*Implantable heart prosthesis with independent ventricular chambers*)	France	FR9812941 FR2784585	15/10/1998	Granted on 26/01/2001 Expiring on 15/10/2018
« Prothèse cardiaque monobloc implantable en position anatomique » *(One-piece heart prosthesis implantable in an anatomical position)*	France	FR0605333 FR2902345	15/06/2006	Granted on 05/09/2008 Expiring on: 15/06/2026
	Europe	EP07290725.6 EP1867352	11/06/2007	Granted on 15/07/2009 Expiring on: 11/06/2027
	International	PCT/FR2007/000962 WO2007/144497	11/06/2007	Published on 21/12/2007
« Prothèse cardiaque monobloc implantable » *(Implantable one-piece heart prosthesis)*	France	FR200800184 FR2926223	14/01/2008	Granted on 22/01/2010 Expiring on: 14/01/2028
	Europe	EP09290009.1 EP2078533	07/01/2009	Granted on 15/07/2009 Expiring on: 07/01/2029
	International	WO2009FR00008 WO2009/112662	07/01/2009	Published on 05/11/2009

Title	Geographical area	Application/publication number	Date filed	Status
« Matériau hémocompatible composite et son procédé d'obtention » *(Composite haemocompatible material and method for its production)*	France	FR0511430 FR2892939	10/11/2005	Granted on 22/01/2010 Expiring on : 10/11/2025
	Europe	EP06291657.2 EP1785154	25/10/2006	Granted on 23/09/2009 Expiring on : 25/10/2026
	International	PCT/FR2006/002471 WO2007/054637	07/11/2006	Published on 18/05/2007
« Pompe volumétrique rotative à encombrement radial réduit » *(Volumetric rotating pump with reduced axial space)*	France	FR060004206 FR2900988	12/05/2006	Granted on 01/01/2010 Expiring on : 12/05/2026
	Europe	EP7290571.4 EP1855005	07/05/2007	Granted on 28/01/2009 (no opposition within the time allowed) Expiring on : 07/05/2027
	International	PCT/FR2007/000778 WO2007/135261	07/05/2007	Published on 29/11/2007
« Dispositif de connexion rapide entre une prothèse cardiaque totalement implantable et des oreillettes naturelles » *(Device for rapid connection between a totally implantable heart prosthesis and natural atria)*	France	FR0605331 FR2902343	15/06/2006	Granted on 05/09/2008 Expiring on : 15/06/2026
	Europe	EP07290723.1 EP1867350	11/06/2007	Granted on 24/09/2008 (no opposition within the time allowed) Expiring on : 11/06/2027
	International	PCT/FR2007/000959 WO2007/144495	11/06/2007	Published on 21/12/2007
« Dispositif de raccordement entre une prothèse cardiaque et les oreillettes naturelles » *(Device for connection between a heart prosthesis and the natural atria)*	France	FR0605332 FR2902344	15/06/2006	Granted on 05/09/2008 Expiring on : 15/06/2026
	Europe	EP07290724.9 EP1867351	11/06/2007	Granted on 24/09/2008 (no opposition within the time allowed) Expiring on : 11/06/2027
	International	PCT/FR2007/000960 WO2007/144496	11/06/2007	Published on 21/12/2007

Title	Geographical area	Application/publication number	Date filed	Status
« Procédé pour la réalisation d'un objet hémocompatible de configuration complexe et objet ainsi obtenu » (*Process for producing a haemocompatible item with a complex configuration and item thereby obtained)*	France	FR0703339 FR2915903	10/05/2007	Published on 14/11/2008 Expiring on : 10/05/2027
	Europe	EP08290405.3 EP1992369	28/04/2008	Published on 19/11/2008 Expiring on 28/04/2028
	International	PCT/FR2008/000607 WO2008/1145870	28/04/2008	Published on 04/12/2008
« Procédé pour l'obtention d'un matériau hémocompatible composite et matériau obtenu » (*Process for obtaining a composite haemocompatible material and material obtained*)	France	FR1001724	22/04/2010	Published on 28/11/2011 Granted on 13/07/2012
« Prothèse pour assurer le raccordement d'un canal anatomique » (*Prosthesis to ensure the connection of an anatomical duct)*	France	FR1152364	22/03/2011	Not published

The table below gives details of the number of patents granted and the applications by country of geographical zone:

Country / Geographical zone	Patents granted	Current patent applications
National patents	105	50
South Africa	6	1
Germany	6	0
Australia	1	6
Austria	6	0
Belgium	6	0
Canada	0	7
(People's Republic of) China	2	5
South Korea	0	7
Denmark	4	0
Spain	6	0
United States of America (USA)	4	3
Russian Federation	6	1
France	8	2
Greece	4	0
India	0	7

Country / Geographical zone	Patents granted	Current patent applications
Ireland	4	0
Italy	6	0
Japan	0	7
Norway	1	5
Netherlands	6	0
Poland	6	0
United Kingdom	6	0
Sweden	6	0
Switzerland	6	0
Turkey	4	0
European Patents (EPO)	6	3
International (OMPI)	7	2
Total	**117**	**56**

11.2.2 Exclusive license agreements

11.2.2.1 Exclusive license agreement with the Pierre and Marie Curie University:

Under the terms of an exclusive license agreement of 17 June 1993 – amended by addendum n° 1 on June 27 1995 and by addendum n° 2 on November 12 1997 – the Pierre and Marie Curie University granted Matra Défense the right to use patent No 8800381 in order to plan for additional research and development with a view to the construction of prototype artificial hearts implantable in humans.

Although it was initially Matra Défense that used the intellectual property rights granted, this license was then used again by CARMAT, something that the Pierre and Marie Curie University consented to through an agreement duly signed by the Pierre and Marie Curie University, Matra Défense and the Scientific Research Association of the Alain Carpentier Foundation and CARMAT. Under this agreement:

- the Pierre and Marie Curie University expressly waived any benefit from all intellectual property rights linked to or resulting directly or indirectly from the work on the total artificial heart project and acknowledged that CARMAT was the sole owner of all the intellectual property rights that could have been attributed to the Pierre and Marie Curie University; and
- in return, the Scientific Research Association of the Alain Carpentier Foundation granted at no cost, in its name and for its account and in the interest of Matra Défense, 400 CARMAT shares (equivalent to 10 000 CARMAT shares following the division of the face value by 25) to the benefit of the Pierre and Marie Curie University.

Although patent N° 8800381 has now expired, the above license is valid for five years from the date of initial marketing of the product implementing the claims of the patent. Upon expiry of this initial period, the license is subject to automatic recondition for two subsequent periods of 5 years, unless one of the parties cancels it one year prior to each expiry date by recorded delivery letter with acknowledgement of receipt

11.2.2.2 Exclusive license agreement with the 'Centre Technique des Industries Mécanique' (Technical Centre for the Engineering Industries)

Under a framework agreement of October 30 2001, amended by an initial addendum of August 28 2002, the Centre Technique des Industries Mécaniques (CETIM) granted Professor Carpentier an exclusive right to implement French patent No 2760973 concerning the fully implantable artificial heart project for the duration of its protection that remained to run as at the date of signature (the patent involved expires on September 25 2018), in return for payment of the costs associated with maintaining the patent concerned.

This license was granted without financial consideration. CARMAT then used this license, which the CETIM consented to through a second addendum to the framework agreement, signed on October 2 2008 between the CETIM and Professor Carpentier.

European patent N° EP0971756 (equivalent to French patent N° 2760973) is in force in France, Germany and Great Britain (expires on March 18 2018).

11.2.3 Trademarks

The company has registered the “CARMAT” trademark in the following countries or geographical zones:

Trademark	Number	Status	Date filed	Expiry date	Territories	Classes
CARMAT	023184827	Registered	23/09/2002	30/09/2022	France	9, 10, 42
CARMAT	007374821	Registered	29/10/2008	29/10/2018	European Union	10, 42
CARMAT	1022720	Registered	19/06/2009	19/06/2019	International : China, Japan, Switzerland, Russia	9, 42
CARMAT	3663230	Registered	07/01/2009	04/08/2019	United States	10, 42
CARMAT	1442665	Registered	25/06/2009	27/09/2026	Canada	10, 42
CARMAT	200911637(1)	Filed	24/06/2009	24/06/2019	South Africa	10, 42
CARMAT	1838058	Registered	09/07/2009	09/07/2019	India	10, 42

(1) Application number

11.2.4 Domain names

The Company has registered the following domain names :

Domain name	Date reserved	Renewal date
carmatsas.com	29/10/2008	29/10/2012
carmatsas.fr	29/10/2008	29/10/2012
carmatsas.eu	29/10/2008	29/10/2012
carmat.tel	23/03/2009	23/03/2013
carmatsa.fr	29/04/2010	29/04/2013
carmatsa.com	29/04/2010	29/04/2013
carmatsa.eu	29/04/2010	29/04/2013
carmatsa.tel	29/04/2010	29/04/2013

12 TRENDS

12.1 MAIN TRENDS SINCE THE END OF THE PREVIOUS FINANCIAL YEAR

Please refer to paragraph 20.8 “Significant changes in the financial or commercial situation”

The company is exclusively dedicated to the development of the total artificial heart project.

During the year 2012, the Company intends to finalize the preclinical trials necessary to obtain the ACT from the ANSM. This authorization will enable the Company to start the clinical trials in light of filing for the CE Conformity Marking, end of 2013; the CE Conformity Marking being a requirement before commercialization.

The equity of the Company as well as the expected subsidies should allow the Company to ensure the advancement of the abovementioned activities up to the filing for the CE Conformity Marking (please refer to paragraph 4.4.2 Liquidity Risks).

12.2 EXISTENCE OF ANY KNOWN TREND, UNCERTAINTY OR DEMAND OR ANY UNDERTAKING OR EVENT REASONABLY LIKELY TO SIGNIFICANTLY INFLUENCE THE PROSPECTS FOR THE COMPANY

Please refer to paragraphs 4 Risks Factors, 6.2 Heart Failure, 6.3.3 Process and development stage of the total artificial heart project and 6.4 Market and Strategies.

13 PROFIT FORECASTS OR ESTIMATES

The Company does not intend to make any profit forecasts or estimates.

14 ADMINISTRATIVE, MANAGEMENT AND SUPERVISORY BODIES AND EXECUTIVE BOARD

The Company is organized in the form of a French public limited company with a board of directors. The functions of the Chairman and Chief Executive are separated.

14.1 COMPOSITION OF THE COMPANY'S ADMINISTRATIVE AND MANAGEMENT BODIES

14.1.1 Composition of the Board of Directors

As at the date of registration of this "Document de Référence", the directors are as follows:

Full name or registered name of the member	Term of office	Functions fulfilled within the Company	Other positions currently held in other companies	Other positions and functions in other companies over the last five years, but not exercised at the date of registration of this "Document de Référence"
M. Jean-Claude Cadudal	1st nomination (as a plc) : May 7 2010 Term of office: Until GM to consider the accounts for year ending 31/12/2015	Chairman of the Board of Directors	- Chairman of KARDIOZIS SAS - Chairman of HOLDING INCUBRATRICE MEDICAL DEVICES - Chairman of ZETAVACS SAS	- Chairman and Chief Executive of Matra Défense ; - Director of International Operations of Group EADS
Pr. Alain Carpentier	1st nomination (as a plc) : May 7 2010 Term of office: Until GM to consider the accounts for year ending 31/12/2015	Director	- Member of the Board of Director for FONDATION SINGER POLIGNAC - Director of l'ASSOCIATION RECHERCHE SCIENTIFIQUE DE LA FONDATION ALAIN CARPENTIER - Chairman of l'ACADEMIE DES SCIENCES	None
M. Marcello Conviti	1st nomination (as a plc): May 7 2010 Term of office: Until GM to consider the accounts for year ending 31/12/2015	Director & Chief Executive	None	- Director of EUCOMED - Director of EDWARDS LIFESCENCES ITALY - Senior Vice President of Strategy and Business Development at EDWARDS LIFESCENCES

Full name or registered name of the member	Term of office	Functions fulfilled within the Company	Other positions currently held in other companies	Other positions and functions in other companies over the last five years, but not exercised at the date of registration of this "Document de Référence"
Truffle Capital represented by Dr. Philippe Pouletty	1st nomination (as a plc): May 7 2010 Term of office: Until GM to consider the accounts for year ending 31/12/2015	Director	- Chairman of the Board of THERADIAG SA (Philippe Pouletty) - Chairman of the Board of DEINOVE SA (Philippe Pouletty) - Director of DEINOVE SA (Truffle Capital) - President and Director of SPLICOS SAS (Philippe Pouletty) - Director of THERACLION SA (Truffle Capita) - Director of NEOVACS SA (Truffle Capita) - Director of PHARNEXT SAS (Truffle Capita) - Director of PLASMAPRIME SAS (Truffle Capita) - Director and Chief Executive of TRUFFLE CAPITAL SAS - Director of de VEXIM SA (Truffle Capita) - Director of WITTYCELL SAS (Truffle Capita) - Director of IMMMUNE TARGETING SYSTEMS LTD (Royaume-Uni) (Truffle Capital) - Director of SYMETIS (Suisse) (Truffle Capital) - Member of the Supervisory Board of INNATE PHARMA SA (Philippe Pouletty) - Director of MYOPOWERS SA (Suisse) (Truffle Capital) - Director of NAKOSTECH SARL (Philippe Pouletty) - Director of FRANCE BIOTECH (Association Loi 1901)	- Director, until 2008, of CONJUCHEM BIOTECHNOLOGIES Inc. (Canada) - Director, until 2008, of DRUGABUSE SCIENCES SAS - Chairman 2001 to 2009 of FRANCE BIOTECH - Member of the Supervisory Board of CYTOMICS SA until December 2010 (compulsory liquidation)
M. André-Michel Ballester	1st nomination (as a plc): May 7 2010 Term of office: Until GM to consider the accounts for year ending 31/12/2015	Independent Director	- CEO Sorin Spa – Milan (Italie) - Independent Director Nexway SAS – Nanterre - Independent Director IMI Gmbh – Bonn (Allemagne) - Independent Director Mauna Kea Technologies	None

Full name or registered name of the member	Term of office	Functions fulfilled within the Company	Other positions currently held in other companies	Other positions and functions in other companies over the last five years, but not exercised at the date of registration of this "Document de Référence"
M. Michel Finance	1st nomination (as a plc): May 7 2010 Term of office: Until GM to consider the accounts for year ending 31/12/2015	Independent Director	- CEO of HOLDING INCUBATRICE BIOTECHNOLOGIE SA - Chairman of ZOPHIS SAS - Chairman of BIOKINESIS SAS - Director of NEOVACS SA - Director of France Biotech (Not for profit - Association Loi 1901) - Chief Executive and Director of de THERADIAG SA	None
M. Henri Lachmann	1st nomination (as a plc): December 23 2010 Term of office: Until GM to consider the accounts for year ending 31/12/2015	Independent Director	- Chairman of the Supervisory Board of SCHNEIDER ELECTRIC SA - Vice-chairman of the Supervisory Board of VIVENDI SA - Member of the Supervisory Board of Group NORBERT DENTRESSANGLE SA - Chairman of the Board of CENTRE CHIRURGICAL MARIE LANNELONGUE - President of the FONDATION POUR LE DROIT CONTINENTAL - Chairman of L'INSTITUT TELEMAQUE	- Member of the Supervisory Board of AXA, - Director of AXA ASSURANCES IARD MUTUELLE - Director in different companies of the Group SCHNEIDER ELECTRIC - Member of the CONSEIL DES PRELEVEMENTS OBLIGATOIRES

As far as the Company is aware:

- there is no family link between the Company's directors;
- no director has been convicted of fraud in the last five years;
- no director has been associated with any bankruptcy, sequestration of assets or liquidation in the last five years;
- no director has been found guilty of any offence or any official public sanction pronounced by the statutory or regulatory authorities (including designated professional bodies) in the last five years; and
- no director has been prevented by a court from acting as a member of an administrative, management or supervisory board of an issuer or from taking part in the management or conduct of the affairs of an issuer over the past five years

14.1.2 Biographies of the Members of the Board of Directors

Jean-Claude Cadudal is the Chairman of the CARMAT Board of Directors. He was previously Director of International Operations at the EADS Group until early 2008, a former director of Matra Défense, former group finance controller at MBDA, where he was CARMAT Program Director. He was involved in the Matra Group's principal mergers and acquisitions. With a degree in industrial automation, he began his career in the design and development departments of nuclear power stations, before moving on to industrial management at ITT, where he received the "Production & Inventory Control Worldwide Award" in 1979. After a spell in the Operations Department at Revlon Europe, he rejoined the Matra Group in 1983.

Pr Alain Carpentier is a director at CARMAT. Professor emeritus at the Pierre and Marie Curie University (University of Paris VI) and lecturer at the Mount Sinai School of Medicine in New York, he is the founder and director of the Bio-surgical Research Laboratory at the Scientific Research Association of the Alain Carpentier Foundation. Winner of the Foundation for Medical Research Prize in 1998 and President of the French Academy of Sciences (2010), he received the prestigious Albert Lasker Award for Clinical Medical Research in 2007 in recognition of his two main contributions to the field – the invention of the first valve bioprosthesis (Carpentier-Edwards valve) and the development of techniques for plastic and reconstructive surgery of heart valves, which benefit several hundred thousand patients worldwide every year.

Dr Philippe Pouletty is the permanent representative of Truffle Capital on the CARMAT board of directors. Philippe Pouletty is a medical doctor (University of Paris VI) and an immunologist. He worked as an intern at the Pasteur Institute and was a post-doctoral research fellow at the University of Stanford. He is the inventor of 29 patents, the second of which has been the most lucrative for Stanford University in life sciences. In 2012, he is admitted into the prestigious Stanford University Hall of Fame of Inventors. Philippe Pouletty was founder and chief executive of Truffle Capital, a private equity firm whose funds come to a total of 520 million euros. He was chairman of France Biotech and chairman of the French Association of Biotechnology Enterprises and former vice-chairman of the Europabio, the European Federation of Biotechnologies. He is also the founder of three biotechnology companies in Europe and the United States, which have generated stock market shares worth more than US$800 million, and he is a member of the board of directors of 12 biotechnology and medical device undertakings in Europe and North America (Conjuchem, Cytomics, Deinove, Innate Pharma, ITS, Neovacs, Pharnext, Splicos, Theraclion, Vexim and Wittycell). Philippe Pouletty helped set up several government initiatives in France, including the 1999 Act simplifying the law on joint stock companies (SAS), the 2002 Biotech Plan to re-launch and develop biotechnology and the Young Innovative Enterprise status, which grants significant tax exemptions to technological enterprises.

Marcello Conviti is the Chief Executive of CARMAT. He began his career in Italy with IBM in 1978. After a few years working for Italian companies, including Fiat, Marcello Conviti quickly focused on European positions within the life sciences industry. For 12 years he held several strategic positions in SORIN BIOMEDICA, an Italian company that designs cardiac medical devices. Before joining CARMAT, Marcello Conviti held several senior international positions with EDWARDS LIFESCIENCES during a period of 17 years (most recently Senior Vice President for Strategy and New Business Development). EDWARSDS LIFESCIENCES is the world leader in heart valves, including its flagship product, the Edwards-Carpentier heart valve, which revolutionized cardiac surgery. Marcello Conviti is also a member of the Board of Directors at EUCOMED, the European confederation of associations of manufacturers of medical devices. Marcello Conviti speaks five languages, and he has an MBA from the University of Turin and a PhD in IT technologies from the University of Pisa.

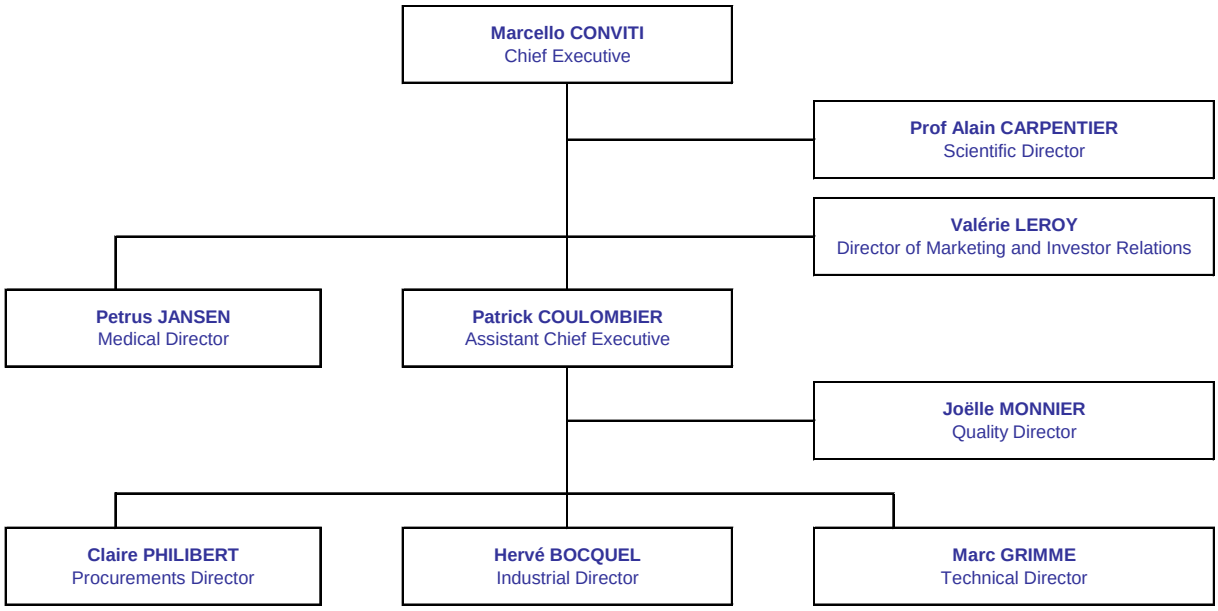
André-Michel Ballester is an independent director at CARMAT. He is currently Chief Executive of Sorin S.P.A., one of the world leaders in the manufacture of devices for cardio-vascular illnesses, and he has an excellent knowledge of the workings and the international issues of this industry. André-Michel Ballester is a cardiac surgery specialist, and he began his career in the medical industry with Travenol S.A. more than 25 years ago. He then occupied several management positions in the cardiac medical device and life science industries in several European countries and in the United States. André-Michel Ballester is a graduate of INSEAD and the Ecole Centrale in Lille.

Michel Finance is a director at CARMAT and was acting chief executive from June 2008 to September 2009. He has experience both as a manager and a financier. He is currently the Chief Executive and President of Theradiag. He began his career as a auditor at PricewaterhouseCoopers, and over a period of 25 years he occupied different posts as Chief Executive and Financial Director in the pharmaceutical and biotechnology industries for multinationals such as Sanofi Aventis. Before joining CARMAT, Michel Finance was Assistant Chief

Executive at Flamel Technologies (from 2005 to 2008). Michel Finance is a graduate of the EM Lyon Business School and a Chartered Accountant. He has also been a director at Neovacs since 2010, where he held the position of Assistant Chief Executive from 2009 to 2010 and handled the company's flotation on the Alternext Paris market, and has been a director with France Biotech (the French association of life sciences enterprises) since 2006.

Henri Lachmann is an independent director at CARMAT. Henri Lachmann began his career in 1963 with the international auditing firm, Arthur Andersen. In 1970, he joined Strafor Facom, which he became Chairman of in 1981. A director at Schneider Electric since 1996, Henri Lacmann was appointed Chairman-Chief Executive of the Group in 1999. Since 2006, he has chaired the Schneider Electric Supervisory Board. Henri Lachmann has occupied other important positions: Vice Chairman of the Supervisory Board of Vivendi, Member of the Supervisory Board of the Norbert Dentressangle Group, Director of the AXA Group Mutuelles, Chairman of the Board of Directors at the Marie Lannelongue Surgical Centre since 2006, Chairman of the Continental Law Foundation, Chairman of the *Fondation Télémaque*, non-executive director at Fimalac, Director at the *Fondation Entreprendre*, Chairman of the Advisory Council of the Campus of Excellence at the Office of the Commissioner General for Investment (Large Loans), Vice-Chairman and Treasurer of the *Institut Montaigne* and Member of the Steering Committee of the Enterprise Institute. Henri Lachmann is also an Officer of the Legion of Honour, an Officer of the Academic Palms and a Commander of the National Order of Merit. Henri Lachmann is a graduate of the *Ecole des Hautes Etudes Commerciales* (HEC) and is a chartered accountant.

14.1.3 Other Members of the Management



Marcello Conviti – Chief Executive. Please refer to paragraph 14.1.2 "Biographies of the Members of the Board of Directors".

Pr Alain Carpentier, Scientific Director. Please refer to paragraph 14.1.2 "Biographies of the Members of the Board of Directors".

Patrick Coulombier, Chief Operating Officer/ Deputy Chief Executive. Patrick Coulombier has headed the project team for the CARMAT total artificial heart within the EADS Group since July 2001. Before that he worked for MBDA France as director of two international programmes in the area of defence, one concerning a British air combat training system and the other relating to a Franco-German drone system. Between 1978 and 1990, before joining MBDA France, Patrick Coulombier had a number of different research and development posts in connection with a range of aeronautic and space projects at THALES AVIONIQUE (Airbus A130, A320, Rafale Combat Aircraft, Super Puma Helicopter and the Hermes Spacecraft). Patrick Coulombier has a degree in electronic engineering.

Dr Petrus Jansen, Medical Director. Petrus Jansen began his career in 1997 in the Netherlands with EDWARDS LIFESCIENCES as Head of Research and Clinical Trials, particularly in connection with the NOVACOR programme (left ventricular assistance device). Petrus Jansen then held similar positions in Europe and the United States with JARVIK HEART in charge of clinical trials and obtaining the CE Conformity Marking for its products. Before joining CARMAT in December 2009, Petrus Jansen was the Medical Director at WORLD HEART USA for five years. Petrus Jansen qualified as a medical doctor from the Catholic University of Nijmegen, he has a PhD in medicine from the University of Amsterdam, and he was research fellow at the University of Rotterdam.

Valérie Leroy, Director of Marketing and Investor Relations. Valérie Leroy began her career in IT in 1984, and she held a number of different sales positions until 1996. In particular she was in charge of key accounts with TOSHIBA SYSTEMS from 1988 to 1994. In 1996, she joined the marketing teams at MEDTRONIC to market their range of pacemakers. In 2001, Valérie Leroy joined EDWARDS LIFESCIENCES, where she spent over nine years working in different sales and marketing management positions at their European headquarters in Switzerland and their world headquarters in California. From 2008 to 2010, she became Director of European Marketing for their range of surgical heart valve therapies (repair and bioprosthesis). Valérie Leroy holds a Master's Degree in Marketing (IAE, Paris – Panthéon, Sourbonne, 1996).

Marc Grimmé, **Technical Director.** As project manager, Marc Grimmé has piloted the technical studies for the CARMAT total artificial heart since 1996, giving him over ten years' experience in the artificial heart field. Between 1991 and 1996 at MBDA France, Marc Grimmé covered the full range of activities connected with developing critical electronic equipment: from upstream studies ahead of production, to the design phases, missile equipment, such as an image processing calculator, and installation of the firing system. Marc Grimmé has a degree in electronic engineering.

Joëlle Monnier, Quality Director. Joëlle Monnier held a number of different positions as marketing and regulatory affairs coordinator at DEPUY FRANCE from 1991 to 1997. She was in charge of quality assurance and regulatory affairs and was site manager at an orthopedic implants company from 1998 to 2007, before becoming project coordinator for the medico-economic and organizational studies at IRIS HEALTH CONSULTING. Since 2009, as Quality Director at CARMAT, Joëlle Monnier has been in charge of training and putting in place the management system on quality, monitoring sub-contractors and preparing for the ISO 13485 Certification and the CE Conformity Marking for the CARMAT total artificial heart project. Joëlle Monnier qualified as a medical doctor from the Rennes Faculty of Medicine. She also has a diploma (epidemiology elective) from CESAM, the education centre for applied statistics in medicine and medical biology, and a quality assurance and certification diploma from CEGOS.

Claire Philibert, Procurements Director. Claire Philibert began her career in marketing at GRANDOPTICAL, when the chain of opticians was first launched. She then worked as a procurement manager for over 10 years in different companies, including NYCOMED AMERSHAM MEDICAL SYSTEMS (manufacturer of cardiology, radiology and interventional neuro-radiology products) and DIAGNOSTICA STAGO, global specialists in hemostasis. Claire Philibert is a graduate of EAD, the School of Business Administration and Management.

Hervé Bocquet, Industrial Director. Since 2001, Hervé Bocquet held the posts of chief engineer on a drones programme, developed as part of an international collaboration, and head of UAV production at CASSIDIAN, the defense and security branch of EADS. Previously, he worked on upstream industrialization and the integration of on-board equipment and drone systems at MBDA. Before that he was technical manager of missile equipment and the motor division of aerospace systems from 1985 to 1990. Hervé Bocquet has a degree in mechanical engineering and aeronautics.

14.2 CONFLICTS OF INTEREST IN THE ADMINISTRATIVE, MANAGEMENT AND SUPERVISORY BODIES AND THE EXECUTIVE BOARD

14.2.1 Potential conflicts of interest

As at the date of registration of this "Document de Référence" and as far as the Company is aware, there are no current or potential conflicts of interest between the private interests of the members of the Board of Directors of the Company and the interests of the Company.

Similarly, as at the same date, the Company has no knowledge of any current or potential conflicts of interest between the private interests of the members of the audit committee, the remunerations committee or the scientific committee and the interests of the Company.

As far as the Company is aware, there are no potential conflicts of interest between the duties of the members of the Board of Directors towards the Company and their private interests and/or other duties.

14.2.2 Commitments of the directors and executive members to preserve shareholdings

At the date of registration of this "Document de Référence", there exist no commitments to preserve shareholding by the directors and executive members.

15 COMPENSATION AND BENEFITS

15.1 COMPENSATION AND BENEFITS IN KIND OF THE MANAGEMENT AND DIRECTORS

15.1.1 Remuneration of directors[88] for the years ending December 31 2009, December 31 2010 and December 31 2011

It will be recalled that the company was registered on June 30 2008 and operated three periods ending respectively on December 31 2009 (19 months), December 31 2010 (12 months) and December 31 2011 (12 months)

All the information required under the terms of AMF recommendation of December 22 2008 on the compensation of Officers and Directors is given thereafter.

Remuneration of directors for the financial year ended 31 December 2009:

In Euros	Position	Fixed compensation	Variable compensation	Special compensation	Director's fees	Benefits in kind
M. Jean-Claude Cadudal (1)	Chairman of the Board of Directors	0	0	0	60 000	0
Pr. Alain Carpentier	Director	0	0	0	0	0
Dr. Philippe Pouletty représentant de Truffle Capital	Director	0	0	0	0	0
M. André-Michel Ballester (2)	Director	0	0	0	5 000	0
M. Peter Steinmann(2) (3)	Director	0	0	0	5 000	0
M. Michel Finance (2)	Director	0	0	0	5 000	0

(1) At the board meeting of 17 February 2009, it was decided to allocate to the directors a sum of EUR 100 000 per annum by way of director's fees to compensate them for the work they do. This sum can be shared freely between the directors. At the Board meeting of 22 April 2009, it was decided to allocate the sum of EUR 60 000 to Jean-Claude Cadudal in his position as Chairman of the Board of Directors, payable half-yearly and for period running from 1 July 2008 until 31 December 2009.
It was also decided to allocate to Jean-Claude Cadudal a fixed sum of EUR 40 000 gross by way of supplementary remuneration, payable in the event of him securing for the company financing in excess of EUR 2 million (see below).

(2) At the board meeting of 8 July 2009, it was decided to grant EUR 10 000 per annum in director's fees to Messrs Ballester, Steinmann and Finance (EUR 30 000 in total), or EUR 5 000 for the 2009 year, payable during the second half-year.

(3) On 16 December 2009 Peter Steinmann resigned from his post as company director because a change in his employment circumstances meant that his new role was incompatible with being a director of CARMAT.

88 *The remuneration of Marcello Conviti, who is also a director, for his duties as Chief Executive, is shown in paragraph 15.1.2 of this "Document de Référence" "Remuneration of the Chief Executive"*

Compensation of directors for the financial year ended 31 December 2010:

In Euros	Position	Fixed compensation	Variable compensation	Special compensation	Director's fees	Benefits in kind
M. Jean-Claude Cadudal [2]	Chairman of the Board of Directors	0	0	0	60 000	0
Pr. Alain Carpentier	Director	0	0	0	0	0
Dr. Philippe Pouletty représentant de Truffle Capital	Director	0	0	0	0	0
M. André-Michel Ballester	Director	0	0	0	10 000	0
M. Michel Finance	Director	0	0	0	10 000	0
M. Henri Lachmann	Director	0	0	0	0	0

[1] During the Board of Directors meeting of May 7 2010, it was decided to attribute 60 000 € to M. Jean-Claude Cadudal for his services as Chairman of the Board, payable in semester and for the 2010 period.

[2] During the Board of Directors meeting of May 7 2010, it was decided to attribute 2 000 € to M. Ballester and M. Finance for each Board meeting which they attend in person, with a max of 10 000€ each for the 2010 period

Compensation of directors for the financial year ended 31 December 2011:

In Euros	Position	Fixed compensation	Variable compensation	Special compensation	Director's fees	Benefits in kind
M. Jean-Claude Cadudal	Chairman of the Board of Directors	0	0	0	60 000	0
Pr. Alain Carpentier	Director	0	0	0	5000	0
Dr. Philippe Pouletty représentant de Truffle Capital	Director	0	0	0	5000	0
M. André-Michel Ballester	Director	0	0	0	10 000	0
M. Michel Finance	Director	0	0	0	10 000	0
M. Henri Lachmann	Director	0	0	0	10 000	0

[1] During the Board of Directors meeting of June 6 2011, it was decided to attribute 60 000 € to M. Jean-Claude Cadudal for his services as Chairman of the Board, payable in semester and for the 2011 period.

[2] During the Board of Directors meeting of June 6 2011, it was decided to attribute 2 000 € to M. Ballester and M. Finance for each Board meeting which they attend in person, with a max of 10 000€ each for the 2011 period

[3] During the Board of Directors meeting of June 6 2011, it was decided to attribute 1 000 € to M. Carpentier and Truffle Capital for each Board meeting which they attend in person, with a max of 5 000€ each for the 2011 period

The Directors do not benefit from any particular retirement plan, indemnity to be received if their involvement with the Company stopped or indemnity of non-compete.

15.1.2 Remuneration of the Chief Executive

In Euros	Position	Year	Fixed compensation received	Variable compensation	Special compensation	Director's fees	Benefits in kind
M. Marcello Conviti [(1)]	Chief Executive	2009	96 023	0	0	0	9 800
		2010	337 582	123 965	0	0	23 211
		2011	326 625	23 729	0	0	6 612

[(1)] Marcello Conviti has performed the role of non-salaried Chief Executive of CARMAT since 1 September 2009. On top of this variable remuneration is payable of up to 40% of this fixed sum by way of OTE. For the 2012 year, the targets set by the Compensation Board relate to the ANSM ACT. Marcello Conviti also benefits from a company car worth EUR 1 350 per month.

The Chief Executive does not benefit from any particular retirement plan, indemnity to be received if their involvement with the Company stopped or indemnity of non-compete.

15.2 SUMS SET ASIDE OR DETERMINED BY THE COMPANY FOR THE PAYMENT OF PENSIONS, RETIREMENT OR OTHER BENEFITS OF THE MANAGEMENT AND DIRECTORS

No sum has been set aside or determined by the company for the payment of pensions, retirement or other benefits of the corporate officers

In application with the preferred method, the provisions for enforcing retirement plans were accounted for on December 31 2011.

The retained hypotheses for calculating are as followed:

- A method of prorated temporal rights, in accordance with Regulation 01 of the 2003 R CNC;
- Retirement at the employee's initiative, at age 62 (non-management) or 65 (management);
- Staff progression of 2% per year
- Slow rotation rate
- Discount rate of 4.6% per year

The global amount of the provision totals 35 660 € at the end of the December 31 2011 period, an increase of 17 303 € on the period.

15.3 STOCK SUBSCRIPTION WARRANTS (BSA) OR START-UP COMPANY SHARE OPTIONS (BCE) ASSIGNED TO MANAGEMENT AND DIRECTORS

The following table shows as at the date of registration of this "Document de Référence", all the stock subscription warrants (BSA) and start-up company share options (BCE) issued by the company to its corporate officers and management and subscribed by the beneficiaries; it should be noted that at the date of registration of this "Document de Référence", none of these BCE and BSA has been exercized.

Holder		BSA-2009-1	BCE-2009-1	BCE-2009-2	BCE-2012-1
Jean-Claude CADUDAL	Chairman of the Board of Directors	1 554			
Michel FINANCE	Director	518			
André-Michel BALLESTER	Director	518			
Marcello CONVITI	Chief Executive		3 108		4000
Patrick COULOMBIER	COO / salaried			1 492	

The exercising of each BSA-2009-1 or BC-2009-10 and BCE-2009-2 gives an entitlement to 25 new shares in CARMAT.

The exercising of each BCE-2012-1 gives an entitlement to 1 new share in CARMAT.

For a detailed description of the characteristics of BSA-2009-1, BCE-2009-1 and BCE-2009-2, please refer to paragraph 17.1.2 "Interests and share options held by members of the management and supervisory bodies".

16 OPERATION OF THE ADMINISTRATION AND MANAGEMENT BODIES

16.1 EXPIRY OF THE TERM OF OFFICE OF DIRECTORS

Please refer to paragraph 14.1.1 Composition of the Board of Directors

16.2 SERVICE CONTRACTS LINKING THE MEMBERS OF THE BOARD OF DIRECTORS AND THE GENERAL MANAGEMENT OF THE COMPANY

As at the date of registration of this "Document de Référence", there were no service contracts linking the members of the Board of Directors and the general management of the company.

16.3 BOARDS

As at the date of registration of this "Document de Référence", the company had set up the following boards:

16.3.1 Board of Auditors

By decision of the Board of Directors of 8 July 2009 the company set up a Board of Auditors for an unlimited duration. As at the date of this "Document de Référence", the Board of Auditors is comprised of three members:

- Michel Finance, director and chairman of the Board of Auditors;
- Jean-Claude Cadudal, Chairman of the Board of Directors and member of the Board of Auditors;
- Christian Pierret, independent member of the Board of Auditors.

In accordance with the stated intentions of the company expressed at the time the company was listed on the Alternext Paris market of NYSE-Euronext, the company has appointed two further members to its Board of Auditors : Jean-Claude Cadudal, appointed at the Board meeting of 7 May 2010 and Christian Pierret, appointed at the Board meeting of 15 December 2010.

Michel Finance – Chairman of the Board of Auditors. Please refer to paragraph 14.1.2 "Backgrounds of the members of the Board of Directors".

Jean-Claude Cadudal – Member of the Board of Auditors. Please refer to paragraph 14.1.2 "Backgrounds of the members of the Board of Directors".

Christian Pierret - Independent member of the Board of Auditors. Christian Pierret is a former Minister for industry, SMEs, commerce and the trades, a role which he held from June 1997 until May 2002. Christian Pierret has had a career that spans both politics and the private sector, as follows: Rapporteur général for the budget to the National Assembly (1981-1986), Chairman of the monitoring committee of the Caisse des Dépôts (1988-1993). Deputy Chairman of the Accor Group (1993-1996). He was a Member of Parliament in Vosges from 1978 to 1993 and mayor of Saint-Dié des Vosges since 1989. Christian Pierret is a specialist in public company regulation, company and business law, the public-private interface (concerning the environment, for example) and European law (concentration, competition, state aid). He was behind the "Pierret law" of February 2002 opening up the French electricity and telecommunications markets to competition. Christian Pierret holds a post-graduate diploma in economic sciences (IEP Paris, 1970) and a masters degree in public administration (1972).

The mission of the Board of Auditors is to assist the Board of Directors, independently from the company's management, in ensuring the truthfulness of the financial statements, the quality of the internal control, the quality and relevance of the information provided and the correct discharge by the statutory auditors of their mandate. To that end the Board of Auditors issues opinions and makes proposals and recommendations to the Board of Directors.

The Board of Auditors' vocation is thus to:

- evaluate the existence and relevance of the financial control and internal audit procedures;
- assess the relevance of the accounting policy of the company;
- examine the company accounts and the information provided by these prior to them being presented to the Board of Directors;
- examine the changes and adaptations to the accounting principles and rules used in the preparation of the company accounts and the relevance of these;
- examine the candidates proposed for the positions of regular statutory auditor or substitute statutory auditor;
- ensure the independence and competence of the statutory auditors;
- review the significant risks faced by the company, and in particular the off-balance sheet risks and commitments.

It reports to the board on its activities at regular intervals. The committee met twice during the 2010 financial year.

The Board of Auditors met:

- Twice in the 2011 period; Once to review the annual account and the procedures relative to human resources, purchases and finances and for the recommendation to initiate a fundraising in 2011; and another time to review the semester accounts and the recommendation to invest the funds raised from the secondary fundraising.
- And twice in 2012, to this date; once to examine the 2012 budget and another time to approve the annual accounts.

16.3.2 Compensation Board

The company has established a Compensation Board which as at the date of this "Document de Référence" is comprised of two members, appointed by the Board of Directors at its meeting on 22 April 2009 for an unlimited term:

- Philippe Pouletty, director and Chairman of the Compensation Board;
- Jean-Claude Cadudal, chairman of the Board of Directors and member of the Compensation Board.

The Compensation Board makes recommendations to the Board of Directors on the remuneration (fixed and variable) of the corporate officers and its senior management, and on shareholder policy and ownership schemes for management and employees, taking into account the objectives of the company and the levels of individual or collective performance.

It also plays a part in setting up the company's corporate governance bodies.

It reports to the Board of Directors on its activities at regular intervals. The Committee met twice during the 2011 financial year. At the first meeting it reached a decision on the on-target earnings for 2012 and at the second on the awarding of special bonuses linked to the 2011 objectives. Since the start of 2012 the Compensation Board has met once to decide on the payment of on-target earnings.

16.3.3 Medical and Scientific Advisory Boards

The meeting of the Board of Directors of 16 December 2009 approved the setting of two scientific boards for an unlimited term.

16.3.3.1 Medical Advisory Board

The Medical Advisory Board is responsible for preparations for the clinical trials.
The Medical Advisory Board is comprised:

Professeur Christian Latrémouille : Cardiac Surgeon in charge of transplantation at the European Hospital George Pompidou, former student of Professor Alain Carpentier, he has perfomed part of his internship in the United States, in Washington D.C. and in Philadelphia. He is also professor of Clinical Anatomy at the Medical University of Paris V – René Descartes. He has published numerous scientific articles such as '*L'organisation des appareils et des systèmes* (2011)' and numerous academic publications in well-known scientific journals such as the European Journal of Cardio-Thoracic Surgery or the Journal of Thorac Cardiovascular Surgery.

Professeur Daniel Duveau : Professor of thoracic and cardiovascular surgery at the Guillaume et René Laënnec hospital. He is a full member of a number of associations including, in particular, the Société Française de Chirurgie Thoracique et Cardio-vasculaire (French Society of Thoracic and Cardiovascular Surgery), the International Society of Heart and Lung Transplantation and also the European Society for Cardiovascular Surgery. He also has an administrative role within the Scientific Council of the Nantes Faculty of Medicine and the In-house Medical Commission. He is also Medical Director of the Institute of the Thorax and Vice-chairman of the National Commission for Materiovigilance (AFSSAPS). Winner of first prize from the Conseil Général in 1966 and 1967, he received the médaille d'Or des Hôpitaux in 1967.

Docteur Rémi Nottin : Surgeon and head of department at the Marie Lannelongue hospital, where he specialises in the areas of adult cardiac surgery and peripheral vascular surgery. He is also a specialist in coronary artery bypass, aortic dissection, heart transplant, mitral valve repair, repair of the aortic root and aortic aneurysm.

Professeur Alain Carpentier : Please refer to paragraph 14.1.2 "Backgrounds of the members of the Board of Directors".

16.3.3.2 Scientific Advisory Board

The Scientific Advisory Board is responsible for monitoring the international development of the total artificial heart project.

The Scientific Advisory Board is comprised:

Professor Günther Laufer: Professor and Head of the Department of Cardiac Surgery at the Vienna Medical University, he specialises in the area of mini-invasive coronary surgery. He is currently Chairman of the Austrian Society for Cardiothoracic Surgery. He is also a member of the European Society for Cardiothoracic Surgery.

Dr Paul Mohacsi: Head of the Department of Cardiac Insufficiency and Transplantation at the Bern Clinic and Polyclinic for Cardiology.

Professor Frederick Mohr: Professor of Cardiac Surgery and Medical Director of the Centre for Cardiology at the University of Leipzig and Professor of Cardiovascular Surgery at the University of Göttingen in Germany, Frederick Mohr carries out research in various areas including adult cardiac surgery, peripheral vascular surgery and valve repair. He is also a member of a number of associations such as the German Society for Vascular Surgery, the American Association for Thoracic Surgery and the International Society of Heart and Lung Transplantation.

Dr Edoardo Gronda: Wirth a degree in medicine and surgery, Dr Edoardo Gronda is the Director of the Department of Clinical Cardiology and Cardiac Insufficiency at the Humanitas Clinical Institute in Italy. He was also a professor at the Faculty of Internal Medicine at the University of Milan until 2000. He is in addition Chairman of the Working Group of the International Society of Heart and Lung transplantation. He has contributed to the European Journal of Congestive Heart Failure, and to the Journal of Heart and Lung Transplant. He is also a medical consultant to the Precision Reports in collaboration with the American Heart Association.

Professor Gilles Dreyfus: Professor in Cardio-Vascular Surgery at Imperial College School of Medicine (United Kingdom, London), Professor Gilles Dreyfus has been consultant in cardio-thoratic surgery and Director of Research at the Royal Brompton & Harefield Trust Hospital where he focused his studies on cardiac valvulopathy, heart failure, and transplantation as well a Left Ventricular Assist Devices. He directed, until 2001, the cardiovascular surgical department of the Foch Hospital (Paris, France). Internationally recognized as an expert in mitral valve repair, he is the managing editor of Heart Failure Journal and has published numerous article on this matter in numerous scientific journals. He is, since January 2010, Medico-Surgical Director at the Cardio-Thoracic Center in Monaco (CCM)

Dr Mark Slaughter: Professor of Surgery and Head of the Thoracic and Cardiovascular Surgery Division at the University of Louisville in Kentucky, Dr Mark Slaughter is also Director of the Cardiac Transplantation and Mechanical Assistance Devices Program. He is also a member of the scientific advisory board of Cardiology Online Inc. and a council member of the Society for Artificial Internal Organs.

Professor Alain Carpentier: Please refer to paragraph 14.1.2 “Backgrounds of the members of the Board of Directors”.

The Scientific Boards met once during the 2011 financial year in order to look into developments with the CARMAT total artificial heart and to prepare for clinical trials.

More precisely, the Medical Committee has met before and after each trial run in-vivo or ex-vivo in order to share the information of these experiments.

The Scientific Committee met during the 25th European Congress of the European Society of Cardio-Thoracic surgery in Lisbon on October 25 2011, and focused on the anatomical compatibility and haemocompatibility tests on animals. Its members frequently come to the Company’s facilities to check particular developments and the review the test data.

16.3.4 Advisory Board

Article 17-VI of the Articles of Association gives the Ordinary General Meeting the power to appoint, at its discretion, three actual persons or legal entities, who may or may not be shareholders, for a term of office of one year expiring at the General Meeting of Shareholders called to decide on the accounts for the year just ended and held during the year in which their terms of office expire. This term of office may be renewed an unlimited number of times.

The task of the observers on the Advisory Board is to ensure the strict application of the Articles of Association and to present their observations at the meetings of the Board of Directors. The observers perform a general and permanent task within the company through advice and monitoring. In connection with their role they may make observations to the Board of Directors.

Observers must be invited to each meeting of the Board of Directors in the same way as directors. Observers have only consultative powers on an individual or joint basis and have no voting rights on the Board.

As at the date of registration of this “Document de Référence” no observer had been appointed

16.4 STATEMENT ON CORPORATE GOVERNANCE

16.4.1 Corporate governance

The aim of the company is to follow the principal recommendations of the Code of Corporate Governance for Quoted Companies issued by the AFEP-MEDEF in December 2008, to the extent that these principles are compatible with the organization, the size, the resources and the ownership structure of the company.

To this end the company has proceeded with a review of its corporate governance in respect of the 22 recommendations of the Code of Corporate Governance for Quoted Companies issued by the AFEP/MEDEF. The principal recommendations not applied are as follows:

- given the size of the company and the fact that it has only recently been listed on the Alternext Paris market, it has not yet proceeded with an evaluation of the Board of Directors;
- the Articles of Association of the company provide for terms of office of the directors of 6 years, whereas the AFEP/MDEF recommends a limit of 4 years;
- given the size of the company, no appointments board has been set up and no independent director sits on the Compensation Board.

Apart from setting up the Board of Auditors, the Compensation Board and the Scientific Boards mentioned in paragraph 16.3 “Boards” and in order to meet the standards of corporate governance that the company has set itself the elements described below have now been put in place.

16.4.2 Bylaws

The Board of Directors has provided itself with Bylaws, the purpose of which is to define the ways in which it is organized and operates over and above the legal and statutory provisions in force.

The Bylaws specifically provide that the Board of Directors shall decide on corporate policy and monitor the implementation of this. It deals with any matter affecting the proper operation of the company and through its deliberations rules on matters relating to it. In this context the Board of Directors approves significant operations by the company before these are carried out. These specifically include:

- the strategic, economic, social, financial and scientific policy of the company;
- operations extending beyond the company’s stated strategy;
- the securing of loans or advances in order to acquire shares or securities of any subsidiary company except where such subsidiary is wholly-owned;
- the furnishing of guarantees on behalf of a subsidiary or to guarantee bank accounts;
- all investments in excess of 250 000 €;
- all commitment in excess of 100 000 € and not provided for in the annual budget;
- hiring, laying off and amending of the contracts of employment of employees at management level;
- a change in the normal business of the company and in its development strategy;
- the disposal, transfer, licensing or pledging of any industrial or intellectual property or of any substantial asset;
- any decision relating to a secondary offering.

The Board of Directors shall proceed with the controls and verifications that it deems appropriate and may call for the documents that it deems appropriate for performing its task.

16.4.3 Separation of the mandates of the Chairman of the Board of Directors and the Chief Executive

When the company converted to a limited liability company, the Board of Directors opted for a dissociation of the mandates of the Chairman of the Board of Directors and of the Chief Executive.

In respect of the shareholders and without this restriction being binding upon third parties, the Chief Executive may not take any decision on behalf of the company in the following areas without the prior authorisation of the Board of Directors:

- the securing of loans or advances in order to acquire shares or securities of any subsidiary company except where such subsidiary is wholly-owned;
- the furnishing of guarantees on behalf of a subsidiary or to guarantee bank accounts;
- all investments in excess of 250 000 €;
- all commitment in excess of 100 000 €and not provided for in the annual budget;
- hiring, laying off and amending of the contracts of employment of employees at management level;

- a change in the normal business of the company and in its development strategy;
- the disposal, transfer, licensing or pledging of an industrial or intellectual property or of any substantial asset;
- approval of the budget and the strategic plan.

Furthermore, the Chief Executive may not take, without a prior decision of the Board of Directors by a qualified majority of three quarters of the directors making up the Board as at the date that the decision is taken:

- any decision to proceed with the transfer of any substantial asset or any intellectual/industrial property belonging to the company;
- any decision to take a holding in a company, quoted or unquoted.

For a detailed description of the provisions governing the functioning of the Board of Directors and the General Management, please refer to paragraph 20.2.2 “Provisions of the articles, a charter or a regulation of the company regarding members of the Board of Directors and of the General Management”.

16.4.4 Independent Directors

The company has three independent directors: Messrs André-Michel Ballester, Michel Finance and Henri Lachmann. The company considers that these have since their nomination complied with the AFEP-MEDEF code of December 2008, namely:

- not being a member of staff or corporate officer, member of staff or director of the parent company or a company with which it consolidates and not having been so in the previous five years;
- not being a corporate officer of a company in which the company holds, directly or indirectly, a position of director or in which a member of staff appointed as such or a corporate officer (current or having been so within the last five years) holds a director’s post;
- not being a major client, supplier, commercial banker or financial banker of the company or its group, or for whom the company or its group represents a significant part of its business;
- not having a close family tie with a corporate officer;
- not having been an auditor of the company within the last five years; and
- not having been a director of the company for more than twelve years.

André-Michel Ballester received director’s fees amounting to EUR 10 000 for the financial year ended on 31 December 2010 and was assigned 506 BSA 2009-1 at the meeting of the Board of Directors on 8 July 2009 and director’s fees amounting to 10 000 for the year 2011.

Michel Finance received director’s fees amounting to 10 000 for the period ending on December 31 2010 and was assigned 506 BSA 2009-1 at the meeting of the Board of Directors on 8 July 2009 and director’s fees amounting to 10 000 for the year 2011.

Henri Lachmann was appointed as a director of CARMAT at the Ordinary General Meeting of 23 December 2010, he received director’s fees amount to 10 000 for the year 2011.

16.4.5 Internal control

The company does not have an obligation to prepare an internal control report as provided by Article L.225-37 of the Commercial Code. Nevertheless, at the date of registration of this “Document de Référence”, the company has internal control procedures, particularly in the scientific, administrative, accounting and financial areas, with a view to implementing its strategic policies.

During the 2011 financial year the Board of Auditors of the company reviewed the internal procedures concerning human resources, purchasing and finance.

The company uses an accounting firm to handle all its accounts. Two staff members deal with management control.

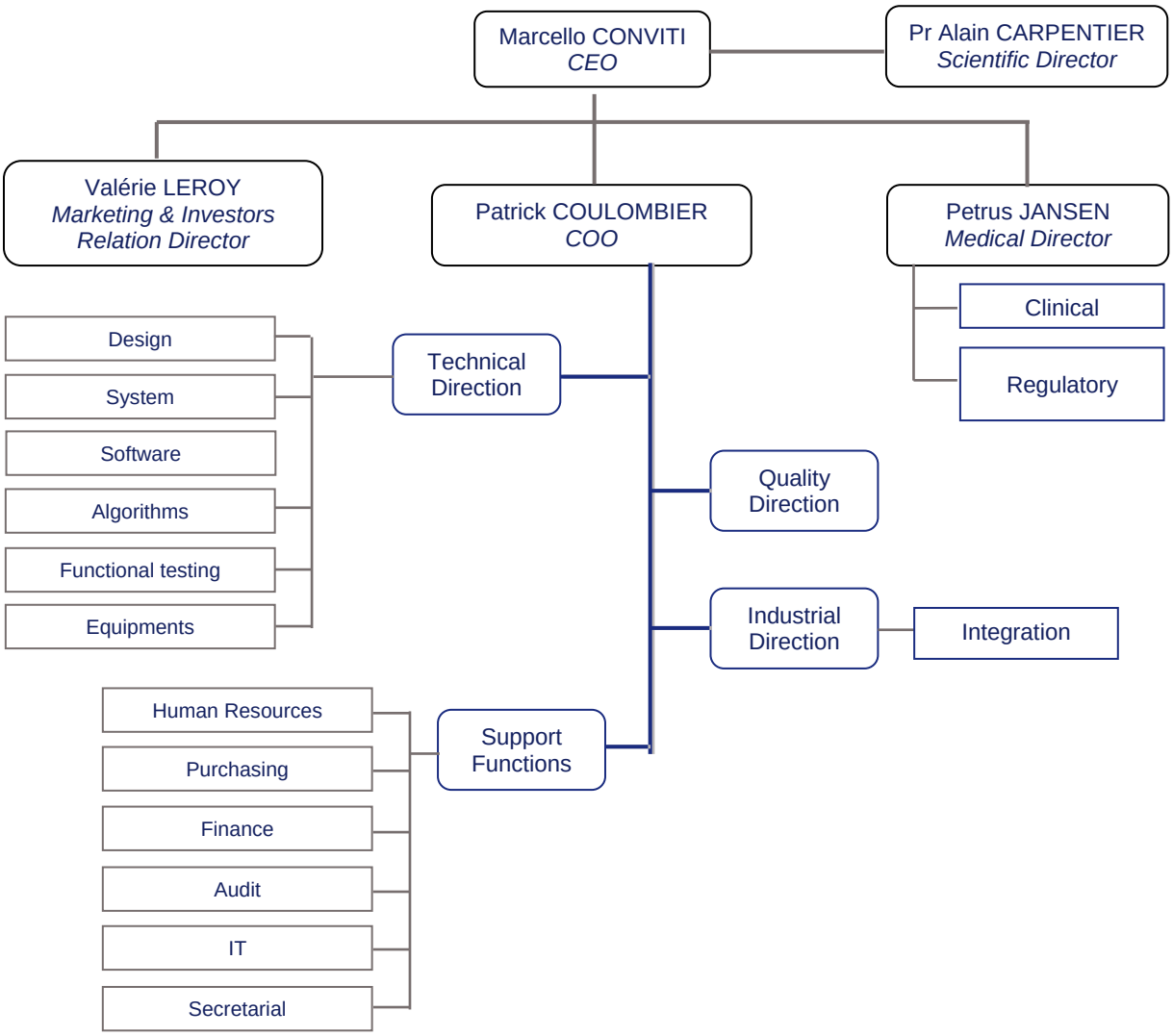
The company has implemented a procedure concerning delegation of power and signatories for payment of invoices and signing off orders. So, orders of up to 20 000 € must be signed off by Jean-Claude Cadudal, or Marcello Conviti or Patrick Coulombier; above 100 000 € orders must be signed by two people, Jean-Claude Cadudal and M. Patrick Coulombier, or Jean-Claude Cadudal and Marcello Conviti or Patrick Coulombier and Marcello Conviti.

17 STAFF

17.1 HUMAN RESSOURCES

17.1.1 Operational structure

As at the date of registration of this “Document de Référence”, the operational structure of the company was as follows



For a description of the experience and roles of the main members of the management, please refer to paragraph 14.1.3 “Other members of the management”.

At certain stages of the development of the total artificial heart project, the company has used a number of outside providers of specific services. As at the date of registration of this “Document de Référence”, 54 outside service providers were working for CARMAT. The breakdown of these is as follows:

- Technique : 44 providers :
  - Management : 2 providers
  - Prosthesis : 6 providers
  - System : 5 providers
  - Software : 15 providers
  - Trials : 5 providers
  - Algorithms : 5 providers
  - Equipment : 6 providers
- Regulatory and Clinical : 3 providers
- Integration : 1 provider
- Quality : 3 providers
- Purchases : 1 provider
- IT Department : 2 providers

17.1.2 Number and breakdown of staff

As at the date of registration of this “Document de Référence”, the workforce of the company numbered 36.

17.1.2.1 Change in workforce

Change in workforce for	31/12/2011	31/12/2010	31/12/2009	31/12/2008
Management	29	25	17	11
Non-management	7	7	8	3
Total	36	32	25	14

All staff is employed full-time under open-ended contracts of employment, except for six staff members on fixed-term contracts. Two staff members are employed part time.

17.1.2.2 Status of Young Innovative Enterprise (JEI)

In September 2008, CARMAT opted for the status of Young Innovative Enterprise (JEI). On 8 July 2009, the Yvelines Tax Office issued a favorable opinion (“ruling”) on the application from the company for JEI status. This opinion is valid vis-à-vis the URSSAF.

Le statut de JEI est un statut fiscal pour les jeunes entreprises réalisant des projets de recherche et développement et dont l’effectif est inférieur à 250 salariés. Si les conditions de son bénéfice sont remplies, l’employeur bénéficie d’une exonération des cotisations patronales au titre des assurances sociales et des allocations familiales. La durée du bénéfice de ces exonérations est de 8 années au maximum suivant la date de création de l’entreprise, soit, pour la société CARMAT, jusqu’à 2015 (se référer au paragraphe 4.2.10 « Risques liés à la perte de statut de Jeune Entreprise Innovante »).

The status of JEI is a tax status for young enterprises conducting research and development projects and whose workforce comprises less than 250 staff. If the conditions surrounding its profits are met, the employer enjoys exemption from employer contributions towards social security and family benefits. The period of exemption is a maximum of 8 years from the date of establishment of the company,, or for CARMAT up until 2015 (please refer to paragraph 4.2.10 “Risks associated with loss of Young Innovative Enterprise status”).

Parliament voted for an amendment to the system of JEI status in connection with Article 78 of the Finance Act 2011, aimed at setting a limit on and making regressive the system for exemption from employer’s social contributions for JEIs by introducing:

- a limit to the gross monthly remuneration per person set at 4.5 times the minimum wage (or 6 142.50€ in 2011);
- an annual limit on eligible contributions for each organization, set at three times the annual social security limit, or EUR 106 056 for 2011;
- a progressive reduction in exemptions over the lifetime of the company. In fact, the new system of exemption provides that, based on the amount of exemption that the organization is able to claim, the level of exemption stands at 100% of this sum for years 1 to 4, then experiencing a progressive reduction over the next four years to 75%, 50%, 30% and 10% of this amount respectively, before being discontinued completely.

This reform constitutes an additional cost for CARMAT of the order of EUR 0.5 million for the financial year 2011 and of the order of EUR 3 million in total from the financial years 2011 to 2015, which is the eighth and final year for which CARMAT may enjoy the status of JEI.

17.1.3 Human resources policy

Staff management is of considerable importance to the company. In fact, the company must have qualified employees available with strong skill sets since the business of CARMAT relies to a significant extent on the quality and effectiveness of its members of staff. The company believes that it has good staff relations.

The workforce, as of December 31 2011, was composed of 11 women and 25 men, and comprised 2 doctors in medecine, 24 engineers and 7 graduate technicians. The mean age for the workforce was of 38. Around one quarter of the workforce is below 30. In 2011, the Company has funded about 300 hours of training, an important part of which was geared towards the regulatory requirements.

The company applies the National Collective Agreements of the “Industries Métallurgiques: ouvriers, employés, techniciens et agents de maîtrise” (*Metallurgical Industries: workers, staff, technicians and supervisors*) and of the “Industries Métallurgiques: ingénieurs et cadres” (*Metallurgical Industries: engineers and managers*), as well as the Regional Collective Agreement of the "Industries Métallurgiques: ouvriers, employés, techniciens et agents de maîtrise de la Région Parisienne” (*Metallurgical Industries: workers, staff, technicians and supervisors of the Paris Region*).

There are no company agreements other than the company Bylaws.

Standard contracts of employment contain no clauses relating to breach of the contract of employment or an anti-competition and anti-poaching undertaking (staff and/or customers).

With regard to remuneration policy, all staff members of the company benefit, in addition to their basic salary, from a potential annual bonus subject to achieving quantitative and qualitative targets set in advance by the Board of Directors of the company and individual targets agreed in advance with the line manager. The amount of this bonus is limited to a percentage of the gross annual salary (between 5% and 40% of the gross annual salary according to the staff or managers concerned).

The working week at the company is 35 hours for non-managers with a fixed number of days per year for managers of 218.

There is no agreement on work time within the company, but an internal memorandum concerning work time and working hour arrangements was issued on 16 January 2009 (over and above the provisions of the collective agreement applicable within the company). This memorandum makes provision for the length of the working day (07:00 – 20:00 hours), and for its core time (10:00 – 15:30 hours).

17.2 INTERESTS AND SHARE OPTIONS HELD BY MEMBERS OF THE MANAGEMENT AND SUPERVISORY BODIES, AND BY STAFF

The following table shows as at the date of registration of this “Document de Référence”, all the stock subscription warrants (BSA) and start-up company share options (BCE) issued by the company to its corporate officers and staff and not yet exercised.

The number of BSA-2009-1, BCE-2009-1 and BCE-2009-2 allocated to each corporate officer or member of staff is the result of the decision of the Compensation Board, and is confirmed by the Board of Directors.

Emanating from a shareholder consensus on July 8 2009, the Board of Directors meeting of June 27 2012 decided, upon recommendation of the Compensation Board of the Company and under conditions (i) the approval by owners of BCE 2009-2 (ii) the retroactive ratifying by the next Shareholder’s General Assembly, to modify the details and procedure to enforce the BCE 2009-2 stipulated in Article 4 of the Bylaws as followed:

Old text:

“Specific conditions:

The Owners may exercise the BCE 2009-2 that were assigned to them in the under the following conditions:

- 20% of the BCE-2009-2, will become exercisable at the first anniversary of Owner’s entry into the Company, subject to his effective and sustained presence in the Company to that date;
- 40% of the BCE-2009-2 will become exercisable by full monthly terms, with up to X number of BCE-2009-2 calculated using the following rule and, for the first time, after the Owner’s the anniversary of arrival to the Company, subject to his effective and sustained presence in the Company to that date:
- X = (40% of the BCE-2009-2 held by the Owner) multiplied by ((number of months since the Owner’s first anniversary of presence in the Company) / 48)
- 40% of the BCE-2009-2 will become exercisable after the completion and success of the first clinical trials of CARMAT’s artificial heart before the end of second quarter 2012 (final medical report including aspects of study safety and endpoint), subject to an effective and sustained presence in the Company to that date."

New text:

“Specific conditions:

The Owners may exercise the BCE 2009-2 that were assigned to them in the under the following conditions:

- 20% of the BCE-2009-2, will become exercisable at the first anniversary of Owner’s entry into the Company, subject to his effective and sustained presence in the Company to that date;
- 40% of the BCE-2009-2 will become exercisable by full monthly terms, with up to X number of BCE-2009-2 calculated using the following rule and, for the first time, after the Owner’s the anniversary of arrival to the Company, subject to his effective and sustained presence in the Company to that date:
- X = (40% of the BCE-2009-2 held by the Owner) multiplied by ((number of months since the Owner’s first anniversary of presence in the Company) / 48);
- 10% of the BCE-2009-2 will become exercisable after the completion and success of the first clinical trials of the artificial heart CARMAT before the end of second quarter 2012 (final medical report including aspects of study safety and endpoint), subject to an effective and sustained presence in the Company to that date;

- 10% of the BCE-2009-2 will become exercisable after the completion and success of the first clinical implantation of CARMAT's artificial heart before the end of November 2012 (report from third party), subject to an effective and sustained presence in the Company to that date;
- 6.5% of the BCE-2009-2 will become exercisable after the success of the clinical trials pivotal study of CARMAT's artificial heart (report from Scientific Committee), subject to an effective and sustained presence in the Company to that date;
- 6.5% of the BCE-2009-2 will become exercisable after obtaining the CE Conformity Marking for CARMAT's artificial heart before, subject to an effective and sustained presence in the Company to that date;
- 7% of the BCE-2009-2 will become exercisable after December 31 of the first year of commercialization of CARMAT's artificial heart before confirmed by the Board of Directors as conform with expectations in term of revenue and gross profit margin established by the Management's business plan and approved by the Board, subject to an effective and sustained presence in the Company to that date."

The obsolescence of 10% of the BCE-2009-2 whose exercise depends on the completion and success of the first clinical trials of the CARMAT artificial heart before the end of second quarter 2012 will be recognized by the next Board and the aforementioned BCE-2009-2 will be subsequently canceled.

Holder		**BSA-2009-1**	**BCE-2009-1**	**BCE-2009-2**	**BCE-2012-1**
Jean-Claude CADUDAL	Chairman of the Board of Directors	1 554			
Michel FINANCE	Director	518			
André-Michel BALLESTER	Director	518			
Marcello CONVITI	Chief Executive/ Director		3 108		4 000
Patrick COULOMBIER	Chief Assistant Executive/ Staff member			1 492	
Marc GRIMME	Staff member			683	
Petrus JANSEN	Staff member			593	
Jean-Marc PARQUET	Staff member			401	
Paul KOHLER	Staff member			391	
Fabien BOUSQUET	Staff member			202	
Antoine CAPEL	Staff member			237	
Marion MELOT	Staff member			281	
Joëlle MONNIER	Staff member			211	
Pierre DA CRUZ	Staff member			184	
Hélène LEBRETON	Staff member			88	
Julien BACLET	Staff member			81	
Clément DUCROS	Staff member			134	
Karima DJABELLA	Staff member			146	
Nathalie BOTTEREAU	Staff member			79	
Rekia BENMERRAH	Staff member			45	
Yann MERY	Staff member			79	
Gregory MINGOT	Staff member			79	
Hervé BOCQUET	Staff member				15 000
Valérie LEROY	Staff member				10 000
Claire PHILIBERT	Staff member				5 000
Emmanuel LECLERC DE HAUTECLOCQUE	Staff member				2 500
Mohammed ZAGDOUD	Staff member				3 500
Jean-Christophe PERLES	Staff member				2 500
Nicolas GRAS	Staff member				2 500
Alexandre MENDES	Staff member				2 000
Aurélien CORBEL	Staff member				2 000
Marine BONNENFANT	Staff member				2 000
Pierre Emeric DESTORS	Staff member				2 000
Sylvie CLAQUIN	Staff member				1 500
Clément VALLOIS	Staff member				2 000
TOTAL ASSIGNED		**2 590**	**3 108**	**5 406**[(1)]	**56 500**
NON ASSIGNED		0	0	0	0
TOTAL		**2 590**	**3 108**	**5 406**	**56 500**
NUMBER OF SHARES LIKELY TO BE CREATED BY THE EXERCISING OF BSAs OR BCEs		**64 750**	**77 700**	**135 150**	**56 500**

(1) Accounting for the obsolescence of 10 % of the BCE-2009-2 that will be acknowledged during the next meeting of the Board of Directors.

The following table shows the main characteristics of the BSAs granted to member of the Board of Directors and of the BCEs assigned to members of management and to staff:

Type of security	BSA-2009-1	BCE-2009-1
Beneficiaries	3 members of the Board of Directors: Jean-Claude Cadudal, Michel Finance and André-Michel Ballester	Marcello Conviti – Chief Executive and Director
Date of the General Assembly	July 8 2009	July 8 2009
Date of the meeting of the Board of Directors	July 8 2009	September 9 2009
Exercise price per new share subscribed	8 Euros	8 Euros
Exercise deadline	10 years from the date of assignment of the BSAs	10 years from the date of assignment of the BCEs
Ratio	1 BSA-2009-1 per 25 new CARMAT shares	1 BCE-2009-1 per 25 new CARMAT shares
General conditions of exercise	- 25% of BSA-2009-1 warrants may be exercised on the date of the first anniversary of the beneficiary joining the company, subject to actual and continued presence within the company at that date; - 75% of BSA-2009-1 warrants may be exercised on the basis of full monthly periods in tranches of 1/36th from date of the first anniversary of the beneficiary joining the company over a period of 3 years, subject to actual and continued presence within the company at that date. Early exercise at the end of a period expiring 18 months after the establishment of the company if the beneficiary has occupied the position of Chairman of the company for a period expiring 18 months after the establishment of the company. As a result of the success of the initial listing of the company on the Alternext market of NYSE-Euronext Paris, according to the assessment of the meeting of the Board of Directors of 8 September 2010, 20% of BSA-2009-1 warrants that were not exercisable as at the date of the initial listing may be exercised early.	- 25% of BCE-2009-1 options may be exercised on the date of the first anniversary of the beneficiary joining the company, subject to actual and continued presence within the company at that date; - 75% of BCE-2009-1 options may be exercised on the basis of monthly periods in tranches of 1/36th from date of the first anniversary of the beneficiary joining the company over a period of 3 years, subject to actual and continued presence within the company at that date. Early exercising in the event of a share transfer agreement being entered into, with or without conditions precedent, resulting in a change in control of the company to the benefit of the transferee on the basis of a valuation in excess of EUR 100 million. As a result of the success of the initial listing of the company on the Alternext market of NYSE-Euronext Paris, according to the assessment of the meeting of the Board of Directors of 8 September 2010, 20% of BCE-2009-1 options that were not exercisable as at the date of the initial listing may be exercised early.
Number of new shares that may be subscribed	64 750 shares for the BSA-2009-1 warrants assigned	77 000 shares

Type of security	BCE-2009-2	BCE-2012-1
Beneficiaries	Patrick Coulombier – Chief Operating Officer – Staff member and 17 other members of staff	M. Marcello Conviti – Chief Executive and 13 member of staff
Date of the General Assembly	8 July 2009	April 26 2012
Date of the meeting of the Board of Directors	8 July 2009	June 27 2012
Exercise price per new share subscribed	8 Euros	108,483 €
Exercise deadline	10 years from the date of awarding of the BCEs	10 years from the date of awarding of the BCEs
Ratio	1 BCE-2009-2 per 25 new CARMAT shares	1 BCE-2009-2 per 1 new CARMAT shares
General conditions of exercise(2)	- 20 % of BCE-2009-2 options may be exercised on the date of the first anniversary of the beneficiary joining the company, subject to actual and continued presence within the company at that date; - 40 % of BCE-2009-2 options may be exercised on the basis of monthly periods in tranches of 1/36th from date of the first anniversary of the beneficiary joining the company over a period of 4 years, subject to actual and continued presence within the company at that date. - 10% of the BCE-2009-2 will become exercisable after the completion and success of the first clinical trials of the artificial heart CARMAT before the end of second quarter 2012 (final medical report including aspects of study safety and endpoint), subject to an effective and sustained presence in the Company to that date(1); - 10% of the BCE-2009-2 will become exercisable after the completion and success of the first clinical implantation of CARMAT's artificial heart before the end of November 2012 (report from third party), subject to an effective and sustained presence in the Company to that date. - 6.5% of the BCE-2009-2 will become exercisable after the success of the clinical trials pivotal study of CARMAT's artificial heart (report from Scientific Committee), subject to an effective and sustained presence in the Company to that date." - 6.5% of the BCE-2009-2 will become exercisable after obtaining the CE Conformity Marking for CARMAT's artificial heart before, subject to an effective and sustained presence in the Company to that date." - 7% of the BCE-2009-2 will become exercisable after December 31 of the first year of commercialization of CARMAT's artificial heart before confirmed by the Board of Directors as conform with expectations in term of revenue and gross profit margin established by the Management's business plan and approved by the Board, subject to an effective and sustained presence in the Company to that date	- 50 % of BCE-2009-2 options may be exercised on the basis of monthly periods in tranches of 1/48th from date of the first anniversary of the beneficiary joining the company over a period of 4 years, subject to actual and continued presence within the company at that date. - 17% of the BCE-2009-2 will become exercisable after the completion and success of the first clinical implantation of CARMAT's artificial heart before the end of November 2012 (report from third party), subject to an effective and sustained presence in the Company to that date. - 6.25% of the BCE-2009-2 will become exercisable after the success of the clinical trials pivotal study of CARMAT's artificial heart (report from Scientific Committee), subject to an effective and sustained presence in the Company to that date." - 16.25% of the BCE-2009-2 will become exercisable after obtaining the CE Conformity Marking for CARMAT's artificial heart before, subject to an effective and sustained presence in the Company to that date." - 17.5% of the BCE-2009-2 will become exercisable after December 31 of the first year of commercialization of CARMAT's artificial heart before confirmed by the Board of Directors as conform with expectations in term of revenue and gross profit margin established by the Management's business plan and approved by the Board, subject to an effective and sustained presence in the Company to that date
Number of new shares that may be subscribed	135 150 shares(3)	45 000 actions

(1) These BCE-2009-2 have become obsolete since July 1 2012. The obsolescence will be acknowledged by the Board of Directors in their next meeting.
(2) Please refer to paragraph 17.2 for the terms modifying the delays and conditions to enforce the BCE-2009-2, if (i) the holder of BCE 2009-2 agree and (ii) the General Assembly retroactively approves that decision during its next meeting.
(3) Accounting for the obsolescence of 10 % of the BCE-2009-2

If all the BSA-2009-1 warrants, BCE-2009-1, BCE-2009-2 and BCE-2012-1 options assigned were exercised, 334 100 new shares, representing 8.07% of the capital and 4.84% of the voting rights as at the date of this “Document de Référence” would then be created.

17.3 EMPLOYEE OWNERSHIP AND PROFIT SHARING SCHEMES

As at the date of registration of this “Document de Référence”, the company had not set up any employee ownership or profit sharing scheme.

18 MAJOR SHAREHOLDERS

18.1 DISTRIBUTION OF CAPITAL AND VOTING RIGHTS

18.1.1 Current distribution of capital and voting rights

The table below shows the distribution of the capital and voting rights (please refer to paragraph 18.2 of this "Document de Référence" "Voting rights" which indicates the conditions under which double voting rights may be obtained) of the company at the date of registration of this "Document de Référence":

Shareholder	Number of shares (undiluted capital)	Number of voting rights	% of capital	% of voting rights
MATRA DEFENSE (EADS Group)	1 265 382	2 246 782	30.57	32.53
Professor Alain Carpentier	548 583	1 097 166	13.25	15.88
Scientific Research Association of the Alain Carpentier Foundation	115 000	230 000	2.78	3.33
FCPI UFF INNOVATION 5	542 546	1 085 092	13.11	15.71
FCPI EUROPE INNOVATION 2006	220 497	440 994	5.33	6.38
FCPR TRUFFLE CAPITAL II	199 872	399 744	4.83	5.79
FCPI FORTUNE	74 909	149 818	1.81	2.17
FCPI UFF INNOVATION 7	76 298	152 596	1.84	2.21
FCPI INNOVATION PLURIEL	5 833	5 833	0.14	0.08
Sub-total for funds managed by Truffle Capital	**1 119 955**	**2 234 077**	**27,05**	**32,34**
Pierre and Marie Curie University	10 000	20 000	0.24	0.29
Treasury shares	1 733	0	0.04	0.00
Secondary offering	1 079 292	1 079 302	26.07	15.63
TOTAL	**4 139 945**	**6 907 327**	**100.00**	**100.00**

As far as the Company is aware, there is no other shareholder owning more than 5% of the capital or the voting rights.

Truffle Capital:

Founded in 2002 in Paris, Truffle Capital is an acknowledged European player in the area of investment capital, investing in and developing innovative SMEs and building technological leaders in the areas of life sciences, information technology and energy.

Backed by 520 million Euros from "Fonds Communs de Placements à Risques" (Mutual Funds for Risk Investment - FCPR) or "Fonds Commun de Placement dans l'Innovation" (Mutual Funds for Investment in Innovation - FCPI), Truffle Capital is run by a team of four partners with successful entrepreneurial and investment backgrounds both in Europe and in North America.

Truffle Capital thus manages:

- two institutional funds: Truffle Venture FCPR (launched in 2003) and Truffle Capital II (launched in 2008);
- private funds: Europe Innovation 2002 FCPI, Europe Innovation 2003 FCPI, Europe Innovation 2004 FCPI, Europe Innovation 2006 FCPI, UFF Innovation 5, UFF Innovation 7, Fortune FCPI, and Pluriel FCPI.

Truffle Capital often acts as leader, as the single or majority investor, and finances in particular technological spin-offs from large industrial groups, technological research institutes and universities, but also new start-ups. Truffle Capital's concern is for socially responsible investment and this is demonstrated by the sectors in which it invests - specifically health and energy-saving.

The unique feature of Truffle Capital's team of "entrepreneurial investors" is its ability to identify innovations that respond to new markets; to promote operational aspects and breakthrough innovations, beyond simple finance, with the aim of building and developing technology companies with high potential in terms of their value and their capacity to be the leaders of tomorrow.

Truffle Capital is a shareholder in CARMAT through four funds: Truffle Capital II FCPR, Europe Innovation 2006 FCPI, UFF Innovation 2006 FCPI and Fortune FCPI.

EADS Group:

The EADS Group, born out of a merger in July 2000 between DaimlerChrysler Aerospace AG, Aérospatiale-Matra and Construcciones Aeronáuticas SA, is a world leader in the aeronautic, space and defence and associated services sectors. In 2009 the EADS Group comprising specifically Airbus, Eurocopter, EADS Astrium and EADS Défense & Sécurité, turned in sales of EUR 49.1 billion with a workforce of over 133 000.

The EADS Group hold shares in CARMAT through its wholly-owned subsidiary Matra Défense.

Professor Carpentier:

Emeritus professor at the Pierre and Marie Curie University (University of Paris IV) and professor at the Mount Sinaï School of Medicine in New York, he is the founder of the Biosurgical Research Laboratory – Scientific Research Association of the Alain Carpentier Foundation. Winner of the 1998 Foundation for Medical Research Prize, and vice-chairman of the Academy of Sciences, he also received the prestigious Albert Lasker Award for Clinical Medical Research in 2007 in recognition of his two main contributions to the field - invention of the first valve bioprostheses (Carpentier-Edwards valves) and the development of techniques for plastic and reconstructive surgery of heart valves, which benefit several hundred thousand patients worldwide each year.

Scientific Research Association of the Alain Carpentier Foundation:

Set up in December 2007 by Professor Alain Carpentier, the purpose of the Scientific Research Association of the Alain Carpentier Foundation is to finance medical research projects, in particular in the surgical, cardiovascular and neurological areas.

Pierre and Marie Curie University:

Founded in 1971, the Pierre and Marie Curie University is the largest and foremost French university dedicated to sciences and to medicine. It attracts around 30 000 students (8 000 in medicine) who are supervised by 5 600 researchers and research students and has 122 research laboratories. The University came 40th in the Academic Ranking of World Universities by the University of Jiao-tong in Shanghai, which classifies 6 000 colleges and universities according to the volume and quality of their electronic publications. It is the highest ranking French and the sixth-placed European university in this list.

18.1.2 Change in the distribution of capital and voting rights

The table below shows the change in distribution of capital and voting rights in the company as at 31 December 2011 2010, 2009 and 2008:

Shareholder	As at 31/12/2011			
	Number of shares (undiluted capital)	Number of voting rights	% of capital	% of voting rights
MATRA DEFENSE (EADS Group)	1 265 382	2 140.382	30,66	34,06
Professor Alain Carpentier & Scientific Research Association of the Alain Carpentier Foundation	663 583	1 309 833	16,07	20,84
FCPI UFF INNOVATION 5	565 326	865 576	13,70	13,78
FCPI EUROPE INNOVATION 2006	238 022	400 522	5,77	6,38
FCPR TRUFFLE CAPITAL II	234 916	365 916	5,69	5,82
FCPI FORTUNE	81 043	112 293	1,96	1,79
FCPI UFF INNOVATION 7	81 553	81 553	1,98	1,30
FCPI INNOVATION PLURIEL	6 715	6 715	0,16	0,11
Sub-total for funds managed by Truffle Capital	**1 207 575**	**1 832 575**	**29,25**	**29,18**
Pierre and Marie Curie University	10 000	20 000	0,24	0,32
Treasury shares	1 395	0	0,03	0,00
Secondary offering	979 860	979 860	23,74	15,60
TOTAL	**4 127 795**	**6 282 650**	**100,00**	**100,00**

Shareholder	As at 31/12/2010

	Number of shares (undiluted capital)	Number of voting rights	% of capital	% of voting rights
MATRA DEFENSE (Group EADS)	1 248 066	2 123 066	32,60	37,59
Professor Alain CARPENTIER	548 583	1 079 833	14,33	19,12
Scientific Research Association of the Alain Carpentier Foundation	115 000	230 000	3,00	4,07
FCPI UFF INNOVATION 5	597 051	897 301	15,60	15,89
FCPI EUROPE INNOVATION 2006	257 923	257 923	6,74	4,57
FCPR TRUFFLE CAPITAL II	260 482	260 482	6,80	4,61
FCPI FORTUNE	86 850	86 850	2,27	1,54
FCPI UFF INNOVATION 7	85 430	85 430	2,23	1,51
FCPI INNOVATION PLURIEL	7 204	7 204	0,19	0,13
Sub-total for funds managed by Truffle Capital	**1 294 940**	**1 595 190**	**33,83**	**28,24**
Pierre and Marie Curie University	10 000	10 000	0,26	0,18
Treasury shares	1 118	0	0,03	0,00
Secondary offering	610 154	610 154	15,94	10,80
TOTAL	**3 827 861**	**5 648 243**	**100,00**	**100,00**

Taking into account on the one hand the division of the face value of the shares by 25 and the subsequent multiplication of the number of shares by 25 by application of the Resolution 18 of the Combined General Meeting of 7 May 2010, and on the other the conversion of the category A preference shares at a ratio of one for one (under the condition precedent of the admission for trading and initial listing of the shares of the company on the Alternext Paris market of NYSE-Euronext).

Shareholder	As at 31/12/2009		
	Number of shares and voting rights (undiluted capital)		% of capital and of voting rights
	Category O	Category A	
MATRA DEFENSE (Group EADS)	24 999	10 001	40,58
Professor Alain CARPENTIER	19 999	1 251	24,64
Scientific Research Association of the Alain Carpentier Foundation	4 600	0	5,33
FCPI UFF INNOVATION 5	0	12 010	13,92
FCPI EUROPE INNOVATION 2006	0	6 500	7,54
FCPR TRUFFLE CAPITAL II	0	5 240	6,08
FCPI FORTUNE	0	1 250	1,45
Sub-total for funds managed by Truffle Capital	**0**	**25 000**	**28,99**
Pierre and Marie Curie University	400	0	0,46
TOTAL	**49 998**	**36 252**	**100,00**

Shareholder	As at 31/12/2008		
	Number of shares and voting rights (undiluted capital)		% of capital and of voting rights
	Category O	Category A	
MATRA DEFENSE (Group EADS)	24 999	10 001	40,58
Professor Alain CARPENTIER	19 999	1 251	24,64
Scientific Research Association of the Alain Carpentier Foundation	5 000	0	5,80
FCPI UFF INNOVATION 5	0	12 010	13,92
FCPI EUROPE INNOVATION 2006	0	6 500	7,54
FCPR TRUFFLE CAPITAL II	0	5 240	6,08
FCPI FORTUNE	0	1 250	1,45
Sub-total for funds managed by Truffle Capital	**0**	**25 000**	**28,99**
Pierre and Marie Curie University	0	0	0,00
TOTAL	**49 998**	**36 252**	**100,00**

18.2 VOTING RIGHTS

The voting right attaching to shares is proportional to the percentage of capital that they represent and each share gives an entitlement entitled to at least one vote.

However, by application of No 14 of the Articles of Association and in accordance with the provisions of the Commercial Code, all fully paid up shares which can be shown to have been registered to the same shareholder for at least two years will benefit, with effect from the first listing of the shares of the company on the Alternext Paris market of NYSE-Euronext, from double voting rights compared with those given to other shares having regard to the percentage of common stock that they represent.

18.3 STATEMENT CONCERNING CONTROL OF THE COMPANY

As at the date of registration of this “Document de Référence”, no single shareholder was in control of the company, directly or indirectly or with others, within the meaning of Article L.233-3 et seq. of the French Commercial Code.

18.4 AGREEMENTS THAT MAY BRING ABOUT A CHANGE IN CONTROL

As at the date of registration of this “Document de Référence”, and to the knowledge of the company, there are no agreements that may bring about a change in control of the company.

19 OPERATIONS WITH ASSOCIATED COMPANIES

19.1 ROYALTIES AGREEMENT

Under a royalties agreement signed on 24 June 2008 and amended by an addendum of 5 February 2010 between CARMAT, Professor Alain Carpentier and Matra Défense (a subsidiary of the EADS Group) as a result of contributions made when the company was established, it was agreed that CARMAT will pay Professor Alain Carpentier and Matra Défense, a total sum equal to 2% of the direct net sales generated by the total artificial heart in the countries covered by at least one of the patents initially brought by them to the company. These payments will be made on a half-yearly basis within thirty days of the end of each sixth-month period, according to a distribution between Professor Alain Carpentier and Matra Défense established in proportion to their holdings in the capital of the company on the date it was established.

However, CARMAT may repurchase this right to royalties by paying Professor Alain Carpentier and Matra Défense, in proportion to their holdings in the capital of the company on the date it was established, a total sum of EUR 30 million less the amount of royalties already paid at the time this right to royalties is repurchased. This sum of EUR 30 million is indexed on the basis of the Indice du Prix à la Production de l'Industrie et des Services aux Entreprises – Matériel médicochirurgical et d'orthopédie-exportation zone Euro – Code PVIC 3310921007M (*Production prices index for industry and services to companies – Medico-chiurgical and orthopedic material for export in the Euro zone Code PVIC 3310921007M*) with a base level of 100.3 in April 2008 as calculated and published by the French National Institute for Statistics and Economic Studies (INSEE).

19.2 RELATIONSHIPS BETWEEN CARMAT AND SUBSIDIARIES OF THE EADS GROUP

Because of the specific skills it requires and its historical links the company has commercial relationships with the following EADS Group subsidiaries in the normal context of its business and under normal financial conditions for the types of services provided (amount of charges for the 12 month period ending on 31 December 2010);

- EADS ITS/EADS FRANCE for 279 196 € for the supply of IT and telephone services;
- MATRA ELECTRONIQUE for 508 245 € for the production of the integrated electronics of the prosthesis;
- APSYS for 520 398 € for performing operational safety studies and risk analysis of the system and by way of a staff loan agreement for specialists in the areas of industrialization and onboard equipment testing
- ASTRIUM for 116 655 € for the qualification study on the electronics of the prosthesis and preparation of the performance support file;
- MBDA France for 59 267 € for expert appraisal of electronic and electromechanical aspects and production consultancy;
- EADS AEROASSURANCES for 4 914 € for personal accident insurance cover.

19.3 SPECIAL REPORT OF THE AUDITORS ON REGULATED AGREEMENTS (GENERAL ASSEMBLY TO APPROVE THE FINANCIAL STATEMENTS FOR THE YEAR ENDING 31 DECEMBER 2011)

PricewaterhouseCoopers Audit
63, rue de Villiers
92208 Neuilly-sur-Seine Cedex

Lison Chouraki
13, rue Spontini
75016 Paris

CARMAT SA

36, Avenue de l'Europe

78941 Vélizy-Villacoublay cedex

To the shareholders,

In our capacity as statutory auditors of your company, we hereby report to you on regulated agreements.

The terms of our engagement do not require us to identify other agreements, but to communicate to you, based on information provided to us, the principal terms and conditions of those agreements brought to our attention, without expressing an opinion on their usefulness and appropriateness. It is your responsibility, pursuant to Article R. 225-31 of the French Commercial Code *(Code de Commerce)*, to assess the interest involved in respect of the conclusion of these agreements and commitments for the purpose of approving them.

Furthermore, we are required, as necessary, to provide you with the information pursuant to Article R 225-31 of the Commercial Code concerning the execution of agreements, in the year just ended, previously approved by general meeting.

We have performed all the checks that we considered necessary into the professional practice of the national firm of auditors in relation to this mission. These checks consisted of verifying the correspondence between the information provided to us and the base documents from which this originates.

AGREEMENTS SUBJECT TO THE APPROVAL OF A GENERAL MEETING

We hereby inform you that we were advised of an agreement authorized during the previous year that was submitted for the approval of a general meeting by application of the provisions of Article L. 225-40 of the Commercial Code.

Your Company has agreed to an issuance contract with BNP Paribas, Dexia Securities France and Portzamparc so as to define the condition of the August 10 2011 increase in capital. In this agreement, Truffle Capital, Director of the Company, pledged – in the event that, if when the subscription period ended, the subscriptions were to be insufficient to cover the whole of the issued shares (excluding extension clause) and where the Board of Directors decided to spread the remaining non subscribed shares and to offer them to Truffle Capital – to subscribe to a sufficient number of shares such that the capital increase be subscribed to a hypothetical rate of 75% (excluding extension clause), that is a maximum number of 100 275 new shares corresponding to 10 629 150€.

AGREEMENT PREVIOUSLY APPROVED BY GENERAL MEETING

In addition, in accordance with the provisions of article R. 255-30 of the French Commercial Code (*Code du Commerce),* we have been advised that the following agreement previously authorized by general meeting, was not executed during the year just ended.

ROYALTIES AGREEMENT BETWEEN CARMAT (HEREAFTER REFERRED TO AS "THE COMPANY"), PROFESSOR ALAIN CARPENTIER AND MATRA DEFENSE

On 24 June 2008 your company signed a royalties agreement ("hereinafter referred to as "the Agreement") with Professor Alain Carpentier and Matra Défense, founding shareholders in the Company. Under this Agreement, the Company undertakes to pay Professor Alain Carpentier and Matra Défense 2% of the net proceeds from sales of the "CARMAT" Artificial Heart produced and distributed by CARMAT SAS, with this sum being shared between the two beneficiaries in proportion to their respective shares in the capital of the Company on the date it was established. These royalties will be payable every 6 months within 30 days of the end of the end of each six-month period, following the first marketing of the "CARMAT" Artificial Heart and up until expiry of the patents shown in Annex 1 to the Agreement.

The Company is also authorized to repurchase at any time the right to benefit from these royalties for a sum of EUR 30 000 000, less the royalties already paid under this Agreement, with this total sum being shared between the two beneficiaries in proportion to their respective shares in the capital of the company on the date it was established. This sum of EUR 30 000 000 is indexed-linked to the Indice du Prix à la Production de l'Industrie des Services aux Entreprises - Matériel médicochirurgical et d'orthopédie-exportation zone Euro.

The rights allocated to Alain Carpentier and to Matra Défense in this way are non-transferrable.

As at 31 December 2011, since the marketing of the "Carmat" Artificial Heart had not started, no royalty was paid by the Company under the Agreement.

Paris and Neuilly-sur-Seine, 7 March 2011

The Auditors

PricewaterhouseCoopers Audit — Lison Chouraki

Pierre Riou"

20 FINANCIAL INFORMATION ON THE ASSETS, THE FINANCIAL POSITION AND THE RESULTS OF THE COMPANY

20.1 HISTORICAL FINANCIAL INFORMATION

20.1.1 Company accounts of CARMAT as at 31 December 2011 according to French standards

	BILAN ACTIF EN EUROS	31/12/2011			31/12/2010	31/12/2009
		Gross	Amortization & depreciation	Net	Net	Net
	Uncalled common stock (I)					
FIXED ASSETS	INTANGIBLE FIXED ASSETS (Notes 4.1 and 4.2)					
	Start-up costs					
	Development costs					
	Licenses, patents and similar rights	1 090 522	855 815	234 707	300 112	431 219
	Goodwill (1)					
	Other intangible fixed assets				24 000	
	Advances and payments on account					
	TANGIBLE FIXED ASSETS (Notes 4.1 and 4.2)					
	Land					
	Buildings					
	Technical plant, equipment and tooling	3 587 034	2 324 310	1 262 724	1 849 680	922 508
	Other tangible fixed assets	953 577	244 826	708 751	750 914	653 868
	Assets under construction	476 583		476 583	231 682	1 157 493
	Advances and payments on account					
	FINANCIAL FIXED ASSETS (2) (Notes 4.1 and 4.3)					
	Holdings accounted for on an equity basis					
	Other holdings					
	Other equity investments					
	Loans					
	Other financial assets	465 178		465 178	426 212	78 104
	TOTAL II	**6 572 894**	**3 424 952**	**3 147 942**	**3 582 600**	**3 243 191**
CURRENT ASSETS	STOCKS AND WORK IN PROGRESS					
	Raw materials, supplies					
	Work in progress - goods					
	Work in progress - services					
	Semi-finished and finished products					
	Goods					
	Advances and payments on account made for orders	486 860		486 860		
	DEBTORS (3)					1 916
	Trade receivables and other receivables					
	Other debtors (Note 4.4)	4 120 628		4 120 628	5 695 270	
	Subscribed capital – called, not paid in					1 880 508
	Marketable securities (Note 4.5)	10 039 822		10 039 822	7 074 426	461 455
	Cash instruments (Note 4.6)	17 066 499		17 066 499	2 000 000	
	Cash on hand	2 263 372		2 263 372	2 341 397	251 382
ACCRUALS	Pre-paid expenses (3) (Note 4.8.4)	300 960		300 960	353 995	213 270
	TOTAL III	**34 278 141**		**34 278 141**	**17 465 088**	**2 808 532**
	Bond issuance costs to be amortized (IV)					
	Bond redemption premiums (V)					
	Unrealized foreign exchange losses (VI)					
	GRAND TOTAL (I+II+III+IV+V+VI)	**40 851 034**	**3 424 952**	**37 426 083**	**21 047 688**	**6 051 723**
	(1) Including Lease rights					
	(2) of which less than one year			353 565		
	(3) Of which more than a year					

LIABILITIES		31/12/2011	31/12/2010	31/12/2009
EQUITY	Capital (of which, paid in: 165 112) (Note 4.7)	165 112	153 114	86 250
	Issue, merger and acquisition premiums (Notes 1 and 4.7)	52 625 318	25 779 449	8 163 750
	Excess of restated assets			
	RESERVES			
	Legal reserve			
	Statutory or contractual reserves			
	Regulatory reserves			
	Other reserves			
	Losses brought forward	- 12 458 488	-4 722 004	
	RESULT FOR THE PERIOD (profit or loss)	- 13 441 022	-7 736 485	- 4 722 004
	Capital grants			
	Tax allowable reserves			
	TOTAL I	**26 890 919**	**13 474 075**	**3 527 996**
OTHER EQUITY	Proceeds of issues of participating stock			
	Conditional advances (Notes 4.8.1)	3 743 141	2 018 892	546 304
	TOTAL II	**3 743 141**	**2 018 892**	**546 304**
PROVISIONS	Provisions for risks			
	Provisions for charges (Notes 4.3 and 6.1.3)	35 660	18 357	4 500
	TOTAL III	**35 660**	**18 357**	**4 500**
DEBTS (1)	FINANCIAL DEBTS			
	Convertible bond loans			
	Other bond loans			
	Loans from credit institutions			
	Bank loans and overdraft			
	Sundry loans and financial debts (Notes 4.4 and 4.81)	217 066	78 096	12 219
	Trade accounts payable and related payables			
	Tax and social liabilities			
	Liabilities secured to property and related liabilities (Note 4.4)	4 992 835	4 186 770	923 676
	Other debts (Note 4.4)	1 159 416	834 804	511 441
	FINANCIAL DEBTS			
	Convertible bond loans	380 547	328 089	525 586
	Other bond loans	6 498	5 448	
Accruals	Accrued income (1) (Note 4.8.4)		103 157	
	TOTAL IV	**6 756 362**	**5 536 364**	**1 972 923**
	Foreign exchange losses realized (V)			
	TOTAL GÉNÉRAL (I+II+III+IV+V)	**37 426 083**	**21 047 688**	**6 051 723**
	(1) Debts and deferred income of less than one year	6 539 296	5 536 364	1 972 923

INCOME STATEMENT	31/12/2011			31/12/2010	31/12/2009
	France	Export	Total	Total	Total
OPERATING INCOME (1)					
Sale of goods					
Sales of finished goods					
Sales of finished services					
NET TURNOVER					
Production left in stock					
Fixed asset production					
Subsidies (Note 5.1)			6 051 177	5 048 697	4 822 638
Write-backs of depreciation, provisions (and amortizations) and transfer of expenditure			50 576		
Other revenues					
TOTAL OPERATING INCOME (I)			**6 101 753**	**5 048 697**	**4 822 638**
OPERATING EXPENSES (2)					
Purchase of goods					
Inventory change (goods)					
Purchase of raw materials and other supplies					
Inventory change (raw materials and other supplies)					
Other purchases and external expenditure*			16 276 476	11 190 896	7 582 199
Taxes, fees and similar payments			95 056	72 454	39 184
Wages and salaries			3 057 107	2 497 603	1 950 008
Social security costs			1 099 853	448 869	454 250
Amortization and depreciation					
Buildings: amortization (Note 4.2)			1 496 234	1 227 259	701 501
Buildings: depreciation					
Current assets: depreciation					
Provisions (Note 6.1.3)			67 879	13 857	4 500
Other expenses			100 202	80 001	74 979
TOTAL OPERATING EXPENSES (II)			**22 192 807**	**15 530 940**	**10 806 620**
1 – OPERATING RESULT (I-II)			**-16 091 054**	**-10 482 243**	**-5 983 982**
SHARES IN RESULT FOR JOINT OPERATIONS					
Profits allocated or loss transferred (III)					
Loss or profit transferred (IV)					

INCOME STATEMENT (continued)	31/12/2011	31/12/2010	31/12/2009
FINANCIAL INCOME			
Financial income from equity interests (3)			
Income from other securities and fixed asset receivables			
Other interest receivable and similar income (3)	229 461	46 290	88 554
Write-backs of depreciation and provisions, and transfer of	272		
Positive exchange differences	319	1 126	75
Net proceeds from sales of marketable securities	10 431	2 391	1 713
TOTAL (V)	**240 483**	**49 807**	**90 341**
FINANCIAL EXPENSES			
Amortization, depreciation and provisions		272	
Interest expenses and similar charges (4)	141 504	63 346	12 278
Negative exchange differences	1 708	6 995	427
Net expenses from sales of marketable securities			
TOTAL (VI)	**143 212**	**70 614**	**12 705**
2 – FINANCIAL RESULT (V-VI)	**97 271**	**-20 807**	**77 636**
3 – EARNINGS BEFORE INTEREST AND TAX (I-II+III-IV+V-VI)	**-15 993 783**	**-10 503 050**	**- 5 906 346**
EXTRAORDINARY INCOME (Note 5.5)			
Extraordinary income from management operations			
Extraordinary income from capital operations	133 603	30 731	200 000
Write-backs of depreciation and provisions, and transfer of expenditure			
TOTAL (VII)	**133 603**	**30 731**	**200 000**
EXTRAORDINARY EXPENSES (Note 5.5)			
Extraordinary expenses from management operations		307	
Extraordinary expenses from capital operations	96 370	14 358	200 000
Amortization, depreciation and provisions			
TOTAL (VIII)	**96 370**	**14 665**	**200 000**
4 – EXTRAORDINARY RESULT (VII-VIII)	**37 234**	**16 066**	
Participation of staff in company results (IX)			
Income taxes (X) (note 5.3)	-2 515 527	-2 750 499	-1 184 342
TOTAL PRODUITS (I+III+V+VII)	**6 475 839**	**5 129 235**	**5 112 979**
TOTAL DES CHARGES (II+IV+VI+VIII+IX+X)	**19 916 862**	**12 865 720**	**9 834 983**
5 – BENEFICE OU PERTE (total des produits – total des charges)	**-13 441 022**	**-7 736 485**	**- 4722 004**

* Including fee from real-estate leasing
* Including fee from equipment leasing
(1) Including income from previous years
(2) Including expenses from previous years
(3) Including income from related enterprises
(4) Including interests from related companies

ANNEX TO THE FINANCIAL STATEMENTS

Annex to the balance sheet for the year ending 31 December 2011, totaling EUR 37 426 083 and to the income statement for the year ending 31 December 2011 presented in list form and showing zero turnover resulting in a loss of EUR 13 441 022.

The financial year commenced on 01/01/2011 and ended on 31/12/2011, a duration of 12 months which is identical to that of the comparative period.

The notes and tables presented in the following are an integral part of the financial statements for the period ending on 31 December 2011 as adopted by the Board of Directors on 8 March 2012. Figures are in Euros unless otherwise stated.

1. FEATURES OF THE YEAR

The activity of the company is exclusively focused on the research and development of an innovative product in the medical sector. No marketing is envisaged in the immediate short term. The company has benefited from Young Innovative Enterprise status since 2008.

During the year, the company proceeded to increase its capital on four occasions:

The exercising of 786 BCE-2009-2 warrants allowed an increase in capital to be carried out on 28 April 2011 of EUR 786, taking this from EUR 153 114.44 to EUR 153 900.44, through the issue of 19 650 ordinary shares with a face value of EUR 0.04, issued at a unit price of EUR 8, resulting in an issue premium of EUR 7.96 per share. As a result of this the issue premium was increased from EUR 25 779 449 to EUR 25 935 863.

The exercising of 95 BCE-2009-2 warrants allowed an increase in capital to be carried out on 19 June 2011 of EUR 95, taking this from EUR 153 900.44 to EUR 153 995.44, through the issue of 2 375 ordinary shares with a face value of EUR 0.04, issued at a unit price of EUR 8, resulting in an issue premium of EUR 7.96 per share. As a result of this the issue premium was increased from EUR 25 935 863 to EUR 25 954 768.

The company proceeded to raise new capital with retention of the preferential subscription rights decided upon by the Board of Directors on 11 July 2011 under powers delegated by the Combined General Meeting of 28 April 2011. The subscription period ran from 13 to 29 July 2011. This operation took the form of an increase in capital of EUR 11 068.36 and involved a gross issue premium of EUR 29 320 085.64 with the gross revenue generated from the issue amounting to EUR 29 331 154.

This increase in capital involved the creation of 276 709 new shares with a face value of EUR 0.04 to add to the previous 3 849 886 ordinary shares and took the capital from EUR 153 995.44 to EUR 165 063.80.

Taking into account a sum of EUR 2 661 621.48 for expenses linked to the increase in capital which were deducted from the issue premium through the application of the preferential accounting method, the net value of the issue premium as a result of this increase in capital was EUR 26 658 464.16.

The exercising of 48 BCE-2009-2 warrants allowed an increase in capital to be carried out on 26 September 2011 of EUR 48, taking this from EUR 165 063.80 to EUR 165 111.80, through the issue of 1 200 ordinary shares with a face value of EUR 0.04, issued at a unit price of EUR 8, resulting in an issue premium of EUR 7.96 per share. As a result of this the issue premium was increased from EUR 52 615 766 to EUR 52 625 318.

The company also opted for Research Tax Credit for the 2011 year. The first warrant was exercised in respect of the 2009 calendar year and renewed in 2010. The Research Tax Credit for the 2011 year was shown at EUR 2 566 103 in the entry “Tax on profits” of the income statement (details in Note 5.3 of this Annex) and appears under “Other debtors” in the balance sheet.

During the period the company benefited from repayable advances of EUR 1 724 249 and a subsidy of EUR 6 039 510 from the OSEO, which appears under the “Subsidies” item of the income statement (details in Note 5.1 of this Annex).

2. SIGNIFICANT EVENTS AFTER THE END OF THE REPORTING PERIOD

No event occurring after the close of the reporting period is liable to change the presentation or valuation of the items of the balance sheet or the income statement.

3. ACCOUNTING RULES AND METHODS
(Commercial Code – Articles L.123-12 and L.123-28)
(Decree No 83-1020 of 29/11/83) (Regional Accounting Office Regulation No 99-03: PCG)

The valuation methods for this period have not been changed from those used in the previous financial year.

3.1 GENERAL STANDARDS AND CONVENTIONS

The accounts for the period have been prepared and presented in accordance with the accounting regulations and by application of the principles laid down in Articles 120-1 et seq. of the General Accounting Plan 2005.

The basic method of valuation for the items shown in the accounts is that of historical cost.

The accounting conventions have been applied in accordance with the provisions of the Commercial Code, the Accounting Decree of 29/11/83 and the CRC regulations concerning the redrafting of the General Accounting Plan 2005 applicable as at the end of the period.

The general accounting conventions have been applied in accordance with the prudent person rule, on the basis of the following assumptions:

The business is a going concern;

- the accounting methods are consistent from one year to the next;
- the accounting periods are independent entities.

The assumption that the business is a going concern was made by the Chairman taking into account in particular the following points:

- the liquidity level, cash instruments and investment securities as at 31 December 2011, totaling EUR 29 369 693;
- payment of subsidies (EUR 3 033 000) and refundable advances (EUR 10 764 000) remaining to be paid between now and 2013 under the OSEO aid program signed in 2009.

3.2 SUPPLEMENTARY INFORMATION

3.2.1 Applied research and development costs
(Decree No 83-1020 of 29/11/83, Article 19)

Research and development costs are accounted for under expenses for the year in which they are incurred.

3.2.2 Intangible fixed assets
(Decree No 83-1020 of 29/11/83, Article 24-4)

Patents, licenses and other intangible fixed assets have been valued at their cost of acquisition, excluding the expenses incurred in acquiring them.

The methods and periods of depreciation used are as follows:

Category	Method	Period
Licenses and software	Straight line	1 to 3 years
Patents	Straight line	15 years

3.2.3 Tangible fixed assets
(Decree No 83-1020 of 29/11/83, Article 24-4)

The gross value of tangible items under the fixed assets corresponds to the value at which the goods were entered in the assets, with an allowance being made for the expenditure required to render these items usable but excluding costs incurred in their acquisition.

The methods and periods of depreciation used are as follows:

Category	Method	Period
Fixtures and fittings	Straight line	9 to 10 years
Technical plant	Straight line	3 years
Equipment and tooling	Straight line	2 to 6 years
Furniture	Straight line	8 years
IT equipment	Straight line	3 years

3.2.4 Financial assets

- Other equity investments

In 2010 the company entered into a liquidity contract with Dexia Securities France, the purpose of which is to increase the liquidity of transactions and smooth quotations for CARMAT shares without impeding the normal operation of the market and without introducing any error. To this end the company made available to Dexia a sum of EUR 300 000. Own shares acquired in connection with the execution of this liquidity contract are entered under financial assets at their acquisition price. If necessary, a provision is made for depreciation based on the average official stock market price for the final month prior to the end of the reporting period.

- Other financial assets

These are comprised of:

- obligatory deposits paid, which are shown at face value and
- the balance of the sums paid under the liquidity contract for own shares.

3.2.5 Receivables and payables
(Decree No 83-1020 of 29/11/83, Article 24-5)

Receivables and payables are shown at face value. If necessary, receivables are depreciated, by making a provision, to take into account the difficulties of recovery that are likely to occur. Any provisions for depreciation are determined by comparison between the acquisition value and the likely realization value.

3.2.6 Cash on hand in Euros

Cash on hand or at the bank is entered at face value.

3.2.7 Marketable securities

Marketable securities are shown in the assets at cost of acquisition. This cost of acquisition of marketable securities comprises the purchase price and the directly attributable expense.

Any provisions for depreciation are determined by comparison between the acquisition value and the likely realization value.

Marketable securities comprise certificates of deposit.

3.2.8 Cash instruments

These comprise the time deposit accounts shown under assets at acquisition value.

3.2.9 Cash and cash equivalents

For the purposes of the cash-flow statement, cash and cash equivalents are defined as being the sum of the “Marketable securities”, “Cash instruments” and “Cash on hand” items under the assets, to the extent that marketable securities and cash instruments are available in the very short term and do not present a significant risk of a loss in value in the event of a change in interest rate. An analysis of cash according to this definition is provided at the foot of the cash-flow statement.

3.2.10 Repayable advances made by public bodies

Advances received from public bodies to finance the research activities of the company and which are subject to repayment are shown under liabilities in the “Other equity – Conditional advances” item. The corresponding interest is shown in the balance sheet liabilities under Sundry loans and financial debts.

3.2.11 Subsidies

Subsidies received are recorded immediately the corresponding credit becomes certain, taking account of the conditions set at the time the subsidy was granted. Subsidies are recorded under income taking account, if necessary, of the corresponding rate of expenditure in order to adhere to the principle of matching of expenses with revenue.

3.2.12 Retirement indemnities

The amount of future payments for benefits to members of staff are valued according to an actuarial method, based on assumptions concerning the change in salaries, retirement age and mortality, and then these valuations are discounted to their present value. These commitments are the subject of provisions in the balance sheet liabilities.

3.2.13 Sub-contracting expenses

The progress of third-party sub-contract agreements for certain research services is assessed at the end of each reporting period in order to allow the cost of services already rendered to be recorded under accrued charges.

3.2.14 Share issue costs

By application of the preferential method, share issue costs are recorded in the balance sheet minus a deduction for the issue premium.

4. SUPPLEMENTARY INFORMATION ON THE BALANCE SHEET

4.1 SCHEDULE OF FIXED ASSETS

	Gross value at start of period	Additions	
		Line to line transfers	Acquisitions
Licenses, patents and similar rights (1)	946 873	27 000	116 649
Other intangible fixed assets	24 000		3 000
TOTAL	**970 873**	**27 000**	**119 649**
Technical plant, equipment and industrial tooling (2)	2 991 238	557 697	38 099
General plant, sundry fixtures and fittings	680 708		16 867
Office and IT equipment, furniture	210 605		45 397
Assets under construction (3)	231 682		802 598
TOTAL	**4 114 233**	**557 697**	**902 961**
Other equity investments (4)	31 576		1 002 379
Other financial fixed assets (5)	394 908		15 983
TOTAL	**426 484**		**1 018 362**
GRAND TOTAL	**5 511 590**	**584 697**	**2 040 972**

	Reductions		Gross value at end of period	Revaluation of original value at end of period
	Line to line transfers	Disposals		
Licenses, patents and similar rights (1)			1 090 522	
Other intangible fixed assets	27 000		0	
TOTAL	**27 000**		**1 090 522**	
Technical plant, equipment and industrial tooling (2)			3 587 034	
General plant, sundry fixtures and fittings			697 575	
Office and IT equipment, furniture			256 002	
Assets under construction (3)	557 697		476 583	
TOTAL	**557 697**		**5 017 194**	
Other equity investments (4)		916 426	117 529	
Other financial fixed assets (5)		63 242	347 649	
TOTAL		979 668	465 178	
GRAND TOTAL	**584 697**	**979 668**	**6 572 894**	

(1) This item includes a sum of EUR 411 284, accounted for as the share of the contribution in kind made on 30 September 2008, with a total value of EUR 960 000, relating to the contribution of patents.
(2) This item includes the commissioning of the clean room at a total cost of EUR 943 582. This item also includes a sum of EUR 548 716, accounted for as the share of the contribution in kind made on 30 September 2008, with a total value of EUR 960 000, relating to the contribution of equipment and tooling.
(3) The assets under construction item comprises equipment and industrial tooling valued at EUR 476 583.
(4) This item includes 1 395 own shares held in connection with the liquidity contract and valued at EUR 117 529.
(5) This item includes (i) the liquidities not invested in own shares as at the end of the period under the liquidity contract of EUR 236 035, and (ii) obligatory deposits totaling EUR 111 613, mainly comprising deposits under premises lease contracts.

4.2 SCHEDULE OF DEPRECIATION

Situations and movements for the period	Value at start of period	Allowances for the period	Reductions and write-backs	Value at end of period
Licenses, patents and similar rights	646 761	209 054		855 815
TOTAL	**646 761**	**209 054**		**855 815**
Technical plant, equipment and industrial tooling	1 141 558	1 182 752		2 324 310
General plant, sundry fixtures and fittings	95 935	71 576		167 511
Office and IT equipment, furniture	44 464	32 851		77 315
TOTAL	**1 281 957**	**1 287 180**		**2 569 137**
GRAND TOTAL	**1 928 718**	**1 496 234**		**3 424 952**

Breakdown of allowances for the period	Straight-line depreciation	Reducing balance depreciation	Exceptional depreciation	Depreciation for tax purposes	
				Allowances	Write-backs
Licenses, patents and similar rights	209 054				
TOTAL	**209 054**				
Technical plant, equipment and industrial tooling	1 182 752				
General plant, sundry fixtures and fittings	71 576				
Office and IT equipment, furniture	32 851				
TOTAL	**1 287 180**				
GRAND TOTAL	**1 496 234**				

4.3 SCHEDULE OF PROVISIONS

Provisions	Value at start of period	Additions Allowances	Reductions Amounts used	Reductions Amounts not used	Value at end of period
Sundry risks (1)		50 576	50 576		
Pensions and similar commitments (2)	18 357	17 303			35 660
TOTAL	**18 357**	**67 879**	**50 576**		**35 660**
Depreciation of other equity investments (3)	272			272	
TOTAL	**272**			**272**	
GRAND TOTAL	**18 629**	**67 879**	**50 576**	**272**	**35 660**
Including allowances and operational write-backs		67 879	50 576		
Including allowances and financial write-backs				272	

(1) Corresponds to the provision for the Research Tax Credit for 2010 made on 30 June 2011 and written back when the actual payment was in July 2011.
(2) See Note 6.1.3
(3) Corresponds to the allowance for depreciation of own shares

4.4 SCHEDULE OF MATURITIES OF RECEIVABLES AND PAYABLES

Schedule of receivables	Gross sum	1 year or less	More than 1 year
Income taxes	2 566 103	2 566 103	
Value Added Tax	1 541 479	1 541 479	
Sundry debtors	13 046	13 046	
TOTAL	**4 120 628**	**4 120 628**	

Schedule of payables	Gross sum	1 year or less	1 to 5 years	More than 5 years
Sundry loans and financial debts	217 066		217 066	
Trade accounts payable and related payables	4 992 835	4 992 835		
Staff and related payables	665 324	665 324		
Social security and other social bodies	492 560	492 560		
Other taxes and related payables	1 532	1 532		
Liabilities secured to property and related liabilities	380 547	380 547		
Group and associates				
Other debts	6 498	6 498		
TOTAL	**6 756 362**	**6 539 296**	**217 066**	

4.5 MARKETABLE SECURITIES

The total value of the Marketable securities shown under the balance sheet assets is EUR 10 039 822. These are made up of certificates of deposit totaling EUR 10 000 000. Five contracts are involved, signed in October 2011 and maturing on 25 October 2012. The corresponding interest accrued was calculated at year end in the sum of EUR 39 822. These contracts are negotiable on the market at any time. The buyback price is thus established as a function of the prevailing money market conditions at the time.

4.6 CASH INSTRUMENTS

Cash instruments are made up of time deposit accounts totaling EUR 17 000 000. Twenty-nine contracts are involved, signed in October 2011 and maturing on 25 January 2012 (EUR 5 000 000), 25 April 2012 (EUR 2 000 000), 25 July 2012 (EUR 4 000 000) and 25 October 2012 (EUR 6 000 000). The corresponding interest accrued was calculated at year end in the sum of EUR 66 499. These investments present no risks to the invested capital.

4.7 CAPITAL
(Decree No 83-1020 of 29/11/83, Article 24-12)

4.7.1 Composition of the share capital

Categories of shares	Face value in Euro	Number of shares			
		Opening	Created	Redeemed	Closing
Ordinary shares	0.04	3 827 861	300 301		4 127 795
TOTAL		**3 827 861**	**300 301**		**4 127 795**

The increase in capital, as a result of the exercising of BCE warrants, which took place on 28/04/2011, resulted in the creation of 19 650 ordinary shares with a face value of EUR 0.04 each.

The increase in capital, as a result of the exercising of BCE warrants, which took place on 19/06/2011, resulted in the creation of 2 375 ordinary shares with a face value of EUR 0.04 each.

The increase in capital of 08/08/2011, following the raising of capital with retention of the preferential subscription rights, performed on the Alternext market of NYSE Euronext Paris, resulted in the creation of 276 709 ordinary shares with a face value of EUR 0.04 each.

The increase in capital, as a result of the exercising of BCE warrants, which took place on 26/09/2011, resulted in the creation of 1 200 ordinary shares with a face value of EUR 0.04 each.

4.7.2 Changes in equity

	Equity at the start of the period	**13 474 075**
01/01/2011	BSA 2009-1 and BSA-LI warrants definitively collected	2 534
28/04/2011	Increase in capital through exercising of BCE warrants	157 200
19/06/2011	Increase in capital through exercising of BCE warrants	19 000
08/08/2011	Increase in capital following the raising of capital on the Alternext market of NYSE Euronext Paris	29 331 154
08/08/2011	Deduction of capital increase expenses	-2 661 621
16/09/2011	Increase in capital through exercising of BCE warrants	9 600
31/12/2011	Result for the period	-13 441 022
	Equity at the end of the period	**26 890 919**

4.7.3 Stock Warrants

BSA 2009-1

At the General Meeting and the meeting of the Board of Directors of 8 July 2009, 4 555 BSA 2009-1 warrants were issued, of which 1 519 BSA 2009-1 warrants were not assigned. These 1 519 BSA 2009-1 warrants not assigned lapsed on 08/01/2011. 506 BSA 2009-1 warrants issued were cancelled following the resignation of a director. As at 31 December 2011, there remained 2 530 BSA 2009-1 warrants conferring subscriptions rights to 63 250 new shares, representing 1.53% of the existing capital as at 31 December 2011, at a unit price of EUR 8.

Summary table of BSA warrants

	Issued	**Subscribed**	**Cancelled**	**Reserve**	**Exercised**	**Balance**	**Lapsing on**
BSA-2009-1 GM of 08/07/2009	4 555	2 530	2 025	0	0	2 530	08/07/19

4.7.4 Start-up Company Stock Warrants (BCE)

BCE 2009-1

At the General Meeting and the meeting of the Board of Directors of 8 July 2009, 3 037 BCE 2009-1 warrants were issued. The 3 037 BCE 2009-1 warrants were assigned at the meeting of the Board of Directors of 9 September 2009 and then fully subscribed. These BCE 2009-1 warrants confer subscription rights to 75 925 new shares, representing 1.84% of the existing capital as at 31 December 2011, at a unit price of EUR 8.

Subject to the approval by the forthcoming general meeting of shareholders of the arrangements for adjusting the conditions for the exercising of securities giving access to the capital issued by the company decided by the meeting of the Board of Directors on 8 September 2011 following the increase in capital with maintenance of the preferential subscription rights carried out on 10 August 2011, 25.58 new shares, at a unit price of EUR 8 per new share, would be granted by the exercising of one BCE warrant. However, in order to avoid fractional shares, the adjustment of the BCE warrants would be performed by multiplying the number of BCE warrants held by each holder on 20 September 2011 by a rate of 25.58, and the number of shares obtained would then be divided by 25 to give a number of BCE warrants that takes account of the adjustment. This number of BCE warrants would be rounded up to the next whole number. By application of this calculation, an additional number of 71 BCE-2009-1 warrants would be issued conferring subscription rights to 1 775 additional shares representing in total 1.88% of the capital existing as at 31 December 2011.

BCE 2009-2

At the General Meeting and the meeting of the Board of Directors of 8 July 2009, 7 408 BCE 2009-2 warrants were issued, fully assigned and subscribed, of which 929 have been exercised and 144 have lapsed and have been cancelled. The 6 335 BCE 2009-2 warrants subscribed and not exercised as at 31 December 2011 confer subscription rights to 158 375 new shares, representing 3.84% of the existing capital as at 31 December 2011, at a unit price of EUR 8.

Subject to the approval by the forthcoming general meeting of shareholders of the arrangements for adjusting the conditions for the exercising of securities giving access to the capital issued by the company decided by the meeting of the Board of Directors on 8 September 2011 following the increase in capital with maintenance of the preferential subscription rights carried out on 10 August 2011, 25.58 new shares, at a price of EUR 8 per new share, would be granted by the exercising of one BCE warrant. However, in order to avoid fractional shares, the adjustment of the BCE warrants would be performed by multiplying the number of BCE warrants held by each holder on 20 September 2011 by a rate of 25.58, and the number of shares obtained would then be divided by 25 to give a number of BCE warrants that takes account of the adjustment. This number of BCE warrants would be rounded up to the next whole number. By application of this calculation, an additional number of 158 BCE-2009-2 warrants would be issued conferring subscription rights to 3 950 additional shares representing in total 3.93% of the capital existing as at 31 December 2011.

4.7.4.1 Summary table of BCE warrants

	Issued	Subscribed	Cancelled	Reserve	Exercised	Balance	Lapsing on
BCE 2009-1 GM of 08/07/2009	3 037	3 037	0	0	0	3 037	09/09/19
BCE 2009-2 GM of 08/07/2009	7 408	7 408	144	0	929	6 335	08/07/19
BCE TOTAL	10 445	10 445	144	0	929	9 372	

4.8 OTHER DETAILS OF THE BALANCE SHEET

4.8.1 Conditional advances

The conditional advances item is comprised of repayable advances received from OSEO, the total amount of which as at the end of the period was EUR 3 743 141. Note 6.1.1 below states the repayment conditions of these advances. They are interest-bearing at the contracted rate of 5.59%. The interest accrued as at the close of the period was EUR 217 066 and is shown in the liabilities under the Sundry loans and financial debts item.

4.8.2 Accrued income

(Decree No 83-1020 of 29/11/83, Article 23)

Value of accrued income included in the following balance sheet items	Value
Other debtors	9 124
TOTAL	9 124

4.8.3 Accrued charges

(Decree No 83-1020 of 29/11/83, Article 23)

Value of accrued charges included in the following balance sheet items	Value
Sundry loans and financial debts	217 066
Trade accounts payable and related payables	2 940 092
Tax and social liabilities	944 882
Liabilities secured to property and related liabilities	371 397
Other debts	6 498
TOTAL	4 479 935

4.8.4 Accrued income and charges

(Decree No 83-1020 of 29/11/83, Article 23)

Accrued charges	Value
Operating expenses	300 960
TOTAL	300 960

The accrued charges item is comprised in particular of the following:

- the share of rent for the 2012 year billed in 2011, totaling EUR 117 005;
- the share of software license fees for the 2012 year billed in 2011, totaling EUR 39 852;
- an amount of EUR 85 911 corresponding to the difference between the invoices accounted for under research and development costs (costs of studies and subcontracting) and the percentage progress of the services concerned as at 31 December 2011.

Accrued income	Value
Operating income	NOT APPLICABLE
TOTAL	NOT APPLICABLE

4.8.5 Information on related enterprises

The following balance sheet items include sums in connection with related enterprises:

Trade accounts payable and related payables	709 676

5. SUPPLEMENTARY INFORMATION ON THE INCOME STATEMENT

5.1 Subsidies

The total amount of subsidies accounted for under income for the year is EUR 6 051 177 (2010: EUR 5 048 697). The breakdown of this is as follows:

- OSEO: total amount of EUR 6 039 510 accounted for in the income statement in the “Subsidies” line (2010: EUR 4 297 697). This amount corresponds to:
- the share of the subsidy collected on 3 January 2011 and corresponding to expense incurred in the period 1 January to 30 April 2011, or EUR 2 415 374;
- the subsidy collected on 13 September 2011 of EUR 3 624 136, relating to the period 1 May to 31 October 2011.
- Sundry subsidies: amount received of EUR 11 667 accounted for in the income statement in the “Subsidies” line (2010: EUR 1 000).

5.2 Applied research and development costs

Research and development costs are accounted for under expense. These were EUR 14 281 761 in 2011 compared with EUR 9 419 345 in the previous year.

5.3 Research Tax Credit

The income statement for the period shows a Research Tax Credit for a sum of EUR 2 515 527, broken down as follows:

- EUR 2 566 103 of Research Tax Credit for the period 01/01/2011 to 31/12/2011 compared with the EUR 2 819 267 shown for 2010;
- EUR -50 576 for regularization of the Research Tax Credit for the 2010 year, from a comparison between the amount accounted for as at the close of the 2010 financial year (EUR 2 819 267) and the amount reimbursed by the tax authorities (EUR 2 768 691).

5.4 Auditor’s fee

The total amount of auditors’ fees shown in the income statement for the year is EUR 34 260, broken down as follows:

- fees for statutory auditing: EUR 21 754;
- fees for activities required by law: EUR 2 402;
- fees for consultancy and services rendered in connection with activities directly linked to the statutory auditing function, as defined by the professional standards referred to in Article L.822-11 (II): EUR 10 104.

Additionally, total auditors' fees linked to increases in capital (deducted from “Issue Premiums”) were EUR 39 925, this sum being comprised in full of fees for the activities required by law. These fees billed for auditors’ tasks relate to work on checking the prospectus for the raising of capital that took place in July 2011.

5.5 Extraordinary Expenses
(Resolution of 27 April 1982)

Type	2011	2010
Extraordinary income		
- Property disposal		955
- Disposal of own shares	119 081	29 776
TOTAL	119 081	30 731
Extraordinary expense		
- Property disposal		913
- Disposal of own shares	81 847	13 445
- Fines and penalties		307
TOTAL	81 847	14 665

6. FINANCIAL COMMITMENTS AND OTHER INFORMATION

6.1 Financial Commitments

6.1.1 Commitments made

The total value of orders signed by the company as at the end of the period, for items not yet delivered or built, came to EUR 3 575 738.

A sum of EUR 1 724 249 by way of a repayable advance was received during the period, adding to the EUR 2 018 892 received prior to 1 January 2011 and making a total of EUR 3 743 141 received as at 31 December 2011. This sum is repayable subject to achieving sales of at least EUR 38 000 000. The OSEO agreement provides for supplementary payments if certain conditions are met, so that the total amount repayable could exceed the amount of the advance initially granted.

On 24 June 2008 the company signed a royalties agreement with Professor Alain Carpentier and Matra Défense, who owned 13.29% and 30.66% respectively of the shares as at 31 December 2011. Under this agreement, the company undertakes to pay Professor Alain Carpentier and Matra Défense 2% of the net income from sales of the “Carmat” Artificial Heart produced and distributed by Carmat SA, with this amount being shared between the two beneficiaries in proportion to their respective share in the capital of the company on the date it was established. These royalties will be payable every 6 months within 30 days of the end of each six-month period, following the first marketing of the “Carmat” Artificial Heart and up until expiry of the patents shown in Annex 1 to the agreement.

The company is also authorized to repurchase at any time the right to benefit from these royalties for a sum of EUR 30 000 000, less the royalties already paid under this agreement, with this total sum being shared between the two beneficiaries in proportion to their respective shares in the capital of the company on the date it was established. This sum of EUR 30 000 000 is indexed-linked to the Indice du Prix à la Production de l'Industrie des Services aux Entreprises - Matériel médicochirurgical et d'orthopédie-exportation zone Euro (Production prices index for industry and services to companies – Medico-chiurgical and orthopaedic material for export in the Euro zone).

The rights allocated to Professor Alain Carpentier and to Matra Défense in this way are non-transferrable.

As at 31 December 2011, since the marketing of the “Carmat” Artificial Heart had not started, no royalty had been paid by the company under the agreement.

6.1.2 Commitments received

The OSEO agreement provides for payment of a total sum of EUR 17 442 639 by way of subsidies, of which EUR 3 032 793 remains to be paid between now and 2013.

It also provides for payment of a total sum of EUR 14 507 324 by way of repayable advances, EUR 10 764 169 of which remains to be paid between now and 2013.

6.1.3 Pension and retirement commitments

The company has not signed a specific agreement on retirement commitments. These are therefore limited to the agreed retirement lump-sum payment.

By application of the preferential accounting method, the provision for retirement commitments has been accounted for as at 31 December 2011.

The calculation assumptions made were as follows:

- time-apportioned rights method in accordance with Regulation 2003 R-01 of the CNC;
- retirement at the initiative of the member of staff, at 62 years (non-management) or 65 years (management);
- salaried employee progression of 2% per annum;
- low staff turnover;
- discount rate of 4.6% per annum.

The overall amount of the provision was EUR 35 660 as at the end of the financial year ending 31 December 2011, an increase of EUR 17 303 over the period.

6.2 Other Information

6.2.1 Cash-flow statement

	As at 31/12/2011	As at 31/12/2010
Net result	**-13 441 022**	**-7 736 485**
Amortization and provisions	1 564 113	1 241 387
Write-backs of amortizations and provisions	-50 848	0
Capital gains/losses from asset sales	0	-42
Capital grants transferred to the result	0	0
Self-financing capacity	**-11 927 757**	**-6 495 140**
Tax and social liabilities	324 612	323 363
Trade accounts payable	858 523	3 065 597
Other debts	1 050	5 448
Accrued income	-103 157	103 157
Stocks and work in progress	0	0
Advances and payments on account made for orders	-486 860	1 916
Other debtors	1 574 642	-3 814 762
Trade receivables	0	0
Accrued charges	53 035	-140 725
Changes in cash position (Variation in Working Capital Requirements)	**2 221 845**	**-456 006**
Cash flow from operations	**-9 705 912**	**-6 951 146**
Acquisition of tangible fixed assets	-878 960	-1 114 205
Acquisition of intangible fixed assets	-143 649	-105 266
Acquisition of financial fixed assets	-38 694	-348 380
Proceeds from fixed asset disposals	0	955
Cash flow from investment operations	**-1 061 303**	**-1 566 896**
Increase in capital	11 997	62 597
ORA/BSA	0	0
Issue premium	26 845 869	15 619 966
Capitalization of current accounts	0	0
Loans and conditional advances	1 863 219	3 538 465
Cash flow from financing operations	**28 721 085**	**19 221 028**
Change in cash and cash equivalents	**17 953 870**	**10 702 986**
Opening cash and cash equivalents (Note 3.2.9)	**11 415 823**	**712 837**
Closing cash and cash equivalents (Note 3.2.9)	**29 369 693**	**11 415 823**

6.2.2 Information on the management

- Advances and loans to management

No loans or advances were made to the management of the company during the year, in accordance with the provisions of Article R. 123-197 of the Commercial Code.

- Management remuneration

The total remuneration paid to directors in the form of director's fees was EUR 100 000 for the financial year.
The total remuneration allocated to members of the management bodies was EUR 537 275 for the year and was broken down as follows:

Type	**2011**	**2010**
Gross salaries	533 444	503 179
Benefits in kind	9 780	
Bonuses	34 051	193 104
Total remuneration	**577 275**	**722 628**

6.2.3 Increases and reductions in future tax liabilities
(Decree No 83-1020 of 29/11/83, Article 24-24)

Type of temporary differences	**Value**
Allowable loss carry-forwards (1)	36 118 532

This amount comprises:

- the tax loss carried forward made during previous periods and available as at 1 January 2011, in the sum of EUR 17 591 697;
- the tax loss made in the 2011 financial year in the sum of EUR 18 526 835.

6.2.4 Average staffing levels
(Decree No 83-1020 of 29/11/83, Article 24-22)

Salaried staff	**2011**	**2010**
Managers	30	22
Supervisors and technicians	1	1
Employees	4	3
Total	**35**	**26**

6.2.5 Individual right to training

In connection with the individual right to training instituted by Law 2004-391 of 4 May 2004 concerning ongoing professional training, on 31/12/2011 the cumulative number of hours training in relation to rights accrued and not exercised was 1 414.50 hours.

20.2 PRO-FORMA FINANCIAL INFORMATION

None.

20.3 CHECKS ON THE ANNUAL HISTORICAL FINANCIAL INFORMATION

20.3.1 Report from the auditors on the financial statements of CARMAT as at 31 December 2010 according to French standards

To Shareholders
CARMAT SA
36, Avenue de l'Europe
78941 Velizy-Villacoublay

In compliance with the terms of your statutes and approval by the shareholders on 16 October 2008, we hereby present our report for the period ending on December 31, 2011, on:

- The audit of the company's annual CARMAT SA, as attached to this report;
- The justification of our assessments;
- The specific verifications and information required by law.

The annual accounts were approved by the Board of Directors. Our responsibility is to provide, based on our audit, an opinion on these accounts.

I - Opinion on the financial statements

We conducted our audit in accordance with professional standards applicable in France; these standards require the implementation of an audit to obtain reasonable assurance as to the financial statements' absence of material misstatement. An audit includes examining, on a sample or by other selection methods, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made and the overall presentation of the accounts. We believe that the evidence we have obtained is sufficient and appropriate basis for our opinion.

In our opinion, the financial statements, under the rules and French accounting principles, and accurate and fairly present the results of operations for the past year and the financial position and assets of the company at the end of this exercise.

II - Justification of our assessments

Pursuant to the provisions of Article L.823-9 of the Commercial Code relating to the justification of our assessments, we inform you that the assessments we process focused on the appropriateness of accounting principles.

Therefore, the assessments made, as a whole in the context of our audit of the financial statements contributed to the formation of the opinion expressed in the first part of the report.

III-Specific verifications and information

We have also carried out in accordance with professional standards applicable in France, specific verifications required by law.

We have no comment to make on the sincerity and consistency with the financial statements of the information in the report of the Board of Directors and the documents sent to shareholders on the financial position and financial statements.

In accordance with the law, we verified that the information concerning the identity of shareholders are disclosed in the management report.

Paris and Neuilly-sur-Seine, March 13 2012

The Auditors

Lison Choura — **PricewaterhouseCoopers Audit**
Pierre Riou

20.4 DATE OF THE MOST RECENT FINANCIAL INFORMATION

The most recent financial information available relating to the company is that for the financial year ended 31 December 2011.

20.5 FINANCIAL INFORMATION ON INTERMEDIARIES AND OTHERS

None.

20.6 DIVIDEND DISTRIBUTION POLICY

The company has not paid any dividends since it was established.

The company is focusing on growth and as at the date of registration of this “Document de Référence” had no plans to adopt a policy of paying regular dividends.

20.7 LEGAL AND ARBITRATION PROCEDURES

As at the date of registration of this “Document de Référence”, there were no governmental, legal or arbitration procedures under way (including any procedure of which the company was aware that was in abeyance or threatened), capable of having or having had, in the past 12 months, any significant effect on the financial situation or the profitability of the Company

20.8 SIGNIFICANT CHANGES IN THE FINANCIAL OR COMMERCIAL SITUATION

No significant change of the financial or commercial situation has taken place since the period ended on December 31 2011.

21 ADDITIONAL INFORMATION

21.1 COMMON STOCK

21.1.1 Value of common stock

As of the date of registration of this “Document de Référence”, the common stock was € 165 527.80. It is expected that the common stock should increase to € 165 597.80 following the next Board of Directors meeting for the reason that 70 BCE – 2009 – 2 were exercised by CARMAT’s employees and as a result, have created 1 750 new shares.

The common stock is divided in 4 139 945 ordinary shares with a nominal value of € 0.04 each, all of which are of the same category and fully paid up.

21.1.2 Securities not representing capital

As at the date of registration of this “Document de Référence”, no securities not representing capital existed.

21.1.3 Pledges, guarantees and collateral

As at the date of registration of this “Document de Référence”, and to the Company’s knowledge, there exists no pledge, guarantee or collateral taken on the Company’s equity.

21.1.4 Acquisition by the company of its own shares

At the date of registration of this “Document de Référence”, the company holds 1 395 of its own shares.

The Combined General Assembly of April 26 2011, in accordance with the provisions of Articles L.225-209-1 et seq., then in effect, of the Commercial Code authorized the implementation by the Board of Directors of a program to repurchase company shares up to a maximum of 10% of the capital of the company. This program will expire on the 26 October 2013 at the latest.

The terms and conditions of the repurchase program are as follows:

- The aggregate quantity of shares held by the Company will not exceed 10% of the total number of shares (this condition will apply to an amount of the common stock that would be adjusted, if needed, to take into account the operations which would impact the common stock during the mandate of this authorization, the acquisitions made by the Company cannot directly or indirectly result in its holding more than 10% of its own common stock);

- The number of shares taken in account to determine the limit of 10% referred to previously corresponds to the number of shares bought, minus the number of shares sold during the period of authorization;

- The unit price at which a share can be bought should not be over 250 € (transaction costs non-included). The boards of directors, holding the power of sub delegation, can nevertheless adjust the maximal unit price at which a share can be bought in the case of the incorporation of reserves, profits or share premium, of a merger, a capital contribution, or any other quantity of money which would be considered capitalization, and resulting in either an increase in the nominal value of the shares, or to the creation and attribution of free shares as well as in the case of a division of the nominal value of a share or a group of shares or any other operation affecting equity to take in account the value of those operations of the value of the share;

- Purchase, sale or transfer of shares may take place by any means on the market or by private sale, including by purchase or sale of blocks, under the conditions allowed by the market authorities. These operations may be carried out at any time, in accordance with the regulations in force.

This authorization is intended to allow the company to ensure liquidity and stimulate the market by means of a liquidity contract through the intermediary of an investment services provider in accordance with the professional charter of the AMAFI of 8 March 2011 acknowledged by the decision of 21 March 2011 of the Financial markets authority.

21.1.5 Other securities giving access to capital

- Start-up company share options ("**BCE**")

Type of security	**BCE-2009-1**
Number of BCE options issued and assigned	3 108 (1)
Number of BCE options issued and not assigned	0
Number of BCE options exercised	0
Balance of BCE options to be exercised	3 108
Date of the General Meeting	July 8 2009
Date of the meeting of the Board of Directors	September 9 2009
Exercise price per new share subscribed	8 €
BCE option exercise deadline	10 years from the date of assignment of the BCEs
Ratio	1 BCE-2009-1 option for 25 new CARMAT shares
General conditions of exercise	- 25% of BCE-2009-1 options may be exercised on the date of the first anniversary of the beneficiary joining the company, subject to actual and continued presence within the company at that date; - 75% of BCE-2009-1 options may be exercised on the basis of monthly periods in tranches of 1/36th from date of the first anniversary of the beneficiary joining the company over a period of 3 years, subject to actual and continued presence within the company at that date. Early exercising in the event of a share transfer agreement being entered into, with or without conditions precedent, resulting in a change in control of the company to the benefit of the transferee on the basis of a valuation in excess of EUR 100 million. As a result of the success of the listing of the company on the Alternext market of NYSE-Euronext Paris, according to the assessment of the meeting of the Board of Directors of 8 September 2010, 20% of BSA-2009-1 warrants that were not exercisable as at the date of the initial listing may be exercised early.
Number of new shares that may be subscribed	77 700
Maximum dilution of shares and % resulting from exercising of BCE options	77 700 shares or a maximum dilution of approximately 1,88% (2)

(1) After adjustments resulting from the increase in capital with preferential subscription rights performed in August 2011.
(2) Given a capital of 4 139 945 shares as at the date of registration of the present "Document de Référence".

Type of security	**BCE-2009-2**
Number of BCE options issued and assigned	7 566 [(1)]
Number of BCE options issued and not assigned	0
Number of BCE options exercised	1 415
Balance of BCE options to be exercised	5 406 [(2)]
Date of the General Meeting	July 8 2009
Date of the meeting of the Board of Directors	July 8 2009
Exercise price per new share subscribed	8 €
BCE option exercise deadline	10 years from the date of assignment of the BCEs
Ratio	1 BCE-2009-1 option for 25 new CARMAT shares
General conditions of exercise[(3)]	- 20% of the BCE-2009-2, will become exercisable at the first anniversary of Owner's entry into the Company, subject to his effective and sustained presence in the Company to that date; - 40% of the BCE-2009-2 will become exercisable by full monthly terms, with up to X number of BCE-2009-2 calculated using the following rule and, for the first time, after the Owner's the anniversary of arrival to the Company, subject to his effective and sustained presence in the Company to that date: - X = (40% of the BCE-2009-2 held by the Owner) multiplied by ((number of months since the Owner's first anniversary of presence in the Company) / 48); - 10% of the BCE-2009-2 will become exercisable after the completion and success of the first clinical trials of the artificial heart CARMAT before the end of second quarter 2012 (final medical report including aspects of study safety and endpoint), subject to an effective and sustained presence in the Company to that date; - 10% of the BCE-2009-2 will become exercisable after the completion and success of the first clinical implantation of CARMAT's artificial heart before the end of November 2012 (report from third party), subject to an effective and sustained presence in the Company to that date; - 6.5% of the BCE-2009-2 will become exercisable after the success of the clinical trials pivotal study of CARMAT's artificial heart (report from Scientific Committee), subject to an effective and sustained presence in the Company to that date; - 6.5% of the BCE-2009-2 will become exercisable after obtaining the CE Conformity Marking for CARMAT's artificial heart before, subject to an effective and sustained presence in the Company to that date; - 7% of the BCE-2009-2 will become exercisable after December 31 of the first year of commercialization of CARMAT's artificial heart before confirmed by the Board of Directors as conform with expectations in term of revenue and gross profit margin established by the Management's business plan and approved by the Board, subject to an effective and sustained presence in the Company to that date."
Number of new shares that may be subscribed	135 150
Maximum dilution of shares and % resulting from exercising of BCE options	135 150 shares or a maximum dilution of approximately 3,26% [(4)]

[(1)] After adjustments resulting from the increase in capital with preferential subscription rights performed in August 2011..
[(2)] Given the obsolescence of 10% of the BCE-2009-2
[(3)] Using a delegation approved by the shareholder on July 8 2009, the Board of Directors meeting of June 27 2009 decided, upon recommendation of the Compensation Board of the Company and under conditions of (i) the approval by owners of BCE 2009-2 (ii) the retroactive ratifying by the next Shareholder's General Assembly, to modify the details and procedure to enforce the BCE 2009-2 stipulated in Article 4 of the BylawsPlease refer to paragraph 17.2 for the terms modifying the delays and conditions to enforce the BCE-2009-2, if (i) the holder of BCE 2009-2 agree and (ii) the General Assembly retroactively approves that decision during its next meeting.
[(4)] Given a capital of 4 139 945 shares as at the date of registration of the present "Document de Référence".

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Type of security	**BCE-2012-1**

Number of BCE options issued and assigned	56 500
Number of BCE options issued and not assigned	0
Number of BCE options exercised	0
Balance of BCE options to be exercised	56 500
Date of the General Meeting	April 26 2012
Date of the meeting of the Board of Directors	June 27 2012
Exercise price per new share subscribed	108,483 €
BCE option exercise deadline	10 years from the date of assignment of the BCEs
Ratio	1 BCE-2012-1 option for 1 new CARMAT shares
General conditions of exercise	- 50 % of BCE-2009-2 options may be exercised on the basis of monthly periods in tranches of 1/48th from date of the first anniversary of the beneficiary joining the company over a period of 4 years, subject to actual and continued presence within the company at that date. - 17% of the BCE-2009-2 will become exercisable after the completion and success of the first clinical implantation of CARMAT's artificial heart before the end of November 2012 (report from third party), subject to an effective and sustained presence in the Company to that date. - 6.25% of the BCE-2009-2 will become exercisable after the success of the clinical trials pivotal study of CARMAT's artificial heart (report from Scientific Committee), subject to an effective and sustained presence in the Company to that date." - 16.25% of the BCE-2009-2 will become exercisable after obtaining the CE Conformity Marking for CARMAT's artificial heart before, subject to an effective and sustained presence in the Company to that date." - 17.5% of the BCE-2009-2 will become exercisable after December 31 of the first year of commercialization of CARMAT's artificial heart before confirmed by the Board of Directors as conform with expectations in term of revenue and gross profit margin established by the Management's business plan and approved by the Board, subject to an effective and sustained presence in the Company to that date
Number of new shares that may be subscribed	56 500
Maximum dilution of shares and % resulting from exercising of BCE options	56 500 shares or a maximum dilution of approximately 1,09% (1)

(1) Given a capital of 4 139 945 shares as at the date of registration of the present "Document de Référence".

- Stock subscription warrants (« **BSA** ») :

Type of Security	**BSA-2009-1**
Number of BSA warrants issued and assigned	3 096[(1)]
Number of BSA warrants issued and not assigned	1 579
Number of BSA warrants lapsed	2 025
Number of BSA warrants exercised	0
Balance of BSA warrants to be exercised	2 590
Date of the General Meeting	July 8 2009
Date of the meeting of the Board of Directors	July 8 2009
Exercise price per new share	8 €
BSA warrant exercise deadline	10 years from the date of assignment of the BSA
Ratio	1 BSA-2009-1 option for 25 new CARMAT shares
General conditions of exercise	- 25% of BSA-2009-1 warrants may be exercised on the date of the first anniversary of the beneficiary joining the company, subject to actual and continued presence within the company at that date; - 75% of BSA-2009-1 warrants may be exercised on the basis of monthly periods in tranches of 1/36th from date of the first anniversary of the beneficiary joining the company over a period of 3 years, subject to actual and continued presence within the company at that date. - Early exercise at the end of a period expiring 18 months after the establishment of the company if the beneficiary has occupied the position of Chairman of the company for a period expiring 18 months after the establishment of the company. - As a result of the success of the listing of the company on the Alternext market of NYSE-Euronext Paris, according to the assessment of the meeting of the Board of Directors of 8 September 2010, 20% of BSA-2009-1 that were not exercisable as at the date of the initial listing may be exercised early.
Number of new shares that may be subscribed	64 750
Number of new shares that may be subscribed	64 750 shares or a maximum dilution of approximately 1,56%[(2)]

(1) After adjustments resulting from the increase in capital with preferential subscription rights performed in August 2011.
(2) Given a capital of 4 139 945 shares as at the date of registration of the present “Document de Référence”.

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21.1.6 Common stock authorized but not issued

Resolution	Subject-matter of the resolution	Maximum nominal amount in Euros	Method of determining the issue price	Length of authorisation and expiry
7th	Delegation of authority to the Board of Directors to decide of the emission of shares giving access to the capital stock without the preferential subscription right for the profit any individual, compensated or not, having an activity for the Company and in its interests, with or without subordinations links, in particular employees, any consultant, any member of the Board of Directors or a member of a Board created by the Board of Directors (in accordance with the dispositions of the articles L.225 -129 and those following in the Code of Commerce and especially the articles L.225-129-2; L.225-135, L.225-138 and the articles L.228-91 to L.228-93 of the Code of Commerce).	5 000 (2260 already assigned)	At least equal to the weighted mean of volumes of the previous five trading days, preceding its fixation, if needed, diminished by a maximum of 20%.	26 October 2013 (18 months)

Note: the abovementioned ceilings may if necessary be raised by the additional value of shares or securities issued in order to preserve the rights of holders of securities giving access to capital in accordance with the provisions of the Commercial Code.

The integral text of the resolutions of the Combined General Meeting held on April 26, 2012 is available on the Company website.

21.1.7 Details of common stock subject to an option or a conditional or unconditional agreement making them subject to an option

None.

21.1.8 Table of changes in the company common stock since its creation

Date operation carried out	Type of operation	Increase in capital (€)	Issue premium or contribution (€)	Number of shares created		Face value of shares (€)	Cumulative number of shares			Common stock following the operation (€)
				Cat.O	Cat. A		Cat.O	Cat. A	Cat. O et A	
28/06/2008	Creation of the Company Increase in capital by cash contribution	40 000,00	0,00	39 998	2	1	39 998	2	40 000	40 000,00
30/09/2008	Increase in capital by contribution in kind	960 000,00	950 000,00	10 000	0	1	49 998	2	50 000	50 000,00
01/10/2008	Increase in capital by cash contribution	7 250 000,00	7 213 750,00	0	36 250	1	49 998	36 252	86 250	86 250,00
05/02/2010	Increase in capital by cash contribution	950 000,00	945 250,00	0	4 750	1	49 998	41 002	91 000	91 000,00
05/02/2010	Increase in capital by cash contribution by exercising BSA	21 478,00	0,00	0	21 478	1	49 998	62 480	112 478	112 478,00
07/07/2010	Division of face value by 25	0,00	0,00	0	0	0,04	1 249 950	1 562 000	2 811 950	112 478,00
07/07/2010	Conversion of A-shares into common stock	0,00	0,00	1 562 000	0	0,04			2 811 950	112 478,00

Date operation carried out	Type of operation	Increase in capital (€)	Issue premium or contribution (€)	Number of shares created	Face value of shares (€)	Cumulative number of shares	Common stock following the operation (€)
07/07/2010	Increase in capital by cash contribution	33 080,08	15 473 207,42	827 002	0,04	3 638 952	145 558,08
07/07/2010	Increase in capital by cash contribution by exercising of BSA	1 751,00	0,00	43 775	0,04	3 682 727	147 309,08
07/07/2010	Increase in capital with cash by *exercising* of convertible options	4 266,64	1 995 720,86	106 666	0,04	3 789 393	151 575,72
07/07/2010	Increase in capital by cash contribution by exercising of BSA	426,64	0,00	10 666	0,04	3 800 059	152 002,36
22/07/2010	Increase in capital by cash contribution	1 112,08	520 175,42	27 802	0,04	3 827 861	153 114,44
28/04/2011	Increase in capital with cash by exercising of BCE	786,00	156 414,00	19 650	0,04	3 847 511	153 900,44
19/06/2011	Increase in capital with cash by exercising of BCE	95,00	18 905,00	2 375	0,04	3 849 886	153 995,44
10/08/2011	Increase in capital by cash contribution	11 068,38	29 320 085,64	276 709	0,04	4 126 595	165 063,80
08/03/2012	Increase in capital with cash by exercising of BCE	166,00	33 034,00	4 150	0,04	4 130 745	165 229,80
27/06/2012	Increase in capital with cash by exercising of BCE	298,00	59 302,00	7 450	0,04	4 138 195	165 527,80
19/07/2012(1)	Increase in capital with cash by exercising of BCE	70.00	13 930.00	1 750	0.04	4 139 949	165 597.80

(1) This increase in capital will be acknowledged during the next meeting of the Board of Directors.

Supplementary table showing the changes in the Company common stock since its creation:

Date operation carried out	Type of operation	Number of shares issued	Face value of shares (€)	Issue premium or contribution (€)	Issue price or contribution (€)	Increase in capital (€), issue premium included
28/06/2008	Establishment of the company Increase in capital by cash contribution	1 000 000	0,04	0,00	0,04	40 000
30/09/2008	Increase in capital through contribution in kind	250 000	0,04	3,00	3,84	960 000
01/10/2008	Increase in capital by cash contribution	906 250	0,04	7,96	8,00	7 250 000
05/02/2010	Increase in capital by cash contribution	118 750	0,04	7,96	8,00	950 000
05/02/2010	Increase in capital by cash contribution by exercising of BSA	536 950	0,04	0,00	0,04	21 478
07/07/2010	Increase in capital by cash contribution	827 002	0,04	18,71	18,75	15 506 287,50
07/07/2010	Increase in capital by cash contribution by exercising of BSA	43 775	0,04	0,00	0,04	1 751,00
07/07/2010	Increase in capital by cash contribution by exercising of convertible options	106 666	0,04	18,71	18,75	1 999 987,50
07/07/2010	Increase in capital by cash contribution by exercising of BSA warrants	10 666	0,04	0,00	0,04	426,64
22/07/2010	Increase in capital by cash contribution	27 802	0,04	18,71	18,75	521 287,50
28/04/2011	Increase in capital with cash by exercising of BCE	19 650	0,04	7,96	8,00	157 200,00
19/06/2011	Increase in capital with cash by exercising of BCE	2 375	0,04	7,96	8,00	19 000,00
10/08/2011	Increase in capital by cash contribution	276 709	0.04	105,96	106	29 331 154,00
08/03/2012	Increase in capital with cash by exercising of BCE	4 150	0,04	7,96	8	33 200,00
27/06/2012	Increase in capital with cash by exercising of BCE	7 450	0,04	7,96	8	59 600,00
19/07/2012(1)	Increase in capital with cash by exercising of BCE	1 750	0.04	7.96	8	14 000.00
TOTAL		4 138 195			TOTAL	56 865 372,14

(1) This increase in capital will be acknowledged during the next meeting of the Board of Directors

21.2 MEMORANDUM AND ARTICLES OF ASSOCIATION

21.2.1 Corporate purpose (Articles of Association No 2)

The purpose of the company is, either directly or indirectly, both in France and abroad:

- research and development in the area of medical devices and equipment, specifically in the cardiovascular area, and in all areas of science directly or indirectly related thereto;
- production and marketing of (i) medical devices and equipment in the cardiovascular area and (ii) all associated technologies;
- acquisition or creation of technology products and licenses connected with the cardiovascular area;
- investment in French or foreign enterprises having activities that are similar or which complement those mentioned above;
- and, more generally, all operations of any kind - economic, legal, financial, civil or commercial, industrial, movables or real estate – that may be directly or indirectly connected with the abovementioned purpose or likely to contribute to the development thereof.

21.2.2 Provisions of the articles, a charter or regulation of the company concerning the members of the Board of Directors and the General Management (Articles of Association No's 15 – 21)

Article 15 – Board of Directors

The company is administered by a Board of Directors consisting of a minimum of five (5) and a maximum of eighteen (18) members subject to the derogation provided for by law in the case of a merger.

Article 16 – Appointment and removal of directors

I. Appointment / removal of directors

Over the life of the company, the directors are appointed by the Ordinary General Meeting. However, in the event of a merger or demerger, appointments may be made by the Extraordinary General Meeting. Their term of office is six (6) years. It finishes at the end of the Ordinary General Meeting of shareholders that approves the accounts for the period just closed and which is held in the year in which the term of office of said director expires.

Any outgoing director may be re-elected subject to meeting the conditions of this Article.

Directors may be removed and replaced at any time by the Ordinary General Meeting.

Actual persons with an age of more than eighty-five (85) years may not be directors; where a director passes this age during a term of office they are deemed to have officially resigned at the very next General Meeting. Any appointment made in breach of the above provisions is null and void, with the exception of those which may be made on an interim basis.

Any director who is an actual person must, at the time of appointment and throughout the term of office, meet the legal conditions in terms of the total number of directorships that the same person may hold in limited companies based in Metropolitan France, save as otherwise provided for by law.

A company staff member may only be appointed as a director if their contract of employment relates to an actual position within the company. The number of directors having a contract of employment with the company may not exceed one third of the directors in post.

II. Director in the form of a legal entity

Directors may be actual persons or legal entities. In the latter case, at the time of appointment, the legal entity is required to designate a permanent representative who will be subject to the same conditions and obligations and with the same civil and criminal liabilities as if they were a director in their own right, without prejudice to the joint and several liability of the legal entity that they represent. The permanent representative of a director in the form of a legal entity is subject to the age conditions relating to directors who are actual persons.

The term of office of the permanent representative designated by the legal entity appointed as director is the same as the term of office of the latter.

If the legal entity revokes the mandate of its permanent representative, it is required to notify the company without delay, by registered letter, of this revocation and the identity of its new representative. The same applies in the case of death or resignation of the permanent representative.

The designation of the permanent representative and the termination of their mandate are subject to the same publicity formalities as if they were a director in their own right.

III. Vacancies, death, resignation

In the event of a vacancy due to death or resignation of one or more directorships, the Board of Directors may proceed with interim appointments between two General Meetings.

When the number of directors falls below the legal minimum, the remaining directors must immediately call an Ordinary General Meeting in order to bring the Board up to strength.

Interim appointments made by the Board are subject to ratification by the very next Ordinary General Meeting. In the absence of ratification, resolutions passed and acts performed previously by the Board are no less valid.

Article 17 – Organisation and deliberations of the Board

I. Chairman

The Board of Directors includes among its members a Chairman who is an actual person, on pain of the appointment being null and void. The Board of Directors sets his remuneration.

The Chairman of the Board of Directors organizes and directs the work of the latter and reports on this to the General Meetings. He ensures that the company bodies are operating properly and in particular that the directors are capable of performing their duties.

In order to perform his duties the Chairman of the Board of Directors must be less than eighty-five (85) years of age. Where during his mandate the Chairman of the Board of Directors passes this age, he will be deemed to have officially resigned and the appointment of a new Chairman will take place under the conditions provided for in this Article.

The Chairman is appointed for a term that may not exceed that of his directorship. He may be re-elected.

The Board of Directors may revoke the appointment at any time.

In the event of the Chairman being temporarily impeded, or of his death, the Board of Directors may delegate the duties of Chairman to a director.

In the event of a temporary impediment this delegation is made for a limited period; it is renewable. In the event of death it is valid until the election of a new Chairman.

II. Board meetings

The Board of Directors meets as often as the interests of the company dictate at the invitation of the Chairman and at least every two (2) months.

Where it has not met for more than two (2) months, a minimum of one third of the members of the Board of Directors may request that the Chairman calls a meeting with a specific agenda.

The Chief Executive may also request that the Chairman calls a meeting of the Board of Directors with a specific agenda.

The Chairman is bound to act on requests made to him by virtue of the above two paragraphs.

Notices may be given by any means and even verbally.

The Board meets at the head office or at any other location (in France or abroad) indicated in the notice, under the chairmanship of the Chairman or, if he is impeded, the member designated by the Board to chair it.

The Chairman of the Board of Directors chairs the meetings. In the event of the Chairman being impeded, the Board appoints a chairman for each meeting from among the members present.

The Board may nominate at each meeting a secretary, who does not necessarily have to be member.

A register is kept which is signed by the directors taking part in the meeting of the Board.

The directors and any person called upon to attend the meetings of the Board of Directors are bound by secrecy in respect of information of a confidential nature indicated as such by the Chairman.

III. Quorum, majority

Deliberations of the Board will only be valid if at least half of the directors are present or deemed present under the arrangements laid down in the Bylaws where videoconferencing and other means of telecommunication are used.

Unless otherwise stipulated by these Articles of Association and subject to the arrangements laid down in the Bylaws where videoconferencing or other means of telecommunication are used, decisions are taken by a majority of votes of the members present or represented or deemed present.

Directors are deemed present for the purposes of calculating a quorum or majority where they take part by means of videoconferencing or other means of telecommunication under the conditions defined by the Bylaws of the Board of Directors. However, physical presence or representation will be necessary for all deliberations of the Board relating to adoption of the annual accounts and the consolidated accounts and for drawing up the management report and the group management report as well as for decisions concerning the removal of the Chairman of the Board of Directors, the Chief Executive and the Deputy Chief Executive.

Furthermore, half of the directors in post may oppose a meeting of the Board being held by videoconferencing or telecommunications means. Such opposition must be notified in the forms and by the deadline required by the Bylaws and/or in those that may be laid down in the legal or regulatory provisions.

IV. Representation

Any director may give another director written authority to represent him at a meeting of the Board.

Each director may hold only one proxy for the same meeting given by application of the above paragraph.

These provisions are applicable to the permanent representative of a director in the form of a legal entity.

V. Minutes of deliberations

The deliberations of the Board of Directors are recorded in minutes drawn up in a special register, numbered and initialled, and kept at the head office in accordance with the regulatory provisions.

VI. Observers

Throughout the lifetime of the company, the Ordinary General Meeting may proceed with the appointment of observers who may or may not be shareholders.

The number of observers may not exceed three (3).

Observers are appointed for a term of one (1) year. Their terms of office come to an end at the close of the Ordinary General Meeting of shareholders called to approve the financial statements for the period just ended and held in the year during which their terms of office cease.

Any outgoing observer may be re-elected subject to meeting the conditions of this Article.

Observers may be removed and replaced at any time by the Ordinary General Meeting without any compensation being due to them. The functions of the observers also cease with the death or incapacity of an observer who is an actual person, or dissolution or going into receivership in the case of an observer in the form of a legal entity.

Observers may be actual persons or legal entities. In the latter case, at the time of appointment, the legal entity is required to designate a permanent representative who will be subject to the same conditions and obligations and with the same civil and criminal liabilities as if they were an observer in their own right, without prejudice to the joint and several liability of the legal entity that they represent.

The task of the observers is to ensure the strict application of the Articles of Association and to present their observations at the meetings of the Board of Directors.

The observers perform a general and permanent task within the company through advice and monitoring. In the context of their duties they may make observations to the Board of Directors and request access to information at the head office of the company.

Observers must be invited to each meeting of the Board of Directors in the same way as directors.

Observers have only consultative powers on an individual or joint basis and have no voting rights on the Board.

Failure to invite an observer or to send documents prior to the meeting of the Board of Directors to an observer or observers may in no case constitute grounds for nullity of the deliberations of the Board of Directors.

Article 18 – Powers of the Board of Directors

The Board of Directors sets the business policy of the company and ensures that this is implemented.

Save for the powers expressly reserved to the meetings of shareholders and within the scope of the corporate purpose, the Board of Directors considers any matter relating to the proper operation of the company and through its deliberations deals with matters affecting it.

In its relations with third parties, the company is obligated even for acts of the Board of Directors that do not fall under the corporate purpose, unless it can prove that the third party knew that the act went beyond this purpose or that it could not be unaware of this bearing in mind the circumstances with the simple publication of the Articles of Association being insufficient to constitute such proof.

The Board of Directors will proceed with the controls and verification that it deems appropriate.

Each Director must receive the information necessary to perform his duties and may obtain from the general management all documents he considers useful.

The Board of Directors may decide to set up working groups to look into matters that the Board or its Chairman may refer to them.

Article 19 – General management – Delegation of powers

I. Organizational principles

In accordance with the legal provisions, general management of the company is undertaken under its responsibility either by the Chairman of the Board of Directors, or by another actual person appointed by the Board of Directors and bearing the title Chief Executive.

The choice between the two methods of undertaking general management is made by the Board of Directors which must inform the shareholders and third parties of this under the regulatory conditions.

The decision of the Board concerning the choice of method for undertaking general management is taken by a majority vote of the directors present or represented subject to the specific provisions of Article 17-III in the event of participation of directors in the meeting by videoconference or other means of telecommunication.

A change in the method for undertaking general management does not result in a change to the Articles of Association.

Where general management of the company is undertaken by the Chairman of the Board of Directors, the following provisions relating to the Chief Executive are applicable to him.

II. General management

Chief Executive

According to the choice made by the Board of Directors in accordance with the provisions of the above paragraph, the general management of the company is undertaken by the Chairman of the Board of Directors, or by an actual person, who may or may not be a director, appointed by the Board of Directors and bearing the title Chief Executive.

Where the Board of Directors chooses to separate the functions of Chairman and Chief Executive, it will proceed to appoint the Chief Executive, set his term of office, and decide on his remuneration and, as necessary, the limits to his powers.

A person over the age of eighty-five (85) years may not be appointed as Chief Executive. On the other hand, if a Chief Executive in post passes this age he is deemed to have officially resigned.

The Chief Executive may be removed at any time by the Board of Directors. Where the Chief Executive does not perform the role of Chairman of the Board of Directors, his removal may be subject to payment of compensation if this takes place without good reason.

The Chief Executive is invested with the widest powers to act in all circumstances on behalf of the company. He exercises these powers within the scope of the corporate purpose save for those which the law expressly reserves to the meetings of shareholders and to the Board of Directors.

He represents the company in its relations with third parties. The company is obligated even for acts of the Chief Executive that do not fall under the corporate purpose, unless it can prove that the third party knew that the act went beyond this purpose or that it could not be unaware of this bearing in mind the circumstances with the simple publication of the Articles of Association being insufficient to constitute such proof.

In respect of the shareholders and without this restriction being binding upon third parties, the Chief Executive may not take any decision on behalf of the company in the following areas without the prior authorization of the Board of Directors:

- the securing of loans or advances in order to acquire shares or securities of any subsidiary company except where such subsidiary is wholly-owned;
- the furnishing of guarantees on behalf of a subsidiary or to guarantee bank accounts;
- all investments in excess of EUR 250 000;
- all commitment in excess of EUR 100 000 and not provided for in the annual budget;
- hiring, laying off and amending of the contracts of employment of employees at management level;
- a change in the normal business of the company and in its development strategy;
- the disposal, transfer, licensing or pledging of any industrial or intellectual property or of any substantial asset;
- Approval of the budget and the strategic plan.

The Chief Executive may not take, without a prior decision of the Board of Directors by a qualified majority of three quarters of the directors making up the Board as at the date that the decision is taken:

- any decision to proceed with the transfer of any substantial asset or any intellectual/industrial property belonging to the company;
- Any decision to take a holding in a company quoted or unquoted.

Deputy Chief Executives

At the proposal of the Chief Executive, that this function be assumed by the Chairman of the Board of Directors or by another person, the Board of Directors may appoint one or more actual persons, known as Deputy Chief Executives, who may or may not be chosen from among the directors and shareholders, charged with assisting the Chief Executive. The number of Deputy Chief Executives may not exceed five. If the Deputy Chief Executive is a director, his term of office may not exceed that of his directorship.

A person over the age of eighty-five (85) years may not be appointed as Deputy Chief Executive. On the other hand, if a Deputy Chief Executive in post passes this age he is deemed to have officially resigned.

Deputy Chief Executives may be removed at any time by the Board of Directors at the proposal of the Chief Executive. Removal without just cause may give rise to damages.

By agreement with the Chief Executive, the Board of Directors decides on the scope and the duration of the powers granted to the Deputy Chief Executives. The Deputy Chief Executives have the same powers in respect of third parties as the Chief Executive.

Where the Chief Executive ceases or is presented from performing his duties, the Deputy Chief Executives will retain, unless otherwise decided by the Board, their functions and powers until the new Chief Executive is appointed.

The Board of Directors decides on the remuneration of the Deputy Chief Executives.

III. Delegation of powers

The Board of Directors may entrust to its agents, who may or may not be directors, the permanent or temporary duties it decides upon, delegate powers to them and set the remuneration it considers appropriate.

Article 20 – Directors' remuneration

The General Meeting may allocate to the directors, to compensate them for their work, by way of directors' fees, a fixed annual sum which this meeting determines without being bound by previous decisions. The value of this is posted to operating expenses.

The Board of Directors freely distributes among its members the overall sums allocated to the directors in the form of directors' fees; it may in particular allocate to the directors, who are members of working groups, an additional share over and above that of the other directors.

The Board of Directors may award exceptional remuneration for the duties or mandates entrusted to directors.

The Board of Directors may authorize the reimbursement of travel and subsistence costs and expenses incurred by the directors in the interests of the company.

Article 21 – Agreements between the company and a director, the Chief Executive or a Deputy Chief Executive

I. Agreements subject to authorization

Except for those relating to day to day operations and entered into under normal conditions, any agreement that is made, directly or through a nominee, between the company and one of its directors, Chief Executives and Deputy Chief Executives or a shareholder holding more than 10% of the voting rights in the company, or if a shareholding company or the controlling company according to Article L.233-3 of the Commercial Code is involved, must be referred for prior authorization by the Board of Directors.

The same applies to agreements in which one of the persons referred to in the above paragraph has an indirect interest.

Agreements entered into by the company and an enterprise are also subject to prior authorization if they are with an enterprise where the Chief Executive, one of the Deputy Chief Executives or one of the directors of the company, is the owner, partner with unlimited liability, manager, director, member of the supervisory committee or, generally speaking, an executive of the enterprise.

Such agreements must be authorized and approved in accordance with the statutory provisions.

II. Prohibited agreements

It is prohibited, on pain of nullity of the contract, for directors other than those who are legal entities, to contract for loans of whatever kind with the company, to have an overdraft granted by it, on a current or other account, or to have it act as guarantor or stand surety for undertakings by them to third parties.

The same prohibition applies to the Chief Executive, Deputy Chief Executives and permanent representatives of directors in the form of legal entities. And it also applies to the spouses, ascendants and descendants of the persons mentioned in this article and to any nominee.

III. Current agreements

Agreements relating to day to day operations and entered into under normal conditions are not subject to the legal process of authorization and approval. However, these agreements, unless as a result of their subject-matter or their financial implications they are not significant for any of the parties, must be notified by the interested party to the Chairman of the Board of Directors. A list and subject-matter of such agreements are notified by the Chairman to the members of the Board of Directors and to the Auditors at the latest on the day of the meeting of the Board to approve the financial statements for the year just closed.

Shareholders may also be sent the list and subject-matter of these agreements.

21.2.3 Rights, privileges and restrictions attaching to shares (Articles of Association No's 9 to 14)

Article 9 – Depreciation of the common stock

The common stock may be depreciated in accordance with the provisions of Article L.225-198 et seq. of the Commercial Code.

Article 10 – Settlement of shares

At the time of any increase in capital, cash shares are settled, upon subscription, for at least a quarter of their face value and, as appropriate, the full issue premium.

Settlement of the balance must take place on one or more occasions at the call of the Board of Directors and within five years of the date when the transaction becomes definitive in the case of an increase in capital.

Calls for funds are notified to the subscribers and shareholders at least fifteen days prior to the date set for payment by individual recorded delivery letter with acknowledgement of receipt.

A shareholder who does not make the required payments for shares on the due dates will be liable to pay the company, automatically and without prior warning, delay interest calculated on a daily basis from the due date at the legal rate for commercial court matters plus three points.

In order to obtain payment of these sums the company is entitled to take the enforcement action and apply the sanctions provided for by Article L.228-27 et seq. of the Commercial Code.

Article 11 – Form of shares

Shares may be registered or bearer shares, at the option of the shareholder. They may not take the form of bearer shares until they have been fully paid up.

The company is authorized to identify holders of bearer shares by simple request, to the body in charge of the clearing of securities, for the name or company name, nationality, year of birth or establishment, shareholders' addresses or number of shares held by each of them.

21.2.3.1 Article 12 – Transfer of shares – Rights and obligations associated with shares – Exceeding of limits

12.1 Transfer of shares

Shares are may be freely traded once issued in accordance with the procedures set out by law.

They remain tradable following the dissolution of the company and until liquidation is complete.

They give rise to a book entry and are transferred by a movement between accounts under the conditions and according to the procedures set out in the law and the rules in force.

The provisions of this Article are generally applicable to all securities issued by the company.

12.2 - Rights and obligations attaching to shares

Each share gives an entitlement to a share in the company profits in proportion to the percentage of the capital represented by it. It also gives an entitlement to participate, under the conditions set by law and by these Articles of Association, in the General Meetings and in votes on resolutions.

Ownership of a share entails unreserved compliance with the Articles of Association and decisions of the General Meeting of the company.

Shareholders are liable for the company's debts only to the limit of their contributions.

The rights and obligations attaching to a share follow the security whoever is the owner.

When it is necessary to own more than one share in order to exercise a particular right, in the event of an exchange, grouping, allocation of shares, increase or reduction in capital, merger or any company operation, the owners of isolated securities or of a number less than that required, may only exercise such right on condition that they personally arrange a grouping and, if necessary that they buy or sell the necessary number of securities.

12.3 – Exceeding of limits

Any actual person or legal entity, acting alone or together with others, for the purposes of Article L.233-10 of the Commercial Code, who comes to hold or ceases to hold a number of shares representing a fraction equal to 5%, 10%, 15%, 20%, 25%, 33.33%, 50%, 66.66% or 95% of the common stock or of the voting rights, is required to inform the company of this at the latest prior to the close of the fourth trading day of the stock market after the abovementioned holding limit is reached, stating the number of shares and votes held. A person or entity required to provide the abovementioned information will state the number of securities held giving access to capital and the voting rights attaching to these.

Furthermore, any actual person or legal entity, acting alone or together with others, who comes to hold a number of shares representing a fraction equal to 50% or 95% of the common stock or of the voting rights, is required to inform the French Financial Markets Authority of this at the latest prior to the close of the fourth trading day of the stock market after the abovementioned holding limit is reached, under the conditions set by the general regulations of the French Financial Markets Authority.

Failure to declare the excess shares according to the above conditions will result in the votes attaching to the fraction that should have been declared being removed in accordance with the provisions of the Commercial Code.

12.4 – Stock price guarantee

While the securities issued by the company are admitted for trading on the Alternext market of NYSE-Euronext Paris, any actual person or legal entity, acting alone or together with others, within the meaning of Article L.233-10 of the Commercial Code, who acquires or agrees to acquire a block of securities conferring upon them, taking into account the securities or voting rights already held, a majority of the capital or the voting rights in the company, is required to lodge a draft stock price guarantee under the legal and regulatory provisions in force.

21.2.3.2 Article 13 – Indivisibility of shares – Bare ownership - Usufruct

1 – Shares are indivisible with respect to the company.

Co-owners of undivided shares are represented at General Meetings by one of these or by a single proxy. In the event of disagreement, the proxy is appointed by a court at the application of the most diligent co-owner.

2 – The voting right belongs to the usufructuary at Ordinary General Meetings and to the bare owner at Extraordinary General Meetings. However, shareholders may agree any other distribution of the voting right at General Meetings. The agreement is notified by recorded delivery letter to the company which will be required to

apply this agreement at any meeting that takes place following expiry of a period of one month after such letter is sent.

The voting right is exercised by the owner where securities are pledged.

21.2.3.3 Article 14 – Double voting rights

The voting right attaching to capital or dividend shares is proportional to the percentage of the capital that they represent. Each share gives an entitlement to one vote.

However, a voting right that is double that conferred on other shares having regard to the percentage of the capital that they represent is attributed to all shares that are fully paid up and which can be shown to have been registered to the same shareholder for at least two (2) years. This right is exercised subject to the provisions of No 12.3 (3) of the Articles of Association.

The double voting right is also conferred, from the time they are issued, in the event of an increase in capital through capitalization of reserves, profits or issue premiums, upon registered shares in a scrip issue to a shareholder based on previous shares providing such an entitlement.

The transfer of a share as a result of succession, liquidation of community of property between spouses or donation between living persons to a spouse or a parent entitled to inherit does not result in loss of the right acquired and does not interrupt the periods provided for above.

The transfer of a share by an FCPR (Mutual Fund for Risk Investment) or an FCPI (Mutual Fund for Investment in Innovation) to any FCPR or FCPI that manages the management company, and to any FCPR or FCPI managed by a management company falling within the group of companies to which this management company belongs, and if it is a company, to any company falling within the group to which it belongs (for the purposes of Article L.511-7 (3) of the Monetary and Financial Code), does not result in loss of the right acquired and does not interrupt the periods provided for above.

A share transfer by the management company to holders of shares following the liquidation of an FCPR does not result in loss of the right acquired and does not interrupt the periods provided for above.

21.2.4 Conditions for changing shareholders' rights

The Articles of Association of the company do not make any special provision that derogates from general company law.

21.2.5 General Meetings of shareholders (Articles of Association No’s 24 to 31)

Article 24 – Quorum and majority

General Meetings deliberate under the conditions set by law.

The Ordinary General Meeting takes all decisions other than those reserved to the Extraordinary General Meeting by law and by these Articles of Association. It may not validly deliberate at the first calling unless the shareholders present or represented hold at least one fifth of shares with voting rights. At the second calling no quorum is required. It acts by a majority of the votes cast by the shareholders present or represented.

The Extraordinary General Meeting alone has the power to modify any of the provisions of the Articles of Association. It may not validly deliberate unless the shareholders present or represented hold at least one quarter of shares with voting rights at the first calling and one fifth of the shares at the second calling. In the absence of the latter quorum, the second meeting may be postponed to a later date not more than two months after that when it was originally called. It acts by a two-thirds majority of the votes cast by the shareholders present or represented.

Where videoconferencing or other means of telecommunications permitted by law is used under the conditions set out in Article 25 below, shareholders are deemed present for the purposes of calculating a quorum or majority where they take part by such videoconferencing or other means of telecommunications.

Article 25 – Calling of General Meetings

General Meetings are called either by the Board of Directors, or by the Auditors, or by a proxy appointed by a court under the conditions and arrangements laid down by law.

They take place at the head office or at any other location specified in the notice of the meeting.

Where shares in the company are not traded on a regulated market or if all its shares are not registered shares, the company is required to publish in the Bulletin des Annonces Légales Obligatoires (BALO - French Mandatory Legal Announcements Bulletin) at least thirty-five (35) days before the meeting a notice of such meeting containing the information required by the current regulations in force.

General Meetings are called by publication in a journal authorized to carry legal notices in the department where the head office is based and also in the Bulletin des Annonces Légales et Obligatoires (BALO).

However, the publications referred to in the above paragraph may be replaced by a call made, at the cost of the company, by normal or recorded delivery letter sent to each shareholder. Such a call may also be sent by electronic means of telecommunication employed under the regulatory conditions.

If this is decided by the Board at the time the meeting is called, any shareholder may also take part and vote in meetings by videoconference or by any other means of telecommunication allowing them to be identified, under the following conditions and according to the arrangements provided for by law and decree.

Any Meeting not duly called may be cancelled. However, cancellation may not take place if all shareholders are present or represented.

Article 26 – Meeting agenda

The agenda is set by whoever issues the notice of the meeting.

However, one or more shareholders representing at least 5% of the capital (or an association of shareholders meeting the legal conditions) are empowered to request, under the conditions laid down by law, the inclusion in the agenda of draft resolutions. Such a request must be accompanied by the text of the draft resolutions which may be accompanied by a brief outline of the reasoning.

These draft resolutions, which must be brought to the attention of the shareholders, are included in the agenda and put to a vote of the meeting.

The meeting may not deliberate on a matter that is not included in the agenda.

However, it may under any circumstances remove one or more directors and proceed with their replacement.

The agenda may not be changed if the meeting has to be called a second time.

Where the meeting is called upon to deliberate on changes to the economic or legal organization of the company, regarding which the works council has been consulted by application of Article L.2323-6 of the Labor Code, notice of this is sent to the latter.

Article 27 – Admission to meetings

Any shareholder may participate personally, by proxy, or by correspondence in General Meetings, of whatever kind.

A legal right of participation in General Meetings exists:

- for registered shares, as a result of the entry of these in the books of registered shares kept by the company at midnight at the start of the third working day prior to the meeting, Paris time;
- for bearer shares, as a result of the entry of these in the books of bearer shares kept by the authorized intermediary, at midnight at the start of the third working day prior to the meeting, Paris time;

The entry or registration of securities in the books of bearer shares kept by the authorized intermediary is acknowledged by a shareholding certificate issued by the latter.

However, the Board of Directors may reduce or remove these periods, provided that it is in the interests of shareholders.

Shareholders who have not settled their shares by making the payments due are not admitted to meetings.

Article 28 – Representation of shareholders and postal voting

I. Representation of shareholders

A shareholder may be represented by another shareholder or by their spouse.

Any shareholder may be empowered by other shareholders to represent them at a meeting, without any restriction other than those resulting from the legal provisions setting the maximum number of votes that the same person may hold in their own name and as a proxy.

II. Postal voting

Once the meeting has been called, a postal voting form and attachments will be sent, at the cost of the company, to any shareholder who makes a written request for this.

The company must comply with any request filed or received at the head office at the latest six days prior to the date of the meeting.

Article 29 – Officers for the meeting

Shareholder meetings are chaired by the Chairman of the Board of Directors or, in his absence, by a director delegated for this purpose by the Board. Failing this, the meeting elects a chairman itself.

Where a meeting is called by the auditors, a court-appointed proxy or by the liquidators, the meeting is chaired by whichever of these has called it.

The two attendees at such meeting holding the largest number of shares and accepting this function will act as vote tellers.

The officers for the meeting will appoint a secretary who may need not be a shareholder.

Article 30 - Minutes of deliberations

The deliberations of shareholder meetings are recorded in minutes drawn up by the meeting officers and signed by them.

These will state the date and place of the meeting, how it was called, the agenda, the composition of the meeting officers, the number of shares participating in the voting and the quorum achieved, the documents and reports submitted to the meeting, a summary of the proceedings, the text of the resolution voted upon and the outcome of these votes.

The minutes are recorded in a special register kept at the head office under the conditions laid down in the regulations.

If in the absence of a quorum, a meeting is unable to deliberate properly, minutes to that effect are drawn up by the officers of said meeting.

Article 31 – Shareholders' right of information and control

Before each meeting, the Board of Directors must make available to shareholders the documents necessary to allow these to speak in full knowledge of the facts and to come to an informed judgment on the functioning of the company.

Upon receipt of the communication referred to above, any shareholder will be entitled to submit written questions to which the Board of Directors will be required to respond during the meeting.

At any time, any shareholder has an entitlement to receive the documents that the Board of Directors is required, as the case may be, to keep available at the head office, or to send them, in accordance with the legislative and regulatory provisions in force.

21.2.6 Provisions of the articles, a charter or a regulation of the company that may have the effect of delaying, deferring or preventing a change in its control

The Articles of Association of the company do not make any special provision that derogates from general company law.

21.2.7 Passing of statutory limits (Articles of Association No 12.3)

Any actual person or legal entity, acting alone or together with others, for the purposes of Article L.233-10 of the Commercial Code, comes to hold or ceases to hold a number of shares representing a fraction equal to 5%, 10%, 15%, 20%, 25%, 33.33%, 50%, 66.66%, 90% or 95% of the common stock or of the voting rights, is required to inform the company of this at the latest prior to the close of the fourth trading day of the stock market after the abovementioned holding limit is reached, stating the number of shares and votes held. A person or entity required to provide the abovementioned information will state the number of securities held giving access to capital and the voting rights attaching to these.

Furthermore, any actual person or legal entity, acting alone or together with others, who comes to hold a number of shares representing a fraction equal to 50% or 95% of the common stock or of the voting rights, is required to inform the French Financial Markets Authority of this at the latest prior to the close of the fourth trading day of the stock market after the abovementioned holding limit is reached, under the conditions set by the general regulations of the French Financial Markets Authority.

Failure to declare the excess shares according to the above conditions will result in the votes attaching to the fraction that should have been declared being removed in accordance with the provisions of the Commercial Code.

21.2.8 Changes to the common stock (Articles of Association No 8)

1 – The common stock may be increased by any process and under any arrangements provided for by law.

Only an Extraordinary General Meeting is competent to decide on an increase in capital based on a report from the Board of Directors.

Shareholders have a preferential right in proportion to the number of shares they hold to subscribe to cash shares issued in order to increase the capital, which right may be waived on an individual basis. The Extraordinary Meeting may decide to withdraw this preferential right of subscription in accordance with the statutory provisions.

2 – A reduction in capital is authorized or decided upon by the Extraordinary General Meeting and may in no case adversely affect the equality of shareholders.

A reduction in capital to below the legal minimum may only be decided on the condition precedent of an increase in capital intended to bring this up to at least the legal minimum, unless the company converts into another form of company that does not require capital in excess of that after it has been reduced.

Failing this, any interested party may seek a legal order to dissolve the company. This may not be issued if as at the day when the court rules on the merits of the case, the situation has been normalized.

22 IMPORTANT CONTRACTS

The significant contracts to which the company is a party are as follows:

- A Royalties Agreement signed on 24 June 2008 and amended by an addendum of 5 February 2010 between CARMAT, Professor Alain Carpentier and Matra Défense (an EADS Group subsidiary): please refer to paragraph 19.1 “Royalties agreement”.
- An exclusive license agreement with the Pierre and Marie Curie University relating to patent No 8800381: please refer to paragraph 11.2.2 “Exclusive license agreements”.
- An exclusive license agreement with the Centre Technique des Industries Mécanique (*Technical Centre for the Engineering Industries*) relating to patent No 2760973: please refer to paragraph 11.2.2 “Exclusive license agreements”.
- A framework aid agreement for the CARMAT industrial Strategic Innovation project and a contract in support of the CARMAT project entered into on 24 July 2009 for a total sum granted by OSEO Innovation of EUR 33 006 398,

22.1 A FRAMEWORK AID AGREEMENT WITH OSEO

22.1.1 Initial conditions of the agreement

A framework aid agreement for the CARMAT industrial Strategic Innovation project and a contract in support of the CARMAT project entered into on 24 July 2009 for a total sum granted by OSEO Innovation of € 33 006 398, made up of € 18 499 074 in subsidies and € 14 507 324 of repayable advances.

The company acts as leader in the project and as a result receives all the repayable advances and € 17 442 639 in subsidies, with the balance being received by the other four partners involved in the project (DEDIENNE SANTE, PAXITECH, VIGNAL ARTRU INDUSTRIE and HEF R&D).

22.1.2 Relationship with the Partners

- DEDIENNE SANTE is responsible for the work relating to manufacture of parts in implantable PEEK. The agreement was entered into for a term of 4 years with effect from 7 July 2009. If DEDIENNE SANTE wishes to use the results in any area outside the medical domain it will have to obtain the prior authorisation of CARMAT which may not be refused without good reason.
- PAXITECH is responsible for the work relating to development of a portable fuel cell. The agreement was entered into for a term of 2 years with effect from 7 July 2009. If PAXITECH wishes to use the results in any area outside the medical domain it will have to obtain the prior authorisation of CARMAT which may not be refused without good reason.
- It is worth noting that, at the end of the aforementioned agreement, a new agreement was reached between CARMAT and PAXITECH, outside of the OSEO framework, on September 13 2011, in light of the progress realized in the first two years that allowed for the possibility to create the first industrial prototypes.
- HEF R&D is responsible for the work relating to qualification of the motor pump set. The agreement was entered into for a term of 6 years with effect from 7 July 2009. In return for ownership of the results of the work which will be claimed by CARMAT, the latter undertakes to grant HEF R&D an exclusive and transferrable usage right, free of charge and without time limit, to these results for application outside of the medical devices domain.
- VIGNAL ARTRU INDUSTRIE is responsible for the work relating to construction of the motor pump set. The agreement was entered into for a term of 4 years with effect from 7 July 2009. If VIGNAL ARTRU INDUSTRIE wishes to use the results in any area outside the medical domain it will have to obtain the prior authorisation of CARMAT which may not be refused without good reason.

Under the OSEO Innovation framework aid agreement, each of the partners has undertaken to provide the resources necessary to complete the development project for the total artificial heart and its components. In return, OSEO Innovation will pay its subsidies and repayable advances as a function of the execution of certain phases and key stages described below.

22.1.3 Key stages (EC) of the project, associated deliverables and specific conditions for the continuation of the project

Key stage	Provisional Date	Name of the determining deliverable	Specific condition for the continuation of the project.
EC1	T0+6 months	Documentation defining prosthesis D1 Mechanical and biological Documentation with a preliminary definition of prosthesis D1 Electronics and software	
EC2	T0 +12 months	D1 prototypes certificate of acceptance (2 non-clinical)	Presentation of a document certifying a contribution in equity* and in cash at least equal to the payments by OSEO at key stages EC2 and EC3
EC3	T0 +23 months	Pre-clinical trials documentation	
EC4	T0 +29 months	Pre-clinical trials documentation	Conditional authorization from the AFSSAPS and the CPP to progress to clinical trials in humans Presentation of a document certifying a contribution in equity and in cash at least equal to the payments by OSEO at key stage EC4
EC5	T0 +39 months	D1 clinical trials monitoring report First Article records of 8 clinical grade prototypes)	Presentation of a document certifying a contribution in equity* and in cash at least equal to the payments by OSEO up until the end of the R&D project
EC6	T0 + months	D3 system design documentation	Conditional authorization from the AFSSAPS and the CPP for the second series of clinical trials and consideration of the results.
EC7	T0+ 54 months	CE Conformity Marking documentation	

T0: effective start date of the project, or 1 June 2009.

* In the form of capital, convertible bonds, issue premiums or current accounts of associates grouped together by the corresponding tranche of the R&D programme. Payments under industrial agreements with no immediate consideration may be acceptable.

22.1.4 Maximum initial payments by type of aid, by partner and by key stage (in €) of the initial agreement

22.1.4.1 Subsidies (initial contract)

Maximum subsidy payment schedule for IR (Industrial Research)

(€)	Initial payment	Maximum payment per key stage							TOTAL payments
		EC1	EC2	EC3	EC4	EC5	EC6	EC7**	
CARMAT	4 072 638	3 193 168	3 519 904	3 624 136	2 873 627	159 166	0	0	17 442 639
HEF	177 700	235 275	170 175	5 032	34 413	59 725	29 381	0	711 700
VAI	0	0	0	0	0	0	0	0	0
PAXITECH	0	15 734	19 717	2 534	0	0	0	0	37 985
DEDIENNE	0	0	0	0	0	0	0	0	0

Maximum subsidy payment schedule for ED (Experimental Development)

(€)	Initial payment	Maximum payment per key stage							TOTAL payments
		EC1	EC2	EC3	EC4	EC5	EC6	EC7**	
CARMAT	0	0	0	0	0	0	0	0	0
HEF	0	0	0	0	0	0	0	0	0
VAI	118 750	68 750	4 500	4 500	9 000	9 000	0	0	214 500
PAXITECH	0	0	0	0	0	0	0	0	0
DEDIENNE	19 406	10 406	10 406	10 406	20 813	20 813	0	0	92 250

* Maximum amount paid for the key stage; ** Balance

22.1.4.2 Repayable Advances (initial agreement)

(€)	Initial payment	Maximum payment per key stage							TOTAL payments
		EC1	EC2	EC3	EC4	EC5	EC6	EC7**	
CARMAT	546 304	760 022	712 565	1 724 264	3 771 913	5 251 038	290 486	1 450 732	14 507 324

* Maximum amount paid for the key stage; ** Balance

22.1.4.3 Accounting and financial conditions

The subsidies are permanently acquired by the Company and will not be subject to reimbursement if the project were to succeed.

The subsidies are therefore accounted for on the “Operating subsidies” line of the income statement.

The repayable advances will need to be reimbursed by CARMAT within the explicit condition thereafter. The repayable advances are therefore accounted for in the liabilities of the balance sheet in the “Other Equity – Conditioned Advances” line.

The corresponding interest rates are present in the liabilities of the balances sheet in the “Loans and Diverse Financial Debts” section.

Starting when the Company will have realized a cumulated turnover of 38M€ on the commercialization of the total artificial heart issued from the project, CARMAT will have to pay OSEO Innovation as follows:

- 0.5% of its turnover during two years
- Then 1% of its turnover during two years
- Then 2% of its turnover during two years
- Then 2.5% of its turnover during one year, thus a cumulated seven years of payments or until the said payments reach a cumulated amount of 50M€ if reached before said seven years.

22.1.5 Addendum of framework agreement and OSEO-ISI beneficiary dated on June 15 2011

In order to account for the acquired results and of the evolution of the regulatory context resulting from discussions with the AFSSAPS, which imposed the necessity to freeze the definition of the implantable part of the prosthesis before the first clinical trials, CARMAT requested OSEO Innovation to modify the ISI agreement with CARMAT.

In a letter dated December 29 2010, OSEO Innovation has therefore given a favorable approval for modifying the following clauses of the agreement:

- The D2 prosthesis will be directly studied on Man (no implantation of the D1 prosthesis);
- The other systems (excluding the prosthesis) that participated to the prosthesis’ power supply and the patient’s monitoring will be external, only for hospital use at first, and then in a portable version to take home;
- Addendum of the agreement which transfer the activities linked to the D2 prosthesis towards the EC3 and EC4 periods.

As such, there have been significant modifications of the planning and cost profiles without impacting the actual monetary aid or the end-date of the project.

These modifications take into account the evolving context and allow for the continuation of the project without altering its original purpose.

These modifications have been subject to an addendum dated June 15 2011 to the CARMAT ISI framework aid agreement and to the beneficiary agreement of the CARMAT project.

The principal elements of the addendum concern the key stages and the payment of subsidies and repayable advances.

22.1.6 Dates and content of the key stages as revised by the addendum

Key stages	Date*	Deliverables
EC1	*December 1 2009*	*Documentation defining the prosthesis, mechanical and biological* *Document of preliminary definition of electronics and software*
EC2	*November 1 2010*	*First article records on 2 clinical grade prototypes*
EC3	*May 1 2011*	*Functional trials records*
EC4*	2nd semester of 2012	In vitro pre-clinical trials documentation
EC5*	1st semester of 2013	D1 clinical trials monitoring report
EC6*	2nd semester of 2013	D3 system design documentation
EC7*	1st semester of 2014	CE Conformity Marking documentation

In Italics are the achieved key stages at the date of registration of this "Document de Référence"

* The upcoming dates are provisional and correspond to the estimated achievement date and not to the payment of the corresponding amounts which arrive several weeks or months later after experts' review and administrative processing.

22.1.7 Revised maximum payments according to the addendum by type of aid and key stage (€):

22.1.7.1 Subsidies (addendum)

(€)	Initial payment	Maximum payment per key stage							TOTAL payments
		EC1**	EC2**	EC3**	EC4	EC5	EC6	EC7***	
Date****		01/12/09	01/11/10	01/05/11	2nd semester of 2012	1st semester of 2013	2nd semester of 2013	1st semester of 2014	
CARMAT	4 072 638	3 193 168	3 519 904	3 624 136	2 873 627	159 166	0	0	17 442 639

* Maximum payable amount for each key stage
** Stages already reached at the date of registration of this "Document de Référence"
*** Balance

22.1.7.2 Repayable advances (addendum)

(€)	Initial payment	Maximum payment per key stage							TOTAL payments
		EC1**	EC2**	EC3**	EC4	EC5	EC6	EC7***	
Date****		01/12/09	01/11/10	01/05/11	2nd semester of 2012	1st semester of 2013	2nd semester of 2013	1st semester of 2014	
CARMAT	546 304	760 022	712 565	1 724 264	3 771 913	5 251 038	290 486	1 450 732	14 507 324

* Maximum payable amount for each key stage
** Stages already reached at the date of registration of this "Document de Référence"
*** Balance

22.1.8 Financial and Scientific calendar established by the addendum

22.1.8.1 Stages reached

The first milestone of the OSEO Innovation agreement, EC1, was passed on 1 January 2010 with a delay of one month for the administrative and accounting formalities associated with the approval of the accounts as at 31 December 2009. In this connection on 22 March 2010 CARMAT received advance payments in the sum of € 760 022.93 and subsidies of € 3 193 166.93.

The second milestone of the OSEO agreement, EC2, was passed on 1 November 2010 with the manufacture of the first two artificial hearts. As a result of this on 31 December 2010 CARMAT received a repayable advance of € 712 565 and on 3 January 2011 a subsidy of € 3 519 904, of which € 1 207 587 are shown under assets as accrued income as at 31 December 2010. The payment of the OSEO Innovation subsidy for EC2 is slightly less than the sum provided for in the agreement due to the level of expenditure on system design activities being lower than expected.

The third milestone of the OSEO agreement, EC2, was passed on May 1 2011 on the basis of the functional trials' report. CARMAT received on September 13 2011 a repayable advance of 1 724 264 € and a subsidy for operating expenses of 3 624 136 €.

22.1.8.2 Amounts received and to be received

Thus, following validation of the first three key stages in connection with the OSEO-ISI project, CARMAT received:

- subsidies of € 4 072 638 shown under income for the 2009 financial year;
- net subsidies of € 4 297 697, accounted for as income for the 2010 financial year (€ 1 207 587 of which are shown under assets as accrued income as at December 31 2010), thus making a net total for subsidies collected of € 10 785 710 as at the date of registration of this "Document de Référence", € 2 415 374 of which remain to be entered under income for the 2011 financial year;
- total repayable advances of € 2 018 892 as at December 31 2010.
- total net repayable advances of 1 724 249 € and operating subsidy for 6 039 510 € for the 2011 period.

In summary, as at the date of registration of this "Document de Référence", there have been 14.4M€ of subsidies and 3.7M€ of repayable advances corresponding to the key stages EC1 to EC3.
There remains 3.0M€ to be received in subsidy and 10.8M€ in repayable advances corresponding to key stages EC4 to EC7.

REMAINING TO ACHIEVE AND RECEIVE

	2nd semester of 2012	1st semester of 2013	2nd semester of 2013	1st semester of 2014	TOTAL
Key stage	EC4	EC 5	EC 6	EC 7	
Content	Pre-clinical, in-vitro, trials documentation	Report of clinical trials monitoring	D3 system design documentation	CE Conformity Marking documentation	
Subsidies	2 873 627 €	159 166 €	-	-	3 032 793 €
Repayable Advances	3 771 913 €	5 251 038 €	290 486 €	1 450 732 €	10 764 169 €

22.2 OTHER IMPORTANT CONTRACTS

22.2.1 Conseil Général des Yvelines

An agreement between the Yvelines Departmental Council and the company for the financing of a research and development program by application of Article L.1511-5 of the Code général des Collectivités Territoriales (General Local Authorities Code) entered into on October 21 2009 for a sum of € 1 500 000.

All these subsidies have now been received by the company, with CARMAT having been paid € 300 000 on February 4 2011 corresponding to the balance of the € 1 500 000 in financing for the CARMAT R&D project from the Yvelines Departmental Council.

22.2.2 Edwards Lifesciences

An agreement with an initial term of one year, automatically renewable for one year at a time, was entered into on November 5 2010 by CARMAT and EDWARDS LIFESCIENCES, the world leader in the heart valves sector and in hemodynamic monitoring, for the use and supply of Carpentier-Edwards biological heart valves for the CARMAT total artificial heart.

22.2.3 Centre Hospitalier Universitaire de Nantes (« CHU de Nantes »)

A medical research collaboration agreement was entered into on January 6 2011 with retroactive effect to October 1 2009, between CARMAT and the Nantes University Hospital (Nantes CHU) under a research protocol entitled “Etude de compatibilité anatomique par implantation virtuelle” (*Study of anatomical compatibility by virtual implantation*). In fact, given the particular expertise of the CHU Nantes in the area of heart transplants, artificial heart transplantation and the diagnosis and monitoring of patients with severe cardiac insufficiency, CARMAT approached the CHU Nantes on order to run scientific research protocols aimed at:

- analysis of clinical and imaging data from patients with a transplant or for whom a heart transplant is indicated;
- a study to validate the virtual implantation procedure of the CARMAT prosthesis on “implanted” corpses.

Under this collaborative agreement, CARMAT undertakes to ensure that the CHU Nantes is reimbursed the costs associated with the protocols, or a total of € 17 043.

23 INFORMATION FROM THIRD PARTIES, DECLARATIONS BY EXPERTS AND DECLARATIONS OF INTEREST

None.

24 PUBLICALLY ACCESSIBLE DOCUMENTS

Copies of this “Document de Référence” are available free of charge from the company and from the company’s website (www.carmatsa.com) and from the website of the French Financial Markets Authority (www.amf-france.org).

Throughout the period of validity of this “Document de Référence”, the following documents, or a copy of such documents, may be consulted:

- the memorandum and Articles of Association of CARMAT;
- all reports, letters and other documents, historical financial information, assessments and declarations prepared by experts at the request of CARMAT and which are included in part or referred to in this “Document de Référence”;
- the historical financial information of CARMAT for the financial year prior to the publication of this “Document de Référence”.

All such legal and financial documents relating to the company and which must be made available to shareholders in accordance with the applicable regulations in force may be consulted at the company’s head office at 36 avenue de l’Europe – 78140 Vélizy Villacoublay.

In accordance with the terms of article 221-3 of the AMF General Regulations, the totality of the regulatory information, as defined by article 221-1 of the AMF General Regulation, is available on the Company’s website.

25 INFORMATION ON HOLDINGS

As at the date of the stamp on this “Document de Référence”, the company did not have any holdings in the common stock of other companies.

26 GLOSSARY

Actuator	A device that controls the movement of a fluid or a solid.
Acute heart failure	Sudden inability of the heart to ensure a sufficient blood flow to meet the needs of peripheral organs. The symptoms are severe at the outset. Often a consequence of a heart attack (see myocardial infarction) resulting in lesions on a region of the heart, or as a result of a sudden inability of the body to compensate for a chronic heart failure (see corresponding entry and Decompensation).
Angiotensin-converting-enzyme inhibitor (ACE inhibitors)	Drugs causing the dilatation of blood vessels which results in lower blood pressure
Annuloplasty	Surgical operation aiming at the correction of mitral insufficiency due to the dilatation of the mitral annulus.
ANSM	*Agence Nationale de Sécurité du Médicament et des produits de santé* (National Agency for the Safety of Medicines and Healthcare Products). It replaces AFSSAPS since mid 2011.
Antiaggregant	A type of medication that reduces platelet aggregation and prevents the formation of clots. Antiaggregants are effective in arterial circulation where anticoagulants have little effect. They are widely used in the primary and secondary prevention of cerebrovascular or cardiovascular thrombotic diseases.
Anticoagulant	Drug (usually warfarin) limiting the blood clotting and preventing the formation of clots by acting on coagulation factors other than platelet aggregation (please refer to previous entry). Commonly called blood- thinners. Its management is complex: too much creates a risk of hemorrhage, not enough may lead to a thromboembolic accident. Its prescription at high doses is required for all implantable devices that are not haemocompatible, although the drug itself may induce many complications.
Aorta	The aorta is the largest artery in the body. It leads from the left ventricle of the heart and supplies in particular oxygen to all parts of the body.
Atrium (atria)	One of the two small upper cavities of the heart in which blood enters the heart, as opposed to the ventricle, where it is pushed out of the organ. Each cavity communicates with the ventricle by an atrioventricular valve; the tricuspid valve on the right side, the mitral valve on the left side.
Autorisation d'Essai Clinique (AEC) Authorization of a Clinical Trial	Authorization of a Clinical Trial, delivered by the ANSM. It is one of the two authorizations required to undertake a biomedical research on human subjects (the other being the Ethics Committee approval – refer to Comité de Protection des Personnes).
Beta-blockers	Drug that reduces the rate and cardiac output to decrease blood pressure.
Bioprosthetic (valve) or bioprosthesis	An artificial valve intended to replace a heart valve and manufactured from haemocompatible animal tissue. By extension, also qualifies a medical device including biological components.
Cerebrovascular accident (CVA)	The rapid loss of brain function(s) due to disturbance in the blood supply to the brain. This can be due to ischemia (lack of blood flow) caused by blockage (thrombosis, arterial embolism), or a hemorrhage. As a result, the affected area of the brain cannot function, which might result in an inability to move one or more limbs on one side of the body, inability to understand or formulate speech, or an inability to see one side of the visual field. Commonly called stroke.
Cardiogenic shock	Failure of the myocardial pump to generate blood flow to the peripheral organs.
Chemically treated animal pericardium	A double-walled sack that contains the heart and the roots of the large blood vessels of animal origin (cow or pig) treated with glutaraldehyde known to be

	the least thrombogenic biomaterial even without anticoagulant treatment.
Chronic heart failure	Sudden inability of the heart to ensure a sufficient blood flow to meet the needs of peripheral organs. The main causes of chronic heart failure are angina and myocardial infarction, arterial hypertension, valvular disease and degenerative damage post-myocardial infarction. In all cases, there is a progressive destruction of the heart muscle due to a loss of contractile strength.
Clean room	Room or series of rooms where the particle concentration is controlled to minimize the introduction, generation, retention of particles indoors, usually for a specific purpose, industrial or research. Parameters such as temperature, humidity and relative pressure are also maintained at a specific level.
Comité de Protection des Personnes (CPP) Patient Protection Committee	Research Ethics Panel whose role is to make sure that any project of biomedical research on humans conducted in France meets various considerations (medical, ethical and legal) to ensure the protection of persons participating in this research.
Compliance	In medicine, the ability of an organic cavity to change volume under the influence of a change in pressure.
Coronary disease	Narrowing or blockage of the coronary arteries, usually caused by atherosclerosis, the buildup of cholesterol and fatty deposits on the inner walls of the arteries, which clogs the artery Without an adequate blood supply, the heart becomes starved of oxygen. If blood supply to a portion of the heart muscle is cut off entirely, a heart attack (injury to the heart muscle – see myocardial infarction) may occur.
Crédit d'Impôt Recherche (CIR) Research Tax Credit	Tax credit created to encourage research and business development efforts.
Decompensation (cardiac)	Sudden worsening of heart failure, requiring immediate hospitalization.
Destination Therapy	Definitive implantation, (as opposed to temporary e.g. as in a bridge to transplant indication).
Diastole	Relaxation of a cardiac cavity, to allow the blood to fill it.
Diuretics	Drug that eliminates the excess fluid and thus relieves the burden of the heart and prevents pulmonary edema.
Ex vivo	Said of tests that take place on corpses (also refer to: In vivo).
Etiology	Medical field that studies and analyzes the causes of diseases.
FDA	Food and Drug Administration, US Agency which authorizes marketing of medicinal products and medical devices in the United States.
Full human blood	The blood and all of its components including, plasma, red blood cells, white blood cells and platelets.
Fuel cell	Cell in which electricity is produced through the oxidation on an electrode of a reduction fuel (for example hydrogen) coupled with the reduction on the other electrode of an oxidant, such as oxygen from the air.
Graft	Organ or tissue harvested from a donor for transplantation in a recipient.
Haematocyte	Red blood cell.
Haemocompatibility	Quality of the biological compatibility of non-living materials, used in a medical device, in contact with the blood and other biological organs.
Hemolysis	Destruction of red blood cells releasing hemoglobin in the blood plasma, thereby reducing their ability to carry oxygen.
HIL simulator	Hardware In the Loop: Real-time Simulator that makes computers believe they operate the real system.
Hyperlipidemia	Pathology caused by a high amount of fat in the blood.

Hypertension	Cardiovascular disease characterized by a higher than normal level of blood pressure and resulting in an increase in the volume of the left ventricle.
Hypertrophy	The abnormal increase in the volume of an organ or tissue due to the enlargement of its component cells.
IDE (Investigational Device Exemption)	Authorization from the FDA which allows an investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification [510(k)] submission to the Food and Drug Administration (FDA).
Immunosuppressant	Agent (such as cyclosporine) limiting the immune response of the body to reduce the risk of rejection following transplantation of an organ.
Incidence	Number of new cases of a pathology observed for a defined period (e.g. each year) in a defined population (e.g. in a specific country). It is distinguished from the prevalence which counts all cases (new or not) at a given time.
Inotrope	Agent that alters the force or energy of muscular contractions: positively inotropic agents increase the strength of muscular contraction. Dependency to inotropes signals end-stage heart failure.
In silico	Tests taking place on computer and/or by numerical simulation.
In vitro	Tests that take place outside of the body, in the laboratory or on test benches. Originally these tests were in glass tubes.
In vivo	Tests that occur in a living organism. (see also ex vivo)
Ischemia	Decrease of the arterial blood supply to a body.
ISO norms	Standards established by the International Organization for Standardization (ISO) in order to ensure reliable services and products with good quality.
Marquage CE CE Marking	A mandatory conformity mark for products placed on the market in the European Economic Area (EEA). With the CE marking on a product, the manufacturer declares that the product conforms to the essential requirements of the applicable EC directives. (respect of formal conditions in terms of safety, efficiency, manufacturing, traceability...).
Mitral (valve)	Heart valve separating the left atrium from the left ventricle.
Myocardial infarction	Necrosis (cell death) of a portion of the heart muscle. Commonly called heart attack, it occurs when one or more coronary arteries become clogged. The myocardium (the muscle that make up the heart) is then not irrigated any longer by this (or these) artery (s), which may lead to short-term death if the damage is extensive.
New York Heart Association (NYHA) classification	Scale used to quantify and monitor the functional (activity) impact of heart failure in an individual.
Ordre des Médecins French Physicians' Association	Professional, administrative and judicial body for the defense and regulation of the medical profession.
Orthotopic	Organ transplant in its normal anatomical position.
OSEO Innovation	Program of the public company OSEO to promote innovation through financial guarantees and partnership activities.
Prevalence	The proportion of a population found to have a condition (typically a disease or a risk factor). It is arrived at by comparing the number of people found to have the condition with the total number of people studied.
Product Lifecycle Management (PLM)	Describes the software used to create and maintain the definition of products throughout their life cycle, from when the offering is made until the end of their life. PLM covers the management of the definition of products, including

	configuration management, development management and project management.
Polyurethane	A plastic material obtained by polymerization.
Proteinic	With regards to proteins.
Pulmonary artery	Artery that carries blood from the heart to the lungs.
Pulmonary edema	Fluid accumulation in the airspaces of the lungs through the wall of capillaries (small vessels). Acute pulmonary edema is an absolute emergency, often a dreadful consequence of cardiac decompensation (see corresponding entry).
Pulmonary embolism	Situation where a blood clot clogs a pulmonary artery.
Pulsatile	Pulsed animation to the rhythm of the heart beat.
Sepsis	A potentially deadly medical condition that is triggered by an infection. The body develops an inflammatory response to microbes in the blood, skin, or other tissues. A popular term for sepsis is blood poisoning.
Stasis	In medicine, the term refers to the abnormal stagnation of blood in an organ.
Systole	Contraction of cardiac cavity, enabling the ejection of the blood it contains.
Telemetry	A technology that allows data measurements to be made at a distance. It can monitor physiological or technical parameters.
Thrombosis	Thrombosis is the formation of a blood clot (thrombus) inside a blood vessel, obstructing the flow of blood through the circulatory system.
Thromboembolism	A clot (thrombus) that breaks free and begins to travel around the body is known as an embolus. Thromboembolism is the combination of thrombosis and its main complication, embolism.
Thombogenic, thrombogenicity	Favoring the formation of thrombi (blood clots).
Total artificial heart (TAH)	Artificial cardiac prosthesis aiming to replace the native heart. It differs from ventricular assist devices that are implanted in parallel to a diseased ventricle.
Transplantation	Surgical operation that replaces a failed organ with a functional one harvested from a donor.
Vasodilatators	Drug that relaxes the vessels to increase the supply of blood and oxygen to the heart without increasing his work.

27 TABLE OF REFERENCES

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