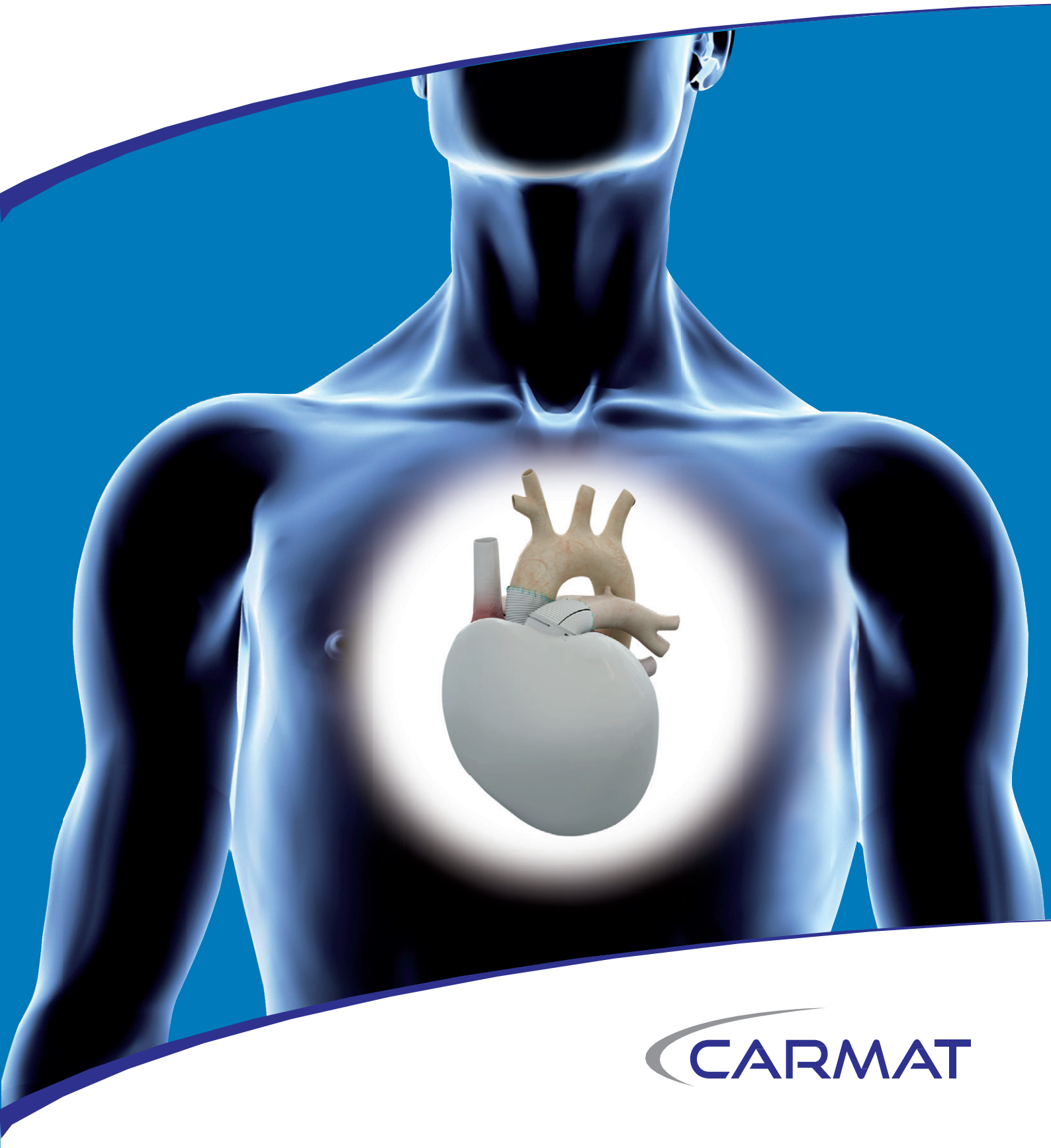
2013 REGISTRATION DOCUMENT

INCLUDING THE ANNUAL FINANCIAL REPORT



CARMAT

CONTENTS

THE CONTENT OF THE ANNUAL FINANCIAL REPORT IS IDENTIFIED IN THE SUMMARY TABLE WITH THE HELP OF THE PICTOGRAM. FAR

2013 REGISTRATION DOCUMENT

INCLUDING THE ANNUAL FINANCIAL REPORT

► The registration document may be viewed and downloaded from the website **http://www.carmatsa.com/**

DISCLAIMER

The English version of the 2013 registration document is a free translation of the official "*document de référence 2013*" prepared in France and filed with the *Autorité des marchés financiers* on 17 March 2014 under number D.14-0145. All information indicated herein as having been provided as of the date of this registration document shall therefore be understood to have been provided as of 17 March 2014. All possible care has been taken to ensure that the translation is an accurate representation of the original French version. However, in all matters of interpretation of information, views or opinions expressed therein, the original version of the 2013 registration document in French takes precedence over this translation.

GENERAL REMARKS

In this registration document, the terms “CARMAT” or the “Company” shall mean the company, CARMAT.

This registration document 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 registration document could be affected by known and unknown risks, or by uncertainties linked specifically to the very nature of clinical trials, the regulatory, economic, financial and competitive environment or by other factors which could lead to the Company’s future results, performance and achievements being significantly different from the objectives that have been formulated or suggested here.

In particular, these factors may include those set out in Chapter 3 Risk Factors, of this registration document. It is therefore possible that these objectives and avenues for development may not be achieved, and the statements or information in this registration document may turn out to be erroneous. As such, the Company will under no circumstances be required to provide updates, subject, that is, to the applicable regulations, and in particular the General Regulations for the French Financial Markets Authority (AMF).

This registration document 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 other 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 that 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 3 Risk Factors in this registration document. 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.

In addition, other risks, not currently identified or considered as non-significant by the Company, could have the same negative effect.

Drawings, images, graphics and photographs used in this document are purely for illustration purposes, and shall in no case constitute a commitment of any kind on the part of CARMAT.

To assist the reader’s understanding, this registration document has a glossary attached. Words identified by an asterisk “*” when they first appear can be found in this glossary. A summary of references used in the document and their sources is provided at the end of the document.

MESSAGE FROM THE CHAIRMAN

Jean-Claude CADUDAL

The artificial heart is an ambitious yet promising project: we must remain steadfast and, most importantly, we must remain confident, confident, and again, confident, in the success of CARMAT.

What conclusions do you draw from 2013?

It was an extraordinary year. With the teams of the Georges Pompidou European Hospital, guided by Professor Carpentier, we wrote one of the most beautiful pages in the history of cardiovascular surgery. For the first time ever a bioprosthetic heart* beat in the chest of a human being. In addition, four internationally renowned cardiology centers showed their formal interest in CARMAT. These positive events allowed the Company to take a key step forward in our contractual relationship with Bpifrance*. CARMAT is thus well positioned to focus on the important milestones of 2014 and 2015. Three centers are now trained and qualified in France. The training plan will continue throughout 2014, both in France and abroad, in order to complete the clinical trials needed for CE marking and commercialization as soon as possible.

I would like to pay tribute to everyone who was so involved in this extraordinary project, to our employees, to our industrial partners, to our shareholders both small and large, who showed their confidence in us, and to the authorities who understood the scope of the challenges.

I would like to pay tribute to everyone who was so involved in this extraordinary project, to our employees, to our industrial partners, to our shareholders both small and large, who showed their confidence in us, and to the authorities who understood the scope of the challenges.

I would also like to pay my deepest respects to the first patient ever to be given a CARMAT artificial heart, a courageous volunteer and endearing individual who will forever be a part of medical history for the benefit of all humanity.

What was the most powerful moment of the year, the first human implant, like for you?

Intellectually we were quite confident. We had validated everything we thought needed to be examined in the lab and using animals. But there is always some doubt. What if there was something we did not anticipate? Paradoxically, in times of uncertainty, the people who are the most exposed are the ones who give us confidence. I remember when Professor Latrémouille said to me, with his hand on my shoulder: "but you'll see, everything will be fine…". There is always positive stress that remains after the implantation period and which pushes us forward.

We knew that the medical and technical teams had been working towards this for many months, and that the components of the prosthesis had been tested for durability over several years: we had a lot of objective data that gave us confidence on the big day. It was a very emotional moment when the patient woke up after the operation.

Do you have a few words to say on the financial performance during the year?

There are two essential financial indicators that we must bear in mind concerning this fiscal year. First, our operating expenses are under control and their level is down compared to 2012, reflecting the gradual change from research to clinical development and production, as anticipated in our development strategy.

The second concerns our financial structure. On December 31, 2013 we had more cash than one year ago (€16.9 million versus €11.1 million), allowing us to approach 2014 with confidence. This cash level resulted mainly from financing received from Bpifrance, since we had reached key milestones in the project, and from the issue of share subscription warrants (BEA) as part of the equity line set up with Kepler Cheuvreux.

In view of these achievements, what are the outlooks and main challenges ahead for 2014?

There are two important issues that we need to successfully manage in 2014. Obviously, we will rigorously pursue clinical trials in order to maximize our chances of receiving CE marking and the commercialization of the CARMAT heart. On an industrial level, we will enter a phase in which we will need to manufacture more prostheses to guarantee the progress of the project. To do this, we have not only organized appropriate internal resources but we have also made arrangements with all our industrial partners in order to have adequate resources available.

These are thus the two focuses that we must monitor very closely in 2014. We are confident in our industrial ability, but we must remain reserved about the clinical element, taking into account that we are still at an early stage.

In conclusion, what message would you like to send to CARMAT shareholders?

Everyone knows that the artificial heart is an ambitious yet promising project. The need is already widespread and increasing each year. Being slightly audacious, I would say that the technological feasibility is the process of being proven. The pace of technological innovation, however, is not the same as the stock market's one and we must remain steadfast and, most importantly, we must remain confident, confident, and again, confident, in the success of CARMAT.

We are fortunate to have a large number of individual shareholders who are and have been with us since our initial public offering, but we also have economic and financial institutions and partners that have been committed to Professor Carpentier since the very beginning of the project. Their support has allowed us to be successful in the many pre-clinical steps taken to arrive at this crucial stage of the project. We still count on them to help CARMAT reach our forthcoming milestones.

PROFILE

CARMAT, the most highly-performing artificial heart project in the world

CARMAT would eventually like to address a major public challenge linked to cardiovascular diseases, the leading cause of death worldwide: end-stage biventricular heart failure. The bioprosthetic artificial heart developed by the Company aims to become a credible alternative to heart transplantation.

2008
date of creation of CARMAT

40
employees supported by approximately 50 outside technical assistants

€57,250,000
raised on the stock exchange at December 31, 2013 (gross amount, issue premiums included)

Currently more than 100,000 patients are affected each year by this disease in developed countries, whereas only 4,000 heart transplantations are carried out each year. By developing its bioprosthetic heart, CARMAT hopes to provide an alternative which offsets the well-known shortage of transplants that impacts tens of thousands of people who suffer from heart failure.

The collaborative result of two unique international experts

CARMAT has the medical expertise of Professor Alain Carpentier, recognized throughout the world for inventing the "Carpentier-Edwards®" biological heart valve, the most widely implanted in the world, and the technological expertise of Airbus Group (formerly EADS), world leader in aeronautics.

Imitating the natural heart

By its size, weight, choice of structural materials and totally new physiological features, the CARMAT bioprosthetic artificial heart could, provided it is successful in clinical trials, save the lives of patients every year, without risk of biological rejection and provide an unprecedented quality of life.

A lead project recognized in Europe

In accord with the European Commission, CARMAT received the largest financial award ever granted by Bpifrance (formerly Oseo) to an SME, in the amount of €33 million.

The founders and the highly-involved, prestigious shareholders

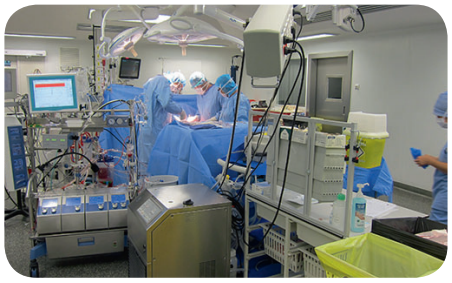
Truffle Capital, Airbus Group, Professor Alain Carpentier and the Scientific Research Association of the Alain Carpentier Foundation, the Marie Lannelongue Surgical Center, as well as thousands of institutional and individual shareholders, support the CARMAT project.

2013 HIGHLIGHTS

May

International agreements

CARMAT obtains clinical cooperation agreements from four internationally renowned cardiac surgery centers in four countries: Saudi Arabia, Belgium, Poland and Slovenia.



July

Receipt of €6.7 million from Bpifrance

This payment, composed of grants (€2.9 million) and repayable advances (€3.8 million) corresponds to the submission of the in vitro and in vivo preclinical trials documentation and validates the satisfactory progress of the project.

October

Participation in the EACTS in Vienna

Having received authorization for a first clinical trial involving four patients in France, the 27th annual meeting of the EACTS enabled concrete discussions with the international cardiac surgery community on the clinical aspects of the project.

June

Optional financing

To strengthen its financial flexibility, CARMAT has put in place an optional line of equity financing with Kepler Cheuvreux, allowing the issue of 200,000 new shares with a maximum discount of 7%.

September

ANSM* authorization in France

The *Agence nationale de sécurité du médicament et des produits de santé* (French national agency for medicine and health product safety) approves CARMAT's request to proceed with implantation of its artificial heart in four patients. The selection of patients begins in trained centers.

December

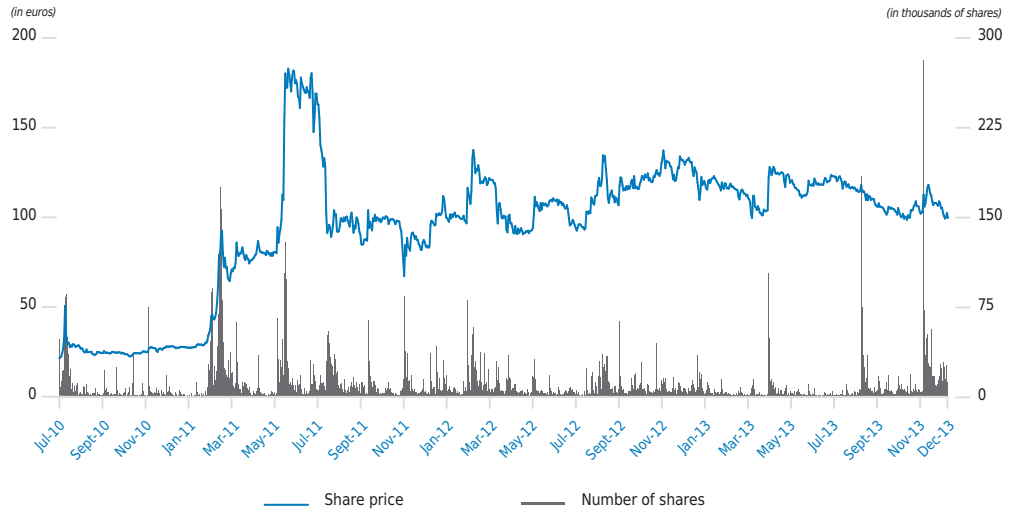
First human implantation

The first ever worldwide CARMAT heart implantation is performed on December 18, 2013 by the team at the Georges Pompidou European Hospital in Paris, France. The patient survives 74 days and the clinical trial continues (see paragraph 8.6, Recent Events).

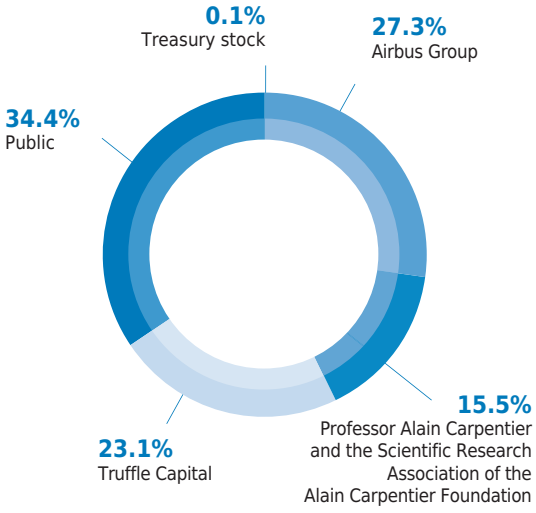
STOCK MARKET AND SHAREHOLDERS AT DECEMBER 31, 2013

Change in the market price

since the market listing



Breakdown of capital (at December 31, 2013)



NUMBER OF SHARES AT DECEMBER 31, 2013

4,283,470

SHARE CODES

Name: CARMAT

Mnemonic: ALCAR

ISIN Code: FR0010907956

1

OVERVIEW OF CARMAT

1.1 SELECTED FINANCIAL INFORMATION

The main financial information presented below is taken from the corporate financial statements for the years ended December 31, 2013, 2012 and 2011, prepared in accordance with French generally applicable accounting practices (French GAAP), shown in Chapter 6 of this registration document.

These must be read in conjunction with the information contained in paragraph 5.2 Financial situation of the Company, cash and capital, and especially paragraph 5.2.3 Cash and capital, as well as with Chapter 6 the Annual Financial Statements at December 31, 2013, of this registration document.

Summary income statement *(in euros)*	**12 months 2013**	**12 months 2012**	**12 months 2011**
Turnover	0	0	0
Subsidies	2,873,627	10,500	6,051,177
Operating expenses	18,990,251	22,403,502	22,192,807
OPERATING RESULT	**-16,116,624**	**-22,385,513**	**-16,091,054**
Financial result	-323,611	110,099	97,271
EARNINGS BEFORE INTEREST AND TAX	**-16,440,235**	**-22,275,415**	**-15,993,783**
Extraordinary result	25,219	70,290	37,234
Research Tax Credit*	-1,770,114	-5,015,433	-2,515,527
NET RESULT	**-14,644,902**	**-17,189,691**	**-13,441,022**

Summary cash flow statement *(in euros)*	**12 months 2013**	**12 months 2012**	**12 months 2011**
NET RESULT	**-14,644,902**	**-17,189,691**	**-13,441,022**
Self-financing capacity	-13,263,605	-15,505,462	-11,927,757
Cash flow from operations	-9,637,682	-17,952,868	-9,705,912
Cash flow from investment operations	-316,948	-522,387	-1,061,303
Cash flow from financing operations	15,704,166	240,000	28,721,085
Change in cash and cash equivalents	5,749,536	-18,235,255	17,953,870
OPENING CASH	**11,134,438**	**29,369,693**	**11,415,823**
CLOSING CASH	**16,883,974**	**11,134,438**	**29,369,693**

Summary balance sheet	**12 months**	**12 months**	**12 months**
ASSETS *(in euros)*	**2013**	**2012**	**2011**
NET FIXED ASSETS	**1,633,314**	**2,266,763**	**3,147,942**
including intangible fixed assets	125,412	168,468	234,707
including tangible fixed assets	945,370	1,556,204	2,448,058
including financial fixed assets	562,532	542,090	465,178
CURRENT ASSETS	**20,350,868**	**17,430,133**	**34,278,141**
including cash and cash equivalents	16,883,974	11,134,438	29,369,693
TOTAL ASSETS	**21,984,183**	**19,696,896**	**37,426,083**
LIABILITIES *(in euros)*	**2013**	**2012**	**2011**
Equity	7,228,579	9,941,228	26,890,919
Other equity(1)	7,515,054	3,743,141	3,743,141
Provisions for risks and charges	142,100	73,304	35,660
Creditors	7,098,449	5,939,193	6,756,362
including financial payables	822,187	460,054	217,066
including operational payables	6,276,262	5,326,771	6,152,251
TOTAL LIABILITIES	**21,984,183**	**19,696,896**	**37,426,083**

(1) Other equity represents advances received from Bpifrance. These advances may be repaid in the conditions specified in the notes to the annual financial statements (Notes 6.4.4.7.1 or 6.4.6.1.1 for the period ended December 31, 2013). In the event that the projects in question succeed, they will therefore constitute debt.

1.2 HISTORY AND DEVELOPMENT OF THE COMPANY

CARMAT and its bioprosthetic artificial heart project are the result of the collaboration between a world-class medical team – that of Professor Alain Carpentier – and a high-technology company, Matra Défense.

The bioprosthesis was born after the meeting, in the early 1990's, between Professor Alain Carpentier – who had been working on a bioprosthetic artificial heart project since 1988 with the application for a first patent and initial conceptual work with the Technical Center for Mechanical Industries (CETIM) – and Jean-Luc Lagardère, then chairman of Matra (now a subsidiary of Airbus Group). The resulting business arrangement gave rise to very energetic cooperation starting in 1993, with the aim of designing a bioprosthetic artificial heart with ventricles, sensors* and electronic controls integrated into a single device. Within this partnership, Professor Alain Carpentier contributed his extensive knowledge of bioprosthetic valves and the chemical treatments for animal-origin biological tissues which he had developed (Carpentier-Edwards valves®). For its part, Matra brought its expertise in embedded systems and their constraints (reliability, severe environments, mass and volume), thus allowing their engineers to work on the concept using simulations, modeling and test benches. The objective is to develop the most physiologically compatible artificial heart possible, capable in particular of:

- offering a bioprosthetic blood flow interface so as to reduce the major thromboembolic* complications encountered by previous projects;
- providing the patient with an immediate response appropriate to his or her metabolic needs in terms of flow and heart rate.

In 2001, the project gained new impetus thanks to successful implantations of the first prototype in calves. These implantations highlighted the efforts that were still to be made but confirmed the feasibility of the concept. A dedicated team of a dozen complementary experts (system design, biocompatible materials, specific 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 prosthesis and transplants laboratory at the Université Pierre et Marie Curie and at the Georges Pompidou European Hospital to optimize the prosthesis.

The joint work of these two multidisciplinary teams, with backgrounds in both medicine (doctors and biologists) and the field of aviation and space research, enabled considerable progress to be made, specifically resulting in the miniaturization of the integrated system in terms of volume, energy consumption, weight and human biocompatibility, through the development of unique biomaterials and procedures (see paragraph 2.2.2 Innovations and competitive advantages).

A large number of processes were patented, including the architecture, the hybrid membrane which is both impervious and hemocompatible*, the locking interface device (connecting to the patient's atria* thanks to an interface device which allows an easy suture to which the prosthesis is then connected), the pump and the physiological regulation system.

Thus, after 15 years of research and development, a new prototype weighing less than 900 g (compared to the previous 1200 g prototype designed four years earlier) and completely optimized (savings in volume, mass and energy consumption of approx. 25%) allowed CARMAT to be founded in June 2008.

CARMAT's 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 bring it to full-scale industrial production and sale.

To date, CARMAT has devoted its activity entirely to the research and development of the bioprosthetic artificial heart and has thus not yet generated any revenue. To finance its project, the Company has benefited from:

- in September 2008, a capital increase of €7.25 million (€5 million invested by the funds managed by Truffle Capital, €2.25 million by Matra Défense and Professor Alain Carpentier), issue premium included;
- in September 2008, a total of €33 million in subsidies and repayable advances granted by Bpifrance in connection with the Strategic Industrial Innovation program (ISI), the largest amount of aid ever given to a Young Innovative Company (JEI) by this body (see paragraph 5.7 Important contracts);
- in June 2009, a €1.5 million subsidy granted by the Yvelines General Council;
- in February 2010, a capital increase of €0.95 million (issue premium included) underwritten by the funds managed by Truffle Capital;
- in May 2010, the raising of €2 million from an issue of convertible bonds, underwritten by the funds managed by Truffle Capital and converted at the time of CARMAT's flotation on the NYSE/Euronext Alternext Paris market;
- in July 2010, a capital increase of €16 million (issue premium included) in connection with the Company's IPO on the NYSE/Euronext Alternext Paris market;

- in August 2011, a capital increase of €29.3 million (issue premium included) with retention of preferential subscription rights, carried out on the NYSE/Euronext Alternext Paris market;
- in June 2013, the establishment, with Kepler Cheuvreux, of an optional equity financing line, for a maximum of 200,000 new shares, including 116,800 shares issued in 2013, representing a capital increase of approximately €12 million (issue premium included).

In France, the Company began the first clinical trial of its bioprosthetic artificial heart in December 2013, after obtaining authorization from official regulatory authorities in September 2013. A second clinical trial is expected in 2014, to prepare for commercialization in Europe as early as 2015, subject to receipt of CE marking (certificate of compliance with essential health and safety requirements), a regulatory requirement for commercialization.

1.2.1 Registered name

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

1.2.2 Place and number of the Company's registration

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

1.2.3 Date of incorporation and term

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

1.2.4 Registered office, 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 corporation *(Société Anonyme)* under French law with a board of directors, and it is governed by the provisions of Book II of the french commercial code.

1.2.5 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 a first prototype artificial heart (1,900 g) Industrial approval of concepts
2001	First successful animal transplantation Creation of a full-time dedicated project team within Airbus Group
2004	Creation of a second prototype bioprosthetic artificial heart (1,200 g)
2004-2008	Optimization of volume, weight and energy consumption of the bioprosthetic artificial heart
2008	Creation of CARMAT by Matra Défense (Airbus Group) and Professor Alain Carpentier Contributions in kind (patents, licenses, software, equipment, etc.) to CARMAT from the Carpentier Foundation *("Association Recherche Scientifique de la Fondation Alain Carpentier")* and the Airbus Group (*via* its subsidiary Matra Défense) Grant to CARMAT and its partners of €33 million in subsidies and repayable advances by Bpifrance under the Strategic Industrial Innovation scheme, the largest amount ever granted to a Young Innovative Company by Bpifrance Capital increase of €7.25 million, including issue premium (€5 million invested by Truffle Capital and €2.25 million by Matra Défense and Professor Alain Carpentier)
2009	Grant of a subsidy of €1.5 million to CARMAT by the Departmental Council of Yvelines Authorization from the European Commission for the grant of €33 million to the CARMAT research and development program Appointment of Marcello Conviti as chief executive officer of CARMAT SAS Opening of the CARMAT clean room* by Valérie Pécresse, Minister of Higher Education and Research Completion of modeling and optimization work on the artificial heart (900 g) in readiness for the assembly and implantation phase for the preclinical trials
2010	CARMAT Capital increase in the amount of €0.95 million, issue premium included, by the funds managed by Truffle Capital Transformation of the Company from an SAS into an SA *(Société Anonyme)* Appointment of Jean-Claude Cadudal, Marcello Conviti, Professor Alain Carpentier, André-Michel Ballester and Truffle Capital, represented -by Philippe Pouletty, to CARMAT's board of directors Issue of convertible bonds for €2 million 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" by Bpifrance for the Mutual Funds for Investment in Innovation (FCPI) Capital increase of €16 million, including issue premium, on the occasion of CARMAT's flotation on NYSE-Euronext's Alternext market in Paris Conclusion of an agreement with Edwards Lifesciences, the world leader in the cardiac valves sector and hemodynamic monitoring, for the use of Carpentier-Edwards biological cardiac valves in the CARMAT bioprosthetic artificial heart Industrial assembly of the first two CARMAT bioprosthetic artificial heart prostheses in the clean room Henri Lachmann joins the CARMAT board of directors
2011	CARMAT is listed on the NYSE Alternext Bpifrance index Presentation of promising test results regarding physiological compatibility CARMAT submits its preliminary application to the AFSSAPS* CARMAT receives ISO 13485: 2003 and ISO 9001: 2008 certification (Quality system certification) Capital increase in the amount of €29.3 million (issue premium included) CARMAT presents preclinical hemocompatibility data to the 25th Annual Congress of the European Association for Cardio-Thoracic Surgery Approval from the CPP (patient protection committee*)
2012	CARMAT publishes its twice-yearly Shareholder Newsletter 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 Participation in the Franco-American Biotechnology Symposium (FABS 2012) in Nice and in the Techno-College of the 26th Annual Congress of the European Association for Cardio-thoracic Surgery (EACTS) in Barcelona
2013	CARMAT receives €5 million in Research Tax Credits (CIR) for the year 2012, in line with the Company's 2013 financing plan CARMAT obtains clinical cooperation agreements from four internationally renowned cardiac surgery centers in four countries CARMAT obtains authorization from the ANSM to conduct a feasibility study in France involving four patients CARMAT takes part in the 27th meeting of the European Association of Cardio-thoracic Surgery First successful implantation performed on December 18, 2013 at the Georges Pompidou European Hospital by Professor Christian Latrémouille
2014	Continuation, in France, of the clinical trial on the first bioprosthetic artificial heart. First patient survives 74 days

1.3 GENERAL OVERVIEW OF ACTIVITY

Founded in 2008, and after more than 15 years of research, CARMAT has developed a total artificial heart, orthotopic*, bioprosthetic*, self-regulating and implantable, together with its electrical energy supply system and its control and remote diagnostic systems.

Until now, the Company has dedicated its entire activity to the research and development of the bioprosthetic artificial heart project and has therefore not yet generated any sales. The funds raised, the existing cash and the expected financial resources, in particular from Bpifrance and the research tax credit, are expected to be sufficient to finance the artificial heart project until 2015.

Nevertheless, major scientific and regulatory steps described in the schedule below as well as in paragraphs 2.3.7 and 5.7.1. remain to be completed. If required, new fundraising, likely to represent an accumulated amount of approximately €50 million to €150 million, will be necessary to finance the clinical trials and the scale up to industrialization, as well as the European commercialization planned for 2015 at the earliest, followed by the launch of a clinical trial in the United States which is currently planned for 2017.

At the date of this registration document, the forecast project schedule is the following:

1st half of 2014

- Continuation of the feasibility study involving four patients in France
- Preclinical tests for the pivotal study
- Training of new centers

2nd half of 2014

- Introduction of new external systems
- Necessary authorizations obtained for the pivotal study in France or in other countries
- Preparation of the file for CE marking

2015

- Submission of the file for CE marking
- Recruitment of the sales force and reimbursement specialists
- CE marking obtained
- Sales launch in Europe (at the earliest)

2016

- Ramp up of industrial tool
- Initiation of regulatory activities in the USA
- Continuation of sales penetration in Europe

2017

- Launch of a clinical trial in the USA

Readers are reminded to read paragraphs 2.2.3 Process and developmental stages, 3.2 Risks related to the Company's activity and 3.5 Financial risks, as well as the Company's press releases. The most recent press releases published at the date of this document (March 4 and 17, 2014) are set out in paragraph 8.6 Recent events. These concern the 74-day survival of the first patient of the clinical feasibility study and the ongoing collection and analysis of data from this trial.

The name CARMAT came from a meeting at the beginning of the 1990s, between Professor Alain Carpentier and Jean-Luc Lagardère, who was then chairman of Matra. The resulting merger gave rise to a very active cooperation from 1993 with the aim of designing a bioprosthetic artificial heart. This unique partnership combines:

- over 30 years of experience of Professor Alain Carpentier[1], father of modern cardiac valve surgery. Professor Carpentier developed the treatment of biological animal tissues that allowed him to design the world's most widely used biological valves (Carpentier-Edwards® valves). Professor Carpentier also developed techniques of reparative surgery and mitral annuloplasty* now used throughout the world, on the principle that a device should always be associated with a reproducible procedure; and
- Matra's expertise in onboard systems and their restrictions (reliability, severe environments, mass and volume) allows engineers to work on the concept using simulations, modeling and test benches.

The Company's objective is to meet a world-wide public health care need, which is the treatment of advanced heart failure. It is a severe disease, progressive, and often fatal, in constant progression in developed countries.

CARMAT's bioprosthetic artificial heart project aims to provide a long-term therapeutic solution to patients suffering from advanced biventricular heart failure, who are not eligible for a transplant and have exhausted all treatment possibilities and for whom no satisfactory solution is currently available.

In addition to the bioprosthetic artificial heart, the Company also plans to eventually develop new applications for its cardiovascular knowledge. However, the Company does not foresee allocating resources to these potential applications as long as the artificial heart project has not been successfully completed.

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

1.4 ORGANIZATION CHART

1.4.1 Organization of the group

The Company is not part of a group.

1.4.2 Subsidiaries and shareholdings

The Company has no subsidiaries or shareholdings.

1.5 PROPERTY, PLANT AND EQUIPMENT

1.5.1 Significant existing or planned tangible fixed assets

The Company performs 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.

Lessee Company	Address	Nature of premises	Surface area	Lease start date	Lease expiry date	2013 rental costs (including charges)
CARMAT	36, avenue de l'Europe Immeuble l'Étendard Energy III 78140 Vélizy Villacoublay – France	Business premises	1,053 m²	02/01/2009	01/31/2018	€266,655.35
CARMAT	36, avenue de l'Europe Immeuble l'Étendard Energy III 78140 Vélizy Villacoublay – France	Business premises	595 m²	10/01/2010	09/30/2019	€135,614.84
CARMAT	36, avenue de l'Europe Immeuble l'Étendard Energy III 78140 Vélizy Villacoublay – France	Business premises	595 m²	07/01/2011	03/31/2022	€103,102.33

For the current financial year at the date of this registration document, the Company considers that it has suitable premises that will be adequate for its projected growth and employees.

1.5.2 Environmental issues

In connection with search for non-thrombogenic* material, CARMAT decided to follow a path originally opened by Professor Alain Carpentier's work on biological valves, which uses animal pericardium that has been chemically treated to render it inert and biologically stable, so that rejection by the body is avoided. In designing the bioprosthetic artificial heart, the Company is therefore subject to chemical and biological risks, obliging it to put in place preventative and protective measures for the benefit of its operators and for waste management in line with current environmental and safety regulations governing the use, storage, handling and disposal of hazardous materials. The Company believes that it complies with these regulations.

In particular, the Company has entrusted two specialized subcontractors to manage its waste products. It undertakes an annual evaluation of the risks by work unit. This involves analyzing each hazardous situation, quantifying the risks by severity and occurrence and describing preventive measures. Generally, all operations in which there is the possibility of substance evaporation are performed under hoods or in chambers with activated carbon filters.

1.6 INVESTMENTS

1.6.1 Principal investments made in the last two financial periods

During the financial year ended December 31, 2013, the Company recognized the use of assets that were under construction as of December 31, 2012 in the amount of €184,621. The Company has moreover committed new investment expenses in the order of €199,288 corresponding to:

- tangible fixed assets (€118,075) mainly comprising the acquisition of test benches for the prosthesis and software validation, work related to the office premises, and purchases of measuring equipment and furniture;
- intangible assets in the amount of €81,213 for the acquisition of licenses and computer software.

In the 12-month financial period ended December 31, 2012, the Company incurred capital expenditure of €310,773, corresponding to:

- tangible fixed assets (€220,809) mainly comprising the acquisition of test benches for the prosthesis and software validation, work related to the office premises, and purchases of measuring equipment and furniture;
- assets under construction (€89,964), relating to the acquisition of test benches and laboratory equipment, approved but not yet in service at the year end.

1.6.2 Principal capital expenditure underway and method of financing

The current intangible assets at the end of the 2013 financial period correspond to the acquisition of Enterprise Resource Planning (ERP) management software. This acquisition represents an amount of €66,436 corresponding to invoices received by December 31, 2013.

These investments will be financed from the Company's cash totaling €16.9 million on December 31, 2013.

1.6.3 Main investments envisaged

The main short-term investments concern computer equipment for backing up data and the installation of integrated ERP management software and additional benches for training surgical teams.

2

DESCRIPTION OF ACTIVITIES

2.1 HEART FAILURE

2.1.1 Pathology and etiology*

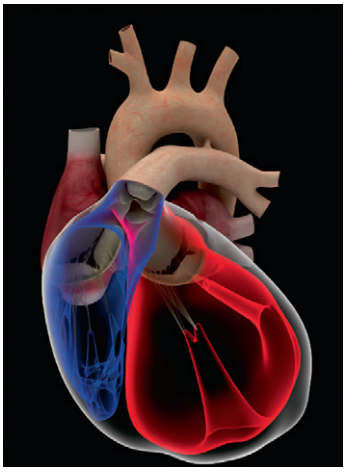
Heart failure occurs when the myocardium (cardiac muscle) can no longer carry out its essential function as a blood "pump" and provide a sufficient cardiac output to satisfy the metabolic needs of the organism. When the failure reaches the left ventricle, we talk of left ventricular failure; when it reaches the right ventricle, we talk of right ventricular failure; when the failure reaches both ventricles, the left and the right, we talk of congestive or biventricular heart failure.

The main cause is coronary artery disease* (in particular myocardial infarction*) for about two-thirds of cases of systolic heart failure[2], high blood pressure* is estimated as a significant contributing factor in many cases.

- In a heart attack, a plaque of lipids or a blood clot forms in one of the arteries of the heart, which are called coronary arteries, and the flow is interrupted. The part of the cardiac muscle that does not receive any blood is no longer oxygenated (ischemia*). It dies and is replaced by scar tissue.
- If this damaged part is important, the cardiac muscle weakens and the heart tends to expand; this secondary expansion, due to the increase in pressure within the heart, will in turn damage the healthy part of the heart and the heart failure will worsen over time.
- In high blood pressure (HBP), the resistance to blood flow increases in the arteries. The heart must fight against this resistance. As with all muscle subjected to an increased effort, it will first of all increase in size (hypertrophy*).
- If HBP is not correctly treated, the heart can dilate; its contractile force will progressively weaken and heart failure will develop. This heart failure is frequently aggravated by the tendency of hypertensive hearts to have cardiac arrests.

The left ventricle is the most frequently affected ventricle.

Right ventricular failure is most often a consequence of a pressure overload in the right ventricle, *i.e.* a pulmonary hypertension. But the principal cause of pulmonary hypertension is, in fact, left heart failure[3]. That is why heart failure frequently progresses from the left ventricle to the right ventricle.



Dilated ventricle

Up to 30% of patients whose left heart failure is treated by a left ventricular assist device develop a right heart failure[4, 5].

The most frequent complications are the following:

- irregular heart beat: the heart must pump faster to ensure the same flow rate despite its expansion; a serious ventricular arrhythmia can then develop which may go so far as a cardiac arrest;
- thromboembolic accidents (formation of clots): when a clot reaches the brain, it leads to a stroke*, with dramatic and often crippling consequences; and
- renal failure, the kidney being an organ very sensitive to variations in pressure caused by an inadequate cardiac pump.

Being a progressive disease, the prognosis is poor: less than 50% survival five years after the diagnosis[6], more than 40% of deaths within a year following initial hospitalization[7].

Doctors distinguish the severity of heart failure or the extent of the handicap with the aid of the NYHA *(New York Heart Association)* classification system based on symptoms and consisting of four categories.

2 *Adamopoulos S et al. ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012. European Heart Journal (2012) 33, 1787–1847.*

3 *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.*

4 *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.*

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

6 *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.*

7 *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.

NYHA	Class I	Class II	Class III	Class IV
Symptoms	No symptoms	Tiredness, palpitations, shortness of breath after a sustained effort	Symptoms and discomfort at the slightest effort	Symptomatic even at rest
Activity	No limitation	Modest limitation	Marked reduction	Inability for all activity, permanently confined to bed.

The transition to class III constitutes a determining threshold[8]:

- for the patient: it marks the passage between a virtually normal life and a considerably reduced activity, very often involving a loss of autonomy;
- clinically this means more aggressive therapies, a dependence on drugs, and, with class IV, the start of repeated hospitalizations;
- for society, this represents an explosion of the costs, particularly due to hospitalizations: a class IV patient costs the community up to 15 times more than a class II patient[9].

Class III and class IV patients represent between 20 and 35% of the total, with class IV reaching up to 5% of heart failures[10].

CARMAT's bioprosthetic artificial heart project is initially directed at patients suffering from end-stage heart failure – the most advanced form of the disease, for which the mortality at one year is estimated as being between 60 and 94%[11]. Depending on the benefits shown by the clinical studies, it could then be offered to the patients who have the best prognosis.

2.1.2 Epidemiology, prevalence and incidence

The prevalence* of heart failure is rising sharply in developed countries, affecting around 2% of the general population[12, 13] *i.e.* approx. 15 million Europeans[14, 15]. Prevalence increases greatly with age. A French epidemiological study has shown that it can affect nearly 12% of patients aged over 60 years[16].

More than 5.8 million people suffer from heart failure in the United States, with an annual incidence* higher than 550,000 new patients per year. According to a study published by the *American Heart Association* in February 2001, the prevalence rate of heart failure in the United States should rise by 25% between 2010 and 2030[17].

This progression of the epidemiology is linked to the aging of the population, but also, in the case of advanced heart failure, to the improved survival after a myocardial infarction and to the progress made in the medicinal treatments, such as betablockers* and diuretics*[18] or coronary stents.

Paradoxically, the availability of new drugs or technologies has enabled more effective treatment of acute coronary syndromes, and brought about a significant increase in the survival of patients after myocardial infarction, which is the strongest predictor of left systolic dysfunction and a risk of heart failure: patients no longer die immediately but receive long-term treatment, during which time the disease continues to evolve. As a result, the absolute number of people living with a compromised cardiac function and heart failure in the clinical sense of the term is expected to increase considerably in the coming decades[19]. This development also results in an older population of heart failure patients who suffer from various co-morbidities, and are therefore much less likely to be eligible transplant candidates[20].

8 *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.*

9 *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.*

10 *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.*

11 *Gorodeski EZ et al. Prognosis on chronic dobutamine or milrinone infusions for stage D heart failure. Circ Heart Fail. 2009 Jul ; 2(4) : 320-4.*

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

13 *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.*

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

15 *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)*

16 *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.*

17 *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.*

18 *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.*

19 *Tendera M. Epidemiology, treatment, and guidelines for the treatment of heart failure in Europe. European Heart Journal Supplements (2005) 7 (Supplement J), J5–J9.*

20 *Croft JB et al. Heart failure survival among older adults in the United States : a poor prognosis for an emerging epidemic in the Medicare population. Arch Intern Med 1999 ; 159 : 505–510.*

2.1.3 Economic challenge

Heart failure constitutes a real public health challenge which is set to increase: in Western countries, the cost of heart failure is now the largest of all chronic diseases.

The total cost of heart failure is estimated at $24 billion in the United States in 2015 and $47 billion in 2030[21]. 12 to 15 million consultations per year and 6.5 million days of hospitalization are attributed to it[22]. According to a study published by the American Heart Association in February 2011, the direct treatment costs (medical costs) of patients are expected to rise by 215% within the US population (and even more amongst those over 65 years) and the indirect costs (lost productivity) by 80% between 2010 and 2030[23].

The direct cost of advanced chronic heart failure in France was around €1.5 billion[24] (€3.3 billion for the class of long-term illnesses covering serious cardiovascular pathologies – ALD 5 in 2009, solely for the general health insurance system) and concerned more than 730,000 people in 2011 (an increase of 9% compared to the previous year).

In a communiqué published on May 7, 2010 on the occasion of the European Heart Failure Awareness Day, the French Society of Cardiology and the French Federation of Cardiology recalled some figures. In France there are more than 100,000 new cases a year. 10% of these patients were hospitalized, given that the average length of hospitalization exceeds ten days and that the rate of re-admission within six months is 20%. In 2008, heart failure was the primary diagnosis in 195,800 hospital stays in France, where the daily cost of hospitalization in intensive care in cardiology was over €2,000.

Overall, heart failure represents between 2% and 2.5% of the total expenditure on health care in Western countries, with costs linked to hospitalization alone representing 70% of the total cost of the disease[25]. Due to repeated hospitalizations, class IV chronic heart failure represents between around 61% and 92% of the total cost of heart failure[26].

2.1.4 Available treatments

It should be noted that this disease in incurable in the chronic phase and that current treatments aim solely at reducing the symptoms. Treatments evolve as the disease progresses.

The complexity of the treatment and the need for frequent adjustments leads to low patient compliance: 40% of patients do not follow their treatment in a consistent manner after three months[28].

2.1.4.1 Drugs

In class I and II, treatment is essentially drug-based[27] and, depending on the severity and symptoms, combines:

- anticoagulants* and anti-platelet aggregation medication* to prevent the formation of blood clots;
- angiotensin-converting enzyme inhibitors* to reduce vascular resistance;
- betablockers which reduce the cardiac rhythm and output to decrease blood pressure;
- diuretics to remove excess fluids and, in this way, lighten the burden on the heart to prevent pulmonary edema;
- vasodilators* which relax the blood vessels to increase the flow of blood and oxygen to the heart without increasing its work;
- etc.

2.1.4.2 Devices

From class III, 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 assisted circulatory support systems, implantable or not, and artificial hearts.

21 *GO A et al. Circulation. 2014 ; 129 : e28-e292. Heart Disease and Stroke Statistics – American Heart Association 2014.*

22 *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.*

23 *Heart Disease and Stroke Statistics – American Heart Association 2010.*

24 *Régime général de l'Assurance Maladie – www.ameli.fr/l-assurance-maladie/statistiques-et-publications/donnees-statistiques/affection-de-longue-duree-ald/*

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

26 *Clegg AJ et al. Clinical and cost effectiveness of LVAD for end stage heart failure – Health Technology Assessment NHS – 2005.*

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

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

For the most part, these options continue the objective of recovering the heart's natural function. For example, biventricular pacemakers aim to reeducate the ventricles by synchronizing their contractions. Restrictive mitral annuloplasty aims to reeducate the left ventricle by affecting its geometry. However, although these approaches provide some patients with temporary relief, they face important difficulties in terms of patient selection[29] or technical implementation[30], which restrict their use and do not prevent the progression of the disease.

Finally, the use of stem cells to regenerate damaged heart muscle is a promising avenue of research, but remains very controversial[31], in particular due to difficulties in collection or generation, then in administration (a large number of cells "die" during the injection) and the lack, to date, of a clinical demonstration of regeneration long-term sustainability.

The mechanical circulatory support systems are the devices which could be considered as the closest, in function and indication, to the CARMAT artificial heart project. Their characteristics and development are detailed in paragraph 2.4.2. Technologies and market players.

Positive inotropes* are generally introduced at the most advanced stage of the disease. These are drugs, administered intravenously in the hospital setting, which increase the contractility of the cardiac muscle and that allow, at least temporarily, critical situations of low cardiac output in episodes of acute decompensated heart failure* or cardiogenic shock* to be resolved. Dependence on inotropes marks the end stage of heart failure with a mean survival of three and a half months[32].

2.1.4.3 Transplantation

Indeed, in the end-stage form of the disease, the only treatment possible is the replacement of the diseased ventricles by the transplantation* of a healthy heart*, *i.e.* the heart of a donor.

Professor Christian Barnard preformed the first heart transplant in South Africa on December 3, 1967. The first transplant patients, with few exceptions, did not survive more than a few weeks after the operation, specifically due to rejection (reaction of the host against the transplant which it considered as a foreign biological body). Several important advances have allowed the improvement of patient survival:

- the preservation of donor hearts thanks to cold perfusion, allowing the removal at a distance from the place of transplantation;
- endomyocardial biopsy allowing the early diagnosis of rejection: a probe is introduced, under X-ray control and under local anesthesia, into a large vein and pushed until it is in the right ventricle, permitting a small piece to be sampled which is then analyzed under a microscope;
- last but not least, the advent of cyclosporin, an immunosuppressant*, whose therapeutic use has allowed, since the beginning of the 1980s, considerable development in the field of organ transplants, by preventing acute rejection.

Today, heart transplant survival is slightly higher than 50% at ten years[33]. Nevertheless, survival after one year has progressed very little over the past 20 years.

The hopes founded on this treatment continue to face major problems that limit its mainstreaming. Indeed, if we compare a very conservative estimation of approximately 400,000 class IV end-stage heart failure patients (barely 2% of the total number of patients with heart failure of all classes in Europe and the United States, *i.e.*, more than 20 million) to an optimistic estimation of around 4,000 heart transplants performed in the same geographical regions in 2010 (see paragraph 2.3.1 Market numbers), we observe a considerable difference.

The first reason can be found in the very strict eligibility criteria both for the harvesting of the organ and for the transplant. Notably, the donor[34] must, in principle, be under the age of 61 years, brain dead, not a carrier of certain viruses such as HIV or hepatitis B and C, not a drug addict or have a cancer and, of course, not be suffering from heart disease. This therefore limits the possibility of donation mainly to trauma deaths (in particular road accidents, which are constantly decreasing). So, in France in 2012, only 435 hearts could be harvested and 397 implanted[35].

In France, 41% of donors were over 60 years of age in 2011, versus 22% in 2007, which shows that not all the organs removed can be used.

Considering this shortage of organs, the eligibility criteria of the recipient are even stricter[36] in order to ensure the greatest chance of success with each transplant. Blood groups must be identical, weight and size equivalent. Irreversible pulmonary hypertension, an active infection or a cancer are formal contraindications. Other relative contraindications are also taken into account such as diabetes, advanced pulmonary or hepatic diseases, renal failure, morbid obesity, etc. A psychological assessment is taken into account to ensure that the patient agrees to comply with lifelong complex medicinal treatment. Patients with psychiatric disorders, or addicted to alcohol or drugs are not considered.

Age, which must be below 65 years, is a particularly discriminating criterion. The organs are therefore reserved for the youngest patients,

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

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

31 *Garbern J et al. Cell Stem Cell, Volume 12, Issue 6, 689-698, 6 June 2013.*

32 *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.*

33 *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.*

34 *Latrémouille C et al. Transplantation cardiaque. EMC - ©Elsevier, Techniques chirurgicales - Thorax, 42-748, 2006.*

35 *Agence de la biomédecine - Synthèse nationale de prélèvement et de greffe 2012 et annexe au bilan 2012.*

36 *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.*

while the vast majority of chronic heart failure patients are over 60 years or suffering from comorbidities making them ineligible. Furthermore, the one-year survival rate after transplantation decreased significantly with age, and stands at just 67% for adults over 60 years of age[37].

In this way, the number of transplants is stable or declining in all developed countries for over ten years, while the prevalence of heart failure has considerably increased.

Heart transplant waiting lists therefore do not reflect treatment needs, but simply the number of patients satisfying all the eligibility criteria, particularly age. The low penetration of heart transplantation as treatment of choice for end-stage heart failure is shown in the following table:

	France(1)	United States(2)	Germany(3)	United Kingdom(4)
Transplantations	397	1,949	313	124
Patients on waiting list	325	2,810	904	200
Population(5)	65,700,000	313,900,000	81,900,000	63,200,000
Patients with end-stage heart failure(6)	26,280	125,560	32,760	25,280

(1) 2012 – French Biomedicine Agency - 2012 Annual report.
(2) 2011 – Organ Procurement and Transplantation Network – Scientific Registry of Transplant Recipients.
(3) 2013 – Eurotransplant statistics.
(4) April 2012/March 2013 – NHS Organ Donation Annual Report.
(5) World Bank 2013 - http://wdi.worldbank.org/table/2.1.
(6) Given the lack of epidemiological reference data, cautious estimation based on a prevalence of heart failure of 2% in the general population, 2% of this 2% having reached the end stage of the disease (see paragraph 2.3.1 Market numbers).

Transplant limits also appear in the difficulties of caring for transplanted patients and the complications either of the graft itself or caused by immunosuppression. Consequently, five years after a heart transplant, 95% of patients suffer from hypertension, 81% from hyperlipidemia*, and 32% from diabetes. Furthermore, 25% to 50% develop coronary disease of the graft, and 33% suffer from chronic renal failure[38].

A heart transplant is a heavy treatment at a very high price. Every three years, the Milliman Institute publishes a detailed report[39] on the estimated cost of organ transplants in the United States. With regards to heart transplants, their 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 US dollars):

30 days pre-transplant	Harvesting	Admission	Procedure	180 days post-transplant	Immuno-suppressors and other treatments	TOTAL
42,200	80,400	634,300	67,700	137,800	30,300	997,700

It is difficult to make an international comparison given the very different health care finance systems and the figures available cover heterogeneous periods before and after transplant.

For example, today France uses, – since the transition to T2A (pay-per-use) in 2008, a flat-rate system covering cross-cutting activities such as harvesting and transplant, in addition to reimbursement by various procedures from simple to quadruple depending on the severity and complexity, but there does not exist an annual national summary of the cost. As an illustration, the flat rates and maximum reimbursements are as follows (in euros)[40].

2013	Fee	Per patient
Annual flat rate for coordination of harvesting (at least 40 removals of all organs – public sector)	335,000	
Annual transplant fee (for five transplants)	45,000	
Harvesting		10,727
Level 4 procedure		73,925
Rejection		25,864

These amounts do not cover the pre-operative expenses normally covered by the Health Insurance, such as the hospital fee and the daily rate in the event of hospitalization, up to €2,000 per day in a cardiology intensive care unit, or the drugs, nor the post-operation costs such as functional rehabilitation, examinations, the immunosuppressor treatments or non-acute complications.

37 *Agence de la biomédecine – Rapport d'information au Parlement et au Gouvernement – septembre 2013*
38 *Lindenfeld JA et al. Drug Therapy in the Heart Transplant Recipient. Circulation.2005 ; 111 : 113-117*
39 *Milliman Report 2011 - Table 2 : Estimated U. S Average 2011 Billed Charges Per Transplant (the 2014 report is not yet available at the date of drafting this document).*
40 *Agence de Biomédecine - Modalités de financement 2013 des activités de prélèvement et de greffe d'organes, de tissus et de cellules souches hématopoïetiques - www. agence-biomedecine.fr/*

The objective of CARMAT is to propose an immediately available alternative to transplantation, at a lower overall pre- and postoperative cost, with an equivalent survival rate and reduced complications (see paragraph 2.3.3 Marketing Strategy).

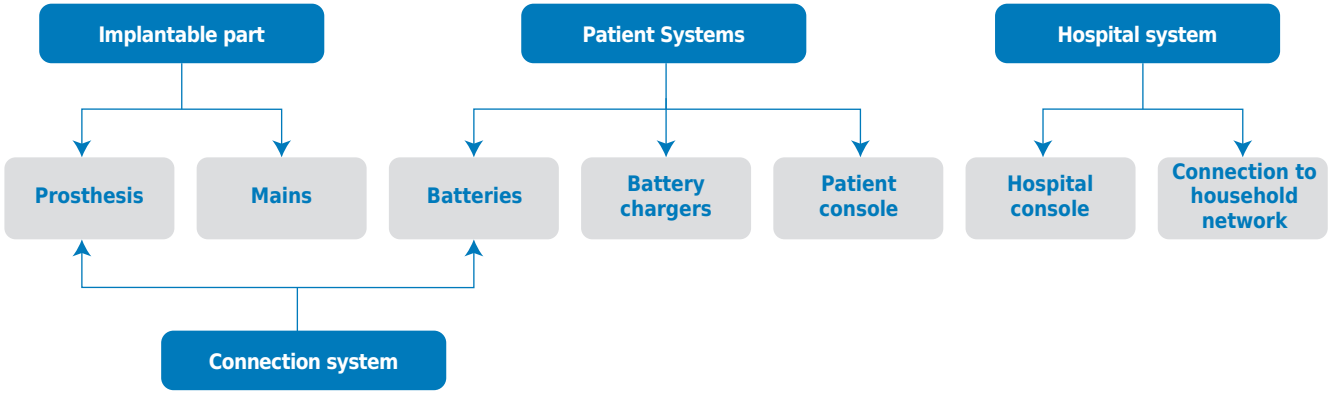
The target price of the CARMAT system is between €140,000 and €180,000 and should allow an attractive economic alternative to be offered, since certain very significant costs, such as those of repeated hospitalizations while waiting for the transplant or immunosuppressor treatments, will be avoided. However, CARMAT is unable to anticipate how much funding there might be or the level of reimbursement for its products, as this is normally decided by the payers (see paragraph 3.3.4 Risks connected with pricing and changes in reimbursement policies for medical devices).

2.2 THE FIRST SELF-REGULATED BIOPROSTHETIC ARTIFICIAL HEART PROJECT

2.2.1 Description

The system consists of:

- *an implantable part, the bioprosthetic artificial heart, as such;*
- *patient systems allowing the return home;*
- *a hospital system allowing complete configuration of the prosthesis and patient monitoring.*



Source CARMAT – The complete CARMAT system project.

2.2.1.1 The prosthesis

The implantable parts include the prosthetic heart and the electrical connection to the power supply, either by battery or by the mains.

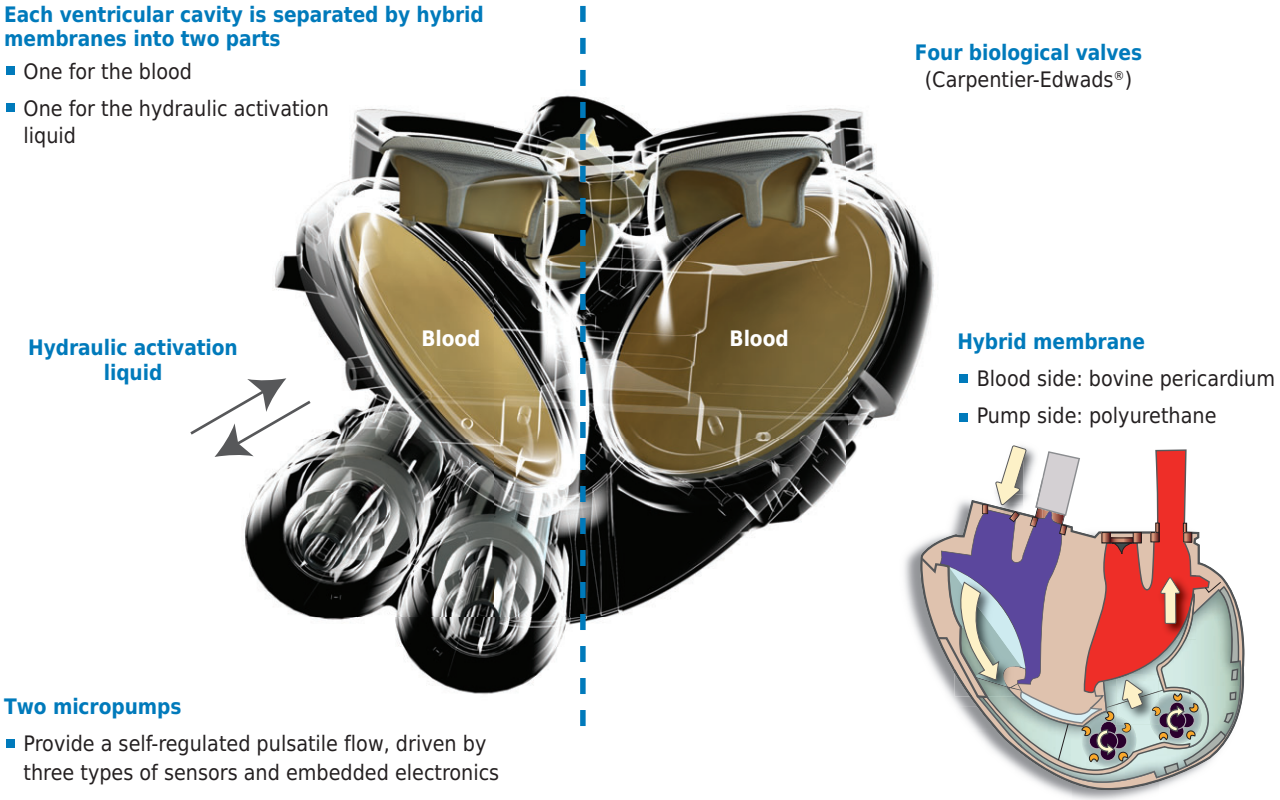
The prosthesis reproduces the operation of the natural heart by using hydraulic actuation, a liquid serving as an intermediary to push the blood. The cardiac rhythm is broken down into two periods, diastole* when the ventricles fill up with blood, and systole* when the blood is pumped into the great vessels and organs.

The prosthesis comprises two ventricular cavities, one on the right and one on the left, with each separated into two volumes, one for blood, one for the actuation liquid, by a flexible hybrid membrane. This membrane reproduces the viscoelastic nature of the cardiac muscle and acts in the same way on the blood, pumping it when it contracts.

A motor-pump group – consisting of two miniature pumps – moves the actuation liquid to the ventricles thus generating systole or by reversing the direction of rotation, towards the external pouch during diastole.

An electronic device regulates how the prosthesis operates according to patients' needs using information given by sensors and processed by a microprocessor.

A flexible external pouch contains the actuation liquid and beats at cardiac rhythm.



Source CARMAT – Functioning of the bioprosthetic artificial heart project.

The internal layout of the artificial heart project has been the subject of continuous optimization over the years.

Engineers endeavored to position the various sub-assemblies of the prosthesis in the best possible place so as to ensure the largest possible ventricular volume, thus ensuring a good blood flow without artificially increasing the operating frequency (see paragraph 2.2.2. Innovations and competitive advantages)

The prosthesis is connected to the patient's atria thanks to an interface device which allows easy suture onto which the prosthesis is then clicked. (See the animation available on the Company website www.carmatsa.com).

In addition, numerous dedicated implant tools have been developed in collaboration with surgeons to make the procedure easier, reduce the operational ischemia time and in this way minimize the inherent complications of a prolonged extracorporeal circulation.

2.2.1.2 Electrical connection

The transfer of electrical energy from the monitoring console or batteries to the prosthesis will be percutaneously for the early clinical trials. This solution has the merit of being proven as it is used by the majority of implantable ventricular assistance systems currently available.

Nevertheless, the percutaneous cable represents a major cause of infections and the Company is currently studying several innovative alternative technologies to reduce the related complications and to provide a further point of differentiation.

In 2011, feasibility studies on the power supply system by way of a retro-auricular plug (behind the ear) did not give the desired results. This technology has therefore been put on hold for the time being and other promising avenues are being explored enabling their clinical trials to be envisaged from the end of 2014.

2.2.1.3 Hospital Monitoring Console

The Hospital Monitoring Console (HMC) – already available – is used solely in implantation centers by certified medical personnel.

It allows the starting of the prosthesis during implantation, the power supply during the hospital stay; the monitoring and configuration of the prosthesis during periodic control visits, and the downloading while functioning of new functions or versions, like for example the software allowing the automatic adaptation to the patient's metabolic needs on the basis of information provided by the sensors, which is downloaded when the patient leaves the hospital[41].

It can import the monitoring data from the patient's systems and, in the long run, it could interface with the doctor's computer to receive and analyze data transmitted by remote transmission. It offers surgeons detailed functions for the analysis of the prosthesis' functioning and of the physiological parameters measured.

2.2.1.4 Patient system

The systems that the patient takes home contribute significantly to their quality of life as they give them the mobility and autonomy essential for a life close to normal.

The Company is currently finalizing a lightweight portable system providing about 3-4 hours' autonomy with Lithium-Ion batteries, allowing good mobility. However, autonomy in the true sense of the term is not limited to four hours, since the patient may carry extra previously-charged batteries, or connect directly to outlet power where possible. The development of an intermediate trolley-based system was thus abandoned.

2.2.1.5 Batteries

- First-generation batteries (Lithium-Ion) will offer three to four hours' autonomy (see below).
- Second generation, which is subject to fuel cell research with PaxiTech, aims to give patients autonomy of more than 12 hours, with a weight of less than 3 kg. The use of a fuel cell should be a first in the medical field. It should provide an original solution integrating the production of hydrogen on demand and optimizing patient security while being ergonomic (useful width: 2 mm). The first operational prototype of this fuel cell could be tested in connection with the portable unit mentioned above.

Other external accessories such as a battery charger, a means to connect to a home mains network or to the power supply of a car *via* the cigarette lighter, bags or belts for transport or to ensure the protection of the system during a shower are also planned. All the elements of the system intended for the patients aim to allow them to feel safe, to have a good quality of life at home and to ensure their mobility for the requirements of everyday life.

The improvement in systems destined for patients – such as the batteries – today make up an important part of the developmental effort of the Company. Indeed, such systems are critical for the patient's quality of life and therefore for take-up of the CARMAT heart by the market. Furthermore, they allow a reduction of direct and indirect costs for the health care systems by promoting a rapid return home, thus creating a favorable cost/benefit ratio for reimbursement.

Source CARMAT – Hospital Monitoring Console (HMC).

2.2.2 Innovations and competitive advantages

Historically, research into the bioprosthetic artificial heart began in the United States in 1963 under the impetus of the American Congress. However, all research on implantable artificial hearts soon hit the snags of hemocompatibility, auto-adjustment of operation to the patient's physiological needs, miniaturization, autonomy and reliability in the long run.

Consequently, Professor Alain Carpentier set the Matra team a large number of challenges:

- design a prosthesis minimizing the risks of thrombosis* (formation of clots), a problem which all the other projects encountered. (see paragraph 2.3.2 Technologies and market players);
- develop an automaton allowing the prosthesis to operate independently, and as such to mimic as closely as possible the operation of the natural heart without the patient or the doctor having to take any action;
- integrate all components necessary for the physiological operation of the artificial heart in a weight and a volume compatible with the thoracic space available in the majority of patients;

41 *Shareholder Newsletter n° 3 - January 2013.*

- optimize the reliability and the lifetime of the prosthesis, essential characteristics of a life-supporting implantable device, to obtain a patient survival equivalent to that of a transplant;
- provide the patient with an autonomy and a mobility as close as possible to a normal life;
- finally, ensure that the implantation procedure for the heart can be performed without difficulties by all cardiac surgery teams.

Numerous innovations and multiple competitive advantages have emerged from the CARMAT team's answers to Professor Alain Carpentier's challenges.

2.2.2.1 Hemocompatibility

The only artificial heart project where all the surfaces in contact with blood are made from compatible biological material to reduce the thromboembolic risk.

All the implants and assistance or organ replacement devices in contact with blood pose the major problem of their hemocompatibility: they must not cause the destruction of red blood cells* (hemolysis*) or activate the coagulation cascade*, thus favoring the formation of a clot blocking a blood vessel which can cause a pulmonary embolism* or a stroke.

The causes of these problems are based around two points:

- hemodynamic, respecting the blood flow, which should prevent stasis (abnormal stagnation and accumulation of blood) or "shearing" of red blood cells (shear stress);
- the surface condition and toxicity of the materials in direct contact with the blood. These materials may be of a varied chemical nature, but their surface condition must be either perfectly smooth and water-repellent so as not to cause any adherence, or else of a microporous structure so as to guarantee satisfactory adherence of proteinic biological tissues.

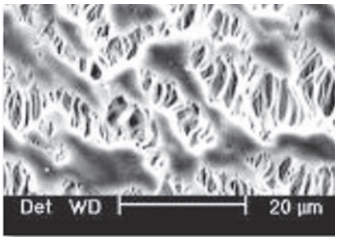
The CARMAT bioprosthetic artificial heart project contributes original solutions to overcoming this major obstacle by developing a type of blood flow actuation which is compatible with physiological blood pressure, thanks to the optimized design of ventricular cavities and the use of microporous biological and synthetic biomaterials which allow continuous proteinic* coverage, adhering to all surfaces in direct contact with the blood. The search for non-thrombogenic materials, essential for the system's ultimate performance, is a quest which has been led by several industrial players without success, in particular in the field of ventricular assistance.

The CARMAT bioprosthetic artificial heart project followed the novel pathway opened by the principles of hemocompatibility as shown by research carried out on Carpentier-Edwards biological valves, designed by Professor Alain Carpentier, and which have been tried and tested over 30 years, with implants on over a million patients, and for implant periods of over 25 years[42,43]. These biological valves, unlike mechanical valves, allow the considerable reduction, or even elimination in certain cases, of the anticoagulant treatment, which is especially restrictive for the patient.

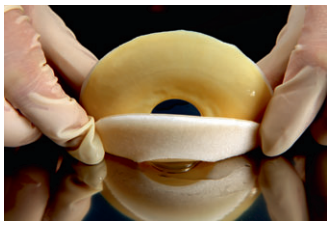
An agreement with an initial period of one year, automatically renewable for one year at a time, was entered into on November 5, 2010 between CARMAT and Edwards Lifesciences, the world leader in the heart valves sector and in hemodynamic monitoring, for the use and supply of Carpentier-Edwards biological heart valves® for the CARMAT bioprosthetic artificial heart project.

Biosynthetic membrane

Carpentier-Edwards pericardial valve®



Ventricle in microporous PTFE



Biosynthetic interface with atria

Source: CARMAT – Hemocompatible materials

42 *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.*

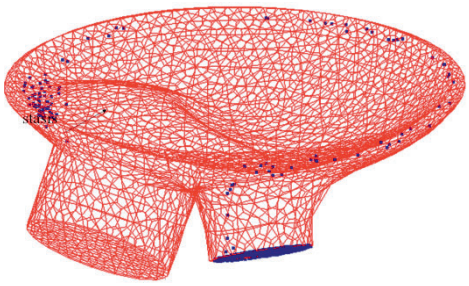
43 *Aupart MR et al. Perimount pericardial bioprosthesis for aortic calcified stenosis : 18-year experience with 1133 patients. J Heart Valve Dis. 2006 Nov ; 15(6):768-75; discussion 775-6.*

Four Carpentier-Edwards pericardial valves will be incorporated into each CARMAT bioprosthetic artificial heart. The atrial connection interfaces are also made from treated bovine pericardium on the blood side. Only the side of the hybrid ventricular biomembranes covered with pericardium is also in contact with the blood. This will mean that all the components coming into contact with the blood will be in hemocompatible or biological materials, setting them apart from other artificial heart projects which specifically use mechanical valves.

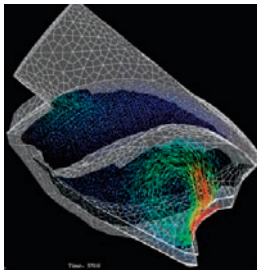
The development and characterization of innovative microporous materials are based on the significant experience of some of the Company's key partners, such as the bio-surgical research laboratory of Professor Alain Carpentier (Broussais Hospital then Georges Pompidou European Hospital) which developed the biological valves, and their treatments, and the FRK (Foundation of Cardiac Surgery Development in Poland), experts in the manufacture of polyurethane implantable elements. Based on this principle, the development of large-sized biosynthetic material, such as biosynthetic membranes and atrial interface covers, represents a significant development in the field of implantable material.

In connection with the preparations for clinical trials and prior to the filing of the technical file with the ANSM with a view to obtaining authorization to set up and run the initial clinical trials in France, tests for resistance to calcification and for hemocompatibility aiming to demonstrate the suitability for implantation of the CARMAT bioprosthetic heart have been performed and published[44], specifically in 2012. The conclusions of these studies are presented in paragraph 2.3.3 Process and developmental stages.

The hemodynamics, studied through various models, were validated through digital simulations. These studies helped to: avoid shear and stasis; ensure that the entire ventricle is "washed" at each cycle and assess the optimal movement of the membrane.



Stasis detection



Hemodynamic intra-ventricular simulation

Source: CARMAT – Digital Simulations.

2.2.2.2 Self-regulation

The first intelligent artificial heart project that provides an immediate and automatic response to the metabolic needs of the patient

To improve patients' quality of life, the CARMAT bioprosthetic artificial heart project was designed to permanently analyze the hemodynamic situation of the patient and to adapt thereto in real time.

Thus, for example, if a patient climbs some stairs, the cardiac output from the artificial heart project will increase, as would be the case with a natural heart. If they lay down to sleep, the heart will slow down to ensure a comfortable sleep. Similarly, the CARMAT bioprosthetic artificial heart project will react to pathological situations such as a hemorrhage by reproducing, with the help of specific algorithms, the behavior that a normal heart would have in the same circumstances.

This automatic response to patients' physiological requirements comes from a bioprosthetic artificial heart design which is as faithful as possible to the physiology of the natural heart thanks to the joint work of the CARMAT teams and the medical and scientific teams led by Professor Alain Carpentier.

Thus, the output of the artificial heart project is pulsating*, just like a natural heart, and its hemodynamic operation is based on Starling's law which governs the operation of the human heart. In line with this law, any modifications to the cardiac flow that occur are mainly based on variations in venous flow back (pre-charge) but are also sensitive to the influence of arterial pressure (post-charge).

The artificial heart project will also simulate the reactions of the natural heart to stimuli from the nervous system, in particular when maintaining aortic pressure in such a way as to permanently ensure satisfactory organ perfusion, in particular the cerebral areas.

Unlike other research projects on bioprosthetic artificial hearts that offer little or no adaptation to the needs of the patient, the medical self-regulating regulation of the CARMAT bioprosthesis aims to reproduce the physiological functioning by implementing:

- an original algorithm allowing replication of the visco-elastic characteristics of the cardiac muscle which changes shape under the effect of pressure depending on its initial elongation, respecting Starling's law;
- an algorithm simulating cardiac function in response to peripheral resistance modifications, which themselves are dependent on the nervous system. The analysis of aortic pressure allows the heart rate to be corrected;

44 *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.*

- an algorithm using information provided by a 3D inclinometer allowing changes to the patient's posture to be identified, and to manage these transitions while respecting physiology for the patient's comfort.

The regulation system was developed over two time frames:

- first of all, on the basis of computerized simulations allowing modeling of the artificial heart, its environment – that is to say the patient's bloodstream, posture and activity. These simulations were designed so as to be as representative as possible and allow the generation of test scenarios;
- then in the laboratory by placing the prosthesis on a hydraulic test bench specially designed for this purpose to recreate the bloodstream (hemodynamic) and simulate human activity (cycles of rest, activity, sleep).

2.2.2.3 Miniaturization

A bioprosthetic cardiac project optimized and anatomically compatible with the majority of patients

In the absence of embedded self-regulation, the other artificial heart projects bypass the problem of adjustment by the use of external control consoles, or by the use of portable extracorporeal devices. These bulky devices, often reserved for hospital doctors, do not allow an acceptable quality of life for the patient.

Taking advantage of progress made in the miniaturization of electronics, the trend among research projects today is to design hearts which integrate the command and adaptation systems as much as possible. But the intrathoracic space is limited. This integration is often realized at the expense of the ejection volume, which requires the artificial acceleration of the cardiac frequency to provide a physiological blood flow.

The shape of the CARMAT bioprosthetic artificial heart project, similar to that of the human heart, has been fully optimized for the anatomy of the thorax so as to satisfy the maximum number of patients while conserving a physiological ejection volume, by using all the space available around the volumes reserved for blood.

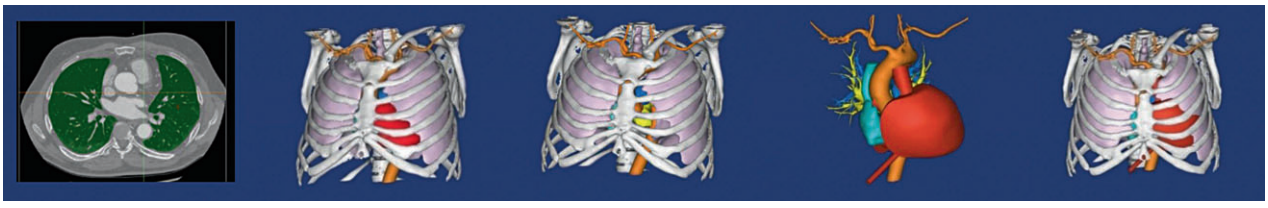
This anatomical shape has been studied taking several criteria into account, such as its total volume, its ventricular volume, its interfaces with the aorta*, the pulmonary artery* and the atria. A reduction in size to the detriment of ventricular volume would have been an anti-physiological choice, since the operating frequency would have been increased, for the same level of flow.

Respecting the obligation of as large a ventricular volume as possible, while conserving a very significant reliability of onboard elements, has required significant miniaturization efforts for all the sub-assemblies involved in its activation: motor-pump unit, control electronics and sensors.

The optimization of the final form was conducted by using a means of CT imaging associated with three-dimensional image fusion mechanisms, which were used to verify the anatomical compatibility of the CARMAT bioprosthetic artificial heart project, on the one hand, and by performing *ex vivo* implantations, on the other hand*.

An advanced virtual 3D implantation system has therefore been developed, based on a sophisticated three-dimensional simulation, which allows, in a completely non-invasive manner, the removal of the natural heart and grafting of the prosthesis to check its anatomical compatibility with a given patient.

A validation of this model has been performed *in silico** by a study based on more than 100 thoracic CT images of patients suffering from cardiac disease, and confirmed by *ex vivo* tests on 15 thoraxes. This study aimed to validate the conformity of the prosthesis to average thoracic dimensions, the feasibility of connecting to the large vessels, and the absence of contact with the diaphragm. According to this study, performed in collaboration with the University Hospital (CHU) of Nantes, the CARMAT bioprosthetic artificial heart project would be compatible with 86% of the chests of the men and 14% of those of the women studied[45].



Source CARMAT – 3D Virtual transplant simulator.

45 *Information presented at the 64th convention of the French Society of Thoracic and Cardiovascular Surgery (SFCTCV) in Lyon, 26-27 May 2011.*

2.2.2.4 Power and autonomy

The first medical use of a fuel cell

Experiences of ventricular assistance have been revelatory in terms of showing the current limits of portable electrical energy technology. These systems use rechargeable batteries with various technologies (Nickel metal hydride, Lithium-ion, etc.). The autonomy on offer is in the region of just 4 to 6 hours, thus forcing the patient's life into a rhythm that is both restrictive and often stressful. Moreover, a number of difficulties stand in the way of immediate use of such devices (levels and types of supply voltage, obsolescence of the technologies used, excessive weight, etc.). Progress is being made every year, but this does not enable any major improvements to be anticipated in the short term. For this reason, this mode of power will only be adopted for the first versions of the system intended for patients.

In order to provide a technology suitable for large-scale manufacturing, and starting from obtaining the CE mark, CARMAT is developing for its bioprosthetic artificial heart project, through its partnership with the company PaxiTech, a high-technology company from the CEA, a portable fuel cell which does not have the problems of storage and refueling of hydrogen traditionally faced by fuel cells. Such a cell could offer patients autonomy of 12 hours, at a maximum weight of 3 kg, thus significantly improving their quality of life.

Moreover, the percutaneous transfer of energy using a wire link poses problems of asepsis in long-term use outside of the hospital environment. The rate of infection from the percutaneous cable is greater than 20% in long-term ventricular assist use[46] (see paragraph 2.3.2 Technologies and market players). Since September 2011, the Company has accelerated its research in two fields to improve the quality of life and reduce the risk of infection for the patients.

Source: PaxiTech – Portable fuel cell.

2.2.2.5 Reliability

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

The CARMAT bioprosthetic artificial heart project is an extremely high-technology system incorporating very varied materials and components, implanted into the human body. The lifespan of such a system represents an essential performance element if this heart is to become a real alternative to transplants. In the long term, the CARMAT bioprosthetic artificial heart project should provide a lifespan comparable to that given by cardiac transplant, that is to say a 50-60% survival rate over a ten-year period.

Few devices have such comparable lifespans during continuous operation without some form of maintenance being necessary. An artificial satellite in orbit several tens of thousands of kilometers from Earth must offer this type of performance. That is why the same test methodology has been applied to the CARMAT bioprosthetic artificial heart project.

The goal for the lifespan durability tests of the bioprosthetic is five years, which represents around 230 million beats. Its theoretical lifespan is assessed with mathematical models used in aeronautics for the electronic parts and endurance tests for mobile electromechanical or mechanical parts.

However, a distinction should be made between the duration of the endurance tests on the bench and the real durability of the device. The duration of the tests corresponds to the minimum regulatory requirements (CE marking or FDA* guidance) which are generally five years, in real time or with an acceleration factor. The real durability may be longer (see the durability of cardiac valves which can exceed 25 years) and can only be established by clinical experience. The real performance of the CARMAT heart project can only be established after the accumulation of clinical data in real time. Moreover, the durability of a device does not predict the survival of the patient, for example, if it leads directly or indirectly to complications.

Endurance bench tests reproduce the conditions in which the tested device will operate during its use in the patient's body.

For some of these tests, it is possible to use an acceleration factor by increasing the frequency of requests, subject to remaining compliant with the future usage profile. For example, a heart can be tested up to an accelerated frequency that remains in the physiological limits of a natural heart.

Source CARMAT – Full system endurance test room, which can host up to 12 systems in a controlled environment.

46 *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.*

Iterative tests conducted for several years have enabled the product design to be optimized by highlighting the possible failure modes and by finding solutions which rectify these weaknesses. With regards to the hydraulic pump, the results show a continuous improvement in its design with no wear visible after four years of tests on the latest generation, while the first generation showed signs of wear after three months. Additionally, 22 pumps have been tested over periods ranging from two years to 6.7 years, with an average of 4.3 years, without any measurable loss of performance. Furthermore, five new motor-pump units are currently being tested, accumulating to date over 38 months of endurance without any significant deterioration in performance.

Moreover, the biosynthetic membrane and the polyurethane pouches have been tested over a period of five years without any alteration of their expected mechanical characteristics.

All these results have been included, in 2012, in the technical file open at the ANSM (refer to paragraph 2.2.3 Process and developmental stages of the CARMAT bioprosthetic artificial heart project).

2.2.2.6 Implantability

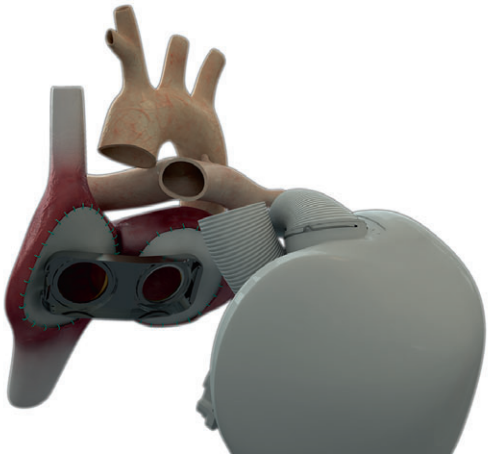
A simple procedure reproducible by all surgical teams

An implantable device can only be a valid therapeutic solution if the implantation is simple and reproducible. Under the supervision of Professor Carpentier, the CARMAT teams have therefore worked in close collaboration with several surgeons, anesthesiologists, perfusionists and nursing personnel of the operating theater to design and develop a procedure that all cardiac surgery teams can perform in good conditions, even in cases of emergency.

Notably an original interface with the patient's atria was developed, which allows the surgeon to have much more room to work, and a better subsequent alignment of the prosthesis. Consequently, the procedure is considerably easier and faster. Indeed, the implantation time must be as short as possible to limit the neurological risks of a prolonged extracorporeal circulation.

Once this interface is sutured to the atria, the prosthesis can simply be clicked into place. The cover of this interface consists of a hybrid material of which the side in contact with the blood is made of bovine pericardia to respect the hemocompatibility philosophy of the prosthesis.

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



Source CARMAT – Rapid connection interface to the atria

2.2.3 Process and developmental stages

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

1. a **preparation** phase of the clinical investigations which consists of studying, designing and manufacturing the systems of the CARMAT bioprosthetic artificial heart implantable in humans, and of performing all the validation tests necessary to obtain a Clinical Trial Authorization from the ANSM in France or from the regulatory authorities in other countries;
2. a **clinical validation** phase consisting of a feasibility study and a pivotal study;
3. a **development** phase which aims to complete the definition of the system and its clinical and *in vitro* validation file in anticipation of the submission of the file for CE marking. This third phase will take place at the same time as the clinical trials.

The aim of this breakdown was to obtain clinical validation data as quickly as possible in order to validate "in real time" the distinctive technical choices on the project (hemocompatibility, physiology, automatic adaptation, anatomy, miniaturization and reliability) or to relate back with the same reactivity in terms of design.

This development plan was accepted by BpiFrance in the contract signed in 2009, and modified by amendments in 2011 and 2013 (see paragraph 5.7 Important contracts). The milestones of BpiFrance development therefore correspond to the stages of this development plan (see paragraph 5.7 Important Contracts). This plan was also presented to AFSSAPS in 2004 and its principle developed when the presubmission file was filed in 2011 (see paragraph 2.3.5 Regulatory strategy) and when the Clinical Trial Authorization (CTA) application was filed in 2013.

As at the date of this registration document, the Company had started its first clinical trial in France. The preparation phase is therefore being finalized. The tests and validations for this phase are thus only summarized in this document. For more details, please refer to previous registration documents.

2.2.3.1 Preparation

The preparation phase is based on a first definition of the CARMAT system. For reasons of robustness, this definition comprises:

- a long-term human-implantable biologized prosthesis;
- intra-extracorporeal wire connection;
- redundant power supply system;
- an alarm module;
- an external wire connection to the power supply and telemetry data storage device (console).

The first step consisted of carrying out a study and detailed design of the system and its sub-assemblies.

The second stage has allowed the development of the various sub-assemblies, as well as their qualification, and system integration.

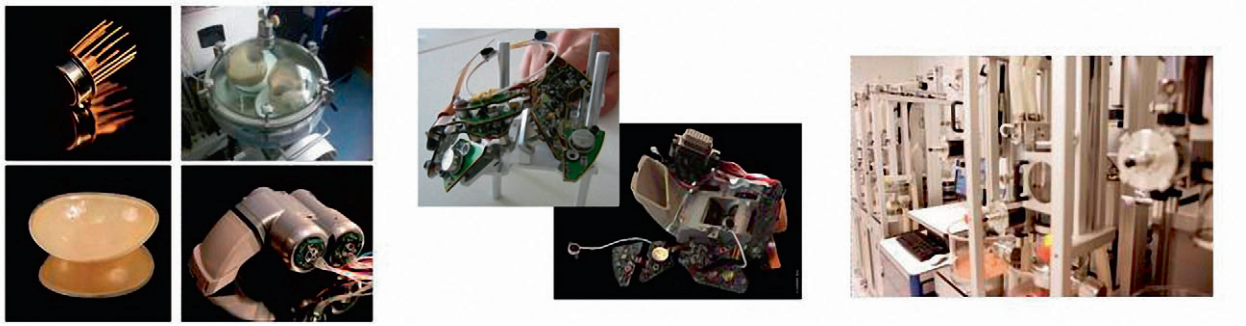
The last step concerned the manufacturing of the systems for the clinical trials. For the purposes of this phase of preparation for clinical investigations, the Company has built an integration clean room and conducted a Bayesian strategy of intensive preclinical tests illustrated and detailed below.

1. Critical components
- Electronics
- Electro-hydraulic convertors
- Membrane
- Bag
- Sensors
- Software

2. Subgroups
- Motor + electronics
- Membrane and sensor
- Generation of flow

3. Integrated system
- Prosthesis + cable + software + console

Functional tests + environmental tests + durability tests

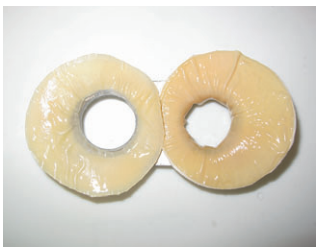


Source CARMAT – preclinical trial strategy derived from aeronautical tests

2.2.3.1.1 Biocompatibility tests

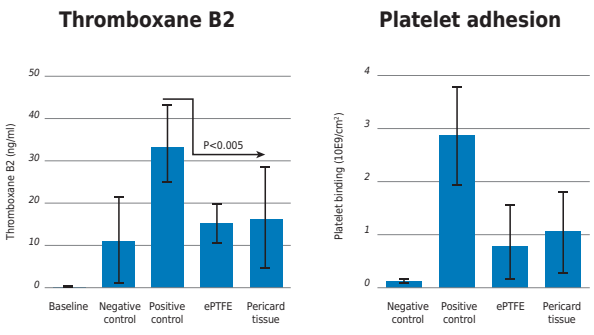
The prosthesis uses hybrid materials forming the ventricular cavity and suture flanges. These materials constitute one of the original features of the CARMAT system. As well as proving their long-term *in vitro* physicochemical stability, the Company has chosen to demonstrate their good long-term implantation properties on the basis of their calcification resistance and excellent hemocompatibility.

The demonstration of the biocompatibility of the material used by CARMAT in direct contact with biological tissue is now concluded and has been published in a scientific journal[47]. The Company now has high confidence *vis-à-vis* the hemocompatibility of its materials.



Atrial connection Interface

Hybrid biomembrane



*Coagulation factors**

Source CARMAT – Results of the hemocompatibility of the hybrid biological interfaces.

47 *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.*

CARMAT has limited the materials interfacing with blood to bovine pericardium and expanded PTFE, which are known for their biocompatibility. As the inlets and outlets, the ventricles have been designed to optimize the blood flow through the device and so minimize contacts and the risks of thrombosis. The pericardium, which also covers the atrial cuffs on the interface between the prosthesis and the auricles – ensures continuity as far as the inlet valves.

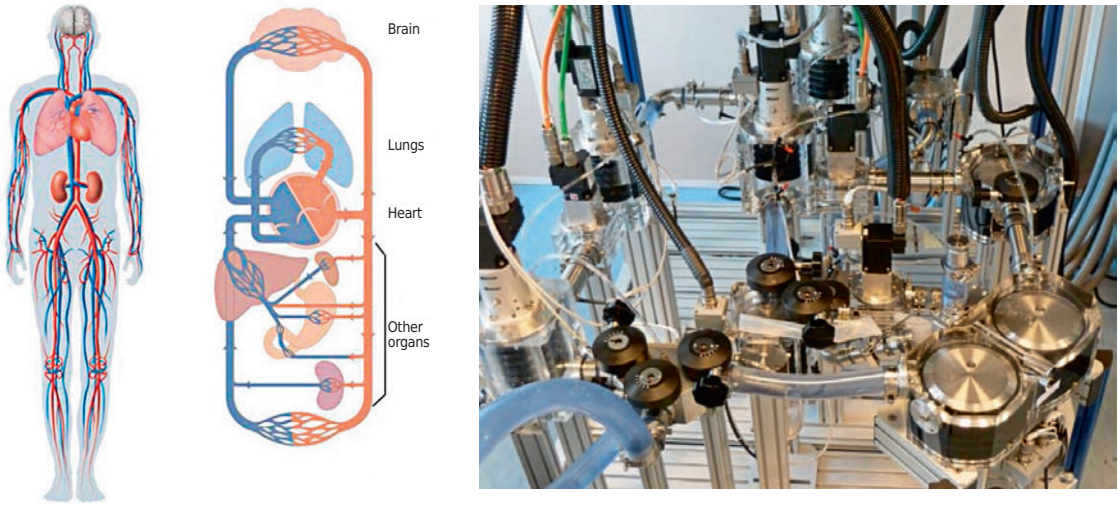
2.2.3.1.2 Verification of the technical requirements – Test-bench testing

All of the test-bench experiments were conducted with constant attention paid to ensuring that every constraint of every component of the system is taken into account with the view of improving the overall quality of the device. CARMAT's testing strategy was to specify the critical components of its device in order to study them separately and then to bring these components together and to test the overall system to obtain a sufficiently high level of confidence for its device. Thus, the Company set up a general test program for its device and specified the sub-components: motor-pump units, hybrid membrane and pouch, sensors, electronics and software according to four major test categories:

A. FUNCTIONAL TESTS

They are based on the demonstration of the product's performance. Specific benches were built for each sub-assembly and for the prosthesis to measure the following in particular:

- the motor's electrical and mechanical performance;
- the pump's hydraulic performance;
- hybrid membrane compliance and imperviousness;
- compliance pouch compliance and imperviousness;
- thermal dissipation of the electronics;
- functional performance of the electronics;
- pressure sensor calibration and testing;
- the major functions of the prosthesis: control of the pumps, ultrasound membrane detection and medical self-regulation.



Source CARMAT – Advanced hemodynamic test bench.

B. SOFTWARE TESTS

Software intended for use in humans for the diagnostic, control or treatment of a disease is considered as a medical device in its own right and must be developed according to the IEC 62304 standard for class C. This is the highest level of requirement intended for software that could cause the death of the patient in the event of failure.

These 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 principal verification phases: unit tests, design verifications, as well as specification verifications. According to Standard EN 62304, all the requirements contained in the specifications and designs must be tested or verified. All these tests and verifications have been successfully passed.

C. ENVIRONMENTAL TESTS

They are based on the verification that the products can withstand and do not have an abnormal effect on the ranges of temperature, pressure and vibration, as well as the magnetic and electrical fields in which they are liable to develop. Performances specifically involving certain equipment are verified as soon as possible, as is the correct operation of equipment according to the ambient temperature, variations in the temperature and in the electrical fields generated by the equipment itself. These tests are complete.

D. INTEGRATION PROCESS VALIDATION AND VERIFICATION TESTING

The integration process of the prosthesis is itself an innovation, no biocompatible self-regulated implantable prosthesis and no associated industrial sector currently existing.

Therefore, the Company must, for each component, part and sub-assemblies, step by step and supplier by supplier, establish a detailed description of each manufacturing stage, the validation procedure for each stage, the control procedures for the component, piece or final sub-assembly, the acceptance testing procedure at CARMAT, the process and instruction manuals for integration into the clean rooms, etc., as well as all the documentation required by the Quality Assurance system of the Company and the requirements of ISO 9001 and 13485 certifications, at CARMAT as well as at its suppliers.

Today, the Company considers that all the procedures put in place respond to this requirement. The setting up of this process has required considerable effort, in the analytical approach allowing the correction of errors or imperfections as they appear, even at the expense of extending the duration of these tests.

E. ENDURANCE TESTS

These are based on the verification of the reliability requirements of the products. CARMAT has performed initial verification of the reliability of the various components of the system, the central element being the prosthesis.

The mobile elements (pumps, membrane, pouch) have been the subjects of specific tests, like the sensors which are subject to mechanical restrictions: the pressure sensors equipped with a silicon membrane and ultrasound sensors made of piezoelectric components.

They are tested on test benches reproducing the environment in which the components normally have to work, but reproducing also 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.

Thirteen new test benches have been set up for the purposes, among other things, of conducting the endurance tests and of simulating the patient's entire life cycle with typical daily scenarios. There are 12 endurance test benches for complete systems (prosthesis, cable, software, console) and an advanced hemodynamic test bench for the performance tests of the self-regulation algorithm.

These sophisticated digital benches are entirely specific to the CARMAT prosthesis and represented a "project within a project". Much proprietary know-how has been acquired during their development.

Given the proven inadequacies of the animal model for the type of prostheses designed for human physiology that the CARMAT bioprosthetic heart represents (see the following paragraph, *ex vivo* and *in vivo* tests), the development of these means of tests, inspired by the aeronautics and space industries, is an additional first to the credit of CARMAT for the medical device industry.

These very sophisticated test benches also allow an acceleration in the limits of physiological conditions. For example, up to 150 beats per minute can be tested, which corresponds to a sustained effort, but not continuously, and of course not up to 300 beats per minute, which corresponds to a potentially lethal ventricular arrhythmia.

As at the date of this registration document, the *in vitro* preclinical validations required to obtain feasibility study authorization in France have been completed. Prior to obtaining authorization for the first phase of clinical trials in France, granted in September 2013, the Company transferred the results of the endurance tests to the file submitted to the ANSM in December 2012 and then the results of additional animal testing in July 2013.

Between the publication of the previous registration document (published on May 30, 2013) and the date of this document, progress has been made and, in particular, concerning:

- quality:
  - verification and validation of the prosthesis software (security software, with the possibility of recovery following failure) in accordance with standard 62304,
  - validation of hospital monitoring console software,
  - analysis report on the risks associated with the system as a whole and of the sub-assemblies,
  - control activities stepped up at suppliers' premises and in the Company;
- industrialization:
  - optimization of the prosthesis production processes in order to ensure enhanced reproducibility, in particular at the Company's subcontractors,
  - improvement of the Company's production processes and tools,
  - production and/or reconditioning of 15 prostheses for the various tests,
  - production of 19 kits for animal testing;
- external systems:
  - prototype and ergonomics study,
  - fuel cell miniaturization study, tank optimization,
  - development (hardware and software) of the configuration worn.

2.2.3.1.3 *Ex vivo* and *in vivo* tests

Between 2010 and 2011, the Company conducted 15 *ex vivo* implantations, in order to assess the anatomical compatibility, the development of ancillary implantation tools, the adjustment of the surgical procedure and the training of the teams. It also conducted around thirty implantations in animals between 2011 and the date of this registration document.

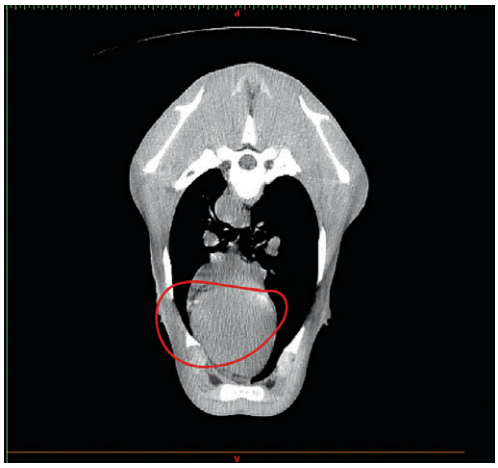
A. LIMITATIONS OF THE ANIMAL MODEL

The animal model, largely used in evaluations of medical devices, does not lend itself well to a bioprosthetic artificial heart project designed for a human thorax and self-regulated on the physiological needs of humans.

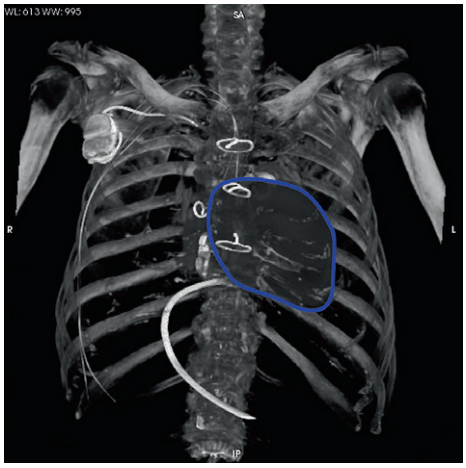
Indeed, the only usable model for its size, weight and thoracic capacity is the calf, if large primates are excluded for ethical reasons. However, it is not possible to test the variations in flow rate linked to a standing position, and therefore the perfusion of organs such as the human brain, on a calf. So, the evaluation of the functioning of the sensor of the CARMAT artificial heart project and the associated algorithms was not possible.

What's more, a calf weighs 40 kg at birth but 300 kg at six months and up to 500 kg at ten months. It is therefore not possible to test – over a long term – a prosthesis designed for human physiology. The output of the CARMAT artificial heart project is not sufficient to perfuse a bovine organism of 150 kg or more.

The thorax of a calf is concave (V-shaped), unlike the human thorax which is ovoid. It is therefore necessary to use an animal of around 100 to 120 kg to have the thoracic space necessary to implant the prosthesis. The position of the large vessels is also different, which complicates the implantation and can negatively influence the results, without the prosthesis being involved.



Thorax of an 80 kg calf, with the position that the prosthesis must occupy in the human thorax marked in red



Human thorax, in blue the anatomical position of the prosthesis

Source CARMAT – In vivo and ex vivo implantations.

It has been shown that the results of the animal model do not predict the results in humans owing to too many differences (physiology, anatomy, and especially blood factors). For example, an American artificial heart project had successfully performed 14 animal implantations at 1 month before proceeding to the human clinical validation. This success transformed into failure in humans with nine strokes in the first 14 patients[48].

A publication from December 2012[49] summarizes the conclusions of six of the most prestigious international learned societies in the field *(Society of Thoracic Surgeons, American Association for Thoracic Surgery, American Heart Association, Heart Failure Society of America, International Society for Heart and Lung Transplantation, and Interagency Registry of Mechanically Assisted Circulatory Support)* on the pre- and post-commercialization of the cardiac assist devices.

The scientific community also declared in this publication that "today, animal models have not answered [many] questions, and different responses between species have been observed that often do not exhaustively reflect the human response". Their conclusion was that "New test methods enabling the assessment of the biological reliability of devices before their clinical introduction must be developed. The improvement in reliability, due to the development of new implantable biomaterials, is a necessary field of research".

This is the strategy CARMAT chose from the start of the project, building, on the one hand, on the extensive biomaterial experience of Professor Carpentier, and, on the other hand, on that of the bench tests performed in the aeronautics industry, thanks to Airbus Group. That is why the preclinical tests were essentially carried out *in vitro* (on test benches) to test endurance and hemocompatibility in particular.

B. USE OF ANIMAL MODELS

Despite these limitations in the animal models for the CARMAT artificial heart project, animal implantation is an indispensable procedural training tool. Between the end of 2011 and mid-2013, CARMAT conducted prosthesis implantations in around thirty animals.

An initial series of short-term animal implants (≤ 48 hours, extubated but not woken) was performed between the end of 2011 and the end of 2012 with the following objectives:

- on the one hand, to validate the surgical procedure, the surgical technique and the ancillary implantation tools;
- on the other hand, to check the start-up process of the prosthesis and re-establish the physiological parameters in the period immediately after the surgery.

These implantations were performed as part of a rigorous protocol on two to four month old Charolaise calves, of a size and weight compatible with the prosthesis, and respecting ethical rules governing animal experimentation. Indeed, all animal experiments are subject to approval by an ethics committee who ensure that the animal model used is likely to provide relevant information for the security of the device, and who can stop the experiments if the animal suffers.

The preliminary results of the first five animals were presented on April 24, 2013 at the 33rd Convention of the International Society for Heart and Lung Transplantation (ISHLT) held in Montreal, Canada[50]. They correspond to the protocol objectives: start-up and correct functioning of the prosthesis, maintenance of a continuous blood flow rate of 7 to 9 liters/minute, etc.

However, the limitations of the model are already apparent: the observed blood flow rate of these animals, weighing approximately 100 to 120 kg, before the operation was between 11 and 15 liters per minute, while the maximum flow rate of the prosthesis, designed

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

49 *Acker MA et al. Statement regarding the pre and post market assessment of durable, implantable ventricular assist devices in the United States. Ann Thoracic Surg 2012 ; 94(6) : 2147-58.*

50 *Latremouille C et al. Sub-Acute Animal Implantation of a Novel Bioprosthethic Artificial Heart. J Heart Lung Transplant 2012 ; 32(4) : S174-S175.*

for an adult man or woman, is 9 liters per minute. During these tests the prosthesis has therefore demonstrated its ability to operate at its maximum output.

On the other hand, the maximum output only just covers the metabolic needs of a two-month-old calf weighing 120 kg which gains another 15 to 20 kg each week: the experiment had to be quickly stopped at short notice in order to avoid the animal suffering in any way. Numerous regulatory agencies, in particular the ANSM or the FDA, continue nevertheless to demand chronic animal experimentation before authorizing a clinical trial in humans.

Animal experimentation thus continued in France over longer periods of time between January and July 2013. The new protocol, developed in collaboration with the ANSM, aims to confirm the return to normal of the clinical indicators (standing, spontaneous feeding, normal diuresis, bowel movement) and the hemodynamic and biological indicators, in particular the absence of hemolysis, over as long a time as possible without the animal suffering. During these tests, the prosthesis operated most of the time at its maximum output (9 liters/minute), with no malfunction or stoppage and post-mortem examinations did not show the presence of blood clots in the in the device and in the organs of the animal.

Source: CARMAT – Prof. Carpentier with an implanted calf in standing position and eating normally.

Each of the three medical surgical teams selected for the first clinical phase of the project in France (George Pompidou European Hospital, Paris (Prof. Latrémouille) - the Marie Lannelongue Surgical Center, Le Plessis Robinson (Prof. Dartevelle and Dr. Nottin) and Laënnec-Nord Hospital, Nantes (Prof. Duveau)) participated in the implantations, accompanied by specialized veterinary teams, particularly the ONIRIS (Nantes) and the National Veterinary School in Maisons-Alfort[51].

2.2.3.1.4 Human clinical validation

A. REQUIRED AUTHORIZATIONS

a. In France

Two authorizations were required to commence a clinical trial in France.

- the favorable opinion of the *Comité de Protection des Personnes* (CPP); and
- the Clinical Trial Authorization (CTA) of the ANSM.

The *Comité de Protection des Personnes* (Île-de-France III, Opinion No. 2925) issued a favorable opinion on November 28, 2011 relating to the ethical aspect of the study protocol and patient consent. The favorable opinion of the *Comité de Protection des Personnes* is valid nationally for all the French centers that participate in the biomedical research on the CARMAT artificial heart project. The favorable opinion obtained in November 2011 was renewed in November 2012.

The ANSM granted Clinical Trial Authorization in late September 2013 and the first human implantation took place on December 18, 2013.

b. Abroad

The regulatory processes are different in each country. Sometimes an authorization application must be made to each individual region, and in certain cases, patient by patient, and, if there is a national authority, it must be notified, without prejudice to a favorable opinion from ethics committees.

After obtaining authorization in France in September 2013, the Company, for obvious practical reasons relating to distance and lower costs and thus to ensure more fluid implementation, focused on performing implantations on four patients in France. The collection and analysis of data relating to this trial was still ongoing as at the date of this document and training of foreign centers is benefiting from feedback from this trial.

51 *Shareholder Newsletter n° 4 - July 2013.*

Clinical cooperation agreements already entered into and current negotiations in other European countries should see the extended establishment of the second study required to obtain the CE mark, subject to satisfactory results being obtained from the initial trial and the completion of preclinical tests.

B. TRAINING OF CLINICAL INVESTIGATION CENTERS

At the end of 2011, CARMAT initiated an intensive training program with three cardiac transplant centers in France with the aim of conducting the first clinical trials. These three centers are:

- George Pompidou European Hospital in Paris (Professor Latrémouille);
- The Marie Lannelongue Surgical Center in Plessis-Robinson (Professor Dartevelle and Dr. Nottin);
- Laënnec Hospital of the University teaching hospital in Nantes (Professor Duveau).

These three teams, as well as the members of the scientific committee, are already longstanding contributors to the development effort, notably in material development and the validation of ancillary implantation tools, development of anatomical compatibility models and medical self-regulation, active participation in animal experimentation and the review of protocols and patient profiles.

Under the supervision of Professor Carpentier, this continual collaboration ensures the transfer and dissemination of knowledge to promote the use of this technology and to build a large body of shared know-how.

The training not only concerns the surgeons but also all the personnel involved in the selection of patients, in the operation, and in the post-operation monitoring. Therefore training must be given, not only to the individuals, but also to teams, including cardiologists, cardiac surgeons, anesthesiologists[52], perfusionists, biomedical engineers, and the nursing staff, in theater as well as in the intensive care units, etc.

This complete and interactive training consists of:

- theoretical training:
  - presentation of the CARMAT system in a demonstration room,
  - training to show how the CARMAT prosthesis operates,
  - visual and theoretical training on the Hospital Monitoring Console (HMC),
  - training in the use of the 3D virtual implantation system for pre-operation planning,
  - training in the implantation procedure: conditions and selection of the patient, preparation of the material, surgical procedure, accessories,
  - training in patient management and their follow-up;
- practical training:
  - HMC training and control of the prosthesis on a training bench and delivery of explanatory documentation,
  - *ex vivo* training, followed by *in vivo* training on the animal: performance of full implantations involving all team members,
  - training on the HMC and patient management,
  - training in the explanation of the device.

The members of the French medical surgical teams already trained provide the training for the international centers. This training program is underway, enhanced by feedback from the feasibility study carried out in France.

C. CLINICAL INVESTIGATION PLAN

The clinical trials will be in two stages:

a. A feasibility study (*First-in-Man*)

The aim of this study is to ensure safety and investigate the main performance variables. This study has been approved by the ANSM for four patients and three investigation centers in France.

As an illustration, the protocol approved by the CPP and the ANSM notably includes the following principal criteria for patient selection (refer to paragraph 2.1 Heart failure, for a proper understanding of the terms and issues).

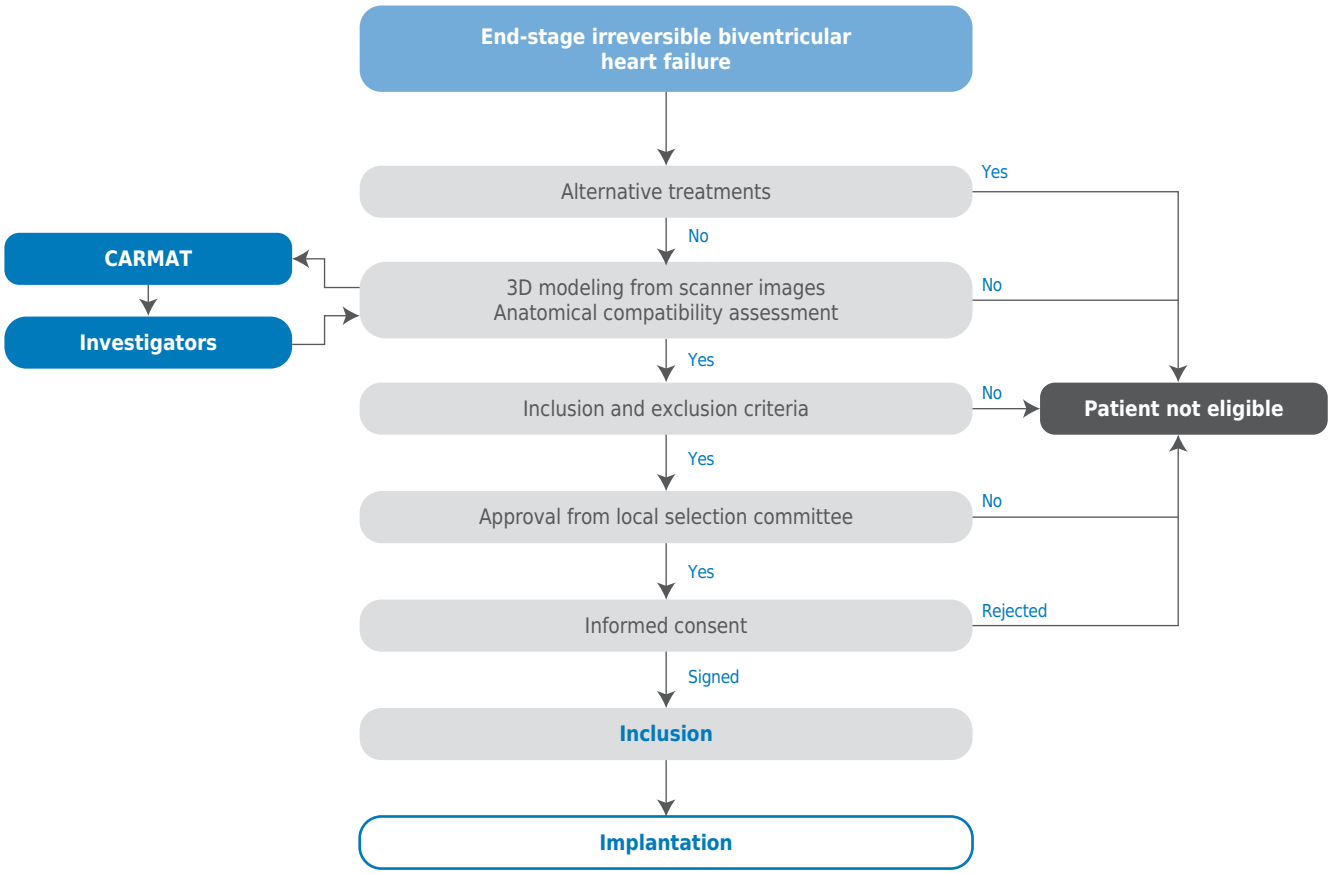
Inclusion criteria:

- end-stage irreversible bi-ventricular heart failure not liable to be helped by a temporary mechanical assisted circulatory support;
- ineligibility for transplantation due to a contraindication;
- patient age ≥ 18 years old;
- functional patient status as evaluated by the INTERMACS® classification: 1 or 2;
- left ventricular ejection fraction ≤ 30%;
- medical treatment optimized according to the recommendations of the European Society of Cardiology and the American Heart Association;
- reliant on the administration of injectable inotropes for at least seven days;
- body surface area: BSA 1.7m^2;
- spatial thorax-prosthesis compatibility confirmed by 3D images and virtual implantation;
- patient registered with a social security scheme;
- opinion favoring inclusion by the local selection committee;
- free and informed consent form signed by the patient or his/her person of trust.

Non-inclusion criteria:

- technical obstacles that would, in the doctor's opinion, lead to excessive surgical risk for the patient;
- coagulopathy determined by platelet numbers < 50,000 or INR > 2.5 not due to anticoagulant treatment;
- neurological contraindication (hemorrhagic cerebrovascular accident in the previous six weeks);
- uncontrolled active progressive infection (septicemia);
- hemodynamically significant peripheral vascular disease;
- confirmed progressive neoplasia with short life expectancy (less than six months);
- irreversible cognitive failure, psychosocial problems or psychiatric illness likely to compromise the application of the study protocol or device management;
- need for corticosteroid therapy exceeding 7.5 mg/day Prednisone equivalent and/or immunosuppressive treatment. The inclusion pathway is shown below.

52 *Shareholder Newsletter CARMAT - January 2014.*



Source CARMAT – Inclusion pathway

This indication relates to patients for whom the disease has progressed to a very advanced stage and whose condition is life-threatening in the short term. Given these specific conditions, the clinical monitoring of a patient for 30 days or more after the artificial heart is implanted is considered to be encouraging. The success criteria therefore include survival at 30 days. The protocol provides for extensive daily monitoring while in the hospital during the first month then at least once a month thereafter.

The Company has also set up two independent data monitoring committees, as recommended by French and European regulations under ISO 13485 and in accordance with good clinical practice[53]. These committees are:

- the Critical Event Committee* (CEC): comprised of three healthcare professionals who are wholly independent from CARMAT and from the trial hospitals, its role is to review all adverse events, serious or otherwise, and to determine their causal link with the device under investigation;
- the Data Safety and Monitoring Board (DSMB): comprising three healthcare professionals who are wholly independent from CARMAT and from the trial hospitals, its role is to review all study data and issue an opinion to the sponsor on whether to continue with inclusions in the clinical study.

As at the date of this registration document, the collection and analysis of data relating to this initial feasibility study was still ongoing.

b. Pivotal study

The purpose of this study is to validate the safety, efficiency and performance of the system and to obtain CE marking (up to 25 patients).

Subject to satisfactory results from the feasibility study, the protocol of the pivot study could include patients with a better prognosis.

The setting up of an international multicenter study is part of good clinical practices and ensures a global basis for a product which is not intended to be limited to the domestic market. It will reinforce the ability of CARMAT to put in place a multicenter pivotal study and to establish an international cardiac surgeon base formed upstream of commercialization.

CARMAT wishes to extend the participation in its pivotal study to other European centers, and has already identified centers in Europe interested in implanting the CARMAT artificial heart in the context of clinical investigations, particularly the four centers identified in May 2013.

The extension of the clinical investigation plan to these international centers requires an effort from the Company in terms of locating all the documentation intended for the doctors and the patients and the establishment of local clinical resources with it being necessary to obtain the regulatory authorization to conduct the clinical trials in each of the centers, in particular the authorization of the local ethics committees.

53 *Paragraphes 3.13 p. 3 et 5.11 p. 16 de la norme Européenne ISO 14155 : 2012-05.*

In total, between 25 and 30 patients should be implanted with the CARMAT artificial heart for the clinical validation required for the submission of the file for CE marking. In the event of successful clinical trials, and subject to the absence of delays, in particular in the rhythm of patient recruitment, the CE marking of the CARMAT total artificial heart could be granted in 2015.

The Company consequently intends to perform clinical trials in the United States in order to obtain authorization from the FDA to market the CARMAT total artificial heart in the United States. These clinical trials will start in 2017 at the earliest (see paragraphs 2.3.5.2 Regulatory Strategy – American Regulations and 3.2.4 Risks connected with clinical trials in the US).

D. COMMUNICATION CONCERNING THE RESULTS OF THE CLINICAL TRIALS.

Subject to regulatory obligations or specific circumstances, CARMAT is not planning to publish any information on the results of the feasibility study until a global analysis of the trial's data has been completed. Results are generally communicated after a study, through the intermediary of a report by the principal investigator on all the subjects of the study, published in the journal of a scientific society after being reviewed by a peer review committee (peer-reviewed publication).

2.2.3.2 Development

The aim of this phase is to complete the definition of the system and its clinical and *in vitro* validation file in anticipation of the submission of the dossier for CE marking.

This third phase will take place in parallel to the pivotal study and some parts have already been initiated. It consists notably of:

- possible modifications made to the system of the CARMAT artificial heart project resulting from the experience gained from the feasibility study, in particular with regards to the procedure, implantation tools, software, packaging, ergonomics or the manuals intended for the physicians and the patients;
- the continuation of the endurance tests on a total of ten systems, which will be continuously tested until their failure;
- localization of the documents – regulatory as well as those intended for users – in view of the extension of the clinical trials outside of France, the CE marking and eventually the commercialization;
- the above-mentioned pivot study;
- the study of potential improvements of the means used in order to increase production, particularly with regards to the continuation of securing supplies by the development of secondary sources and the rationalization of the integration process;
- lastly, the design and development of new equipment or new functions allowing the acquisition of new points of competitive differentiation such as an innovative connection to the prosthesis allowing the limitation of infection, a portable system integrating the fuel cell technology and a remote diagnostic system. Some of these developments are in progress or fully completed, notably their design and specification phase.

2.3 MARKET AND STRATEGIES

2.3.1 Market numbers

CARMAT seeks to market a bioprosthetic artificial heart for patients with end-stage heart failure in class IV of the NYHA classification system, either chronic or following an acute myocardial infarction, in a definitive treatment or *Destination Therapy* indication, in contrast to a *Bridge To Transplant* indication, *i.e.* waiting for a transplant (refer to paragraph 2.3.2 Technologies and market players).

Chronic heart failure affects around 15 million patients in Europe[54] and 5.8 million patients in the United States[55], resulting in a total of approximately 20 million patients in this geographical area.

Referring to the indications obtained by similar devices, this bioprosthetic artificial heart could be recommended for patients suffering with chronic or acute end-stage heart failure, aged less than 70 years old, who cannot be transplanted, not suffering from cancer reducing their life expectancy to less than six months, dependent on inotropes, and suffering from a biventricular attack or mono-ventricular attack with the risk of contamination of the other ventricle.

Considering that:

- each year, 2.3% of these patients reach the end-stage stage of the disease – marked by the first hospitalization – in other words a population of around 475,000 patients[56];
- 38% of this population is less than 70 years old, giving an addressable population of approximately 180,000 patients[63];
- around 12,000 eligible patients are transplanted or on the waiting list[57];
- 67%[58] of patients have no risk of right ventricular contamination; and

54 *ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2008. European Heart Journal (2008) 29, 2388–2442 (out of approximately 900 million inhabitants in the 51 countries member of the European Society of Cardiology).*

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

56 *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.*

57 *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.*

58 *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.*

- the anatomical compatibility of the CARMAT heart for men and women is 86% and 14% respectively (refer to paragraph 2.2.2.3 Miniaturization);

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

Moreover, ***acute myocardial infarction***[59] is a significant source of need for cardiac substitutes.

In France, around 100,000 patients suffer from a myocardial infarction each year. Of those patients hospitalized, 7% die in the first month[60]. Myocardial infarction affects 935,000 per year patients in the United States[61]. Its incidence varies according to gender (less in women) and according to geographical area, notably on account of differences in diet. The incidence ranges from 8% in Finland to 0.75% in Japan.

In total, considering the average incidence of 2% in Europe and the United States[62] whose population represented a total of 1,070 billion inhabitants in 2007, the annual number of myocardial infarctions can be cautiously estimated at 2.14 million[63].

From 7.0%[64] to 18%[65] of patients who suffer an acute myocardial infarction die within 30 days. At this stage, the practitioner's only option is emergency heart transplantation, as the native heart is no longer capable of providing the pumping function.

Considering an average hypothesis of 12% (which corresponds to the mortality rate at 30 days in the United States[66]), there are more than 250,000 people each year who suffer a very short-term fatal myocardial infarction.

This sub-population of critically-ill patients represents the second target market for the bioprosthetic artificial heart.

Hence, considering that:

- the average incidence is 2% *i.e.* 2.14 million patients in Europe and the United States[67];
- 12% of these patients die within 30 days for lack of an emergency transplant[68];
- 65% of these patients are less than 70 years old[69];
- more than two thirds of these patients are men[70,71];
- the anatomical compatibility of the CARMAT heart for men and women is 86% and 14% respectively (refer to paragraph 2.2.2.3 Miniaturization);

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

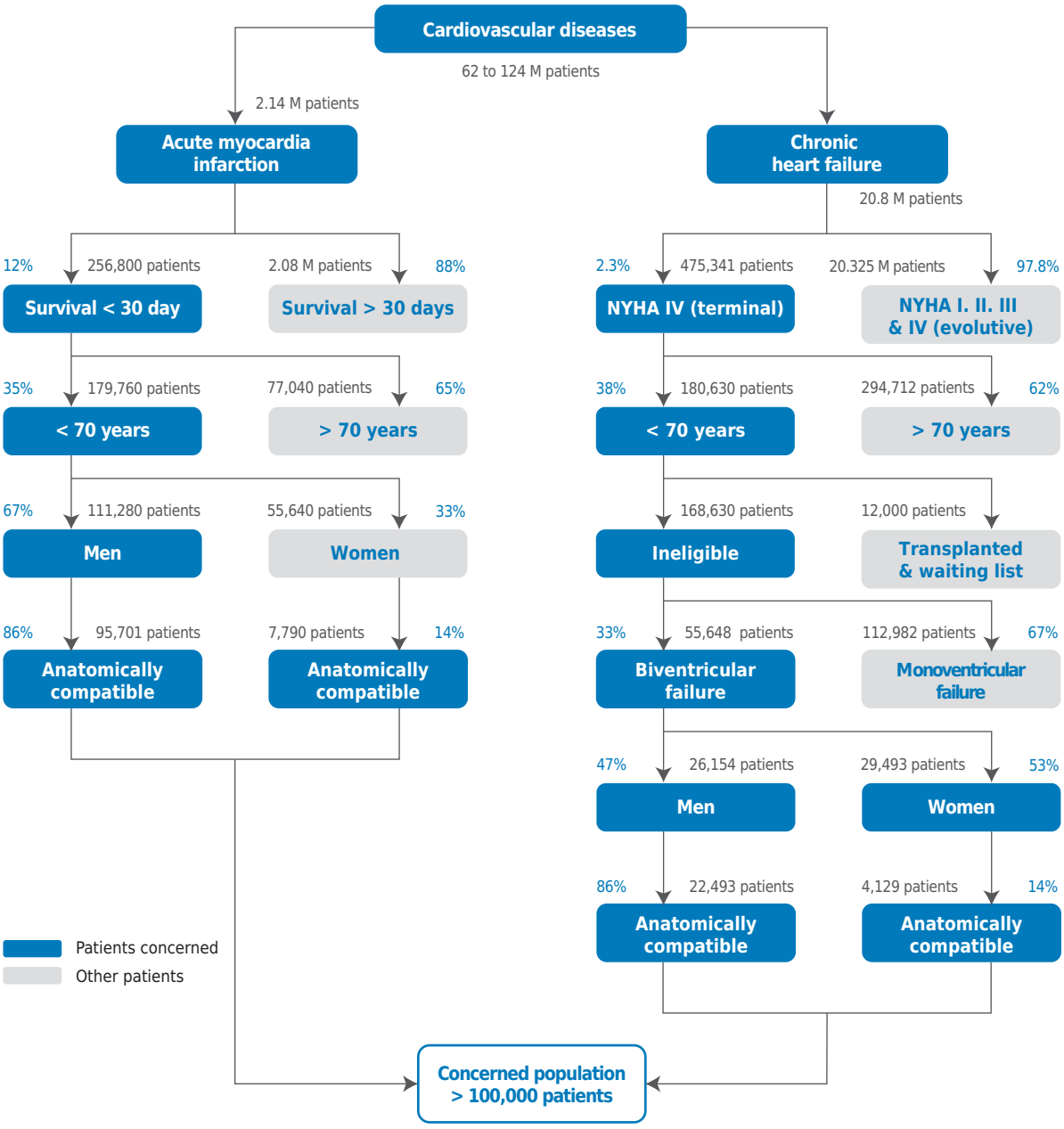
Estimates for the total artificial heart market could therefore stand at around 125,000 prostheses in cases of class IV end-stage chronic heart failure and irreversible acute heart failure following a myocardial infarction for men and women, taking into consideration their respective anatomical structures, in Europe and the United States (refer to the methodological note on the following page).

On a purely prospective basis, it can be expected that, in the years to come, the incidence of acute myocardial infarction decreases, while chronic heart failure increases, as mentioned in paragraph 2.2.1 Pathologies and Etiologies of Heart Failure.

These estimations are summarized in the following illustration.

59 *ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012 - European Heart Journal (2012) 33, 1787–1847.*
60 *Haute Autorité de la Santé website - La HAS s'attaque à l'infarctus du myocarde – Mai 2007.*
61 *Heart Disease and Stroke Statistics – 2010 Update at a glance – American Heart Association and American Stroke Association.*
62 *Yeh RW et al. Population Trends in the Incidence and Outcomes of Acute Myocardial Infarction. N Engl J Med 2010 ; 362 : 2155-2165.*
63 *Perspectives de la population mondiale - Révision de 2006, Organisation des Nations unies - Département des affaires économiques et sociales, 2007.*
64 *Haute Autorité de la Santé website - La HAS s'attaque à l'infarctus du myocarde - Mai 2007.*
65 *Roger VL. Epidemiology of myocardial infarction. Med Clin North Am. 2007 July ; 91(4): 537–ix.*
66 *http://www. cdc. gov/dhdsp/atlas/2010_heart_atlas/docs/Executive_Summary.pdf - page 16.*
67 *Yeh RW et al. Population Trends in the Incidence and Outcomes of Acute Myocardial Infarction. N Engl J Med 2010 ; 362 : 2155-2165.*
68 *http://www.cdc.gov/dhdsp/atlas/2010_heart_atlas/docs/Executive_Summary.pdf - page 16.*
69 *Roger VL. Epidemiology of myocardial infarction. Med Clin North Am. 2007 July ; 91(4): 537–ix- Table 1.*
70 *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.*
71 *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.*

NUMBER OF PATIENTS WITH TARGETED INDICATIONS IN EUROPE[72] AND IN THE UNITED STATES



Source CARMAT

Methodological Note

Estimation established based on the hypotheses detailed and referenced in the previous pages. The Company strives to update this information based on the most recent pertinent scientific publications, and to reduce the number of references so as to avoid the bias incurred by the aggregation of populations or different methodologies. Nevertheless, no official epidemiological reference data exists for these indications and the geographical area considered. Consequently the populations studied can differ from those defined for the indications targeted by the CARMAT artificial heart. For example, the available data is most often split by age at around 65 then 75 years old. The Company has, in this case, cautiously estimated the number of people less than 70 years old based on the demographic data of the considered population. Likewise, it has not been possible to find references on the proportion of patients suffering from end-stage cancer (life expectancy <6 months) in the population with end-stage heart failure. This exclusion criterion could not therefore be taken into account. However, The Company estimated that this situation has little influence on the estimation. This data is provided solely as an indication and does not constitute, in any way, a commitment by the Company on the size of the market at the time of the commercialization of the CARMAT heart or a sales forecast (refer to Chapter 3.1.1 Risks connected to market size).

72 *51 member countries of the European Society of Cardiology, notably including Eastern Europe, Russia and the Gulf countries (refer to Note 54).*

2.3.2 Technologies and market players

Heart transplantation, especially in light of the lack of organs, cannot fulfill the needs of patients in class IV end-stage heart failure (refer to paragraph 2.1.4 Available treatments). Alternative medical devices exist, – often grouped under the term Mechanically Assisted Circulatory Support (MACS).

The principal market players are Thoratec® and Heartware® in the field of ventricular assistance, and Syncardia in the field of artificial hearts.

These devices are indicated in two cases:

- While ***waiting for a transplant*** (*Bridge to Transplant*: BTT)

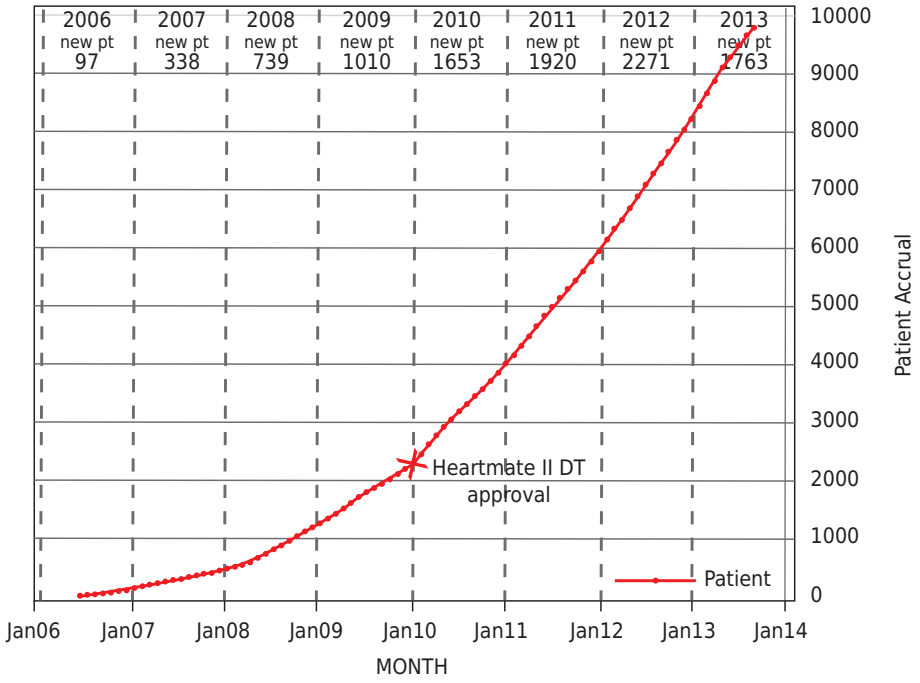
  The device is implanted temporarily until an organ is available or until the patient's condition improves sufficiently to tolerate the operation. Considering the thromboembolic or infectious complications of the available devices, they were, until recently, used mostly for this short-term indication. However they are also limited by cost – the cost of the implantation of the device adding to the cost of the transplant.

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

  This indication was, until recently, reserved for a very small number of patients who were ineligible for a transplant, or who did not wish to have a transplant. However, under the pressure of a fast increasing prevalence and the shortage of organs, numerous patients temporarily implanted actually become destination therapy patients.

  In addition, since the first FDA authorization in 2010 for this indication for the HeartMate® II, and the designation obtained by Syncardia in March 2012 as Humanitarian Use Device as first-line treatment in destination therapy in the United States (refer to paragraph 2.3.2.2 Orthotopic "total" artificial heart), this indication has considerably increased in North America as well as in other European countries such as Germany.

NUMBER OF PATIENTS – ACCUMULATED PROSPECTIVE ENROLLMENT IN 158 CENTERS IN THE UNITED STATES



Source – Adapted from the Interagency Register for Mechanical Assisted Circulatory Systems (INTERMACS)[73]

73 *Kirklin JK et al. The Fifth INTERMACS Annual Report. J Heart Lung Transplant 2012 ; 32 : 141–56 - February 2013 http://www.uab.edu/medicine/intermacs/images/Federal_Quarterly_Report/Federal_Partners_Report_2013_Q3.pdf 9,791 patients at September 30, 2013. (data only for the United -States and only for the devices marketed, outside clinical trials. A EUROMACS registry will be available shortly – www.euromacs.org – it does not yet display public statistics.*

The aim of a destination therapy is to offer a system providing a real quality of life to the patient, *i.e.* a reasonable autonomy and a return home, and even a professional or social life, which is accompanied by an increase of at least 2 NYHA classes, without major complications.

This indication for destination therapy experienced exceptional growth: it comprised only less than 6% of the indications in 2009, but more than 43% in 2013[74], despite a slowdown in the 2nd half-year associated with thrombosis phenomena from Thoratec's HeartMate II® pumps® published last January[75], but probably previously recognized in the centers using it (refer to paragraph 2.3.2.1 below).

50% of patients implanted in destination therapy are in the 60 to 69 years age bracket.

This new information confirms the validity of Professor Carpentier's vision, realized in the CARMAT bioprosthetic artificial heart project: a device that would reduce thromboembolic complications thanks to minimal contact between the blood and the pumps and the use of biomaterials for all surfaces in contact with the blood.

The devices can then be distinguished into two categories:

Note: the following information concerning the other devices has been taken exclusively from public sources such as websites of the companies cited, publicly accessible presentations for investors or referenced scientific publications. Readers are encouraged to conduct their own research in order to form their own opinions. CARMAT accepts no liability concerning the accuracy of this information.

2.3.2.1 Ventricular Assist Devices[76]

These devices are often and incorrectly referred to by the media as artificial hearts.

However, as their name indicates, they are implanted in parallel to the native heart, to assist it by supplementing its flow to meet the metabolic needs, but do not replace it. The historic leader in this category is Thoratec®, with the HeartMate II®, - HeartWare® being its main competitor company. Thoratec® announced that it had exceeded 16,000 implants of the HeartMate II® in 2013 (*i.e.* three years after its approval by the FDA as a destination therapy).

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

Nevertheless, the wider diffusion of these left ventricular assist devices has led to an increase in the need for biventricular assistance. Indeed, the development of a right heart failure is a major complication of left ventricular assist devices. Up to 24% of patients implanted with a HeartMate II® develop right-side heart failure[77]. Studies suggest that the additional indication for a right ventricular assist device represents up to 37% of cases[78, 79, 80, 81].

Methods for evaluating this risk are being developed to identify patients who would benefit from a biventricular assist device at an early stage, as it has been demonstrated that an early implantation results in a very significant improvement in survival rates compared to a late implantation[82, 83]. This could contribute to an increase in the use of biventricular devices, such as the one from CARMAT, as a first-line treatment.

These non-pulsating miniature devices, such as the HVAD® by HeartWare® are designed to supplement the cardiac function and not as a substitute for it. They consequently have limitations in terms of their flow rate. The flow rate of the centrifugal pumps of these left ventricular assist devices is determined by the specific geometry of each device, the speed of rotation of the pumps in turns per minute, and the difference in pressure between the entry into the pump (ventricular pressure) and the ejection from the pump (aortic pressure).

The blood pressures are very different in the right side of the heart. On the left side, the blood needs to reach all the organs, the brain at the highest point, the extremities of the limbs, at the furthest. On the right side, it is "sufficient" to send the blood to the neighboring lungs for reoxygenation. The actual design of a left ventricular assist device with a centrifugal pump and the constant flow rate would have to be significantly modified to adapt it to a right ventricular assist device.

74 *Kirklin JK et al. The Fifth INTERMACS Annual Report. J Heart Lung Transplant 2012;32:141–56 - Février 2013 www.uab.edu/medicine/intermacs : 9 791 patients au 30 septembre 2013. (Données uniquement pour les États-Unis et uniquement pour les dispositifs commercialisés – hors essais cliniques. Un registre EUROMACS est en cours de création – www.euromacs.org – mais ne met pas encore à disposition de statistiques publiques).*

75 *Najjar S et al. An analysis of pump thrombus events in patients in the HeartWare ADVANCE bridge to transplant and continued access protocol trial. J Heart Lung Transplant. 2014 Jan ; 33(1):23-34.*

76 *Devices indicated in waiting for recovery (Bridge to Recovery: BTR) are not mentioned here. Indeed, their indications and their technologies are very different. They can provide only a limited assistance (around 2 liters/minute vs. 9 liters/minute for the CARMAT heart) for a very limited time (from a few hours to a few days) and are intended for patients without permanent ventricular deterioration, who need temporary hemodynamic support, for example after surgical intervention or post-traumatic hemorrhage.*

77 *Presentation by Dr J. Teutenberg (University of Pittsburgh, Pennsylvania) at the International Society for Heart and Lung Transplantation (ISHLT) - Montreal, Quebec, Canada-April 24-27, 2013.*

78 *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.*

79 *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.*

80 *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.*

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

82 *Fitzpatrick JR et al. Risk score derived from pre-operative data analysis predicts the need for biventricular mechanical circulatory support. J Heart Lung Transplant 2008 ; 27 : 1286–92.*

83 *Fitzpatrick JR et al. Early planned institution of biventricular mechanical circulatory support results in improved outcomes compared with delayed conversion of a left ventricular assist device to a biventricular assist device. J Thorac Cardiovasc Surg 2009 ; 137 : 971-977.*

To our knowledge, a single manufacturer of implantable left ventricular assist devices with centrifugal pump currently plans a study for approval as a right ventricular assist device[84].

Some left ventricular assist devices with centrifugal pumps and a constant flow rate have been experimentally tested as biventricular assist devices[85,86]. Very few publications exist on the subject. All indicate that the design for the left side of the heart is a major flaw: currently "the right pump, in a circuit of normal pulmonary pressure, would pump more volume than the left and would result in pulmonary edema".

The options for avoiding this major complication are:

- the reduction of the pump speed below the recommended values, which would cause thrombosis from the pump or rotor instability. This option should therefore be dismissed as it goes against the actual design of the pump;
- the narrowing of the ejection duct, which would cause the increase in the total resistance of the pump and would allow the necessary volume to be pumped, while staying in the rotation speed limits of the pump.

However, in patients with high pulmonary vascular resistance, and in particular when it is irreversible, the narrowing should be less. [...] A system of adjustable narrowing of the ejection duct would therefore be desirable.

A recently presented animal study concluded that "in the case of biventricular support, the adjustment of flow rate of the right ventricular assist device by adjusting the rotational speed of the pump is limited, even when using an ejection duct with a reduced diameter"[87].

How can these adjustments be achieved, how can they be made dynamic and automatic, in short self-regulated? No answer has yet been found to these questions. It is nevertheless vital for the patients at high risk whose long-term hemodynamic stability can, in no way, be guaranteed. It is this self-regulation that the CARMAT artificial heart project proposes.

In the case of biventricular support, each device is controlled independently by two separate portable controllers. The absence of communication between the two controllers severely limits the synchronization between the left ventricular assist device and the right ventricular assist device, as well as the response to the physiological demands. The necessity to wear two controllers and two battery packs obviously limits the quality of life.

To date, the majority of ventricular assist devices with rotatory pumps have fixed rotation speeds that can only be altered by a physician possessing the access codes. The absence of synchronization therefore weighs heavily on patient recovery as well as on device management (use of medical resources for the adjustment).

Moreover, fixed flow pumps are generally set on the slow rotation speeds allowing the native left ventricle to create a left ventricular pressure, and consequently a pulsatile flow. However, in very ill patients for whom biventricular support is indicated, the native ventricle is no longer capable of generating a left ventricular pressure. In this case, the higher rotation speeds required of the centrifugal pump lead to a non-pulsatile flow. In these patients, the renal and hepatic functions are most often already compromised and the long-term effects of a non-pulsatile flow on the organs have not been studied.

Also, in the context of the use of two systems, one on the left and one on the right, the presence of two percutaneous cables also noticeably increases the risk of infection, already high with only one system[88].

The limitations are therefore inherent to the design of these left ventricular assist devices. They remain an attractive solution for temporary left ventricular assist devices, a different population of patients from those targeted by CARMAT.

The physiological self-regulation of the CARMAT device answers the need of synchronization between the pulmonary and the systemic circulation. The instantaneous response to physiological changes is a critical element for the rehabilitation of the high risk group of patients with biventricular heart failure.

While assistance is provided in parallel to the native heart, the latter continues to deteriorate progressively. In particular, with the accumulated experience of long-term support, it is found that the phenomena of native aortic valve regurgitation[89] (up to 38% of patients) and serious ventricular arrhythmia[90] (up to 31% of patients) present rapidly in the medium term. These complications can require other expensive and risky procedures, such as the implantation of a valve or a defibrillator. They obviously do not exist in the case of a replacement. On the other hand, they can lead patients suffering from such complications to need an emergency transplant or the implantation of a biventricular replacement device such as the one by CARMAT.

None of the devices actually approved, and originally designed for short-term implantation while waiting for a transplant, have developed effective solutions to prevent complications from the implantation of thrombogenic materials.

Metals and polymers, except if their design or their nature leads to surface proteinization, such as ePTFE and the bovine pericardium used exclusively by CARMAT for all the surfaces in contact with blood, are thrombogenic: they activate the coagulation cascade and can therefore create blood clots, which can potentially block a pump in direct contact with the blood flow, or migrate into dangerous areas such as the brain – with a risk of stroke (up to 20% of patients[91]) - or the lungs at the risk of pulmonary embolisms.

As previously mentioned, an article[92] published in January 2014 in the prestigious New England Journal of Medicine, reported a significant increase in the rate of thrombosis from the HeartMate II pump of 8.4% as opposed to 2.2% in March 2011, with a high associated mortality.

84 *HeartWare® website HeartWare International 2013 Fourth Quarter and Year-End Results Conference Call - Thursday, February 27, 2014.*

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

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

87 *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/.*

88 *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.*

89 *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.*

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

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

92 *Starling R et al. Unexpected abrupt increase in left ventricular assist device thrombosis. N Engl J Med 2014 ; 370 : 33-40.*

These results – obtained in three centers – are not in line with Thoratec's internal data® or the data from the Intermacs register (about 4%).

Whatever the case, thrombosis from pumps in the CARMAT system is not possible, since the blood is never in contact with the pumps, thanks to the impervious biosynthetic membranes at the heart of the Company's intellectual property.

To limit these complications, existing devices require a heavy anticoagulant treatment for life (blood-thinners). This treatment is restrictive, complicated and unstable, and itself leads to complications[93]: too much risks severe hemorrhage, not enough risks thrombosis or a stroke.

The CARMAT bioprosthetic artificial heart project is also the only device designed to limit thromboembolic risk by using biological, hybrid or synthetic materials with a proven long-term clinical hemocompatibility. Even if an anticoagulant treatment is necessary, which the clinical trial will assess, it could be limited in terms of intensity and constraints, and could more easily be temporarily interrupted if necessary (surgical procedure, even benign dental type procedures, invasive scopic explorations, etc.). That is the case for the use of biological valves which allow, contrary to mechanical valves, reduced anticoagulation and even no anticoagulant treatment, and possible temporary withdrawal if necessary.

Other left ventricular assistance devices are available and/or currently in clinical trials[94].

It can be seen that these devices are intended for different patients from those targeted by CARMAT and opportunities for substitution are limited. Nevertheless, ventricular assist devices allow many patients to benefit from a temporary or longer-term alternative to transplantation. Their growth is strong and has allowed the development of a medical and scientific community dedicated to the problems of circulatory support – which will be a conducive environment for the first clinical, then marketing steps of the CARMAT bioprosthetic artificial heart project. Their success or difficulties have also drawn the attention of the financial community – notably North America, which constitutes another point of interest for CARMAT. Certain recently-listed companies like HeartWare® have had a successful and interesting stock market debut.

2.3.2.2 Orthotopic "total" artificial hearts (Total Artificial Heart: TAH)

Much like a heart transplant procedure, orthotopic "total" artificial hearts replace both failing ventricles, by implanting in their place (orthotopic replacement) two ventricular volumes and a system that ensures a blood flow. The CARMAT bioprosthetic artificial heart project belongs to this category.

The only total artificial heart currently on the market in Europe and the United States belongs to the eponymous private equity company Syncardia[95].

This device was designed in the 1970s and implanted for the first time in 1982 - under the name of Jarvik 7. The patient survived 112 days. In 1985, a patient for the first time reached the transplantation stage after having survived 9 days with an artificial heart. In 1990, the FDA closed the company Symbion Inc., which held the rights for the Jarvik 7 and stopped the clinical study in progress (IDE*) – due to the violation of their regulations. The technology was recovered by a university center in Arizona under the name CardioWest™. A new clinical study started in 1992 in the United States, lasted 10 years and resulted in FDA approval in 2004 for a bridge to transplant indication and CE marking in 2005. In the meantime, a new privately funded company, Syncardia Systems Inc., was created in 2001 to prepare and then ensure the commercialization[96]. Syncardia announced the 1000th implantation of its artificial heart in February 2012, which is 19 years after the first implant in December 1982. The North American Register INTERMACS records 224 commercialized implants (not counting studies) between 2006 and September 2013[97].

There is also an artificial heart whose design dates back more than 40 years. Its functioning is based on a pneumatic actuation. The internal polyurethane diaphragms are activated by the compressed air, generated by a compressor, which is itself powered electrically. Four mechanical valves are used in each device. Two percutaneous plastic tubes of around 2 meters long (7 feet) join the device to the external compressor.

Until the CE marking of the first portable compressor on a trolley in 2006, all patients had to stay in hospital connected to a compressor/controller of several cubic meters – familiarly known as "Big Blue" by the health care teams – until their transplantation. In the FDA study (referenced on the Company website), the average waiting time was 79 days, with a maximum of 411 days and a survival of 50% at 48 weeks. This first generation of portable compressors was approved in the 2nd semester 2012 in the United States, and a second generation – the Freedom™ portable driver – is currently in clinical trials (CE marked in 2010). The possibility of a return home while waiting for an organ has had a snowball effect on Syncardia sales (400% from 2010 to 2012). This of course contributes to the quality of life but also substantial savings to the health care system.

Although it concerns relatively short-term implantations (average 79 days), the rate of complications[98] – particularly infectious (69.5% of 95 patients), hemorrhagic (44%) and thromboembolic (22%) – in this study was high, probably for the same reasons as those described in the previous paragraph concerning the assist systems (design and materials).

Moreover, in 2012 and 2013 Syncardia obtained the designation Humanitarian Use Device (HUD*) for its 70 cc and 50 cc models as first-line treatment in destination therapy, as well as a pediatric indication for the latter. This makes it possible to market a maximum of 4,000 devices per year in the United States for each model in these indications.

93 *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.*

94 *The reader is invited to carry out his or her own research and to form his or her own opinion in this domain. For example, Jarvik 2000 (www.jarvikheart.com), Sunshine Heart (www.sunshineheart.com), etc.*

95 *www.syncardia.com – all the information concerning Syncardia is taken from their website, unless specifi cally stated otherwise.*

96 *Historical information on Jarvik 7 is available on Jarvik Heart's website: www.jarvikheart.com.*

97 *www.intermacs.org – Statistical updates - Quarterly Statistical Report 2013 3rd Quarter .*

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

Today Syncardia is dealing with the end of the production by their manufacturer of the four mechanical valves which each of its devices contains[99] and must adjust the use of more modern mechanical valves.

CARMAT can only welcome the regulatory, financial and commercial success of the market players. Indeed, they maintain the attention of the scientific and financial communities, highlighting the expected advantages of CARMAT's innovations and preparing the route.

Compared to a transplant, the respective advantages and disadvantages of current systems are summarized in the following table[100]:

	Transplantation	Assist systems and artificial heart
Advantages	▸ State of the art destination therapy	▸ Immediately available
	▸ Normal physical activity possible	▸ Planned intervention
	▸ Long-term prognosis favorable	▸ Good level of physical activity
Disadvantages	▸ Lack of donors and organs	▸ Dependence on the device
	▸ Risk of rejection	▸ Autonomy dependent on a continuous electrical power supply
	▸ The transplanted organ is exposed to diseases	▸ Infection of the percutaneous cable(s)
	▸ Risk of coronary disease of the transplanted organ	▸ Risks linked to anticoagulation
	▸ Risks linked to immunosuppression	▸ Severe hemorrhage
	▸ Renal failure	▸ Stroke
	▸ Neoplasia (cancer)	*Regarding assist devices:*
	▸ Susceptibility to infections	▸ Serious cardiac arrhythmias
	▸ Diabetes	▸ Aortic regurgitation
	▸ Hypertension	▸ Thrombosis from pumps

Thanks to the use of breakthrough technologies, such as biological or hemocompatible materials to limit the risks linked to anticoagulation, or fuel cells to increase patient's autonomy and quality of life, CARMAT aims to appreciably reduce the majority of these disadvantages and to offer a real alternative to transplantation.

NB: The AbioCor artificial heart® [101] from Abiomed® is no longer presented in this document. Despite the device having obtained an HDE (Humanitarian Device Exemption) from the FDA in 2006, no implants seem to have been performed since 2009 and the Company has since totally changed its strategic direction towards the Bridge to Recovery (BTR) indication with a system called Impella®. The recent presentations to investors available on the Company's website[102] no longer mention either the AbioCor® product, or its market. CARMAT therefore considers that Abiomed® is no longer part of the market players for artificial hearts or long-term assist devices. Likewise no other artificial heart projects – mostly in universities – seem to have progressed to the clinical phase since the previous edition of this document in May 2013. In particular, the developers of the completely mechanical Reinheart heart[103] do not plan on beginning clinical trials before the end of 2015. The reader is invited to refer to the Company's previous registration documents for this historical information, as well as to paragraph 3.1.3 Risks linked to the competition.*

99 Slepian MJ et al. The SynCardia total artificial heart : in vivo, in vitro, and computational modeling studies. Journal of Biomechanics 46 (2013) 266-275.

100 Adapted from 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.

101 Dowling RD et al. Initial experience with the AbioCor Implantable Replacement Heart System. J Thorac Cardiovasc Surg 2004 ; 127 : 131-41.

102 www.abiomed.com – all information concerning Abiomed® is taken from their website, unless otherwise mentioned.

103 Laumen M et al. Projekt ReinHeart : Lebensretter Kunstherz. Dtsch Arztebl 2013 ; 110(46): [11] (article in German).

2.3.3 Marketing strategy

The Company will be able to market its product throughout Europe once it has been granted CE marking, subject to applying the national systems covering the cost of the device (refer to paragraph 3.3.4 Risks connected with changes in reimbursement policies for medical devices).

The Company considers that the absence of reimbursement is not synonymous with the absence of sales or revenue. Hospitals in some countries have their own budgets to finance innovation and pre-reimbursement financing exists in many countries (NUB in Germany, STIC or Forfait Innovation in France, etc.).

The Company currently plans to proceed with this commercialization through a direct sales force in the principal European countries, at least during the initial phase.

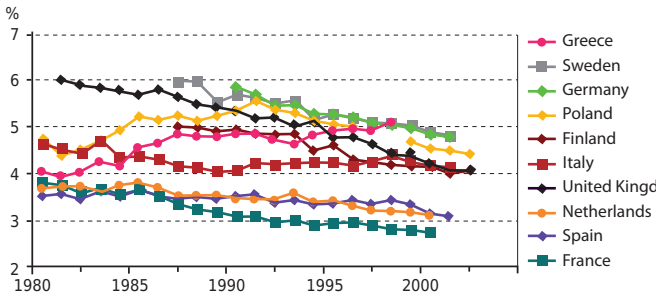
This choice stems from two factors:

- the need for technical and clinical support for each implantation, provided principally by the Company in the training and launch phases;
- a concentric marketing strategy, which consists of focusing first of all on the core targets, *i.e.* the active cardiac transplant centers (at least 20 cardiac transplants per year), then on the centers less active, and then on the centers that have dedicated heart failure teams (surgery and cardiology) but that do not have transplant approval, then finally all cardiac surgery centers.

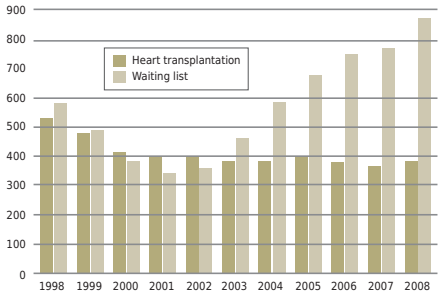
This approach should allow incremental investment. Indeed, considering the very limited number of organs, the number of truly active cardiac transplant centers – *i.e.* who make use of their approval and perform a sufficient volume of transplants to maintain available and trained teams – is very low, less than around ten in each of the major countries. For example, only eight centers in Germany (out of 79 cardiac surgery centers), 7 in France (out of 64 centers) and 2 in the United Kingdom, perform more than 20 transplants a year.

The Company therefore considers that, to cover this target consisting only of centers of excellence, a direct sales force is the most appropriate response in the initial phases of commercial development (one to three years post-commercial launch in Europe). In the longer term, when the Company has built up a solid clinical and medical-economic database and has confirmed the adoption of the therapy by the implantation centers, it may turn its efforts to educating referral centers in order to expand recruitment and promote growth.

With regards to the order in which the different European countries will be targeted, it will depend on the prevalence of cardiovascular diseases, on the size of the centers, and on the national systems to cover the cost of the device. Germany comes first in these three criteria.



Cardiovascular disease mortality (Europe)[104]



Transplantation and waiting list – Germany[105]

In 2013, for a population 25% greater than that in France and a prevalence of cardiovascular diseases almost doubled, Germany[106] conducted fewer cardiac transplants than France[107] (312 vs. 397) and had a waiting list almost three times as long (904 vs. 325).

Consequently, it is the country with the most experience of circulatory assist devices (even ahead of the United States, where innovative devices are generally approved much later than in Europe), the largest European centers in terms of volume and procedures for early reimbursement of innovative treatments in place.

In Germany, a patient needing a transplant is immediately offered a choice between a transplant and a device, fully aware that the choice of a device will remove them from the priority list for a transplant. Studies have shown that the choice of a device gives the patient the same life expectancy as with a transplant, other than when it is a last minute choice in a much deteriorated situation[108,109].

Italy is also an attractive market for these three criteria, despite the lack of centralized decisions (approval at the regional level).

104 *Adapted from European Heart Network – Cardiovascular statistics 2008 - www.ehnheart.org.*

105 *Translated from 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.*

106 *Eurotransplant (register of donor organs and transplants for Germany, Belgium, the Netherlands, Austria, Croatia and Slovenia). www.eurotransplant.org.*

107 *Activité de prélèvement et de greffe : organes, tissus et cellules. Synthèse nationale 2010 - Édition octobre 2011 - Data extraction as at March 2011 - Agence de biomédecine website.*

108 *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.*

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

Establishing centers of excellence with high volume in selected countries would allow the rationalization of clinical and commercial resources, the development of "ambassadors" and training centers, and eventually, the consideration of indirect distribution platforms for other countries.

The development of a commercial approach to the American market is premature at this stage, but will probably require a collaboration with a local financial or industrial player.

With regards to the pricing strategy, the target price of the CARMAT bioprosthetic artificial heart project is between €140,000 and €180,000. This price range is in line with current practices of reimbursement for available devices. For example, a left mono-ventricular implantable assist device is, today, reimbursed between €60,000 and €110,000 in Europe (about €90,000 in France[110]). Being a system that consists of an implantable part, but also external parts and associated pre- and post-operational services, the adjustment variables are many and could allow the adaptation to volume and reimbursement conditions specific to each center or each market.

The reimbursement procedures are many and different for each country. Therefore, the sales force will initially consist of (i) profiles with a strong clinical background to ensure the training and adoption of the device by the medical-surgical community and the collection of medical-economic data, and (ii) of specialists in reimbursement and negotiation with hospital groups or public and private insurers.

2.3.4 Industrial strategy

The industrialization phase, which will commence as soon as the conclusions from the first wave of clinical trials are known, will consist in setting up production facilities at CARMAT and its subcontractors.

2.3.4.1 The choice of a model of integration

Supported by an experienced research department, the Company designs or specifies all of the elements making up the CARMAT artificial heart project, including its external elements as well as all the ancillary tools, packaging, systems and methods intended for the validation (test benches) and production of components, sub-assemblies and systems (clean room). It has also developed strong intellectual property rights (refer to paragraph 2.4 Research and Development, patents and licenses) concerning all of these elements and the integration chain. Nevertheless, considering the very high number of specialties and expertise involved in each component and sub-assembly of the system, it was impossible to develop and even less so to produce them all internally.

For example, the Company did not develop and produce the pressure sensors but used a new and precise miniature model used in aeronautics. It did, on the other hand, develop all the characterization procedures for these sensors, as well as specifying the electronics and the software code that allows them to be used in the prosthesis. These electronics are also subcontracted, the manufacturing of printed circuit boards requiring very high manufacturing volumes to make the installation and the equipment profitable, volumes that the Company would not achieve on a production for the artificial heart alone.

The Company has therefore adopted a model of integration: it designs and specifies, but entrusts the manufacturing of most of the elements to specialized subcontractors, recognized in their domain of activity and selected following rigorous consultation – elements that are then integrated into the Company's clean room.

CARMAT integrates the components and sub-assemblies provided by manufacturers of very different sizes, methods and areas of expertise. Thus the Company has more than 80 manufacturers of elements or services linked to the implantable part of the CARMAT system.

The challenge for a young company like CARMAT is to unite these companies of diverse origins and methods – some being large industrial subcontractors for the aerospace industry, others small businesses, almost cottage industries – around common and strict methods and processes, such as is required in the universe of medical technologies by the regulatory authorities. This coordination relates to technical aspects, logistics and in particular, quality. Great efforts have been made by the Company to validate and qualify these suppliers, so that each one of them conforms to the very high level of quality standards required in the active implantable medical device domain.

CARMAT's mode of operation, its methods, and its integration process are therefore identical to those of a large group in the management of a project as complex as that of the bioprosthetic artificial heart. The creation of this network constitutes an accomplishment in its own right, and creates value for CARMAT as well as for all the industry in France.

In parallel, and as announced at the time of the capital increase in July 2011, the Company actively continues a strategy of secondary source of supplies, in particular the transformation of critical raw materials or the supply of key components. To initiate a second source involves the selection of a new supplier, help in producing the first parts, then qualifying them while ensuring that each part comes from a source that is strictly identical to those coming from another source, including the documentation which comes with them to satisfy traceability. It is important work but vital to reduce the dependency of the Company with regards to their suppliers and to anticipate the industrialization phase.

2.3.4.2 Internalized production and production capacities

In contrast, the Company has kept and retained internally the production of the biosynthetic elements of the prosthesis (ventricular biomembrane, ventricular coverings and atrial connection interfaces), protected by numerous patents and by industrial secrets.

CARMAT's clean room has two distinct areas, one is ISO class 5 used for the manufacturing and sterilization of biosynthetic and ventricular internal elements, the other is ISO class 7 where other elements, essentially outsourced, are assembled around the sterile "heart of the heart". The manufacturing, integration and sterilization of the

110 Liste des Produits et Prestations remboursables – LPP (ameli.fr) : the regulated unit price of a monoventricular HeartMate II® is fixed at €87,565 (11/29/2012 decree).

prosthesis are also performed in this controlled environment by specialized and highly qualified personnel.

In 2013, 15 prostheses and 19 ancillary toolkits for animal implantations (implantation accessories, atrial connection devices, vascular conduits, etc.) were manufactured or reconditioned for the purposes of preclinical and clinical trials. It should be noted that the implantation of each patient requires that two prostheses be present in the implantation center for each procedure, in case a problem – for example accidental desterilization – occurs.

The Company has the objective of producing around 40 systems in 2014. The maximum production capacity inside CARMAT's current clean room is around 200 prostheses a year. Additional production capacities will have to be considered for larger volumes.

2.3.4.3 The main partners

In connection with Bpifrance Innovation financing (refer to paragraph 5.7 Important contracts), the bioprosthetic artificial heart project is based around CARMAT as leader, with four other partners in complementary research and development areas, thereby participating in the development of a high-technology sector in the field of medical devices:

- Dedienne Santé is an SME specializing in the design, manufacture, market introduction and distribution of surgical implants, mainly in the orthopedic domain. For the bioprosthetic artificial heart project, Dedienne Santé uses biocompatible PEEK to develop the assemblies which make up the structural parts of the prosthesis. This development is being undertaken in a dedicated environment at CARMAT, thus preventing any contamination resulting from non-implantable materials;
- Ireis[111] (formerly known as HEF R&D) is a subsidiary of the HEF group specializing in surface engineering, which is behind the invention of several tribological and anti-corrosion surface treatments and coatings since 1953. In connection with the bioprosthetic artificial heart project, Ireis produces the motor-pump unit, which is a sensitive part of the prosthesis;
- PaxiTech[112] is a technological spin-off of the CEA created in September 2003, whose objective is to produce and market portable fuel cells and fuel cell components, regardless of their power range. In connection with the bioprosthetic artificial heart project, PaxiTech is developing a fuel cell which would eventually be used as a source of portable external energy which will give the patient over 12 hours' autonomy. PaxiTech also carries out integration of the fuel cell with the hydrogen tank so as to obtain an alternative solution to portable batteries;
- benefiting from almost 50 years' experience (company created in 1959), Vignal Artru Industries (VAI – Pack'Aero group[113]) is an SME which specializes in the creation of high precision mechanical microsystems. In connection with the bioprosthetic artificial heart project, VAI produces the "motor-pump unit" (MPU) assemblies, made up of two micro-pumps and a duct. VAI is in charge of integrating these units, the various characterization and honing tests, and the acceptance testing for motor-pump unit assemblies.

2.3.5 Regulatory strategy

2.3.5.1 French and European context

The CARMAT heart is an active implantable medical device (AIMD) and must, in particular, satisfy the Safety Requirements of directives 90/385/EEC and 93/42/EEC to obtain the CE marking. It is a very rigorous process of which CARMAT has already successfully passed the first step thanks to the ISO 13485-9001 certification in July 2011. The annual re-certification audits were also successfully passed in May 2012 and May 2013.

The safety regulations mentioned in various directives applicable to medical devices are as follows:

- the medical device must not compromise the clinical state or patient security;
- additionally, they must not present risks for the people who implant them, or for third parties;
- these devices are required to meet the performances determined by the manufacturer;
- they must be designed such that they can resist storage and transportation conditions.

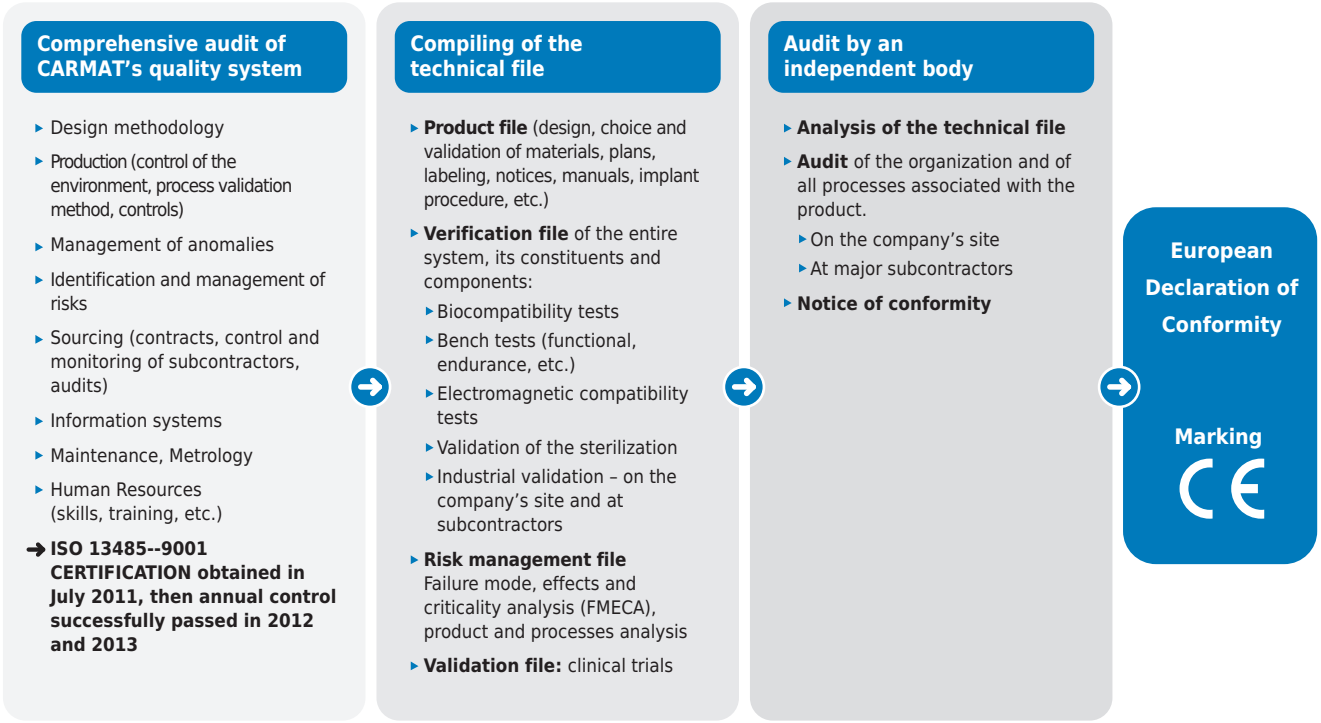
These requirements are also written in more general terms in order to cover a large range of technologies. The manufacturer must review each safety regulation in order to determine if it applies to the device, then identify the harmonized European standard that allows compliance with that safety regulation to be shown. The requirement to comply with the safety regulations must be the priority for the manufacturer in order to ensure that all the necessary measures have been taken so that the device does not compromise the safety and health of the patients, the user and, if required, other people, once installed, maintained and used correctly, depending on the planned use, it being understood that any risks linked to its use constitute acceptable risks with regard to the benefit brought to the patient and compatible with a high level of protection of health and safety.

111 Shareholder Newsletter n° 5 - January 2014.
112 Shareholder Newsletter n° 2 - July 2012.
113 Shareholder Newsletter n° 3 - January 2013.

Compliance with safety regulations must be considered both as an objective (compliance with safety and health), and as a means of obtaining the objective. According to the European directives, each stage of the CE marking process must take into account, in addition to the considerations of security and planned usage of the device, other aspects such as the design or properties related to the construction, protection against radiation, mechanical, thermal or electrical risks, or function measurements or even labeling.

CE marking *via* the declaration of CE compliance is based on a complete audit of the quality assurance system with an assessment of all the Company's processes and focusing on activities linked to the product. An exhaustive technical file must then be prepared, consisting of, in addition to the design elements, the risk management file and all the verification and validation data – in particular the results of clinical trials. Then, the Company will have to submit to an audit by an independent notified body which will verify the technical file and all the processes linked to the product and the organization, at CARMAT, and if necessary at the subcontractors. Once this audit has been successfully passed, CARMAT will be able to obtain the CE marking, which authorizes the commercialization of the product throughout the European community. Certain member states have put in place additional conditions concerning, for example, the registration or notification of market introduction.

In the event of successful clinical trials, and subject to the absence of difficulties, in particular in the continued preclinical trials and in the pace of patient recruitment, the file for CE marking of the bioprosthetic artificial heart project could be submitted in 2015. The validation process by the notified body takes, in general, from six weeks to three months. This process is summarized in the illustration below (refer to Chapter 3.2 Risks relating to the Company's activity and 3.3 Regulatory and legal risks, for the risks associated in particular with preclinical and clinical trials and CE marking).



Source CARMAT – CE marking procedure.

2.3.5.2 American regulations

The market introduction of the CARMAT heart in the United States of America is subject to obtaining approval (PMA: Pre-Market Approval) issued by the American Health Authority (FDA: Food & Drug Administration). Before submitting a PMA application to the FDA, CARMAT will be required to supplement the existing clinical file with new preclinical tests and data from a new multicenter clinical study performed on a larger population (refer to paragraph 3.2.4 Risks connected with clinical studies in the United States).

The realization of this study in the United States is itself subject to obtaining an IDE ("Investigational Device Exemption") authorization from the FDA, based, among other things, on the total preclinical data (technical trials, animal tests, etc.) requested from the clinical trials sponsor and clinical data collected in other countries.

An alternative used by many similar systems (Abiocor, Syncardia, etc.) is to first submit a request to obtain the designation of HUD* (Humanitarian Use Device) after a more limited study (HDE*: Humanitarian Device Exemption). Although it limits the indication to 4,000 patients per year, this route is faster, requires fewer patients than an IDE (about twenty instead of a hundred or so) and makes it possible to progressively develop the skills and partnerships necessary to set up an IDE, at lower cost.

It is possible to obtain financing for the prosthesis during an HDE, or an IDE, and in that case the Company would not have to finance the

costs of the study. With a view to prudence and to avoid spreading its resources too thinly during the commercial launch in Europe, the Company has, for the moment, planned to wait a year after the European commercial launch before starting its regulatory activities in the United States, which could last between two and four years based on the resources allocated to this effort, the type and pace of recruitment for the study.

This cautious strategy would allow the integration of certain clinical data acquired in Europe into the FDA file (the aim is that the majority of the European centers selected for the pilot study would be approved by the FDA) and the self-financing – at least in part – of this new regulatory effort.

This schedule could be accelerated if the Company secures more significant resources or enters into an agreement with a local industrial or financial partner (see Chapter 3.2 Risks relating to the Company's activity and 3.3 Regulatory and legal risks for risks, for risks associated in particular with preclinical and clinical trials in the United States).

2.3.6 Innovation strategy – application of know-how

CARMAT is a young company, created six years ago, but it already enjoys – thanks to its involvement with the bioprosthetic artificial heart project and thanks to its teams – an exceptional and unique dual expertise accumulated over more than 15 years of development and collaboration with the medical world and the world of space and aeronautics, in the application of biomaterials and advanced technologies in the field of bioprosthetic artificial hearts.

Over and above the contributions of the world of medicine and the world of space and aeronautics, the Company has also found ways of bringing together skills in areas that have never been in the habit of working together on so complex a project, each acquiring expertise belonging to these fields.

Emboldened by this unique capacity for creating synergies between skills from industry and from the medical world, CARMAT's future ambition, in addition to the field of the bioprosthetic artificial heart, is to tackle the development of new applications of its know-how in the cardiovascular domain. Original simple devices derived from research already carried out by CARMAT and the patents that it holds, in particular with regard to hemocompatible biomaterials, could also be developed. These products, derived from patents already submitted – in particular in the field of digital simulation and ancillary implantation tools – could also lead to commercial ventures or to transfer of rights. Original services could also be commercialized.

However, the Company does not foresee devoting resources to these potential applications while the artificial heart project is not successfully completed. The Company continues an aggressive protection policy of its intellectual property (refer to paragraph 2.4 Research and development, patents and licenses) and ensures a permanent technological watch of technologies and methods corresponding to its areas of activity.

2.3.7 Provisional project calendar

At the date of this registration document, the forecast project schedule is the following:

1st half of 2014

- Continuation of the feasibility study involving four patients in France
- Preclinical tests for the pivotal study
- Training of new centers

2nd half of 2014

- Introduction of new external systems
- Necessary authorizations obtained for the pivotal study in France or in other countries
- Preparation of the file for CE marking

2015

- Submission of the file for CE marking
- Recruitment of the sales force and reimbursement specialists
- CE marking obtained
- Sales launch in Europe (at the earliest)

2016

- Ramp up of industrial tool
- Initiation of regulatory activities in the USA
- Continuation of sales penetration in Europe

2017

- Launch of a clinical trial in the USA

This schedule is based on all the data of which the Company has knowledge to date. However, in an innovative technological, industrial and regulatory context, data can be revealed after the publication of this document, which could positively or negatively influence this calendar. The significant scientific and regulatory stages described in paragraphs 1.3, 2.2.3, 2.3.7 and 5.7.1 must be completed before the prosthesis can, where appropriate, continue its clinical development, scheduled for 2014, with sales in Europe commencing no earlier than 2015.

The reader is invited to refer to Chapter 3. Risk factors, for an informed appreciation of this calendar, as well as regular Company press releases on the progress of the project. The most recent press releases published at the date of this document (March 4 and 17, 2014) are set out in paragraph 8.6 Recent events. These concern the 74-day survival of the first patient of the clinical feasibility study and the continuing collection and analysis of data from this trial.

2.4 RESEARCH & DEVELOPMENT, PATENTS AND LICENSES

2.4.1 Research and Development

Please refer to paragraphs 2.2.3 Process and developmental stages of the CARMAT bioprosthetic artificial heart project, 2.3.6 Innovation strategy – application of know-how, and to Note 6.4.4.2 in the Notes to the financial statements under paragraph 6.4 Notes to the Financial Statements of this registration document.

2.4.2 Intellectual Property

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

2.4.2.1 Patents

CARMAT's portfolio of patents is made up of ten patents held in the name of the Company, classified in two categories: firstly, patents associated with the architecture of the bioprosthetic artificial heart project and secondly, patents linked to the hemocompatible materials and subassemblies of the prosthesis.

Details of these patents are set out below:

Title	Geographic zone	Application/ publication number	Date filed	Status
Implantable heart prosthesis with independent ventricular chambers	France	FR9812941 FR2784585	10/15/1998	Granted on 01/26/2001 Expiring on: 10/15/2018
One-piece heart prosthesis implantable in an anatomical position	France	FR0605333 FR2902345	06/15/2006	Issued on 09/05/2008 Expiring on: 06/15/2026
	Europe	EP07290725.6 EP1867352	06/11/2007	Issued on 07/15/2009 Expiring on: 06/11/2027
	International	PCT/FR2007/000962 WO2007/144497	06/11/2007	Published on 12/21/2007
Implantable one-piece heart prosthesis	France	FR200800184 FR2926223	01/14/2008	Issued on 01/22/2010 Expiring on: 01/14/2028
	Europe	EP09290009.1 EP2078533	01/07/2009	Issued on 01/12/2011 Expiring on: 01/07/2029
	International	WO2009FR00008 WO2009/112662	01/07/2009	Published on 09/17/2009
Composite hemocompatible material and method for its production	France	FR0511430 FR2892939	11/10/2005	Issued on 01/22/2010 Expiring on: 11/10/2025
	Europe	EP06291657.2 EP1785154	10/26/2006	Issued on 9/23/2009 Expiring on: 10/25/2026
	International	PCT/FR2006/002471 WO2007/054637	11/07/2006	Published on 05/18/2007
Volumetric rotating pump with reduced axial space	France	FR060004206 FR2900988	05/12/2006	Issued on 01/01/2010 Expiring on: 05/12/2026
	Europe	EP7290571.4 EP1855005	05/07/2007	Issued on 01/28/2009 Expiring on: 5/07/2027
	International	PCT/FR2007/000778 WO2007/135261	05/07/2007	Published on 11/29/2007
Device for rapid connection between a totally implantable heart prosthesis and natural atria	France	FR0605331 FR2902343	06/15/2006	Issued on 09/05/2008 Expiring on: 06/15/2026
	Europe	EP07290723.1 EP1867350	06/11/2007	Issued on 09/24/2008 Expiring on: 06/11/2027
	International	PCT/FR2007/000959 WO2007/144495	06/11/2007	Published on 12/21/2007
Device for connection between a heart prosthesis and the natural atria	France	FR0605332 FR2902344	06/15/2006	Issued on 09/05/2008 Expiring on: 06/15/2026
	Europe	EP07290724.9 EP1867351	6/11/2007	Issued on 09/24/2008 Expiring on: 06/11/2027
	International	PCT/FR2007/000960 WO2007/144496	06/11/2007	Published on 12/21/2007
Process for producing a hemocompatible item with a complex configuration and item thereby obtained	France	FR0703339 FR2915903	05/10/2007	Issued on 06/04/2010 Expiring on: 05/10/2027
	Europe	EP08290405.3 EP1992369	04/28/2008	Published on 11/19/2008
	International	PCT/FR2008/000607 WO2008/1145870	04/28/2008	Published on: 12/04/2008
Process for obtaining a composite hemocompatible material and material obtained	France	FR1001724	04/22/2010	Issued on 07/13/2012 Expiring on 04/22/2030
	Europe	EP11161291.7 EP2380608	04/06/2011	Issued on 09/12/2012 Expiring on: 04/06/2031
	International	PCT/FR2011/050768 WO2011/131887	04/06/2011	Published on 10/27/2011
Process to ensure the connection of an anatomical duct	France	FR1152364 FR2972919	03/22/2011	Published on 09/28/2012
	Europe	EP12158011.2 EP2502577	03/05/2012	Published on 09/26/2012
	International	PCT/FR2012/050449 WO2012/127145	03/05/2012	Published on 09/27/2012

The table below indicates the number of patents granted and the applications by country or geographical zone:

Country/Geographical zone	Patents granted	Current patent applications
National patents	127	61
South Africa	6	3
Germany	7	0
Australia	3	6
Austria	7	0
Belgium	7	0
Canada	0	9
China (People's Republic of)	4	5
South Korea	0	9
Denmark	5	0
Spain	7	0
United States of America (USA)	4	5
Russian Federation	7	2
France	9	1
Greece	5	0
India	0	9
Ireland	5	0
Italy	7	0
Japan	2	7
Norway	2	5
Netherlands	7	0
Poland	7	0
United Kingdom	7	0
Sweden	7	0
Switzerland	7	0
Turkey	5	0
European Patents (EPO)	7	2
International (OMPI)	0	9
TOTAL	**134**	**72**

2.4.2.2 Exclusive license agreements

2.4.2.2.1 Exclusive license agreement with the Université Pierre et Marie Curie

Under the terms of an exclusive license agreement of June 17, 1993, amended by *addendum* No. 1 of June 27, 1995 and by *addendum* No. 2 of November 12, 1997, the Université Pierre et Marie Curie 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 initially it was Matra Défense which used the intellectual property rights thus granted, the benefit of this license was subsequently assumed by CARMAT, to which the Université Pierre et Marie Curie consented by way of an agreement duly signed by the Université Pierre et Marie Curie, Matra Défense, the Scientific Research Association of the Alain Carpentier Foundation and CARMAT. Under this agreement (i) the Université Pierre et Marie Curie expressly waived any benefit from all intellectual property rights linked to or resulting directly or indirectly from the work on the bioprosthetic artificial heart project and acknowledged that CARMAT was the sole owner of all the intellectual property rights that could have been attributed to the Université Pierre et Marie Curie; and (ii) 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 25: 1 stock split) to the benefit of the Université Pierre et Marie Curie.

2.4.2.2.2 Exclusive license agreement with the *Centre Technique des Industries Mécaniques* (Technical Center for Mechanical 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 remainder of its duration as at the date of signature (the patent concerned 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. The benefit of this license was subsequently assumed by CARMAT, to which CETIM consented in a second addendum to the framework agreement, signed on October 2, 2008 between CETIM and Professor Carpentier.

European patent No. EP0971756 (equivalent to French patent No. 2760973) is currently in force in France, Germany and Great Britain (expiring on March 18, 2018).

2.4.2.3 Trademarks

The Company has registered the "CARMAT" trademark in the following countries or geographical zones:

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

(1) Application number.

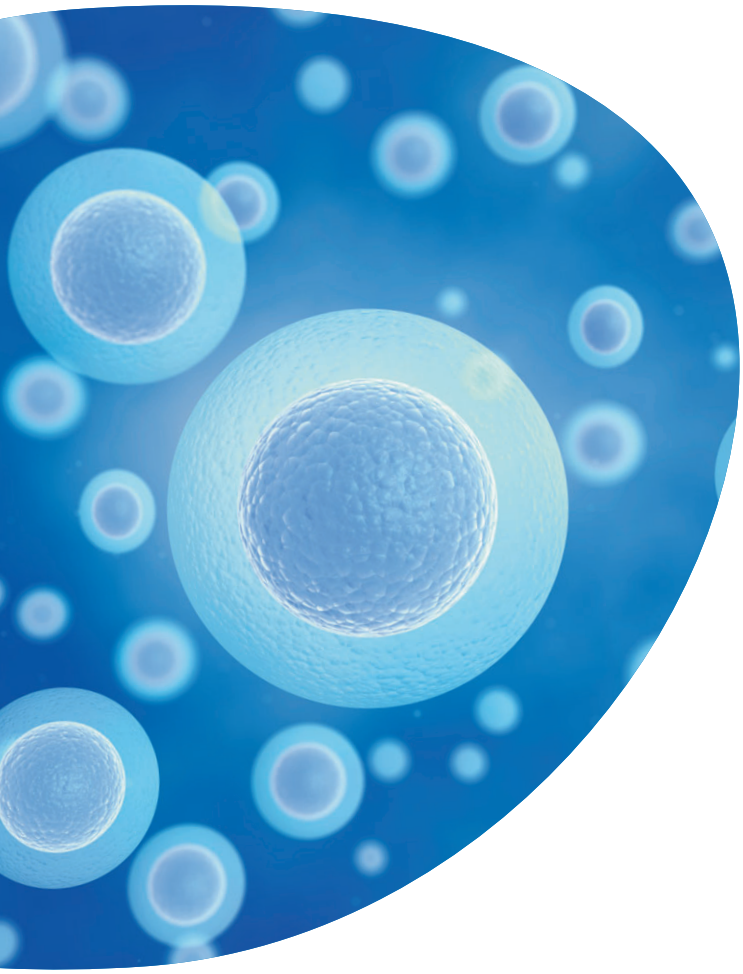
2.4.2.4 Domain names

The Company has registered the following domain names:

Domain name	Date reserved	Renewal date
carmatsas.com	10/29/2008	10/29/2014
carmatsas.fr	10/29/2008	10/29/2014
carmatsas.eu	10/29/2008	10/29/2014
carmat.tel	03/23/2009	03/23/2014
carmatsa.fr	04/29/2010	04/29/2014
carmatsa.com	04/29/2010	04/29/2014
carmatsa.eu	04/29/2010	04/29/2014
carmatsa.tel	04/29/2010	04/29/2014

3

RISK FACTORS



Investors are invited to take into consideration all the information appearing in this registration document, including the risk factors described in this Chapter.

When preparing this registration document, the Company carried out a review of the risks which might have a significant unfavorable impact on its activity, its financial situation, its performance, its development or its prospects, and it considers that there are no other significant risks than those presented.

However, investors' attention is drawn to the fact that other risks, which are unknown or whose materialization is not considered, at the date of filing this registration document, as liable to have a significant unfavorable impact on its activity, its financial situation, its performance, its development or its prospects, can or could exist.

3.1 RISKS RELATING TO THE MARKET IN WHICH THE COMPANY OPERATES

3.1.1 Risks relating to the market size

The Company's bioprosthetic artificial heart targets the definitive treatment indication for patients with biventricular end-stage heart failure whose condition is life-threatening in the short term, who have exhausted all therapeutic alternatives and who do not have access to a heart transplant due to their age, comorbidities, or the shortage of cardiac grafts.

The scientific community agrees that the prevalence of this indication is increasing significantly due to population ageing and progress made in the treatment of myocardial infarction, which prevents many deaths in the short term, but which substantially increases the absolute number of people living with a compromised cardiac function and with a heart failure in the clinical sense.

However, progress that could be made in the area of prevention of certain risk factors of cardiovascular diseases in general (nicotinism, hypertension, obesity, etc.) or specific therapeutic breakthroughs in the field of heart failure could lead to a reduction in the prevalence of the disease in its advanced stage.

Moreover, the population targeted by the indication is heterogeneous and mostly elderly. It is possible that the Company's bioprosthetic artificial heart may not obtain the indication or adoption by the medical and scientific community for the whole of the population currently targeted (about 0.5% of the total number of heart failure patients).

A significant reduction in the market to which the Company could propose its product, due to a reduction in the prevalence of the disease or a limitation of the indications, whether due to a decision by the regulatory authorities or due to a failure of the scientific community and healthcare professionals to adopt its bioprosthetic artificial heart, could have a significant, unfavorable impact on the Company's activity, its financial situation, its performance, its development or its prospects.

3.1.2 Risks relating to competition

Potential competition to CARMAT comprises:

- on the one hand, total artificial hearts, whether on sale or still in development, and implantable biventricular assist devices (BIVADs), with a high potential to serve as substitutes for the heart developed by CARMAT; and
- on the other hand, and to a lesser degree, implantable right/left ventricular assist devices (RVAD/LVAD), which are less apt to serve as substitutes as they only support one ventricle.

CARMAT is not currently aware of any existing device or project which involves or plans to involve the use of either biological materials or self-regulation *via* multiple integrated sensors. These two characteristics are at the core of the technological breakthrough that CARMAT intends to offer.

Nevertheless, the medical devices market is highly competitive and rapidly evolving. In particular, the Company competes with larger companies which possess greater industrial and commercial experience and superior resources. Consequently, the Company cannot warrant that its product will:

- obtain the necessary regulatory approvals and reach its intended markets faster than rival products;

- be competitive *vis-à-vis* other products that have been developed or are in development, which may prove to be cheaper, safer or more efficient;
- adapt rapidly enough to new technological developments and scientific advances;
- be accepted by medical establishments, physicians or patients in place of existing treatments; or
- compete effectively with other products for treatment of the same pathologies.

It is likely that new developments will continue to occur in the medical device industry and in public and private research institutions. In addition to developing products that are cheaper, safer or more efficient than the Company's product, competitors could manufacture and market their products under better conditions. The Company cannot, therefore, exclude the possibility that companies or public institutions that currently compete with it will merge or reach joint venture agreements or other types of mutual accord and consequently become more aggressive competitors. Furthermore, rapid technological developments by these competitors could render the Company's product obsolete before it yields a return on the research, development and selling costs incurred.

Even if the Company's product is marketed successfully, it may be slow to gain acceptance in the market, leaving the Company in a position where its revenues are insufficient to recoup the costs incurred. In order to ensure that its product is accepted by the market ahead of existing products, the Company will have to make significant efforts in terms of both marketing and capital investment. To date, the Company has not undertaken any significant marketing activity since its product has just entered the clinical development phase.

Lastly, the Company's contracts with its employees do not contain non-competition clauses. The Company therefore does not enjoy the protection afforded by such clauses; however, it intends to maintain and develop a policy of securing staff loyalty by awarding shares in the capital to its employees.

If all or part of the aforementioned risks materialized, this could have a significant unfavorable impact on the Company's activity, its financial situation, its performance, its development or its prospects.

3.1.3 Risks of a commercial failure

If the Company succeeds in obtaining CE marking in the European Union for the CARMAT bioprosthetic artificial heart and a product marketing authorization from the FDA in the United States enabling it to market its bioprosthetic artificial heart, it may take time to secure the backing of the medical community, especially cardiologists, cardiac surgeons and third-party payers.

Whether or not the market accepts the bioprosthetic artificial heart quickly or not will depend in particular on the following factors:

- the medical profession's perception of the therapeutic benefit of the bioprosthetic artificial heart;
- the medical profession's and patients' perception of the improvement in comfort and quality of life;
- the number of establishments likely to carry out artificial heart implants;
- the process and the quality of training of cardiac surgeons in a new surgical technique;
- the cost of the treatment;
- the healthcare payment policies of governments and other third parties;
- the effective implementation of a scientific publicity strategy; and
- the support of recognized experts.

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

3.1.4 Risks relating to the performance of external growth operations

The Company's commercial activities will in the long term depend partly on its ability to constantly improve and expand its product offerings, and in particular systems relating to the power supply and remote diagnosis of the bioprosthesis, in order to meet constantly changing market requirements, face up to strong competitive and technological pressure and extend its geographic coverage.

In its current configuration, the Company might not be able to meet these requirements. It could therefore have to consider making selective acquisitions of new or complementary products or technologies. The execution of this strategy partly depends on the Company's ability to identify attractive targets, to acquire them in satisfactory conditions and to integrate the acquired targets successfully into its operations or its technology.

The Company cannot guarantee that it will be capable of identifying the best opportunities and executing these acquisitions, nor can it give an assurance that it will manage to integrate successfully any other product, technology, team or company that it has acquired. Any problem encountered by the Company in the integration of other products, technologies, teams or companies could have a significant unfavorable impact on the activity, financial situation, performance, development and prospects of the Company.

Moreover, the acquisition of products, technologies, teams or companies, and the conclusion of other significant transactions could entail a significant cost burden for the Company. The Company could also have to finance such acquisitions by borrowing or by issuing securities, which could cause it to take financial risks and result in certain restrictions being imposed on it, or have a dilutive impact for its shareholders.

The activity, financial situation, performance, development and prospects of the Company could be significantly affected by the materialization of one or more of these risks.

3.2 RISKS RELATING TO THE COMPANY'S ACTIVITY

3.2.1 Risks of dependence on a single product, the bioprosthetic artificial heart

As at the date of this registration document, the Company is dependent on the clinical development and commercial success of its bioprosthetic 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 authorization and success of clinical trials necessary for CE marking for the CARMAT artificial heart;
- obtaining from the FDA an HDE, or an IDE making it possible to conduct a trial in the United States, necessary to obtain an HUD or a PMA, prior to its introduction in the American market;
- obtaining CE marking* in the European Union and an HUD and/or a PMA from the FDA in the United States;
- the success of the commercial launch; and
- the acceptance of the bioprosthetic 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 finalize the clinical and commercial development of its bioprosthetic artificial heart, the Company's activity, its financial situation, its performance, its development and its prospects could be significantly affected.

In the future, capitalizing on the expertise acquired within the framework of its bioprosthetic artificial heart project, CARMAT plans to develop new applications of its expertise in the cardiovascular field or apply this expertise and its intellectual property to other fields of application. However, the development of complementary projects could be delayed insofar as the artificial heart project is at present the Company's priority. Moreover, CARMAT cannot rule out the possibility that it might not manage to have other products enabling it to reduce this dependence. Such a situation would also have a negative impact on its development and its prospects.

3.2.2 Risks relating to the future results of clinical studies

As part of its development, the Company will make use of numerous studies to confirm the safety and efficiency of its products. The results of clinical studies are uncertain. If the Company were unable to obtain positive results proving the therapeutic breakthrough represented by its products, the Company might not obtain the regulatory approvals required for their marketing. If such a risk were to materialize, the Company's ability to win market share would be negatively affected in a significant manner, and this would have a significant unfavorable impact on the Company, its activity, its financial situation, its performance, its development and its prospects.

These clinical studies are sometimes "randomized", in other words the participants are distributed randomly in an experimental group using the products of its competitors. The Company will also have to conduct clinical studies in so-called "real-life" conditions, which could cause unexpected safety problems and complications related to the use of the medical device on patients. If the patients were exposed to unexpected or serious risks, the Company could decide, or the regulatory authorities could demand, the suspension or termination of the clinical studies. Deaths and other undesirable events, whether related or not to the medical device covered by the clinical studies, could occur and require a delay in or interruption of the clinical studies. Any event of this type could have a significant unfavorable impact on the Company's reputation and on its ability to continue its development and marketing plans for its existing or future products.

If the Company is unable to satisfactorily complete the necessary clinical studies, including obtaining positive results and meeting the other requirements for obtaining a regulatory approval, it is possible that it may never generate revenues with its future products. It could also have to limit or abandon certain development programs.

Lastly, investors could misinterpret the clinical results that the Company might report to the market, partly because it would be hard to establish conclusions in relation to the primary objectives set within the framework of the clinical studies, and partly because the data and analyses provided could be complex to understand.

If one or more of these risks materialized, this could have an unfavorable impact on the Company's activity, its financial situation, its performance, its development or its prospects.

3.2.3 Risks relating to delays in the clinical studies

To obtain the certificate allowing CE marking for its bioprosthetic artificial heart, the Company will have to perform clinical studies on a significant number of patients in several centers in France and abroad. These studies and the publications of the results of these studies should make it possible to rapidly make the products developed by the Company known to important hospital centers and doctors recognized for their expertise in the area of transplantation and circulatory support. However, the quality and relevance of these studies depend on the Company's ability to recruit the planned number of patients within a limited period of time so as to be able to publish the results rapidly. The remoteness or geographic distribution of clinical study centers could give rise to operational and logistic problems, which could cause additional costs and delays.

If the Company were unable to recruit the required number of patients, thereby causing delays in the clinical studies and in the publication of their results, this would postpone the recognition of the Company's products and of its capacity for winning market share, which could have a significant unfavorable impact on the Company, its activity, its financial situation, its performance, its development or its prospects.

Moreover, if the results obtained in these studies proved negative, this would have a significant unfavorable impact on the Company's activity, its financial situation, its performance, its development and its prospects.

Moreover, the Company depends and will depend on third-party clinical research organizations (CROs – Contract Research Organizations) to conduct its clinical studies. Although the Company counts on these organizations to provide a high-quality service relative to the Company's clinical studies, it cannot control all aspects of their activities. If these third parties do not fulfill their contractual duties or obligations, or if they do not meet deadlines, if it is necessary to replace them or if the quality and accuracy of the clinical data that they collect are compromised because of a failure to comply with the Company's clinical protocols or for any other reason, the clinical studies planned by the Company could be extended, delayed or cancelled. Any extension, delay or cancellation would have a significant unfavorable impact on the Company's activity, its financial situation, its performance, its development or its prospects.

3.2.4 Risks relating to clinical studies in the United States

The Company plans to apply to the FDA for an HDE and/or an IDE in order to collect the data necessary for an HUD and/or a PMA, authorizations that are required for the Company to be able to sell its bioprosthetic artificial heart in the United States. The design and setup of clinical studies are costly.

Although the Company has already initiated relations with American opinion leaders and specialists in regulatory matters, it has never carried out clinical studies in the United States or under the authority of the FDA, and this could negatively impact the time and costs involved in such studies. No assurance can be given that the Company will be able to carry out the planned clinical studies in the United States profitably and within a reasonable time frame.

Furthermore, it is possible that the results of these studies will not be positive, that they will cost far more than expected, and that the HUD and/or PMA will never be granted. If one of these events occurred, it could have a significant unfavorable impact on the Company's activity, its financial situation, its performance, its development and its prospects.

3.2.5 Specific risks connected with preclinical studies and clinical trials

The Company is currently in the phase of performing the feasibility test and preparing for the following clinical investigations, in particular the pivot study required for CE marking. It will then initiate the HDE and/or IDE studies necessary to obtain a product marketing authorization within the framework of an HUD or a PMA in the United States.

Studies on test benches, endurance tests and tests for validation of the integration process have been performed to obtain the authorization for the feasibility test. Further studies on a larger number of systems are necessary and require the allocation of a significant proportion of the Company's resources to obtain the authorization to perform the following studies. For this purpose CARMAT will have to perform the industrial assembly of prostheses intended for preclinical and clinical trials.

In a context of validation of an innovative production process involving numerous subcontractors, the planned deadlines may be extended even further for production of the prostheses required for these trials, and then in carrying out the trials themselves. Such a situation, if it occurred, could have a significant unfavorable impact on the Company, its activity, its financial situation, its performance, its development and its prospects.

All the development, production, trial data and clinical data – whether available or remaining to be collected – will be evaluated by the competent regulatory authorities, which could require additional preclinical testing or put a stop to the clinical trials or to further clinical developments if the data submitted prove not to have been produced in accordance with the applicable regulations, or if they consider that the expected benefits of the product do not sufficiently outweigh its potential risks to justify other trials.

In addition, the disclosure of confidential information relating to the performance of clinical trials work in progress, and in particular the disclosure of information making it possible to identify, directly or indirectly, persons taking part in the trials (personal health data) could not only adversely affect the perceptions of the medical community and the general public regarding the CARMAT product and its prospects, and also expose the Company to a risk of legal action initiated by the persons in question and/or their families.

It should be noted that the Company could decide, 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 might occur in connection with the trials, thus causing delays or interrupting the trials and thus preventing the Company from pursuing the development of its bioprosthetic artificial heart in the targeted indication or in other indications.

Clinical and preclinical trials are costly. If the results of these trials are unsatisfactory or inconclusive, 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.

The Company's inability to carry out and complete these preclinical and clinical trials successfully could have a significant, unfavorable impact on its activity, its prospects, its financial situation, its performance and its development.

3.2.6 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 by the Company and that they have at their disposal the necessary instructions to implant the bioprosthetic artificial heart.

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

In addition, any competent authority, such as the FDA in the United States and the ANSM in France could, in particular:

- decide that the training constitutes publicity for unauthorized usage;
- order the Company to modify its training program;
- order the suspension of training by the Company; or
- where the breach of the regulations in question constitutes a criminal offense, 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.

This training process could therefore turn out to be longer than predicted and thus affect growth in the Company's sales. If the Company could not adequately train surgeons, the surgeons are at risk of carrying out inappropriate operations or surgical procedures that could delay or stop performance of the clinical trials, or even cause the death of patients.

This type of situation could undermine the image of the Company and possibly lead to legal proceedings being brought against it. Such situations would have unfavorable impacts on the widespread adoption of the bioprosthetic artificial heart and, more generally, on the Company's activity, financial situation, performance, development and prospects.

3.2.7 Risks relating to the adoption of the CARMAT bioprosthetic artificial heart by cardiac surgeons, cardiologists, healthcare professionals and opinion leaders

The Company considers that cardiac surgeons, cardiologists and other healthcare professionals will make large-scale use of its products only when they have acquired the conviction, through clinical data or scientific publications, that its product offers benefits or represents an interesting alternative to the products already available in the market. Said professionals could be reluctant to change their treatment practices or could reconsider using the Company's bioprosthetic artificial heart, *inter alia* for the following reasons:

- their lack of experience in using the Company's products;
- the lack of favorable clinical data published over a long period of time or other evidence of the beneficial nature of the products for the patients;
- the lack of randomized clinical data, or unconvincing randomized clinical data;
- fear of their liability being involved due to the use of new products and new operating procedures;
- restrictions concerning reimbursements, by public or private health insurance schemes or collective organizations, for the Company's bioprosthetic artificial heart; and
- the time required for training.

The development of ventricular assistance devices has given rise, in recent years, to growing interest for axial or centrifugal miniature mechanical pumps with a non-pulsatile flow. The CARMAT bioprosthetic artificial heart is intended for different indications and will offer characteristics which these products do not have, such as the use of biological materials and sensors designed to ensure a pulsatile physiological flow as a function of metabolic demand.

If the Company were unable to convince cardiac surgeons, cardiologists and other healthcare professionals of the benefits and advantages of its products, the result would be weak market penetration which would have a significant unfavorable impact on the Company, its activity, its financial situation, its performance, its development or its prospects.

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

In order to develop and market its bioprosthetic artificial heart, CARMAT's project has benefited, under the Strategic Industrial Innovation ("ISI") program, from an exceptional €33 million grant from Bpifrance Innovation, of which €32 million for the Company as project leader, and is collaborating with the following four partners (see paragraph 5.7 Important Contracts):

- Dedienne Santé in the preparation of implantable PEEK* parts;
- Ireis (formerly HEF R&D) regarding the approval of the motor-driven pump unit;
- PaxiTech in the development of a portable fuel cell*; and
- Vignal Artru Industries (VAI – Pack'Aero group) to develop the motor-driven pump unit.

As the Company is not involved in producing the various components of the bioprosthetic artificial heart, but rather assembles them in order to create and market this complex bioprosthesis itself, it could be dependent on these partners or other suppliers of raw materials, components, sub-assemblies or essential services.

In particular, the Company cannot control the amount or the timing of the resources which its existing or future partners and suppliers devote and will devote to the bioprosthetic artificial heart. It is possible that these partners and suppliers may not fulfill their obligations in line with the Company's expectations. As a result, the Company could face development delays which could have a significant unfavorable impact on the Company's activity, its financial situation, its performance, its development and its prospects.

Since its foundation, furthermore, CARMAT has always collaborated with renowned cardiac surgery teams. Three French centers have been selected and trained to take part in the first phase of clinical trials on humans: Hôpital européen Georges Pompidou in Paris, Centre chirurgical Marie Lannelongue in Plessis-Robinson and Hôpital Laënnec in Nantes.

If the first implants of bioprosthetic artificial hearts are successful, the Company could become dependent on these first French transplantation centers and their cardiac surgery teams. This could slow down the general acceptance of the artificial heart and the transfer of surgical procedure and skills acquired during the first clinical trials to other transplantation centers and, as a result, 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 Europe and elsewhere with a potential interest in implantation of the Company's artificial heart.

However, if all or part of the aforementioned risks materialized, this could have a significant unfavorable impact on the Company's activity, its financial situation, its performance, its development or its prospects.

3.2.9 Risks connected with outsourcing the manufacture of the components of the bioprosthetic artificial heart

The Company's role is to assemble various components into the bioprosthetic artificial heart, the manufacture of numerous components being outsourced to different suppliers. The Company therefore depends on third parties for the manufacture of most of the components and sub-assemblies forming the bioprosthesis and its power and control systems (see paragraph 2.3.4 Industrial strategy). CARMAT's capacity to market its bioprosthetic artificial heart will partly depend 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 the resources which its suppliers will devote to manufacture of the components of the bioprosthetic artificial heart.

Problems might arise during the manufacturing process for various 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 or sub-assemblies, which could have the following consequences:

- an increase in costs;
- delays and costs involved in identifying the cause of the problem;
- delays in the manufacture of the prostheses required for preclinical trials, clinical trials or for sale;
- the Company becoming liable where the problems are not discovered before the product is put on sale;
- a deterioration in relations with clients;
- a fall in sales;

Certain suppliers may not wish to make commitments beyond the pre-production phase due to specific regulatory or legal risks related to the field of active implantable medical devices.

If relations with its suppliers break down or deteriorate, the Company might find itself unable to form new relations with other suppliers under commercially acceptable conditions, or even not find equivalent suppliers, which could adversely affect its ability to produce, develop and market its bioprosthetic artificial heart successfully.

If the Company were to change critical suppliers (biological cardiac valves, motor-driven pump unit, long-term implantable PEEK, implantable expanded PTFE, etc.) for its products, it would be asked to perform revalidation of the manufacturing process and procedures in accordance with the standards in force. Obtaining this new CE marking could be costly and time-consuming, and it could require the attention of the Company's most qualified staff. If this new CE marking were to be refused, the Company could be forced to find an alternative supplier, which could delay the production, development and marketing of its products and increase their manufacturing costs.

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

- non-compliance of components manufactured by third parties with regulatory provisions and quality control;
- breach of 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 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 it to carry out clinical trials or to grant it CE marking or any other authorization for marketing of its bioprosthetic artificial heart, delays in obtaining authorizations or the suspension or cancellation of authorizations, the revocation of licenses, the seizure or recall of its products, operational restrictions and criminal prosecutions. All these measures could have a considerable 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 revalidation were to be refused, the Company could be forced to find an alternative supplier, which could delay the production, development and marketing of the bioprosthetic artificial heart and increase its manufacturing cost.

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

3.2.10 Risks connected with supplies and increases in costs of raw materials

Given the large number of materials, biological products and electronic and electromechanical components necessary for manufacture of the bioprosthetic artificial heart, its electric power supply system and its remote diagnosis system, the Company is dependent on numerous suppliers and subcontractors for its supplies. The critical nature of certain suppliers is not necessarily related to the volume of business generated with them or their status as partners within the meaning of the Bpifrance contract (see paragraph 3.2.8 Dependence risks relating to current and future strategic partnerships and collaborations), but rather to the unique nature of the raw material, component, sub-assembly or service provided.

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 and 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 bioprosthetic artificial heart for the purposes of the clinical trials, and then to produce and market its bioprosthetic 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 the manufacture of 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 bioprosthetic artificial heart, its electric power supply and its remote diagnosis system profitably and within reasonable time limits.

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, for which CARMAT concluded an agreement on August 28, 2012 with Invibio Ltd. (see paragraph 5.7 Significant Contracts), and other implantable polyurethanes;
- Implantable expanded PTFE for which CARMAT obtains supplies from C.R. Bard; and
- Carpentier-Edwards® biological heart valves, for which CARMAT concluded an agreement on November 5, 2010 with Edwards Lifesciences (see paragraph 5.7 Significant Contracts).

Faced with the problem of recurring overloads faced by certain suppliers in the high-tech sector, CARMAT has already begun to identify secondary suppliers for the most critical parts of the prosthesis and external sub-assemblies, in order to ensure the reliability of supplies and thus ensure sufficient production capacity. This selection must be conducted in line with strict criteria for the quality, skills and production facilities of the suppliers. Consequently, CARMAT must undertake surplus production, validate the industrial processes and verify that the products obtained are identical to those from its first procurement source. In some cases, CARMAT will probably have to vertically integrate certain outsourced processes.

If the Company were to encounter difficulties in the procurement of these materials, biological products or electronic or electromechanical components, if new standards for the use of these materials were to come into force, if it were unable to keep to these sub-contracting agreements, enter into new agreements or obtain the materials or biological products needed to develop and manufacture its bioprosthetic artificial heart, electric power supply system and remote diagnosis system in the future, its activity, its financial situation, its performance, its prospects and its development might be significantly impacted.

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

3.2.11 Risks relating to industrial process dysfunction (such as non-compliance with materiovigilance and product traceability)

The Company's products are classified as medical devices and, as such, are subject to specific regulations in all the countries in which they are manufactured, tested or marketed. These regulations impose obligations regarding, in particular:

- design;
- product preclinical and clinical trials carried out on humans;
- Product manufacturing, quality control and quality assurance;
- product labelling, including User Manuals;
- product storage;
- product identification and traceability;
- data storage procedures; and
- supervision after products are put on the market and reporting of incidents related to the use of the products (deaths, serious injuries, dysfunctions, etc.).

These regulations apply to the Company as a manufacturer of these products.

At present, the Company depends on third-party companies to manufacture most of the components and sub-assemblies forming the bioprosthesis and its power and control systems, and this will no doubt continue to be the case in the future. The Company cannot guarantee that its suppliers or subcontractors comply or will comply with the applicable regulations (see paragraph 3.2.9 above). The notified body, during a certification or monitoring audit, or the regulatory authorities, during an inspection or on the occasion of any other regulatory process, could identify failures to comply with the applicable regulations or standards and request that this be remedied by carrying out corrective actions that could interrupt the manufacture and supply of the Company's products.

The suspension, total stoppage or total or partial prohibition of the activities of the Company's suppliers and subcontractors could adversely affect the Company's reputation and have a significant unfavorable impact on the use or sale of the Company's products.

The Company has established a quality system which is based on procedures aiming, among other things, to detect any nonconforming product internally or externally. This quality system has been certified by a third-party organization in accordance with the regulatory requirements of the applicable European Directive 93/42/EEC and the reference standards (ISO 9001 and ISO 13485). These procedures are included in a compliance defect management system with a view to:

- identification and recording of compliance defects relating to the products or the quality system;
- recording of all investigations and analyses relating to analysis of the causes of these compliance defects and the related risks;
- the identification and implementation of corrections or corrective and preventive measures; and
- measurement of the efficiency of the actions taken to correct the compliance defects.

The treatment of any incident reporting having consequences for the patients and/or users and/or third parties is defined by the regulations relating to materiovigilance which describes the procedures for reporting incidents to the competent authorities. The Company has an internal procedure for monitoring and analysis of incident reports received and, where applicable, for their reporting by the materiovigilance correspondent to the national regulatory authorities (*e.g.*, the French national agency for medicine and healthcare product safety, ANSM).

Dysfunctions could nevertheless occur, and this could have an unfavorable impact on the Company's activity, financial situation, performance, development and prospects.

3.3 REGULATORY AND LEGAL RISKS

3.3.1 Risks relating to regulations and regulatory change

The control, manufacture and sale of the Company's products are subject to obtaining and maintaining the necessary legal and regulatory authorizations and certifications for the marketing of medical devices. Indeed, the Company's products are covered by strict and constantly changing regulations.

Compliance with this regulatory process may prove long and costly, and no guarantee can be given that the authorizations required for new products or changes to existing products will be obtained, or obtained within an acceptable period, or that an authorization will not be withdrawn in the future or be subjected to major post-marketing study requirements. Throughout the world, countries have adopted more demanding regulatory conditions than in the past, and this has increased or could increase the time and uncertainty involved in new product launches, and the clinical and regulatory costs involved in these launches. If certification or authorization for marketing the Company's products were refused or removed or subjected to major post-marketing study requirements, their marketing could be delayed or prohibited in the countries in question, or the margins on sales of these products could be negatively affected by the increase in study costs, and each of these risks could have a significant unfavorable impact on the Company, its activity, its financial situation, its performance, its development and its prospects.

The regulations concerning the development, manufacture and sale of medical devices are subject to changes in the future. The Company cannot predict the impact that such changes could possibly have on its activity. For example, a law recently enacted in France (the "loi Bertrand" of December 29, 2011) stipulates major new reporting measures regarding the markets for pharmaceutical products and medical devices.

The clinical and commercial development of the Company's bioprosthetic artificial heart requires everyday working relations with numerous doctors and healthcare professionals who have knowledge and experience essential for its development. These professionals contribute as researchers, consultants, instructors, inventors or speakers. New laws, regulations or other developments could limit the Company's ability to maintain strong links with these professionals or prevent it from receiving their advice and contributions.

Other similar laws have been adopted or are undergoing examination in other countries. Any change in the legislation or changes in standards or regulations applicable in the states in which the Company markets and plans to market its products, or new regulatory constraints, could prevent marketing of the Company's products in the event of a withdrawal or suspension of the marketing authorizations, or slow it down, notably by making their production more costly. Failure to comply with the regulatory requirements could have a significant unfavorable impact on the Company's activity, its financial situation, its performance, its development and its prospects.

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

- delay and/or significantly increase the cost of developing, testing, manufacturing and marketing the Company's bioprosthetic artificial heart;
- limit the pathologies for which CARMAT would be authorized to market its bioprosthetic artificial heart;
- impose new, more stringent requirements;
- suspend the authorization for the bioprosthetic artificial heart;
- require that clinical trials be halted.

The subsequent detection of problems unknown previously could result in fines, delays or suspensions of regulatory authorizations, product seizures or recalls, notifications of doctors or any other action in the field, restrictions concerning operation and/or legal action in the criminal court. Such a situation, if it occurred, could have a significant unfavorable impact on the Company, its activity, its financial situation, its performance, its development or its prospects.

3.3.2 Risks relating to the regulatory environment in Europe (CE marking)

The Company's implantable bioprosthetic artificial heart, but also all the ancillary tools that accompany it and its monitoring consoles, come within the category of medical devices and are governed, in particular, by the provisions of the 93/42/EEC directive which harmonizes the conditions for the sale and free circulation of these products in the European Economic Area.

These products can be placed on the market only after obtaining the certificates permitting CE marking, valid for a period of five years. This CE marking attests the compliance of the medical device in question with the essential health and safety requirements stipulated by the applicable European directive and certifies that it has undergone the appropriate procedures for evaluation of its compliance.

Incorrect choices or wrong classification of a medical device can have the effect of increasing the costs or the time involved in obtaining the necessary certificates for CE marking, or even make it impossible to obtain the necessary certificates for marketing of the medical device in question.

Such a situation, if it occurred, could have a significant unfavorable impact on the Company, its activity, its financial situation, its performance, its development or its prospects.

The regulations on medical devices which CARMAT is subject to are complex, and they are becoming increasingly strict. Directive 90/385/EEC of June 20, 1990, as amended by directive 2007/47/EEC of September 5, 2007, regarding active implantable medical devices for the European Union, transposed into the public health code in France, the Community regulations being prepared to replace these directives, and similar laws and regulations in other countries worldwide, govern numerous aspects of medical devices, and in particular:

- design, development and manufacture of products;
- product testing and clinical trials carried out on humans;
- product storage;
- product marketing, 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 or future regulations, obligations or directives may rise.

A draft revision of directive 2007/47/EEC governing medical devices was published on September 28, 2012[114] by the European Commission with a 2014 enactment objective and gradual implementation from 2015 to 2019. In particular, it is planned to replace the directive in force with a regulation which would be directly applicable in all the Member States, without any need for transposition into national legislations, designed to overcome the existing disparities between national systems. In substance, the new regulations would significantly reinforce the provisions relating to clinical evaluation during the life of a product and market surveillance and vigilance, in order to ensure patients' safety.

Such a regulatory change would, in particular, have the effect of reducing the Company's operating margin and could have a significant unfavorable impact on the Company, its activity, its financial situation, its performance, its development or its prospects.

Furthermore, data from preclinical and clinical trials can produce divergent interpretations, which could delay the obtaining of or restrict the scope of regulatory authorization, or force the Company to repeat trials in order for them to meet the regulator's requirements. Changes to regulations during the development of the bioprosthetic artificial heart and its regulatory review can lead to delays or to the refusal of authorization.

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

114 http://ec.europa.eu/health/medical-devices/files/revision_docs/citizen_summary_20120926_en.pdf.

3.3.3 Risks relating to the regulatory environment in the United States

The US market is governed by the regulations established by the FDA which regulate preclinical and clinical trials, the manufacture, labelling, distribution and marketing of medical equipment. The FDA has broad powers to prohibit, isolate and seize medical devices that have been falsified or with labelling not meeting standards, to demand a recall, repairs, a replacement or the reimbursement of such devices, to refuse to grant a product marketing authorization, to suspend studies in progress or to demand export certificates from foreign governments.

In 2012, the United States also enacted the FDA Safety and Innovation Act[115], which provides in particular for increased traceability of components and an increase in submission costs, in exchange for clearer instructions regarding the requirements.

The marketing of products such as those manufactured by the Company in the US market is subject to the PMA procedure, which may be long, complex and costly because it must be based on safety and efficiency data, coming in particular from large-scale clinical trials, sometimes randomized where a similar product exists.

In the case of CE marking, the choice of the "Bridge To Transplant" indication, *i.e.* waiting for a transplant, or "Destination Therapy", *i.e.* definitive treatment, is left to the judgment of the medical personnel. In the United States, the FDA demands a clinical safety and efficiency study for each indication, starting with the shortest, *i.e.* waiting for a transplant. No equivalent device (ventricular assist device or artificial heart) has so far submitted an IDE and then a PMA for the "definitive treatment" indication without having first obtained a PMA for the "waiting for transplant" indication (see paragraph 2.3.2 Technologies and market players).

There is an alternative to the conventional IDE and PMA process concerning compassionate indications (see paragraph 2.3.5.2 US regulations). In light of the population targeted by the CARMAT bioprosthetic heart (patients whose condition is life threatening in the short term) and its specific features notably with regard to the use of biological materials (making it possible to address a sub-population of patients for which anticoagulation would be harmful), CARMAT could, initially, aim at a HUD designation. This process is based on safety data collected during a study involving a small number of patients without randomization, and is therefore less expensive and faster. On the other hand, the US product marketing authorization is limited to 4,000 devices per year. This approach could enable the Company to develop gradually and at a lower cost the skills and partnerships necessary for the establishment of an IDE.

While an HDE or an IDE would allow the Company to start clinical studies, there is no guarantee that the Company would subsequently obtain an HUD or a PMA, or obtain it within reasonable deadlines. If the Company were unable to obtain an HUD or a PMA, it could not sell its products in the US market. Such a situation, if it occurred, could have a significant unfavorable impact on the Company, its activity, its financial situation, its performance, its development and its prospects.

Even when products have received an HUD or a PMA, the product marketing authorizations granted by the FDA can be withdrawn following failure to comply with regulatory standards or the occurrence of unexpected problems after the authorization has been granted. There is no guarantee that the Company will receive the necessary authorizations for its products within reasonable deadlines or that such an authorization will not then be withdrawn or subjected to major post-marketing study requirements.

Such a situation, if it occurred, could have a significant unfavorable impact on the Company, its activity, its financial situation, its performance, its development and its prospects.

3.3.4 Risks connected with changes in reimbursement policies for medical devices

The Company's capacity to generate revenues with the bioprosthetic artificial heart and the associated systems and services that it could develop, the degree of success of these products and their performance, partly depend on the conditions of compensation and reimbursement in those countries where it markets or plans to market its products.

Many patients will not be capable of paying themselves to obtain access to a product that the Company could develop. The Company's ability to obtain acceptable levels of reimbursement from government authorities, private health insurers and any other organization will therefore have an impact on its capacity for marketing its products successfully. Reimbursability affects customers' choices concerning the products that they buy and the prices that they are prepared to pay. Reimbursement varies from one country to another and can have a significant impact on the acceptance of new products and services. The Company cannot be certain of obtaining an optimal reimbursement in Europe, the United States or elsewhere for the products that the Company has developed or might develop, and any reimbursement granted could be reduced or cancelled in the future.

In Europe, in the United States and in the other main markets in which the Company could sell its products, there is constant economic, regulatory and political pressure to limit the cost of procedures involving medical devices. Third-party paying organizations are increasingly questioning the prices of medical devices, and many third-party paying organizations could refuse to reimburse or could increase the proportion paid by patients for certain devices.

115 *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ucm310927.htm.*

New legislative or administrative reforms to reimbursement systems in Europe, the United States or other countries which could substantially reduce the reimbursement of operations using the Company's medical devices or which could refuse coverage for these operations, for example by price regulation, competitive pricing, coverage and payment policies, the comparative efficiency of therapies, technological assessments and managed healthcare systems, could have a significant unfavorable impact on the Company, its activity, its financial situation, its performance, its development or its prospects.

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. CARMAT's failure to obtain adequate funding for the bioprosthetic 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.

The absence or insufficiency of reimbursement or funding of the Company's products or the adoption of more restrictive measures in terms of reimbursement or funding could have a significant unfavorable impact on the Company, its activity, its financial situation, its performance, its development or its prospects.

3.3.5 Risks relating to use of the products in circumstances not approved by the authorities

Authorizations for clinical trials and product marketing authorizations are, or will be, restricted to very precise indications by the law, regulations or conditions specific to said authorizations.

It is prohibited for the Company to promote any unauthorized use of its products. It is possible that doctors – even during clinical trials – may use these products in circumstances other than those strictly defined within the framework of the regulatory approvals. Although the contracts binding the Company to healthcare professionals and investigator centers and the information and training given to the doctors and other healthcare professionals specify explicitly that the indications are and will be restricted to the approved uses (including as part of the criteria for inclusion in or exclusion from the clinical trials), no guarantee can be given that the Company could not face a liability claim if its products are used in one way or another in procedures which have not been approved.

If CARMAT were held liable and were unable to protect itself in any way against liability suits arising out of unapproved use of its products by doctors, this would have a serious impact on the clinical development or marketing of the bioprosthetic artificial heart and more generally it would adversely affect the Company's activities, its financial situation, its performance, its development and its prospects.

3.3.6 Risks relating to protection of intellectual property rights

The Company is the owner of patents and a know-how that is specific to it, as well as other intellectual property rights (such as, in particular, copyright, marks and domain names).

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.

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 is free to use, both in the United States and in Europe, the corresponding American and European patents with claims over every device, system and method pertaining to the bioprosthetic 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 priority rights.

However, the Company's patents and other intellectual property rights may offer only limited protection and may not prevent any unlawful use of its technologies. Regarding this, the unauthorized exploitation of the Company's technologies by third parties could, in particular, deprive CARMAT of its competitive advantage.

Despite the efforts made by CARMAT to protect its technologies, its assets and its know-how, there is a risk regarding the validity and/or the value of the intellectual property rights pertaining thereto.

Indeed, the possibility cannot be excluded that:

- the Company's granted patents and more generally its intellectual property rights may be disputed or invalidated at a subsequent stage or that the Company may not be able to enforce them;
- patents for which applications are being considered, including certain important patents in several jurisdictions, or any other claim to a deed pertaining to an intellectual property right, might ultimately not be granted;
- the extent of the protection conferred by a patent or an intellectual property deed might be insufficient to provide effective protection from competitors;
- the Company's products will not infringe, or be accused of infringing, patents or other intellectual property rights belonging to third parties;
- third parties might claim rights over patents or other intellectual property rights that the Company owns directly or that it exploits.

Despite the precautions and measures taken by the Company, notably from a contractual viewpoint, if one of these factors concerning one of the patents or intellectual property rights occurred, it could have an unfavorable impact on the Company's activity, financial situation, performance, development and prospects.

As a reminder, there is great disparity between the national legislations applicable in the various countries where the Company registers or protects its intellectual property rights. These divergences could have an impact on the level of protection granted to the Company, because depending on the country, the level of protection of the Company's intellectual property rights will be unequal or even unsatisfactory.

Moreover, the grant of a patent does not guarantee its validity or the extent of the protection provided by it, and third parties may always try to dispute these two aspects. Therefore, it will be specified that the grant and scope 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.

Lastly, the protection and enforcement of the Company's intellectual property rights will require legal action where necessary, the costs and contingencies of which may have an impact on the Company's activities. In this sense, apart from the expenses that these legal actions entail, they could have the effect of diverting the management team from its priorities and reducing the Company's profits. These legal actions could also, for strategic reasons, result in a large number of proceedings with more or less controlled risks regarding the consequences for the scope of the Company's intellectual property rights. Regarding this, any dispute concerning the validity of one of the Company's patents or intellectual property rights could, if successful, deprive the Company of one or more of its technologies and cause it to lose its competitive advantage.

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.

3.3.7 Risks relating to the confidentiality of the Company's information and know-how

The Company may be required to provide public or private bodies with sensitive proprietary information notably 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 relevant third parties.

However, these agreements and other methods of protecting commercial and technical secrets are not always effective and cannot protect with any certainty the confidentiality of said industrial and technical information and secrets, because any breach of the aforementioned contractual agreements, including through disclosure to competitors, would potentially entail imminent damage for the Company without it having any really appropriate measure for obtaining compensation. If one or more of these risks materialized, this could have a significant unfavorable impact on the Company's activity, its financial situation, its performance, its development and its prospects.

Furthermore, the dissemination, notably *via* the media or by third parties, of confidential or even non-confidential information concerning the Company or its activities, with or without its authorization, and the dissemination of false or inaccurate information by third parties could also have unfavorable consequences for the Company's activity, financial situation, performance, development and prospects.

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

In connection with search for non-thrombogenic* material, CARMAT decided to follow a path originally opened by Professor Alain Carpentier's work on biological valves, which uses animal pericardium that has been chemically treated to render it inert and biologically stable, so that rejection by the body is avoided. In designing and manufacturing the bioprosthetic artificial heart, the Company is therefore subject to chemical and biological risks, obliging it to put in place preventative and protective measures for the benefit of its operators and for waste management in line with current environmental and safety regulations governing the use, storage, handling and disposal of hazardous materials.

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 sizable 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.

3.3.9 Risks connected with product liability

All cardiac surgery involves significant risks of serious complications that can have mortal consequences. The clinical trials and marketing of the bioprosthetic 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.

As the Company has not entered the sales phase for the bioprosthetic artificial heart, it has not taken out insurance against liability for defective products. However, the Company has already taken out insurance policies in relation to the clinical trials phase as a result of which it possesses the level of insurance cover required under current regulations in France (in accordance with the French public health code and the provisions arising from the Huriet Act of December 20, 1988) and in other countries. If necessary, it will take out other insurance policies as its clinical trials program is extended (see paragraph 3.4 Insurance and cover for risks below).

However, the Company cannot guarantee that its insurance cover will be sufficient to meet liability suits that may be filed against it. If CARMAT were held liable and were unable to obtain and maintain appropriate insurance cover at an acceptable cost, or to protect itself in any way against liability suits arising out of defective goods, this would have a serious impact on the marketing of the bioprosthetic artificial heart and more generally it would damage the Company's reputation, its activities, its financial situation, its performance, its development and its prospects.

3.4 INSURANCE AND COVER FOR RISKS

The Company has adopted a policy for covering the main insurable risks with cover limits that it considers compatible with the nature of its activity. The premiums paid by the Company for all insurance policies amounted to €61,803 for the 2013 reporting period, compared with €50,301 for the 2012 period.

As the Company has not entered the sales phase for the bioprosthetic artificial heart, it has not yet taken out insurance against liability for defective products.

The Company has taken out several insurance policies. the most significant of which are summarized in the table below:

Risks covered	Insurer	Value limit	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	Allianz		
Losses not arising out of harm to the environment			
All combined loss or damage, without exceeding the following limits:		€10,000,000 per claim	
Consequential material & immaterial damage, except for cases of employee theft		€7,000,000 per claim €30,000 per claim	€1,500
Non-consequential financial losses		€1,000,000 per claim	€1,500
Damage to property entrusted to others		€1,000,000 per claim	€1,500
Losses arising out of accidental harm to the environment			
All combined loss or damage		€1,500,000 per claim	€1,500
Harm to servants			
Personal injuries and ancillary damage to property		€1,500,000 per claim	€1,500
DIRECTORS' AND OFFICERS' LIABILITY	Allianz	€10,000,000 per annum	
INDIVIDUAL ACCIDENT INSURANCE	Ace Europe	Ceiling:	10%
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, kidnapping or hostage taking)		90 monthly Social Security ceilings	
Individual Accident Insurance			
Repatriation, medical expenses, travel, death			

Risks covered	Insurer	Value limit	Excess per claim
INDEMNITY INSURANCE: INSURED CAPITAL	Allianz		All losses or damage: €5,000 Except: Plate-glass breakage: €1,000 Theft: €1,000 Natural disaster: Legal excess All losses or damage: 5 days Natural disaster: Legal excess
Direct loss or damage			
Damages to property, contents and fixtures and fittings Additional expenses		€8,000,000	
Additional operating costs		€5,000,000	
Indemnity periods		12 months	
PROPERTY DAMAGE INSURANCE		€13,000,000 per claim, subject to the following limits:	
Direct loss or damage			
Plant and equipment everywhere		€1,500,000 per claim	
Natural events excluding natural disasters Land transport		€2,000,000 per claim	
Machinery breakdown		€500,000 per claim	
Electrical damage		€2,000,000 per claim	
Automatic guarantee on investments		€2,000,000 per claim	
Related expenses and losses		€500,000 per claim	
Claims from neighbors and third parties, claims from tenants, loss of peaceful enjoyment, loss of rent		€1,000,000 per claim	
Liability of the owner or lessee		€5,000,000 per claim	
Theft and damage to real or personal property arising out of a theft or an attempted theft		€500,000 per claim	
Additional operating costs:			
Additional operating costs including:		€5,000,000 per claim	
Wages and salaries		€3,500,000 per claim	
Indemnity periods		12 months	
VEHICLE FLEET – ROAD TRAFFIC LIABILITY – LEGAL PROTECTION personal injury damage to property and financial losses arising out of damage to property	AXA Corporate Solutions	Unlimited €100,000,000 per claim	
CIVIL LIABILITY – MEDICAL RESEARCH PROMOTER Clinical studies for the evaluation of the CARMAT total artificial heart	Allianz	€1,000,000 per victim Limited to: €6,000,000 per research protocol €10,000,000 for all claims made during one insurance year for several research protocols	
CIVIL LIABILITY – MEDICAL RESEARCH PROMOTER Clinical trials – Poland *First in man Clinical Evaluation of the TAH*	Compensa Vienna Insurance Group	€500,000 per claim €500,000 per protocol	
CIVIL LIABILITY – MEDICAL RESEARCH PROMOTER Clinical trials – Slovenia *First in man Clinical Evaluation of the TAH*	Triglav	€100,000 per patient €100,000 per claim €1,000,000 per protocol	
CIVIL LIABILITY – MEDICAL RESEARCH PROMOTER Clinical trials – Saudi Arabia *First in man Clinical Evaluation of the TAH*	CHUBB	€50,000 per patient €500,000 per protocol €500,000 per annum	
CIVIL LIABILITY – MEDICAL RESEARCH PROMOTER Clinical trials – Belgium *First in man Clinical Evaluation of the TAH*	CHUBB	€650,000 per patient €650,000 per claim €3,500,000 per protocol	

3.5 FINANCIAL RISKS

3.5.1 History of operational losses – Risks connected with forecast losses

The Company was established in June 2008. As at December 31, 2013, accumulated losses amounted to €57,734,104. This loss for the 2013 financial period comes from research costs and the costs of developing the CARMAT bioprosthetic artificial heart; such costs cannot be capitalized as intangible assets under French accounting rules.

The Company will incur further significant operational losses in the course of the next few years, particularly due to:

- a potential extension of the period for preclinical trials prior to obtaining Clinical Trial Authorizations, in France or abroad;
- the completion of research and clinical trials on the bioprosthetic artificial heart in Europe and then the United States in order to obtain marketing authorizations;
- costs connected with marketing the CARMAT bioprosthetic artificial heart; and
- 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 bioprosthetic artificial hearts.

As of the date of registration of this registration document, the bioprosthetic artificial heart has not generated any operational revenue. The Company's profitability will be dependent on the results of its clinical trials and on sales of the bioprosthetic artificial heart, which could be commenced once CE marking has been obtained. The Company considers that before revenues are generated from sales of the bioprosthetic artificial heart, its only sources of financing will come from funds raised on the Euronext Alternext market in Paris, state grants, research tax credits (CIR) and, to a lesser extent, income from cash investments and current financial instruments, and that this will enable it to deal with short and medium term liquidity risks (see paragraph 3.5.8 Liquidity Risks).

Cash reserves as at December 31, 2012 were bolstered by funds obtained by virtue of entering the next milestones of the Bpifrance program and by the reimbursement of the 2013 CIR, which should enable the Company to cover its requirements until 2015. However, additional financing, particularly in the form of capital increases, will be required for the Company to be able to finance, in particular, the sales phase of the bioprosthetic artificial heart (see paragraph 3.5.3 Dilution risk connected with issuing shares giving immediate or long-term access to the Company's capital).

The increase in these expenses, particularly in the event of a lack or suspension of revenue sources, could have a significant unfavorable impact on the Company's business, financial situation, performance, development and its prospects.

3.5.2 Unreliable capital resources and unreliable additional funding

The Company has made significant investments in research and development since it began its operations in 2008, which has produced operating losses of €5,983,982, €10,482,243, €16,091,054, €22,385,513 and €16,116,624 respectively for the periods ended December 31, 2009, December 31, 2010, December 31, 2011, December 31, 2012 and December 31, 2013.

The total financial cost of developing the bioprosthetic artificial heart (*i.e.* excluding expenses related to preparations for its marketing and industrial production) will have been about €100 million for the Company since it was founded.

This cost has been, and continues to be, financed by:

- government grants or research tax credits:
  - Bpifrance grants and repayable advances for the amount of €26 million already received and €7 million still to be received (see paragraph 5.7 Important Contracts);
  - €1.5 million in subsidies granted by the Yvelines Department Council;
  - research tax credit reimbursements for the amount of €11.4 million already received;

  this first category representing a total amount of €38.9 million already received (excluding research tax credit reimbursements to come and Bpifrance grants and repayable advances still to be received); and
- through equity:
  - cash contributions from the founders for an amount of €8.2 million;
  - initial public offering on the Euronext Alternext market in Paris in July 2010 (amount of €16 million, including issue premium);
  - a capital increase with preferential subscription rights on the Euronext Alternext market in Paris in August 2011 (amount of €29.3 million, including issue premium);
  - a capital increase *via* the exercise of share warrants carried out by Kepler Cheuvreux under the issuance agreement signed in June 2013 (amount of €11.9 million, including issue premium);

  this second category representing a total amount already received of around €61.2 million.

The aforementioned financing should enable the Company to finalize development of the artificial heart and to perform the clinical trials necessary to submit an application for CE marking (see the timetable under paragraph 1.3 General Overview). However, 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 bioprosthetic 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 also expects to have financing requirements notably to prepare for and then begin marketing the bioprosthetic artificial heart once the CE marking has been obtained. At this stage of its expansion, the Company will not be able to finance its growth out of cash flow, and it will be obliged to look for other sources of financing, notably *via* calls for funds for a total amount of around €50-150 million. The purpose of this financing will be to ensure marketing of the bioprosthetic artificial heart in Europe, to carry out regulatory activities in the United States and to allow the ramp-up of industrial production.

The Company might fail to raise sufficient funds in favorable conditions or fail to raise any 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 or marketing 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 negative impact on the Company's business, financial situation, performance, development and its prospects.

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

As mentioned in paragraph 3.5.2 Unreliable capital resources and unreliable additional funding above, the Company could issue shares or new financial instruments giving access to its capital to finance its expansion.

Since its creation, moreover, the Company has allocated or issued BCE warrants and equity warrants as part of its policy of motivating its executives and employees. The Company could in the future allocate or issue new instruments giving access to the capital for employees and/or consultants. As at the date of registration of this registration document, exercising all the instruments allocated by the Company giving access to the capital would allow subscription to 348,125 new shares representing 8.13% of the current issued share capital.

The exercise of instruments giving access to issued capital and all new allocations or issuances would lead to a significant dilution for the shareholders.

3.5.4 Risks connected with changes to the tax on medical devices

In France, 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 (excluding VAT) in relation to the sale of these products is equal to or greater than €763,000.

This tax is levied at 0.25% of total annual revenues (excluding VAT) from medical devices, and the Company must submit a tax return along with payment to the ANSM accounting officer by March 31st each year. If no return is filed within the time limit set or if the return is inaccurate, the ANSM 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%.

In 2010, major healthcare system reforms were adopted in the United States. The legislation now provides for a 2.3% tax on US sales of most medical devices as of 2013.

The introduction of – or an increase in – such taxes in other countries could have a significant unfavorable impact on the Company's business, financial situation, performance, development and prospects.

3.5.5 Risks connected with the loss of Young Innovative Enterprise status

CARMAT opted to take Young Innovative Enterprise ("JEI") status in September 2008. On July 8, 2009, the Yvelines Tax Office approved the Company's application for JEI status.

JEI status is intended to provide significant support to young enterprises which are very active in research and development by allowing them to benefit from exemptions from employers' social security contributions and from tax reliefs.

JEIs thus enjoy exemptions from employers' social security contributions for researchers, technicians, research and development project managers, lawyers responsible for 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 officers in relation to the general social security system.

Article 78 of the 2011 Budget Act *(loi de finances)* reduced the social security exemptions associated with JEI status with effect from January 1, 2011. Article 37 of the revised 2011 Budget Act of December 28, 2011 further modified the social security and tax exemption measures associated with JEI status with effect from January 1, 2012.

The exemption from social security charges, capped since January 1, 2011 at three times the annual social security ceiling (€106,056 in 2011), was raised with effect from January 1, 2012 to five times the annual social security ceiling (€185,160 in 2013). The monthly gross remuneration ceiling for individual employees, set at 4.5 times the French minimum wage in 2011, was not modified by the revised 2013 Budget Act. This ceiling was set at €6,436 per month on January 1, 2013. This represents a threshold above which the exemption does not apply.

The exemption reduces gradually over time. As in 2011, the exemption applies in full until the last day of the third year following the year of the Company's establishment. However, the progressive exemption rates have been brought back up with respect to contributions due in relation to salaries paid on or after January 1, 2012, meaning that the exemption applies:

- in full up to the final day of the third year following the year of the Company being incorporated;
- at a rate of 80% for the fourth year (as against 75% in 2011);
- at a rate of 70% for the fifth year (as against 50% in 2011);
- at a rate of 60% for the sixth year (as against 30% in 2011);
- at a rate of 50% up to the final day of the seventh year (as against 10% in 2011).

The above reform represents an extra cost for CARMAT of €0.2 million for the 2013 financial period and around €3 million overall for financial periods 2011 to 2015, the eighth and final year for which CARMAT can benefit from JEI status.

In order to benefit from JEI status, the Company must comply with five conditions as defined by Article 44 sexies-0 A of the CGI (French general tax code): be an SME, be less than eight years' old, devote 15% of its spending to R&D, perform a new activity and have at least 50% of its share capital owned by individual or quasi-individual shareholders. This condition as to the ownership of capital must be complied with throughout the financial period for which the enterprise 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 Company's business, financial situation, performance, development and prospects.

3.5.6 Risks connected with state subsidies and research tax credits

If the Company were to breach the contractual conditions in the agreements for subsidies and repayable advances concluded with Bpifrance for an overall sum of €31.9 million (see paragraph 5.7 Important Contracts), it might not receive the expected aid.

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

Furthermore, to finance its activities, the Company also opted to take the Research Tax Credit ("CIR") for the financial periods 2009 to 2013. This mechanism involves offering a tax credit to enterprises which invest significantly in research and development.

Research expenditure 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 relating to the 2013 period was recorded under Income taxes in the income statement and appears under Other debtors in the balance sheet. The income statement for the period from January 1, 2013 to December 31, 2013 shows a Research Tax Credit of €1,770,114.

The Research Tax Credit is an important source of financing. It could be jeopardized by a change in regulations or by an objection from the tax authorities, even though the Company complies with the requirements concerning documentation and the eligibility of costs.

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

3.5.7 Interest rate risks

The Company's financial debts are made up of a repayable advance granted by Bpifrance which amounted to €7,515,054 as at December 31, 2013. This repayable advance carries interest at a contractual rate of 5.59%. Accrued interest at year end was €822,187 (see paragraph 5.7 Important Contracts).

At the end of the reporting period, there were cash instruments in the form of certificates of deposit worth €13,500,000: This concerned six agreements, subscribed to with recognized financial institutions, in July, October, November and December 2013 and maturing respectively on January 13, 2014 (€4,000,000), January 26, 2014 (€1,000,000), February 11, 2014 (€4,000,000), March 19, 2014 (€1,000,000), April 18, 2014 (€2,000,000) and April 22, 2014 (€1,500,000). €25,000 was recognized at December 31, 2013 in respect of accrued interest on these contracts. The interest rates on these short-term investments are 1% per annum at most, so a significant change in the interest rate is unlikely. These investments represent no risk for the invested capital, excluding an unlikely default of the depository financial institutions before these very short-term maturity dates.

3.5.8 Liquidity risks

In 2013, the Company burned €9.6 million in cash. The Company finances its growth through equity increases made by way of capital increases or convertible bonds.

At the date of registration of this registration document, the Company has no bank debts (see paragraph 5.2.3.3 Borrowing conditions and financing structure – Bank debts and repayable advances), and it is therefore not exposed to any liquidity risks from the enforcement of clauses on the early repayment of bank loans.

Given the Company's historic deficit situation, which results from the fact that it is still in a development phase during which it is incurring expenditure on (mainly clinical) research and development without earning regular revenues, the Company faces a liquidity risk.

The assumption of business continuity has been adopted by the board of directors based on the following aspects in particular:

- the amount of cash and marketable cash instruments as at December 31, 2013, totaling €16,883,974;
- payment of subsidies (€159,166) and repayable advances (€6,992,256) remaining to be received between now and the end of the Bpifrance aid program signed in 2009.

The Company has performed a specific review of its liquidity risk and considers it is capable of meeting its financing requirements until 2015 in light of the following:

- available cash of €16,883,974 as at December 31, 2013;
- the payment during 2014 of Bpifrance subsidies up to a maximum of €159,166 after completion of milestone 5 of the Bpifrance program in accordance with the amendments to the CARMAT framework and project beneficiary contracts signed in June 2011 (see paragraph 2.2.3 Process and development stage and paragraph 5.7 Important contracts);
- the payment of Bpifrance repayable advances up to a maximum of €5,251,038 after completion of milestone 5 of the Bpifrance program in accordance with the amendments to the CARMAT framework and project beneficiary contracts signed in June 2011 (see paragraph 2.2.3 Process and development stage and paragraph 5.7 Important contracts).

  It should be noted that the receipt of repayable advances linked to milestone 6 (€290,486) is subject to conditional approval being given by the ANSM to proceed with the second clinical trial on humans, for which the Company expects to submit an application in 2014 (see paragraphs 5.7.1.3 *et seq.*) in France and in other countries;
- the reimbursement, planned in 2014, of the 2013 CIR for the amount of €1,770,114; and
- if necessary, the possibility of using the optional equity financing facility set up with Kepler Cheuvreux, and on which 83,200 share warrants remain exercisable.

Additional financing will be necessary for the Company to be able to finance its continued development, notably *via* calls for funds potentially totaling around €50-150 million, to ensure marketing of the bioprosthetic artificial heart in Europe, to carry out regulatory activities in the United States and to allow the ramp-up of industrial production.

These funds will be needed in particular to:

- finance the training of additional surgical centers in addition to those trained for the clinical trials phase of the feasibility study;
- develop and run a direct or indirect sales force, and to provide technical and clinical support to implant centers and their patients;
- carry out clinical activities such as implant registries or comparative or medico-economic studies, upon request by regulatory authorities or voluntarily for marketing purposes;
- implement improvements to the systems or pursue activities necessary to secure the willingness of healthcare providers to pay for the bioprosthetic artificial heart, its external systems and ancillary services in various countries;
- to initiate and finalize a multi-center study (IDE) in the United States, in order to obtain from the FDA the authorization to market the prosthesis there;
- ramp up industrial production by developing automated production processes, securing alternative suppliers for critical supplies and by setting up additional production capacity.

3.5.9 Exchange risk

At present, the Company incurs exchange risks only on its purchases. The Company estimates that:

- 8.68% of its purchases are in US dollars;
- 0.06% of its purchases are in Swiss francs.

Future exposure of the Company to exchange risks will essentially depend on the currency in which it receives its income and incurs all or part of its costs. The extent of this risk will depend on the countries where the Company conducts its developments, the marketing of the bioprosthetic artificial heart and other products it might develop, and the currency in which it pays its operational expenses.

If the Company is able to carry on its industrial and commercial activities in countries outside the Eurozone, it is likely that it will realize turnover and incur costs in other currencies. The Company will then consider the most appropriate method for monitoring and managing its exchange risk.

3.5.10 Equity risk

At the time of registration of this registration document, the Company has no shareholdings in third-party listed companies and is therefore not exposed to risks in relation to third-party shares.

In 2010 the Company entered into a liquidity agreement with an independent financial services provider, the purpose of which is to improve the liquidity of transactions and regularize the CARMAT share price, without hampering the normal functioning of the market and without misleading third parties. To this end the Company made an amount of €300,000 available to this service provider. Treasury shares acquired through the implementation of this liquidity agreement are recorded under financial assets at their purchase price.

Where appropriate, a valuation allowance is recorded with reference to the average official stock market price for the month preceding the end of the period (see paragraph 6.4.3.2 Supplementary information – Financial assets in the Notes to the 2013 financial statements in paragraph 6.4).

3.5.11 Risk related to changes in the share price and market capitalization of the Company

Upon flotation in July 2010, the price of CARMAT shares was set at €18.75, representing a market capitalization of €71.3 million.

As at March 14, 2014, the share price stood at €89.80, representing a rise of 379% relative to the IPO price, and corresponded to a market capitalization of €384.66 million. Between those two dates, CARMAT's share price fluctuated significantly, as the graph opposite shows.

CARMAT's share price has fluctuated essentially as a result of investors' perceptions regarding whether or not the Company will reach, or whether it will be delayed in reaching, further scientific or regulatory stages in the development of the bioprosthetic artificial heart project.

Given the price level and the market capitalization, and given their evolution since the IPO (+379%), any failure or delay in the achievement of further scientific or regulatory stages could have a significant unfavorable impact on the Company's share price and market valuation.

3.6 RISKS RELATING TO THE COMPANY'S ORGANIZATION

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

Given its stage of development, the Company still has only limited experience in the sales, marketing and distribution areas. In order to ensure the large-scale success of sales of the bioprosthetic artificial heart, the Company will have to adapt its organization, expand in global markets, set up a distribution network and recruit dedicated, qualified staff (especially to provide technical and clinical support for implant centers and their patients).

At present, the Company plans to carry out this marketing *via* a direct sales force in the main European countries, at least in an initial phase. In other countries such as the United States, indirect forms of distribution could be considered. The Company cannot guarantee that it will be able to keep its distributors or sign new distribution agreements, nor that these distributors will devote the necessary resources to the commercial success of its products.

Moreover, the Company will have to provide training for doctors in the countries in which it wants to operate, and therefore have "ambassadors" and training centers (see paragraph 2.3.3 Marketing strategy).

The Company might not be able to establish an appropriate structure or it could experience a delay in the organization of marketing and distribution facilities and in the recruitment and training of sales staff or in setting up its distribution network.

Any of these events could have a significant unfavorable impact on the Company's activity, its financial situation, its performance, its development and its prospects.

3.6.2 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 its board of directors and its key scientific personnel, in particular Professor Alain Carpentier, scientific director, Marcello Conviti, chief executive, Patrick Coulombier, Assistant chief executive, Dr. Piet Jansen, medical director, Marc Grimmé, technical director and Hervé Bocquet, industrial director. To date the Company has not taken out any so-called "key person" insurance (insurance policies to cover permanent incapacity/death) and the loss of their skills would affect its capacity for attaining its goals. Although the Company has for several years conducted management and knowledge transfer programs, thereby creating a know-how base which is not confined to specific individuals, the simultaneous departure of several important employees from its executive management or its research and development activities would significantly affect the Company's capacity to attain its goals.

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

Faced with this risk, the Company has established systems for motivating its personnel and strengthening its loyalty, in the form of variable remuneration based on performance and the allocation of securities giving access to the Company's capital, although there is nothing to ensure that these systems will be sufficient to enable the Company to retain or recruit the necessary personnel.

The Company's inability to attract and retain this key personnel would prevent it from attaining its overall objectives, and would thus have a significant unfavorable impact on its activity, its financial situation, its performance, its development and its prospects.

3.6.3 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 bioprosthetic artificial heart. It will therefore need to adapt its organizational structure and employ new skills, and it will therefore need to recruit personnel and extend its operational capacities; this could place significant demands on its internal resources.

To this end, the Company will have to:

- train, manage, motivate and hold on to a growing number of qualified staff and/or distributors;
- anticipate the expenses connected with this growth and the 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 financial situation, its performance, its development and its prospects.

3.7 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, 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.

4

CORPORATE GOVERNANCE

4.1 COMPOSITION OF THE COMPANY'S ADMINISTRATIVE AND MANAGEMENT BODIES

4.1.1 Composition of the board of directors

At the date of registration of this registration document, 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 this registration document
Mr. André-Michel Ballester	First reappointment (as a Plc): May 7, 2010 Term of office: Until GM to consider the accounts for year ending 12/31/2015	Independent director	▸ Amministratore Delegato (CEO) Sorin Spa – Milan (Italy) ▸ Independent director of Mauna Kea Technologies SA ▸ Independent director of Pixium Vision SA	▸ Independent director of Nexway SAS ▸ Independent director of IMI GmbH
Mr. Jean-Claude Cadudal	First reappointment (as a Plc): May 7, 2010 Term of office: Until GM to consider the accounts for year ending 12/31/2015	Chairman of te board of directors	▸ Chairman of Kardiozis SAS ▸ Chairman of Holding Incubatrice Medical Devices ▸ Chairman of Epigo SAS	Not applicable
Professor Alain Carpentier	First reappointment (as a Plc): May 7, 2010 Term of office: Until GM to consider the accounts for year ending 12/31/2015	Director	▸ Former chairman of the Academy of Sciences ▸ Chairman of te Scientific Council of the Fondation Lefoulon-Delalande *(Institut de France)* ▸ Member of te board of directors of the Fondation Singer Polignac ▸ Director of the Scientific Research Association of the Alai Carpentier Foundation (ARSFAC)	▸ Former chairman of the Academy of ciences

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 this registration document
Mr. Marcello Conviti	First reappointment (as a Plc): May 7, 2010 Term of office: Until GM to consider the accounts for year ending 12/31/2015	Director chief executive	Not applicable	▸ Director at Eucomed ▸ Vice-President Strategy and Development, Edwards Lifesciences
Mr. Michel Finance	First reappointment (as a Plc): May 7, 2010 Term of office: Until GM to consider the accounts for year ending 12/31/2015	Independent director	▸ Chairman of the board of directors and chief executive of Holding Incubatrice Biotechnologies SA ▸ Director at Neovacs SA ▸ Chief executive and director at Theradiag SA ▸ Chairman of Zophis SAS ▸ Chairman of Biokinesis SAS ▸ Chairman of Prestizia SAS ▸ Director at France Biotech (an association under the law of 1901) until June 2013	Not applicable
Mr. Henri Lachmann	First reappointment (as a Plc): December 23, 2010 Term of office: Until GM to consider the accounts for year ending 12/31/2015	Independent director	▸ Vice-President, lead director on the board of directors of Schneider Electric SA ▸ Member of the supervisory board of Vivendi SA ▸ Member of the supervisory board of Norbert Dentressangle SA ▸ Chairman of the board of directors of the Centre chirurgical Marie Lannelongue (Marie Lannelongue Surgical Center) (an association under the law of 1901) ▸ Chairman of the Institut Télémaque (an association under the law of 1901) ▸ Director of the Fondation Entreprendre ▸ Vice-chairman and Treasurer of the Institut Montaigne (an association under the law of 1901) ▸ Chairman of the campaign committee of the Strasbourg University Foundation	▸ Chairman of the supervisory board of Schneider Electric SA ▸ Member of the supervisory board of AXA ▸ Director at AXA Assurances IARD Mutuelles ▸ Director of various companies in the Schneider Electric Group ▸ Member of the taxation and social security contributions board ▸ Chairman of the Continental Law Foundation

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 this registration document
Truffle Capital represented by Dr. Philippe Pouletty	First reappointment (as a Plc): May 7, 2010 Term of office: Until GM to consider the accounts for year ending 12/31/2015	Director	Roles of Philippe Pouletty: ▸ Chairman of the board of directors of Abivax SA ▸ Chairman of the board of directors of Deinove SA ▸ Member of the supervisory board of Innate Pharma SA ▸ Manager at Nakostech SARL ▸ Managing director and director at Truffle Capital ▸ Director at the Centre chirurgical Marie Lannelongue (Marie Lannelongue Surgical Center) (an association under the law of 1901) ▸ Honorary chairman and director of France Biotech (an association under the law of 1901) ▸ Director at Immune Targeting Systems Ltd (UK) As representative of Truffle Capital: ▸ Director at Carbios SA ▸ Director at Neovacs SA ▸ Director at Vexim SA ▸ Director at Theradiag SA ▸ Director at Theraclion SA ▸ Director at Biokinesis SAS ▸ Director at Pharnext SAS ▸ Director at Plasmaprime SAS ▸ Director and chairman of Splicos SAS ▸ Director at Wittycell SAS ▸ Director at Myopowers (Switzerland) ▸ Director at Symetis (Switzerland)	▸ Chairman and chief executive from October 2009 to November 2010: Theradiag SA ▸ Chairman of the board of directors from November 2010 to May 2012: Theradiag SA ▸ Chairman from 2001 to 2009 of France Biotech ▸ Member of the supervisory board at Cytomics SA until December 2010 (in liquidation)

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 offense 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.

4.1.2 Backgrounds of the members of the board of directors

JEAN-CLAUDE CADUDAL

Jean-Claude Cadudal is the chairman of the CARMAT board of directors. He was previously director of International Operations at EADS (now Airbus Group) until early 2008, a former director of Matra Défense, former Group Finance Controller at MBDA, and he was the CARMAT program director. He was involved in the Matra Group's principal mergers and acquisitions. A graduate in industrial automation, he began his career in nuclear plant development research offices then in industrial management with ITT where he received the Production & Inventory Control Worldwide Award in 1979. After a period working in operations management with Revlon Europe, he joined the MATRA Group in 1983.

PROFESSOR ALAIN CARPENTIER

Professor 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 Biosurgical Research Laboratory at the Scientific Research Association of the Alain Carpentier Foundation (ARSFAC). Winner of the Foundation for Medical Research Prize in 1998 and President of the French Academy of Sciences (2010-2012), 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 pericardiac 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. He invented CARMAT's artificial bioprosthetic heart.

DR. PHILIPPE POULETTY

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 postdoctoral research fellow at Stanford University. 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 entered 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 more than €550m. 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 a number of biotechnology and medical apparatus undertakings in Europe and North America (Theradiag, Conjuchem, Cytomics, Deinove, Innate Pharma, ITS, Neovacs, Pharnext, Splicos, Theraclion, Vexim and Wittycell, etc.). 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 relaunch and develop biotechnology and the Young Innovative Enterprise status, which grants significant tax exemptions to technological enterprises.

MARCELLO CONVITI

Marcello Conviti is chief executive and director of CARMAT. He began his career in Italy with IBM in 1978. After a number of 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 over a period of more than 17 years (notably Vice-President for Strategy and Development at Edwards Lifesciences, the world leader in heart valves, whose flagship product, the Edwards-Carpentier heart valve, has revolutionized cardiac surgery. Marcello Conviti was 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

André-Michel Ballester is an independent director at CARMAT. He is currently chief executive of Sorin Spa., one of the world leaders in the manufacture of devices for cardiovascular 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 SA more than 25 years ago. He then occupied several management positions in the implantable 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 *École Centrale* in Lille.

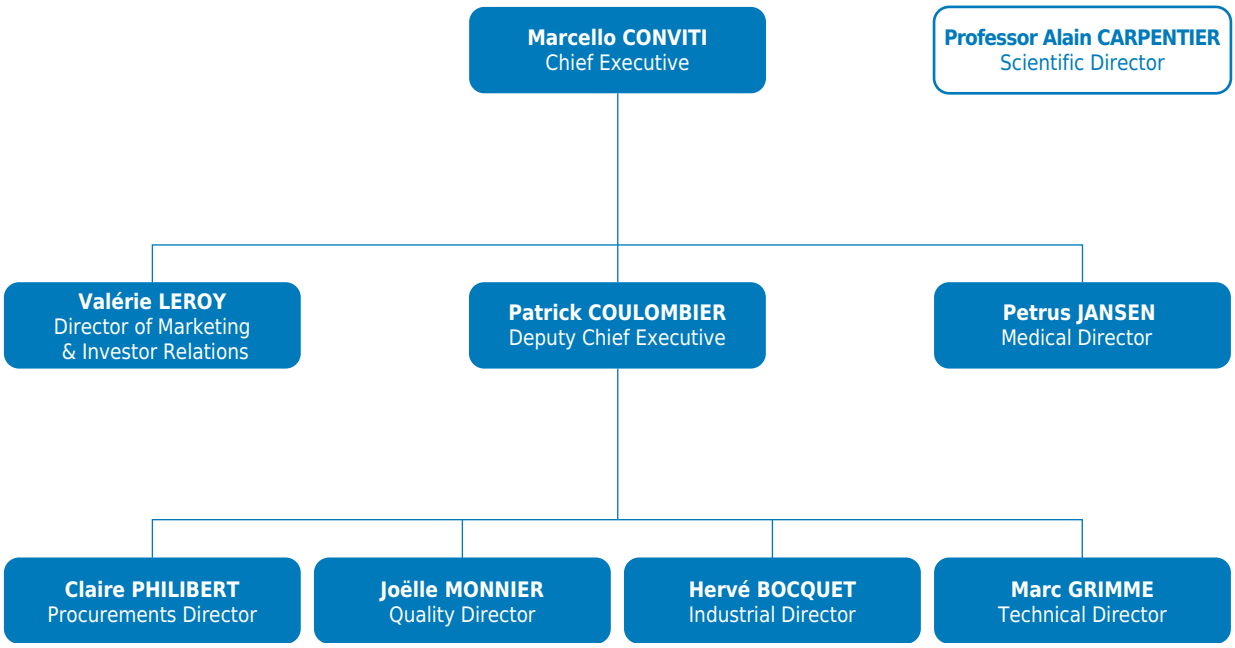
MICHEL FINANCE

Michel Finance is an independent director of CARMAT, of which he was interim chief executive from June 2008 to September 2009. He has dual experience in both general and financial management. He is currently chief executive and director of Theradiag and has overseen the Company's listing on the Euronext Paris Alternext market in December 2012. He began his career as a financial auditor at PricewaterhouseCoopers, and over a period of 25 years has occupied various 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 deputy 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 deputy chief executive from 2009 to 2010 and handled the Company's flotation on the Euronext Paris Alternext market, and has been a director with France Biotech (the French association of life sciences enterprises) since 2006.

HENRI LACHMANN

Henri Lachmann is an independent director of CARMAT. Henri Lachmann began his career in 1963 with the international auditing firm, Arthur Andersen. In 1970 he joined Strafor Facom, of which he became chairman in 1981. A director of Schneider Electric since 1996, Henri Lachmann was appointed chairman and chief executive of the Group in 1999. He has been chairman of the supervisory board of Schneider Electric since 2006. On May 3, 2013, following changes to Schneider Electric's governance, he was appointed deputy chairman, and lead director. Henri Lachmann also holds other important positions: vice-chairman of the supervisory board of Vivendi, member of the supervisory board of Norbert Dentressangle, director of the AXA Group Mutuelles, chairman of the board of directors at the Marie Lannelongue Surgical Center since 2006, chairman of the Continental Law Foundation, chairman of the Fondation Télémaque, observer 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 Honor, an Officer of the Academic Palms and a Commander of the National Order of Merit. Henri Lachmann is a graduate of the *École des Hautes Études Commerciales* (HEC) and is a chartered accountant.

4.1.3 Other members of the board of directors



MARCELLO CONVITI

Marcello Conviti, chief executive. Please refer to paragraph 4.1.2 Backgrounds of the members of the board of directors.

PROFESSOR ALAIN CARPENTIER

Professor Alain Carpentier, scientific director. Please refer to paragraph 4.1.2 Backgrounds of the members of the board of directors.

PATRICK COULOMBIER

Patrick Coulombier, deputy chief executive. Patrick Coulombier has headed the project team for the CARMAT bioprosthetic artificial heart within the Airbus Group since July 2001. Before that he worked for MBDA France as director of two international programs in the area of defense, 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. PIET JANSEN

Dr. Piet Jansen, chief medical officer. Petrus Jansen began his career in 1997 in the Netherlands with Baxter as Head of Research and Clinical Trials, particularly in connection with the Novacor program (left ventricular assistance device). Piet Jansen then held similar positions in Europe and the United States, notably with Jarvik Heart in charge of clinical trials and obtaining the CE marking for its products. Before joining CARMAT in December 2009, Piet Jansen was the chief medical officer at World Heart USA for five years. Piet 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

Valérie Leroy, director of marketing and investor relations. Valérie Leroy began her career in information technology in 1984, where she held various sales positions until 1996. She then joined the marketing teams at Medtronic for the range of cardiac stimulators. In 2001, Valérie Leroy joined Edwards Lifesciences, where she spent almost ten years working in various sales and marketing positions, notably at their global headquarters in California, where she obtained the e3 Award (exploring horizons, expanding boundaries, excelling in performance) in 2005 for the development and marketing launch of the Magna Mitral pericardiac valve in Europe. 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 post-graduate degree from the IAE, Paris (Sorbonne University).

MARC GRIMMÉ

Marc Grimmé, technical director. As project manager, Marc Grimmé has piloted the technical studies for the CARMAT bioprosthetic artificial heart since 1996, giving him over 15 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 prior to 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

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. Joëlle Monnier qualified as a medical doctor from the Rennes Faculty of Medicine. She also has a diploma (epidemiology elective) from CESAM, the education center for applied statistics in medicine and medical biology, and a quality assurance and certification diploma from CEGOS.

CLAIRE PHILIBERT

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 ten years in different companies, including Nycomed Amersham Medical Systems (manufacturer of cardiology, radiology and interventional neuroradiology products) and Diagnostica Stago, global specialists in hemostasis. Claire Philibert is a graduate of EAD, a School of Business Administration and Management.

HERVÉ BOCQUET

Hervé Bocquet, industrial director. Since September 2001, Hervé Bocquet held the posts of chief engineer on a drones program, developed as part of an international collaboration, and head of UAV production at Cassidian, the defense and security branch of Airbus Group. 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.

4.2 CONFLICTS OF INTEREST IN THE ADMINISTRATIVE, MANAGEMENT AND SUPERVISORY BODIES AND THE EXECUTIVE BOARD

4.2.1 Potential conflicts of interest

At the date of this registration document 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 board of auditors, 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.

4.2.2 Commitments of the directors and executive members to preserve shareholdings

At the date of this registration document, there is no commitment of the directors and executive members to preserve shareholdings.

4.3 OPERATION OF THE ADMINISTRATION AND MANAGEMENT BODIES

4.3.1 Expiry of the term of office of directors

Please refer to paragraph 4.1.1 Composition of the board of directors.

4.3.2 Service contracts linking the members of the board of directors and the general management of the Company

As at the date of this registration document, there were no service contracts linking the members of the board of directors and the general management of the Company.

4.4 SPECIALIZED COMMITTEES

As at the date of this registration document, the Company had set up the following boards:

4.4.1 Board of auditors

By decision of the board of directors of July 8, 2009 the Company set up a board of auditors for an unlimited duration. As at the date of this registration document, the board of auditors is comprised of three members:

- Michel Finance, independent 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 line with the Company's intentions, as stated upon its listing on the Euronext Paris Alternext market, the Company has completed its board of auditors with two additional members: Jean-Claude Cadudal, appointed during the meeting of the board of directors of May 7, 2010, and Christian Pierret, appointed during the meeting of the board of directors of December 15, 2010.

MICHEL FINANCE

Michel Finance - Chairman of the board of auditors. Please refer to paragraph 4.1.2 Backgrounds of the members of the board of directors. Michel Finance has a diploma from the EM Lyon and is a Chartered Accountant.

JEAN-CLAUDE CADUDAL

Jean-Claude Cadudal – Member of the board of auditors. Please refer to paragraph 4.1.2 Backgrounds of the members of the board of directors.

CHRISTIAN PIERRET

Christian Pierret – Independent member of the board of auditors. Christian Pierret is a former Deputy Minister for Industry, Small Business, Trade, and Crafts, a position he held from June 1997 to May 2002. Christian Pierret has had a dual career, in both politics and the private sector: *Rapporteur général* for the budget to the National Assembly (1981-1986), chairman of the monitoring committee of the *Caisse des Dépôts* (1988-1993) and deputy chairman of the Accor Group (1993-1996). Member of Parliament for 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 postgraduate diploma in economic sciences (IEP Paris, 1970) and a master's degree from the *École Nationale d'Administration* (ENA) (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 corporate financial statements 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 corporate financial statements 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;
- examine the significant risks faced by the Company, and in particular the off-balance sheet risks and commitments.

It reports to the board of directors on its activities at regular intervals.

The board of auditors met:

- twice during 2013 (once to review the 2012 financial statements and risk factors and once to assess the 2014 budget); and
- once so far in 2014 (to approve the 2013 financial statements and conduct a review of risk factors).

4.4.2 Compensation board

The Company has established a compensation board which as at the date of this registration document is comprised of two members, appointed by the board of directors at its meeting on April 22, 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 compensation board met four times during the 2013 fiscal year:

- initially to decide on the allocation of bonuses against 2012 targets;
- the second time to determine individual salary increases and review promotions;
- the third time to assess progress in relation to 2013 targets; and
- finally to rule on the remainder of the bonuses against 2012 targets.

4.4.3 Medical and scientific advisory boards

The meeting of the board of directors of December 16, 2009 approved the setting up of two scientific boards for an unlimited term.

4.4.3.1 Medical advisory board

The medical advisory board is responsible for preparations for the clinical trials. The medical advisory board comprises:

PROFESSOR CHRISTIAN LATRÉMOUILLE

Professor Christian Latrémouille: Cardiac surgeon in charge of transplantation at the *Hôpital Européen Georges Pompidou*, former pupil of Professor Alain Carpentier, he spent part of his hospital training in the United States, in Washington DC and Philadelphia. He is also Professor of Clinical Anatomy at the Faculty of Medicine at the University Paris V – René Descartes. He has published many scientific works such as *L'organisation des appareils et des systèmes* (2011), and many academic publications in renowned scientific magazines like the European Journal of Cardio-Thoracic Surgery or the Journal of Thorac Cardiovascular Surgery.

PROFESSOR DANIEL DUVEAU

Professor 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.

DOCTOR RÉMI NOTTIN

Doctor Rémi Nottin: Surgeon and head of department at the Marie Lannelongue hospital, where he specializes 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.

PROFESSOR ALAIN CARPENTIER

Professor Alain Carpentier: Please refer to paragraph 4.1.2 Backgrounds of the members of the board of directors.

The medical advisory board met – in person or *via* teleconferencing – after each animal implant and then various times after the start of the feasibility trial to review the patient records and the study's data.

4.4.3.2 Scientific advisory board

The scientific advisory board is responsible for monitoring the international development of the bioprosthetic artificial heart project.

The scientific advisory board comprises:

PROFESSOR GÜNTHER LAUFER

Professor Günther Laufer: Professor and Head of the department of cardiac surgery at the Vienna Medical University, he specializes 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.

PROFESSOR PAUL MOHACSI

Professor Paul Mohacsi: Head of the department of cardiac failure and transplantation at the Bern Clinic and Polyclinic for Cardiology (Inselspital).

PROFESSOR FREDERICK MOHR

Professor Frederick Mohr: Professor of Cardiac Surgery and medical director of the Center 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.

DOCTOR EDOARDO GRONDA

Doctor Edoardo Gronda: With a degree in medicine and surgery, Dr. Edoardo Gronda is the director of the department of clinical cardiology and cardiac failure at the Humanitas Clinical Institute in Italy. He was also a lecturer at the Faculty of Internal Medicine at the University of Milan until 2000. He is also chairman of the working group of the international association of cardiac and pulmonary transplantations. 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 Gilles Dreyfus: Professor of cardiovascular surgery at the Imperial College School of Medicine (United Kingdom), Gilles Dreyfus is a consultant in cardiothoracic surgery and director of research at the Royal Brompton & Harefield Trust where his research is centered on cardiac valvulopathy, cardiac failure, transplantation, and left ventricular assistance devices. He was in charge of the cardiovascular surgery department of the Foch Hospital until 2001. With a worldwide reputation as an expert in repairing the mitral valve, he is editor in chief of the Journal of Cardiac Failure and has published many articles on this subject in numerous scientific magazines. Since January 2010 he has been Medico-surgical director of the *Centre Cardio-thoracique de Monaco* (CCM).

DOCTOR MARK SLAUGHTER

Doctor 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

Professor Alain Carpentier: Please refer to paragraph 4.1.2 Backgrounds of the members of the board of directors.

Members of the scientific and medical boards met several times during the 2013 fiscal year, as a whole, individually, or in small groups, to analyze developments made in the CARMAT bioprosthetic artificial heart and prepare for the clinical trials.

The medical board met many times to discuss study protocols, to validate technical dossiers, and after each *ex vivo* or *in vivo* trial session to share the lessons learned from these experiments.

In particular, the scientific board met during the 27th Conference of the European Society of Cardio-Thoracic Surgery (EACTS) in Vienna in October 2013, to assess the results of animal trials and the methods of the feasibility study and to be informed of the composition of the independent committees. Its members regularly make individual visits to the Association's head office for the project's progress points and to review the results of tests.

4.4.4 Advisory board

Article 17-VI of the Articles of Association gives the ordinary general meeting the power to appoint, at its discretion, a maximum of 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 duty 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 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 this registration document, no observer has been appointed.

4.5 STATEMENT ON CORPORATE GOVERNANCE

4.5.1 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 regularly proceeds with a review of its corporate governance in respect of the recommendations of the code of corporate governance for quoted companies issued by the AFEP-MEDEF. The principal recommendations not applied are as follows:

Exclusions	Reasons
Assessment of the board of directors	There is no formal system to measure the individual contribution of each director. Reason: All members gave positive feedback on the board's operation as a collective body, which is only possible if individual contributions are satisfactory.
Term of office of directors	The Company's Articles of Association provide for terms of office of the directors of six years, whereas the AFEP-MEDEF recommends a limit of four years; Reason: When the Company was established, it was deemed that a longer term would ensure the stability of the Company's governance.
Composition of the board of auditors	The board of auditors only comprises one independent director, Michel Finance. Christian Pierret, who is an independent member of the board of auditors, does not serve the on the board of directors. Reason: Taking into account the size of the Company and the difficulty in identifying and recruiting experts, it has been deemed that Mr. Pierret's skills and independence should prevail over his membership in the board.
Appointments board	Taking into account the size of the Company, no appointments board was established.
Composition of the compensation board	There are no Independent directors on the compensation board. Reason: Taking into account the size of the Company, the number of compensation board members has been capped at two.

Apart from setting up the board of auditors, the compensation board and the scientific boards mentioned in paragraph 4.4 Specialized committees 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.

4.5.2 Bylaws

In 2011, the board of directors adopted 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, 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 commitments in excess of €100,000 and not provided for in the annual budget;
- hiring, laying off and amending 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.

4.5.3 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 authorization of the board of directors:

- the securing of loans or advances in order to acquire shares or securities of any subsidiary, 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 commitments in excess of €100,000 and not provided for in the annual budget;
- hiring, laying off and amending 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.

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:

- take any decision to proceed with the transfer of any substantial asset or any intellectual/industrial property belonging to the Company;
- take any decision to acquire a holding in a listed or unlisted company.

For a detailed description of the provisions governing the functioning of the board of directors and the General Management, please refer to paragraph 7.3.2 Provisions of the articles, a charter or a regulation of the Company regarding members of the board of directors and of the General Management.

4.5.4 Independent director

The Company has three independent directors: André-Michel Ballester, Michel Finance and Henri Lachmann; the Company believes that since their appointment they have met the criteria of the AFEP-MEDEF code of December 2008 (as amended in June 2013), that is:

- 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.

4.5.5 Internal control

The Company has no obligation to draw up a report on its internal control pursuant to Article L.225-37 of the french commercial code.

At the date of this registration document, the Company nevertheless had internal control procedures, in particular in the administrative, accounting, and financial areas, with a view to implementing its strategic policies. The Company's board of auditors reviews all the procedures annually. The internal control procedures in force are summarized below.

4.5.5.1 Administrative and financial organization (see paragraph 4.7.1.1 Organizational chart)

The administrative and financial functions are provided by three employees and four service providers under the direct or delegated supervision of the deputy chief executive. Positions are held by a purchasing manager, a head of finance, and a management controller. The Company uses an accounting firm to handle all its accounts.

The Company has also put in place a procedure to delegate powers and signatures for signing order forms and paying invoices. Thus, starting from €20,000, order forms must be signed by one of the following: the chief executive, the deputy chief executive or the chairman of the board of directors. From €100,000, order forms must be signed either by the chief executive or by the chairman of the board of directors and the deputy chief executive. From €250,000, at least two of them must sign order forms.

4.5.5.2 External purchases

Strategic purchases are the subject of tenders and contracts. Any order, regardless of the amount, nature, or requisitioner, must be the subject in advance of:

- a computerized purchase requisition to the purchasing department, which must make reference to the corresponding budget forecast for deduction and include, as the case may be, the specific purchasing conditions;
- the approval of the deputy chief executive or the approvals defined above depending on the amounts.

Only the purchasing department is then authorized to issue an order form, accompanied by the general conditions of purchase or, as the case may be, the special conditions and specifying the supplier's contact persons in respect of purchasing, content, delivery, and settlement.

4.5.5.3 Settlements

On receipt of an invoice, the Finance division has proper execution of the order by the requisitioner validated. Payments made by the Company to third parties (suppliers, government, employees, etc.) are prepared, on the Company's instruction, by the accounting firm. Settlements are executed, without exception, by bank transfer. Transfer orders are generated exclusively in computerized format and are checked by the Finance division then systematically validated by the Company's Management.

4.5.5.4 "Financial internal control" procedures

Internal control related to the preparation and processing of financial and accounting information is hereinafter called "financial internal control".

4.5.5.4.1 Accounting records and tax returns

The Company entrusts to an accounting firm the holding of all accounting records and the preparation of tax returns. All the elements produced by the accounting firm comply with the ethical obligations laid down by the *Ordre des Experts Comptables* and are in particular reviewed and systematically validated by the partner accountant responsible for the file.

- Accounting

  Accounting is done by the accounting firm, on the basis of information provided by the Company. The accounting firm reports monthly on the progress of the state of the accounts through various dashboards submitted to the Company's Management and coming within the framework of the budget control put in place.

- Tax returns

  All tax returns are prepared by the accounting firm and validated by the partner accountant responsible for the file. The accounting firm complies with the obligations in respect of online returns.

  The Research Tax Credit is the subject of a filing of a full supporting dossier accompanying the return and made available to the tax authorities.

4.5.5.4.2 Preparation of the financial statements

- Financial information published

  The semiannual and annual financial statements, which are notified to the AMF, are prepared by the accounting firm in liaison with the Company's Management and the heads of the departments concerned (management control, finance and human resources, purchasing). The procedures put in place to ensure the reliability of the financial information have been drafted and distributed to the parties concerned.

  The methodology for capturing the Company's expenses is applied systematically and generally. It is applied mainly on the principle of progress of orders under way, which is determined, for each order, by the technical head concerned and is the subject of a monthly control by the management control department.

- Computerized reporting

  The Company's expenses are monitored using a twofold procedure:

  - preparation of an annual budget, revised periodically, constructed in accordance with the forecasts of the divisional heads and confronted with the Company's general objectives,
  - preparation of monthly reporting, on the basis of accounting data, enabling in particular budgetary monitoring of expenses.

The Company takes the view that the procedures in force are suited to its size, organization, and current objectives.

4.6 COMPENSATION AND BENEFITS OF DIRECTORS AND MANAGEMENT

4.6.1 Compensation and benefits in kind of directors and management

Table No. 1: Summary table of compensation and options, warrants and bonus shares awarded to each corporate officer (in euros).

Summary table of compensation and options and shares awarded to each corporate officer

	2012 fiscal year	2013 fiscal year
Jean-Claude Cadudal – chairman of the board of directors		
Compensation for the FY	60,000	63,261
Value of options and warrants awarded during the FY	**0**	**0**
Value of bonus shares awarded for the FY	0	0
TOTAL	**60,000**	**63,261**

Summary table of compensation and options and shares awarded to each corporate officer

	2012 fiscal year	2013 fiscal year
Marcello Conviti – chief executive		
Compensation for the FY(1)	385,009	396,379
Value of options and warrants awarded during the FY	0	0
Value of bonus shares awarded for the FY	0	0
TOTAL	**385,009**	**396,379**

(1) Excluding benefits in kind.

Table No. 2: Summary table of the compensation of each corporate officer (in euros)

	2012 fiscal year		2013 fiscal year	
	Amounts due(1)	Amounts paid(2)	Amounts due(1)	Amounts paid(2)
Jean-Claude Cadudal – chairman of the board of directors				
Fixed remuneration(3)	-	-	-	-
Variable remuneration(3)	-	-	-	-
Special remuneration(3)	-	-	-	-
Directors' fees	60,000(4)	60,000	63,261(5)	63,261
Benefits in kind(3)	-	-	-	-
TOTAL				
Marcello Conviti – chief executive				
Fixed remuneration(3)	332,749	332,749	339,812	339,812
Variable remuneration(1)(6)	56,567(7)	52,260(6)	135,925(8)	56,567(7)
Special remuneration(1)	-	-	-	-
Directors' fees	-	-	-	-
Benefits in kind(1)	6,612	6,612	6,819	6,819
TOTAL	**395,928**	**391,621**	**482,556**	**403,198**

(1) For the fiscal year.
(2) During the fiscal year.
(2) Gross value before tax.
(4) At the board meeting of February 28, 2013, the remuneration of Jean-Claude Cadudal, in his position as chairman of the board of directors, equivalent to that for the 2011 fiscal year, was confirmed for the 2012 fiscal year and is maintained for the following fiscal years until the board decides otherwise.
(5) At the meeting of December 19, 2013, the board decided that, to comply with the applicable regulations, the remuneration of its chairman will be treated for tax and social security purposes as wages and will be increased to €63,261 per year (gross) for the year 2013.
(6) The variable part paid during 2012 corresponds to the bonus for the 2011 targets, approved by the board of directors upon a proposal by the compensation board.
(6) The variable due for 2012 and paid in 2013 has been approved by the board of directors upon a proposal by the compensation board.
(6) The variable part paid for 2013 corresponds to the maximum awardable amount, i.e. 40% of fixed remuneration. The actual amount paid will be approved by the board of directors upon proposal by the compensation committee during the first half of 2014.

The variable portion of Marcello Conviti's remuneration for the years ended December 31, 2012 and 2013, which can reach up to 40% of his fixed compensation, was set by the Company's board of directors upon a proposal by the compensation board in line with the performance conditions established by the compensation board (in particular, in 2012, the validation of the industrial processes and, in 2013 the execution of the first clinical trials and compliance with the annual budget).

Table No. 3: Directors' fees and other compensation allocated to non-executive corporate officers during the fiscal years ended on December 31, 2012 and 2013

Table showing the directors' fees and other compensation allocated to non-executive corporate officers during the fiscal years ended on December 31, 2012 and 2013

	2012 fiscal year	2013 fiscal year
Professor Alain Carpentier – director[1]		
Directors' fees	5,000	5,000
Other compensation	-	-
Philippe Pouletty, Representative of Truffle Capital – director[1]		
Directors' fees	5,000	5,000
Other compensation	-	-
André Michel Ballester – director[2]		
Directors' fees	10,000	10,000
Other compensation	-	-
Michel Finance – director[2]		
Directors' fees	10,000	10,000
Other compensation	-	-
Henri Lachmann – director[2]		
Directors' fees	10,000	10,000
Other compensation	-	-
TOTAL		

(1) At the board meeting of February 28, 2013, the remuneration of Mr. Carpentier and Truffle Capital, equivalent to that for the 2011 fiscal year, was confirmed for the 2012 fiscal year and is maintained for the following fiscal years until the board decides otherwise.
(2) At the board meeting of February 28, 2013, the remuneration of Messrs. Ballester, Finance, and Lachmann, equivalent to that for the 2011 fiscal year, was confirmed for the 2012 fiscal year and is maintained for the following fiscal years until the board decides otherwise.

Table No. 4: Option to subscribe or purchase bonus shares awarded to each executive corporate officer during the fiscal years ended December 31, 2012 and 2013

Not applicable (the Company has never allocated options).

However, the Company has awarded share warrants and start-up company stock warrants (see paragraphs 4.6.3 and 4.7.2).

Table No. 5: Option to subscribe or purchase bonus shares exercised by each executive corporate officer during the fiscal years ended on December 31, 2012 and 2013

The Company has never allocated options.

Table No. 6: Scrip issue awarded to each executive corporate officer during the fiscal years ended on December 31, 2012 and 2013

The Company has never allocated bonus shares.

Table No. 7: Scrip issue awarded to each executive corporate officer which became available during the fiscal years ended on December 31, 2012 and 2013

The Company has never allocated bonus shares.

Table No. 8: History of share subscription or purchase options awarded to executive corporate officers

The Company has never awarded options. However, it has awarded share warrants and start-up company stock warrants (see paragraphs 4.6.3 and 4.7.2).

Table No. 9: History of options to subscribe or purchase shares granted to the top ten non-corporate officer employees and options exercised by them

The Company has never awarded options. However, it has awarded share warrants and start-up company stock warrants (see paragraph 4.7.2).

Table No. 10: History of bonus shares awarded

The Company has never awarded options. However, it has awarded share warrants and start-up company stock warrants (see paragraph 4.7.2).

Table No. 11: Clarification regarding the compensation terms and conditions and other benefits granted to executive corporate officers:

Executive corporate officers	Employment contract		Supplementary pension scheme		Allowances or benefits due or likely to be due upon severance or change in role		Allowance connected to a non-competition clause-	
	Yes	No	Yes	No	Yes	No	Yes	No
Jean-Claude Cadudal, chairman of the board of directors		X		X		X		X
Start date of term of office:						May 7, 2010 (first term as a limited company)		
End date of term of office:						At the end of the annual general meeting approving the financial statements for the fiscal year ending December 31, 2015		
Marcello Conviti, chief executive		X		X		X		X
Start date of term of office:						May 7, 2010 (first term as a limited company)		
End date of term of office:						At the end of the annual general meeting approving the financial statements for the fiscal year ending December 31, 2015		

The chief executive and the directors do not enjoy any particular retirement benefits, severance payments due when they leave office, or non-competition payments.

4.6.2 Sums set aside or determined by the Company for the payment of pensions, retirement or other benefits for the management and directors

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 December 31, 2013.

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 3% per *annum* (unchanged from the rate used at 6/30/2013 and 12/31/12).

The overall provision for managers stands at €17,808 at the end of the period.

4.6.3 Share subscription warrants (BSA) or start-up company stock warrants (BCE) assigned to management and directors

The following table shows all of the share subscription warrants (BSA) or start-up company stock warrants (BCE) issued by the Company to its corporate officers and managers and subscribed by the beneficiaries, at the date of this registration document:

Holder		BSA-2009-1	BCE-2009-1	BCE-2012-1
Jean-Claude Cadudal	Chairman of the board of directors	1,554		
Michel Finance	Director	518		
André-Michel Ballester	Director	468		
Marcello Conviti	Chief executive/director		2,800	4,000

The exercising of each BSA-2009-1 or BCE-2009-1 gives an entitlement to 25 new shares in CARMAT. The exercising of each BCE-2012-1 gives an entitlement to one new share in CARMAT. For a detailed description of BSA-2009-1, BCE-2009-1 and BCE2012-1.

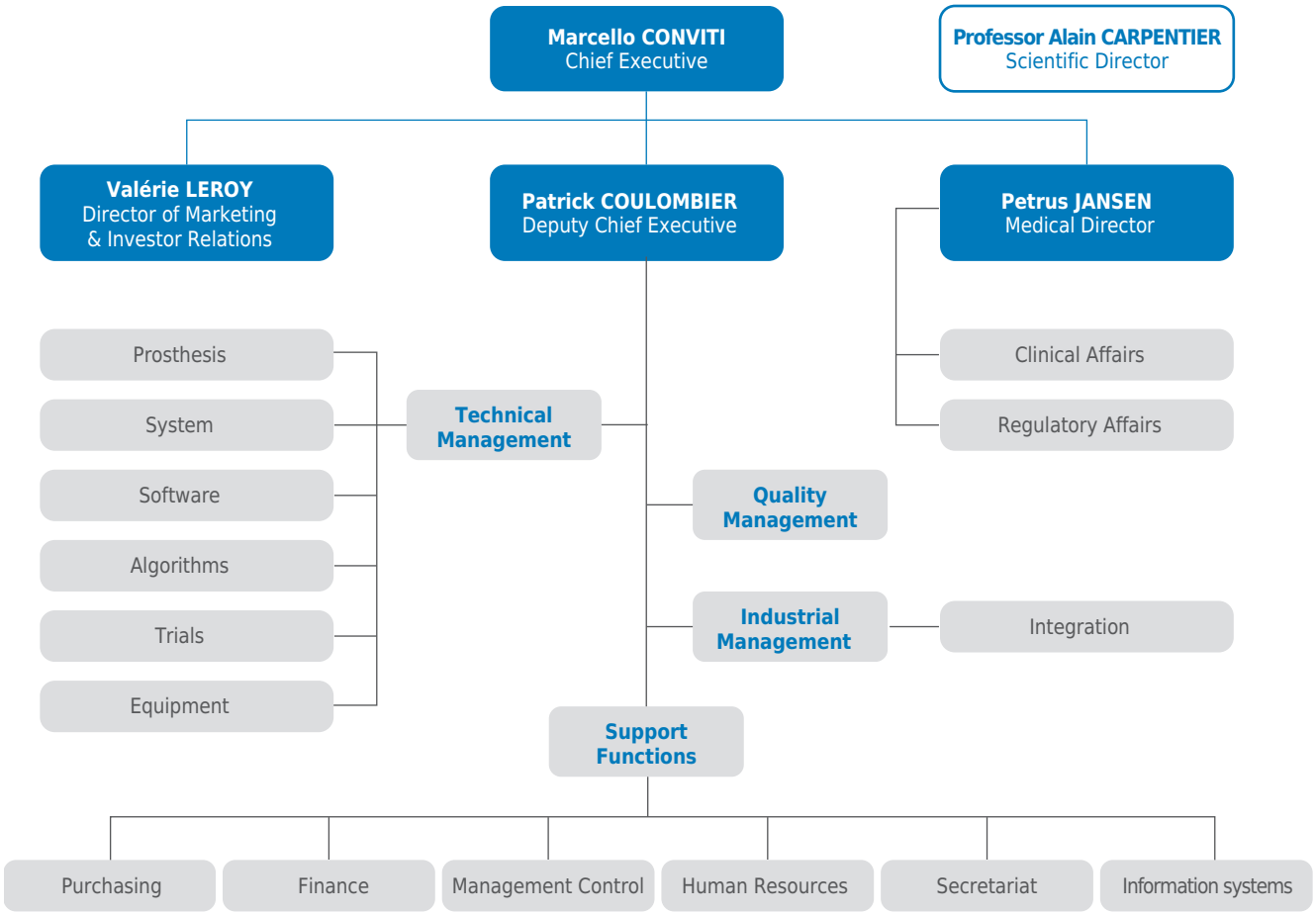
Please refer to paragraph 4.7.2 Interests and share options held by members of the management and supervisory bodies and by employees.

4.7 MEMBERS OF STAFF

4.7.1 Human Resources

4.7.1.1 Organizational chart

As at the date of this registration document, 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 4.1.3 Other members of the management.

At certain stages of the development of the bioprosthetic artificial heart project, the Company has used a number of outside providers of specific services. At the date of the registration document, 47 outside service providers work for CARMAT and are divided up as follows:

- technical department: 29 providers;
- medical department: 5 providers;
- industrial department: 3 providers;
- quality department: 4 providers;
- support: 6 providers.

4.7.1.2 Number and breakdown of staff

At the date of this registration document, the Company's workforce numbered 43 people, including two temporary workers.

4.7.1.2.1 Changes in workforce

Changes in workforce at	12/31/2013	12/31/2012	12/31/2011	12/31/2010	12/31/2009
Managers	29	30	29	25	17
Non-management	9	7	7	7	8
Trainees	2	5	0	0	0
TOTAL	**38**	**42**	**36**	**32**	**25**

At December 31, 2013, all members of staff were employed under permanent employment contracts, except one member of staff under a temporary employment contract and two trainees. One employee is employed part-time.

4.7.1.2.2 Status of Young Innovative Enterprise (JEI)

CARMAT opted for the status of Young Innovative Enterprise in September 2008. On July 8, 2009, the Yvelines tax services department issued a favorable opinion ("ruling") in respect of the Company's JEI application. This opinion is valid *vis-à-vis* the URSSAF.

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 eight years from the date of establishment of the Company, or for CARMAT up until 2015 (please refer to paragraph 3.5.5 Risks associated with loss of Young Innovative Enterprise status).

Parliament has voted two amendments to the arrangements for JEI status, the first within the framework of Article 78 of the 2011 Finance law and the second within the framework of Article 37 of the amended 2011 Finance law of December 28, 2011. These amendments aim to cap and taper the arrangements for exemption from social security contributions payable by the JEI employer.

CARMAT benefited from the JEI exemption at the reduced rate of 80% in 2013, the sixth year of application of the status (date of establishment: June 30, 2008). This reform of the status, effective since January 1, 2011, resulted in an additional social security cost of €380,000 in 2012.

4.7.1.3 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 at December 31, 2013, was made up of 13 women and 27 men and included 2 doctors, 23 engineers, and 8 senior graduate technicians. The average age of the salaried workforce was 40. About a quarter of staff are aged under 30. In 2013, the Company financed around 570 hours of training.

The Company applies the National Collective Agreements of the "Metallurgical Industries: workers, employees, technicians, and supervisors" and the "Metallurgical Industries: engineers and managers", as well as the Regional Collective Agreement of the "Metallurgical Industries: workers, employees, technicians, and supervisors of the Paris Region". There are no company agreements other than the Bylaws.

Standard contracts of employment contain no clauses relating to breach of the contract of employment or non-competition and non-poaching undertakings (staff and/or customers).

All members of staff 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 January 16, 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 core time (10:00 – 15:30 hours).

4.7.2 Interests and share options held by members of the management and supervisory bodies, and by employees

The table in paragraph 7.1.5 Other securities giving access to capital shows all of the share warrants (BSA) and start-up company stock warrants (BCE) issued by the Company for its corporate officers and employees, and yet to be exercised, with the specification that the top ten non-corporate officer employees hold BCE entitling them to subscribe a total of 106,450 Company shares (of which 30,000 for BCE-2012-1 and 76,450 for BCE-2009-1).

The following tables show as at the date of this registration document, all the share subscription warrants (BSA) and start-up company stock warrants (BCE) issued by the Company to its corporate officers only and not yet exercised.

Type of security	**BSA-2009-1**
Beneficiaries	Three members of the board of directors: ▸ Mr. Jean-Claude Cadudal: 1,554 BSA-2009-1 ▸ Mr. Michel Finance: 518 BSA-2009-1, and ▸ Mr. André-Michel Ballester: 468 BSA-2009-1
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
Exercise deadline	Ten years starting from the date of the allocation of the BSA
Ratio	One BSA-2009-1 warrant for 25 new CARMAT shares
General conditions of exercise	▸ 25% of the BSA-2009-1 warrants may be exercised on the date of the first anniversary of the beneficiary joining the Company, subject to his actual and continued presence within the Company at that date; ▸ 75% of BSA-2009-1 options 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 for a period of three years, subject to his 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 September 8, 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	63,500 shares for the BSA-2009-1 warrants assigned

Type of security	BCE-2009-1
Beneficiaries	Mr. Marcello Conviti – chief executive and director: 2,800 BCE-2009-1
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
Exercise deadline	Ten years from the date of award of the BCE options
Ratio	One 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 his actual and continued presence within the Company at that date; ▸ 75% of BCE-2009-1 options may be exercised on the basis of full monthly periods in tranches of 1/36th, from the date of the first anniversary of the beneficiary joining the Company over a period of three years, subject to his 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 €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 September 8, 2010, 20% of BCE-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	70,000 shares

Type of security	BCE-2012-1
Beneficiaries	Mr. Marcello Conviti – chief executive: 4,000 BCE-2012-1
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
Exercise deadline	Ten years from the date of award of the BCE options
Ratio	One BCE-2012-1 option for 1 new CARMAT share
General conditions of exercise	▸ 50% of BCE-2012-1 options may be exercised on the basis of monthly periods in tranches of 1/48th for a period of four years from the date on which the BCE-2012-1 options are awarded to the beneficiary, subject to his actual and continued presence within the Company at that date. ▸ 16.25% of BCE-2012-1 options may be exercised from the success of the pivotal round of clinical trials of the CARMAT total artificial heart (report from the scientific board), subject to his/her actual and continued presence within the Company at that date; ▸ 16.25% of the BCE-2012-1 options may be exercised from the date on which the CE mark is obtained for the CARMAT total artificial heart, subject to actual and continued presence of the beneficiary within the Company at that date; ▸ 17.5% of BCE-2012-1 options may be exercised from the realization at December 31 of the first year of marketing of the CARMAT total artificial heart, recorded by the board of directors, of revenue and gross margin in line with the business plan established by the General Management and approved by the board of directors, subject to his/her actual and continued presence within the Company at that date.
Number of new shares that may be subscribed	4,000 shares

4.7.3 Employee ownership and profit sharing schemes

As at the date of this registration document, the Company had not set up any employee ownership or profit sharing schemes.

5

NOTES ON ACTIVITY IN THE REPORTING PERIOD

5.1 PARTICULARS OF THE ECONOMIC AFFAIRS OF THE COMPANY

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.

5.1.1 Change in the Company's activity in the course of the reporting period

The Company continued its research and development activities and stepped up its efforts to put in place the necessary resources and sub-contractors in preparation for the clinical trials that began in December 2013. At this stage, it is not generating any turnover, and all its resources are dedicated to the bioprosthetic artificial heart development project.

At €13,376,375, purchases and external expenditure fell compared with expenses for the previous period (€16,467,584). This decrease was in line with the budget. It corresponds first of all with the end of the research and development activities for the prosthesis, secondly with continuation of the design work for the external elements, in particular those that will enable patients to return home, and thirdly with growth in the work involved in validating the industrial processes within the Company and at its subcontractors.

The end of the design phase for the prosthesis was marked by the completion of a certain number of tasks, notably the control and validation of the hospital configuration of the prosthesis software, the endurance testing of the components and prostheses prior to clinical feasibility testing and the additional environmental tests.

Development of the external systems has continued for configuration in a mobile environment, taking into account feedback from the tests completed on the hospital configuration, in particular as regards performance in electromagnetic environments.

The work on industrial processes carried out in 2012 continued in 2013. The aim is to be in a position to ensure reproducibility of the manufacture of the various sub-assemblies at subcontractors and their assembly at CARMAT. During the year, 15 prostheses and 19 ancillary toolkits (implantation accessories, atrial connection devices, vascular conduits, etc.) were manufactured or reconditioned in CARMAT's clean room, then used in various validation trials and animal tests.

The Company had 40 salaried employees at December 31, 2013 (including two temporary production and purchasing employees), broadly stable compared with the end of the previous year (42 salaried employees, including five temporary employees). Three new employees were hired, one to strengthen the technical management in relation to the development of external equipment, and two others in the production department to provide extra capacity for prosthesis manufacture and to strengthen the control team. Salary and social security costs rose slightly from €4,183,804 in the previous fiscal year to €4,410,419 in 2013.

During the course of the reporting period, new industrial facilities were added to existing ones in some cases, while other industrial facilities were duplicated. In particular, the Company purchased new measuring facilities in order to successfully complete validation of the prosthesis. The Company's IT systems had to be expanded to enable the storage of data and support for the ERP tool. The Company also purchased new measuring facilities in order to successfully complete validation of the prosthesis.

Investments in property, plant and equipment during 2013 totaled €118,074.

During the year, CARMAT obtained the renewal of ISO 13485: 2003 and ISO 9001: 2008 for its quality management system, following an audit by accredited body DEKRA.

At the medical level, three teams of surgeons from the HEGP (Hôpital Européen Georges Pompidou), the Centre Chirurgical Marie Lannelongue and the Hôpital Nord Laennec in Nantes performed several *ex vivo* implantations of the CARMAT prosthesis in order to optimize the surgical protocol. At the same time, training using animals was intensified, as 19 trials were completed during the 2013 reporting period.

The Company also participated in the 27th annual meeting of the European Association of Cardio-Thoracic Surgery (EACTS) in Vienna. In particular, the scientific committee met on this occasion to evaluate the results of the animal tests and the feasibility testing methodology, and to be informed of the composition of the independent committees.

A request to authorize clinical trials was filed with the ANSM in July 2013 following completion of the second round of testing on calves and the granting of approval to carry out a feasibility test on four patients in three accredited centers in September 2013.

The first implantation was carried out on December 18, 2013 at the Hôpital Européen Georges Pompidou. As of the date of this document, the collection and analysis of data relating to this trial was still under way.

5.1.2 Financing obtained

The Company opted to apply the Research Tax Credit (CIR) for 2013. This option was first exercised for the calendar year 2009 and renewed in 2010, 2011 and 2012. €1,770,114 of the Research Tax Credit pertaining to the 2013 fiscal year was recognized under the Corporation taxes item of the income statement (see details in Note 4.5.3 to the 2012 financial statements) and appears under "Other debtors" in the balance sheet.

On July 10, 2013, the Company received a total amount of €6,645,540 from Bpifrance, divided into a subsidy of €2,873,627, accounted for under "Subsidies" in the income statement, and a repayable advance of €3,771,913, accounted for under "Conditional advances" on the balance sheet (liabilities).

During the fiscal year, the Company carried out several capital increases (see paragraph 6.4.1 Features of the year, for details).

5.1.3 Acquisition of fixed assets

The financial statements for the period show a total of €1,704,901 for acquisition of fixed assets. This amount is essentially made up as follows:

- financial assets which varied little from the net effect of the acquisition of CARMAT shares under the liquidity agreement entered into with DSF Markets in an amount of €1,439,177 and from share disposals amounting to €1,309,496 over the same period, with the balance of the increase in the item relating to new guarantee deposits for the premises;
- property, plant and equipment in the amount of €118,074, primarily for the acquisition of industrial equipment and tooling (test benches), fitting out the premises and the acquisition of computer hardware;
- intangible assets in the amount of €147,649, for the acquisition of licenses and software (of which €66,436 was in progress at the end of the year).

5.1.4 Change in working capital requirements (WCR)

The change in WCR over the reporting period was €3,625,923. The main source of this difference was a change in two balance sheet items:

- a substantial reduction in "Other debtors" of €3,140,601, relating mainly to a decrease in the amount of the research tax credit recognized at December 31, 2013 for the year (€1,770,114), compared with the amount recognized at December 31, 2012 (€5,022,922);
- moderately offset over the year by the item "Trade accounts payable and related payables" of €647,322.

5.1.5 Principal risks and uncertainties faced by the Company

As far as the Company is aware, and at the date of this registration document, the principal risks faced by the Company are described in Chapter 3 of this registration document.

The board of auditors also conducts an annual detailed review of the risk factors, which are brought up to date, as applicable, in each edition or update of the Company's registration document.

5.1.6 Research and development activities

The Company's activity is fully focused on research, development and testing of a bioprosthetic artificial heart.

Research and development activities in 2013 were centered on the following main themes:

- quality:
  - verification and validation of the prosthesis software (security software, with the possibility of recovery following failure) in accordance with standard 62304,
  - validation of the hospital monitoring console software,
  - analysis report on the risks associated with the system as a whole and of the sub-assemblies,
  - more intense control activities at suppliers' premises and in the Company;
- industrialization:
  - optimization of the prosthesis production processes in order to ensure better reproducibility, in particular at the Company's subcontractors,
  - improvement of the Company's production processes and tools,
  - production and/or reconditioning of 15 prostheses for the various tests,
  - production of 19 kits for animal testing;
- external systems:
  - prototype and ergonomics study,
  - fuel cell miniaturization study, tank optimization,
  - development (hardware and software) of the configuration worn;
- clinical trial preparation:
  - training of surgical teams and medium-term experimentation on animals,
  - additions to the ANSM application (animal tests, etc.),
  - signing of agreements with investigation centers,
  - constitution of research monitoring committees (CEC and DSMB);
- clinical trial:
  - 3D modeling of the physiological compatibility of pre-selected patients,
  - implementation of constraints within clinical teams and techniques,
  - first implantation in a human on December 18, 2013 at the Hôpital Européen Georges Pompidou.

5.2 FINANCIAL POSITION, CASH AND CAPITAL

5.2.1 The Company's debt position in relation to the volume and complexity of its business

The Company's debt stood at €7,098,449 as at the close of the period, and is made up as follows:

- €822,187 for interest accrued on repayable advances received from Bpifrance;
- €6,254,255 for trade creditors, mainly comprising trade accounts payable (€4,786,855);
- €22,006 for liabilities secured on property.

The Company does not have any long-term debt except for the Conditional repayable advances (Bpifrance advances repayable in the event of the project being successful) shown under Other equity at €7,515,054 as at December 31, 2013.

This indebtedness must be seen in the context of available cash of €16,883,974 as at December 31, 2013 (Notes 6.3 and 6.4.4.5).

5.2.2 Analysis of the financial situation

Total capital stands at €21,984,183, compared with €19,696,896 for the previous period.

The change in balance sheet assets mainly relates to the increase in cash over the year (€16,883,974 at December 31, 2013, compared with €11,134,438 at December 31, 2012), partly offset by the decrease in the "Other debtors" item, which stood at €2,901,674 at the end of the year, compared with €6,092,119 at the end of the previous year, and the decrease in fixed assets to €1,633,314 from €2,266,763 the previous year. Acquisitions of fixed assets for €1,704,901 (see paragraph 5.1.3 above) were €1,387,951 below the total disposals and €919,614 below the transfers to depreciation and amortization.

Current assets total €20,350,868 as at December 31, 2013, compared with €17,430,133 at the close of the previous period. This amount is primarily made up of other debtors in the amount of €2,951,518 (relating mainly to the research tax credit accrued for 2013 of €1,770,114 and input VAT of €1,149,086), plus cash and investments in the amount of €16,883,974 (Notes 6.3 and 6.4.4.5).

The change in equity during the period totals -€2,712,649, taking the equity to €7,228,579 as at December 31, 2013, compared with €9,941,228 at the close of the previous period. Further information on this decrease is provided in Note 6.4.4.6.2.

Other equity (Bpifrance repayable advances) totals €7,515,054 at the close of the period, compared with €3,743,141 at the close of the previous period. Further information on this increase is provided in Note 6.4.4.7.1.

Finally, debts at the close of the 2013 period total €7,098,449, compared with €5,939,193 at the close of the previous period.

5.2.3 Cash and capital

5.2.3.1 Information on the Company's capital

(in euros)	December 31, 2013	December 31, 2012	December 31, 2011
Equity	7,228,579	9,941,228	26,890,919
Other equity – Conditional advances	7,515,054	3,743,141	3,743,141
Gross financial debt	822,187	460,054	217,066
Cash and cash equivalents	16,883,974(2)	11,134,438	29,369,693
Net financial debt	-16,061,787	-10,674,384	-29,152,627
Net financial debt as a proportion of equity	N/A	N/A	N/A

(1) 19-month period.
(2) Cash comprises:
- *cash instruments in the form of term deposit accounts with a total value of €13,525,000;*
- *cash in hand or at bank, reported at face value (€3,358,974).*

Since the end of the fiscal year at December 31, 2013, no significant event has affected the Company's equity or the low level of risk associated with the treasury instruments.

The board of directors has assumed that the business is a going concern, having taken the following points in particular into account:

- cash, cash instruments and liquid marketable securities totaling €16,883,974 as at December 31, 2012;
- the payment of subsidies (€159,166) and repayable advances (€6,992,256) still to be claimed between now and the end of the Bpifrance aid program signed in 2009;
- the repayment, expected in 2014, of the research tax credit for 2013, of an amount of €1,770,114.

5.2.3.2 Cash flow

Please refer to paragraphs 1.1 Selected financial information and 1.6 Investments, and Chapter 6 Financial statements as at December 31, 2013 of this registration document.

5.2.3.3 Borrowing conditions and financing structure

5.2.3.3.1 Bank debts and repayable advances

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 Bpifrance (see Chapter 5.7 "Significant contracts") and the Yvelines Departmental Council, capital increases carried out in connection with Company's flotation on the NYSE/Euronext Alternext Paris market in July 2010 (a net capital increase of €14.2 million (including exercise of the supplementary issue option) and the rights issue with preferential subscription rights on the NYSE/Euronext Alternext Paris market in August 2011, which raised €26.7 million (including net premiums), and the eight subscriptions carried out in 2013 under the issue agreement with Kepler Cheuvreux for €11.9 million).

Consequently the Company has no bank debt, bearing in mind the particular nature of its activities; the loans and sundry financial debts

shown in the balance sheet as at the end of 2013 comprised solely accrued interest on repayable advances. These repayable advances, which stood at €7,515,054 as at December 31, 2013, are disclosed in the balance sheet under Other equity, in accordance with the provisions of the french commercial code and with the General Chart of Accounts. As stated in Note 6.4.6.1, these advances become repayable if the project is successful. Interest arising on these advances is accrued on a *pro-rata* basis.

Schedule of payables	Gross sum	1 year or more	1 to 5 years	More than 5 years
Sundry loans and financial debts	822,187		822,187	
Trade accounts payable and related payables	4,786,855	4,786,855		
Staff and related payables	785,561	785,561		
Social security and other social bodies	670,707	670,707		
Value Added Tax	8,374	8,374		
Other taxes and related payables	2,759	2,759		
Liabilities secured to property and related liabilities	22,006	22,006		
TOTAL	**7,098,449**	**6,276,262**	**822,187**	

5.2.3.3.2 Leasing debts

None.

5.2.3.3.3 Convertible bonds

Bonds totaling €2.0 million were issued by resolution of the extraordinary general meeting of the Company on May 7, 2010 and were converted automatically into new ordinary shares in the Company on the date the Company's shares were first listed on the NYSE/Euronext Alternext Paris market.

The Company has no bonds in issue as at the date of this registration document.

5.2.3.3.4 Other means of financing

During the year ended December 31, 2013 and up to the date of this registration document, the Company was in a research phase and recorded no sales Finance for the program was provided by:

- eight subscriptions carried out on June 25, June 27, September 24, September 26, October 1, November 12, November 18, and December 23, under the bond issue agreement signed with Kepler Cheuvreux on June 7, 2013, totaling 116,800 BEA, increasing share capital by €4,672, lifting it from €166,311.80 to €170,983.80 through the issue of 116,800 ordinary shares with a nominal value of €0.04, issued at a unit price of €108.86 and with a gross issue premium of €11,938,052 (taking into account the expenses related to the capital increase, of €81,470.84, which were deducted from the issue premium in accordance with the preferential accounting method, the net amount of the issue premium for these capital increases is €11,856,581);
- the receipt on April 11, 2013, of the research tax credit recognized at December 31, 2012, in the amount of €5,022,922;
- the receipt, on July 10, 2013, of the amount of €6,645,540 from Bpifrance, divided into a subsidy of €2,873,627, recognized under "Subsidies" in the income statement, and a repayable advance of €3,771,913, recognized under "Conditional advances" on the balance sheet (liabilities).

5.2.3.4 Restrictions on the use of capital that have had or could have a marked influence, directly or indirectly, on the issuer

None.

5.2.3.5 Anticipated sources of finance

The Bpifrance agreement provides for the payment of a total sum of €17,442,639 by way of subsidies. As at December 31, 2013, €159,166 of this amount remained to be received before the end of the project. It also provides for payment of a total sum of €14,507,324 by way of repayable advances. As at December 31, 2013, €6,992,256 of this amount remained to be received before the end of the project. The payment of the sums corresponding to milestones 5 and 6 in the amount of €5,700,690 is expected in 2014 (see paragraph 5.7 Important contracts).

The Company also opted to apply the research tax credit (CIR) for 2013. This option was first exercised for the calendar year 2009 and renewed in 2010, 2011 and 2012. €1,770,114 of the research tax credit pertaining to the 2013 fiscal year was accounted for under the Corporation taxes item of the income statement (see details in Note 6.4.5.3 of the 2013 financial statements) and appears under "Other debtors" in the balance sheet.

5.3 PROGRESS MADE AND DIFFICULTIES ENCOUNTERED DURING THE REPORTING PERIOD

See paragraph 5.1.6, Research and development activities, for progress made during 2013.

As set out in the Company's 2012 registration document registered by the French Financial Markets Authority on May 30, 2013 under No R. 13-027 (see paragraph 2.2.3 Development process and stage of the CARMAT bioprosthetic artificial heart project), all the pre-clinical tests and validation tests involved a great deal of effort for the Company, its partners and suppliers in 2012 and 2013, since it is entirely innovative, not only in technological terms, but also in regulatory terms (no precedent in France) and in industrial terms (new integration procedures and methods, no existing industrial network).

2013 saw considerable efforts by the Company to meet the requirements of the ANSM, following the application presented at the end of 2012. These requirements mainly concerned the needs to carry out additional animal testing to assess the performance of the device (prosthesis, cables, monitoring console) and its physiological response. A balance of the metabolic flow was sought, as well as the absence of blood clots in the device or the animal's organs after removal. Advanced physiological and pathological studies were required to look for the absence of blood clots (one month after removal). This experimentation on 19 animals in 2013 required the involvement of not only the medical and veterinary teams, but the entire clinical personnel, as well as a substantial portion of the technical personnel and a considerable proportion of the Company's production capacity. As a result, some of the tests planned for 2013, such as the continuation of endurance tests beyond the five systems required to obtain authorization for feasibility testing, had to be postponed.

The ISO 13485 standard recommends, as good clinical practice, the establishment of independent committees of experts. The establishment of these committees, as well as of working methods to govern their functioning required the significant involvement of CARMAT staff. The training of the surgical teams also continued in parallel, to ensure the optimum safety of future operations.

The pre-clinical tests on animals, as required in order to obtain ANSM approval for clinical testing, were completed in July 2013, and the approval was granted in September 2013. It is only from the date that this authorization was granted that the Company was able to finalize clinical cooperation agreements with the centers participating in the trials and put in place the independent monitoring committees recommended by the regulatory authorities. In addition to the time needed to complete the administrative formalities, it was necessary to take the time to make a careful selection of patients, given the importance of this trial for the project (the first implantation took place on December 18, 2013 at the Hôpital Européen Georges Pompidou).

The lessons learned from activities carried out during the year are reflected in the provisional scientific and regulatory timetable for the project, which has been updated in paragraphs 1.3 and 2.3.7 of this document.

5.4 ANTICIPATED DEVELOPMENTS, OUTLOOK AND SIGNIFICANT EVENTS AFTER THE END OF THE REPORTING PERIOD

5.4.1 Anticipated developments and outlook

Over the coming year, the Company will be focusing solely on development, testing and clinical trials of the bioprosthetic artificial heart.

During 2014, the Company is planning:

- to carry out the additional tests and validations required to complete the CE marking application;
- to undertake the clinical trials required by the regulatory authorities with the aim of obtaining the CE marking for marketing the artificial heart in 2015 at the earliest.

As of the date of this registration document, the collection and analysis of data from the first feasibility test was ongoing (see paragraph 8.6 Recent events).

The Company's cash resources, as well as the expected subsidies, refundable advances and research tax credit will enable the Company to ensure the progress of its activities until 2015.

The provisional scientific and regulatory timetable is shown in paragraphs 1.3 and 2.3.7.

5.4.2 Significant events after the end of the reporting period

Nothing occurred after the end of the reporting period that could alter the presentation or assessment of the financial statements as adopted by the board of directors on February 11, 2014.

5.4.3 Main trends since the end of the previous fiscal year

No significant changes have occurred in the Company's financial or commercial position since the end of the reporting period on December 31, 2013.

The Company is exclusively dedicated to the additional pre-clinical trials and clinical tests necessary to bring to fruition its bioprosthetic artificial heart project and to complete its CE marking application, with a view to marketing in 2015 at the earliest, subject to achieving satisfactory results and the absence of difficulties in recruiting patients for the clinical trials.

In 2013, the Company completed the pre-clinical trials on bench tests and on animals prior to obtaining Clinical Trial Authorization from the ANSM for an initial feasibility study on four patients. This authorization was obtained in September 2013. Additional pre-clinical trials are under way, with a view to obtaining authorization to carry out a second study of 20-25 patients, in France and/or abroad. The pre-clinical and clinical data collected will enable the Company to file its application for CE marking from the accredited body following this second trial. CE marking is required prior to commercial launch, which will take place in 2015 at the earliest.

The Company has reached clinical cooperation agreements with four cardiac surgery centers of worldwide renown in four countries. As of the date of this registration document, the training at these centers was receiving feedback gained from the feasibility testing carried out in France. The collection and analysis of data relating to this first trial is under way.

The Company's cash reserves and expected subsidies should allow the Company to ensure the advancement of the aforementioned activities until 2015 (see paragraph 3.4.2 Liquidity risk).

The structural sub-assemblies of the prosthesis are manufactured out of this material.

5.4.4 Profit forecasts or estimates

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

5.5 PRESENTATION OF 2013 FINANCIAL STATEMENTS AND APPROPRIATION OF THE RESULT

This Chapter presents CARMAT's results and financial position for the year ended December 31, 2013. The data for the previous years, ended December 31, 2011 and December 31, 2012, are also included as a reminder. The Company has no subsidiaries and therefore does not prepare consolidated accounts. Its corporate financial statements are prepared in accordance with French standards.

It is suggested that you read this Chapter in the context of the whole of this registration document.

In particular, it is suggested that you read the description of the Company's business activity as presented in Chapter 2, "Business Overview" of this registration document. Similarly, you are encouraged to read the financial statements for the year ended December 31, 2013 – of which the Notes are an integral part – presented in Chapter 6 Financial Statements at December 31, 2013, of this registration document.

The most recent financial information available relating to the Company is that for the fiscal year ended December 31, 2013.

5.5.1 CARMAT'S main revenues and expenses

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 external electrical power supply systems 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 bioprosthetic 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 fine-tuning, approval and validation phase;
- a human clinical validation phase, in parallel with the validation activities necessary to obtain CE 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 (Airbus 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 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 Airbus Group where they were working on the bioprosthetic heart project.

The CARMAT financial statements have been prepared in accordance with the provisions of the french commercial code (Articles L.123-12 to L.123-28) and the general rules for preparation and presentation of annual financial statements (PCG 99-03 as modified by the regulations subsequently issued by the accounting rules committee).

5.5.1.1 Operating income

Since its creation, the Company has been in a research and development phase and has not had any sales. No sales are anticipated for 2014. The program has been financed by its own equity, deriving from funds secured from the main shareholders (Matra Défense (Airbus Group), the Scientific Research Association of the Alain Carpentier Foundation and the funds managed by Truffle Capital), by research subsidies and repayable advances granted, by funds raised at the time of the stock market listing and by capital increases.

Operating income for the year ended December 31, 2013 stood at €2,873,627, comprising exclusively subsidies received from Bpifrance under the aid program signed in 2009.

During the fiscal year ended December 31, 2012, operating income fell by 99.7% to €17,989. This comprised exclusively:

- a €10,500 grant from the *Association Nationale de la Recherche et de la Technologie* for the employment of a doctoral student;
- reversals of provisions totaling €7,489.

During the fiscal year ended December 31, 2011, operating income grew by 20.9% to €6,101,753. This comprised exclusively:

- operating subsidies of €6,051,177;
- reversals of provisions totaling €50,576.

5.5.1.2 Operating expenses

During the 2013 fiscal year, operating expenses amounted to €18,990.251, compared with €22,403,502 in the previous period (a decrease of 15.24%). This essentially relates to the Company's spending on research, which is expensed in the period when it is incurred.

These research activities involved expenses in three main areas:

- purchases (other than raw materials) and external expenditure of €13,376.375, compared with €16,467,584 for the previous period;
- wages and salaries of €4,410,419, compared with €4,183,804 for the previous period;
- depreciation of fixed assets acquired for the research and development phase amounting to €919,614, compared with €1,473,858 for the previous period.

The operating result for the period ended December 31, 2013 was -€16,116,624, compared with -€22,385,513 for the previous period.

5.5.2 Financial result

In 2013, the financial result was negative, recording a loss of €323,611 versus a gain of €110,099 in 2012 and a gain of €97,271 in 2011.

Financial expenses mainly comprise interest paid on refundable advances from Bpifrance. They represent an amount of €362,133 for the 2013 fiscal year, compared with €242,988 for the previous year (see Note 6.4.4.7.1 Other balance sheet details – Conditional advances).

Financial income mainly comprises interest received on the sums invested in time deposit accounts during the year. They represent an amount of €72,444 for the 2013 fiscal year, compared with €355,793 for the previous year (see Note 6.4.4.5 Cash instruments).

Other financial income and expenses comprise foreign exchange gains/losses stemming from payments made in foreign currencies.

5.5.3 Result for the period

The Company opted to apply the Research Tax Credit (CIR) for the calendar years 2009, 2010, 2011 and 2012. This option was retained for the 2013 fiscal year. The CIR system consists of granting 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.

The income statement for the period shows a Research Tax Credit equal to €1,770,114 for the period from 01/01/2013 to 12/31/2013, versus €5,022,922 recognized for 2012.

After taking account of extraordinary income of €25,219 and a CIR of -€1,770,114, the loss for the fiscal year ended December 31, 2013 was €14,644,902, a 14.80% improvement over the loss for the 2012 period (€17,189,691). The loss for the period ended December 31, 2011 was €13,441,022.

STATEMENT OF RESULTS FOR THE PAST FIVE PERIODS

(in euros)	12/31/2013	12/31/2012	12/31/2011	12/31/2010	12/31/2009[1]
Capital at the end of the period					
Share capital	171,339	166,312	165,112	153,114	86,250
Number of existing ordinary shares	4,283,470	4,157,795	4,127,795	3,827,861	86,250
Number of existing preference shares					
Maximum number of future shares to be created					
▸ Through conversion of bonds					
▸ Through the exercise of subscription rights	348,125	295,300	297,550	324,375	
Operations and results					
Turnover excluding taxes					
Profit before tax, staff participation, transfers to depreciation and amortization and to provisions	-15,395,852	-20,693,592	-14,443,285	-9,245,595	-5,200,345
Corporation taxes	-1,770,114	-5,015,433	-2,515,527	-2,750,499	-1,184,342
Participation of staff for the period					
Profit after tax, staff participation, transfers to depreciation and amortization and to provisions	-14,644,902	-17,189,691	-13,441,022	-7,736,485	-4,722,004
Distributed profit					
Profit per share					
Profit after tax and staff participation, but before transfers to depreciation and amortization and to provisions	-3.18	-4.98	-2.89	-1.70	-46.56
Profit after tax, staff participation, transfers to depreciation and amortization and to provisions	-3.42	-4.13	-3.26	-2.02	-54.75
Dividend paid per share					
Staff					
Average workforce employed during the period	38	38	35	26	20
Wage bill for the period	3,283,217	3,102,548	3,067,909	2,523,948	1,963,258
Value of social benefits paid during the period	1,127,202	1,093,916	1,099,853	448,869	454,250

(1) First period of 19 months vs. 12 months for the following periods.

5.5.4 Proposed appropriation of the result

We propose approval of the annual financial statements (balance sheet, income statement and annex) as presented. These financial statements show a net loss of €14,644,902.

We propose appropriation of this loss to Losses carried forward, taking the balance of that item from -€43,089,202 to -€57,783,948.

5.5.5 Non-deductible expenses

In accordance with the provisions of Article 223 *quater* and 223 *quinquies* of the general tax code, it is hereby stated that the financial statements for the period just closed do not include any expenses that are non-deductible for tax purposes.

5.5.6 Main items of the CARMAT balance sheet

At December 31, 2013, the Company's balance sheet total amounted to €21,984,183, compared with €19,696,896 at December 31, 2012 and €37,426,083 at December 31, 2011.

5.5.6.1 Main asset items

Fixed assets stood at €1,633,314 (versus €2,266,763 at December 31, 2012), corresponding to:

- property plant and equipment (€945,370): technical plant, equipment, measurement and special tooling, clean room, gray room, office fixtures and fittings, etc., necessary for the preparation for clinical trials described above;
- intangible assets (€125,412): patents, licenses and software;
- financial assets (€562,532): assets in relation to the liquidity agreement concerning the Company's shares and guarantee deposits linked to the rental contracts for the Company's premises.

Fixed assets fell by 27.95%, notably due to the reduction of the item Technical plant, equipment and tooling (€346,696 in 2013 compared to €725,017 in 2012) and the item Licenses, patents and similar rights (€58,976 in 2013 versus €168,468 in 2012).

The remaining €20,350,868 principally comprised:

- accounts receivable (€2,951,518) from the State: principally the 2013 CIR (€1,770,114) and recoverable input VAT (€1,181,404);
- cash and cash equivalents (€16,883,974).

Current assets increased by 16.76% to €20,350,868 at December 31, 2013 (versus €17,430,133 at the end of the previous year). The fall in the item Other debtors (€2,951,518 in 2013, compared with €6,092,119 in 2012) was offset by the growth of Cash instruments and Cash on hand (€16,883,974 in 2013 versus €11,134,438 in 2012).

5.5.6.2 Main liability items

Liabilities stood at €21,984,183 (compared with €19,696,896 at December 31, 2012) and mainly comprised:

- €64,962,683 in capital and issue premiums;
- -€57,734,104 of losses for 2013 and losses brought forward (-€43,089,202 in 2012);
- €7,515,054 of conditional advances (versus €3,743,141 in 2012);
- €7,098,449 for trade creditors (versus €5,939,193 in 2012), including €4,786,855 for trade accounts payable.

5.5.7 Particulars of supplier payment periods

In accordance with the provisions of Articles L.441-6-1 and D. 441-4 of the french commercial code, we bring your attention to the following details concerning supplier payment periods:

As at December 31, 2013, trade accounts payable totaled €1,242,657. A comparison of the figures from the financial statements is set out below:

(in euros)	12/31/2013	12/31/2012
Trade accounts payable and related payables shown under liabilities	4,786,855	4,012,780
Less: amounts receivable from suppliers shown under assets in the balance sheet	-4,250	-22,549
Less: Accrued charges included under this heading	-3,539,948	-2,697,684
Liabilities secured to property and related liabilities	22,006	148,669
Less: Accrued charges included under this heading	-22,006	-148,669
TOTAL	**1,242,657**	**1,292,637**

The breakdown of this amount by maturities is shown below, based on the payment terms negotiated with suppliers:

(in euros)	12/31/2013	12/31/2012
Due (including amounts receivable from suppliers)	14,830	-20,544
Debts falling due on January 31	1,103,615	936,865
Debts falling due on February 28	124,212	376,316
Debts falling due on or after March 31	0	0

5.6 PARTICULARS OF DIVIDENDS

In accordance with the provisions of Article 243 of the general tax code, it is recalled that no distribution of dividends has taken place for the last three fiscal years.

There are no plans to adopt a policy of paying dividends in the short term, taking into account the Company's stage of development.

5.7 IMPORTANT CONTRACTS

The important contracts to which the Company is a party are as follows:

- a Royalties Agreement *signed* on June 24, 2008 and amended by an addendum of February 5, 2010, between CARMAT, Professor Alain Carpentier and Matra Défense (an Airbus Group subsidiary): please refer to paragraph 7.5.1 Royalties Agreement;
- an exclusive license agreement with the Pierre and Marie Curie University relating to patent No. 8800381: please refer to paragraph 2.4.2.2 Exclusive license agreements;
- an exclusive license agreement with the *Centre Technique des Industries Mécaniques* relating to patent No. 2760973: please refer to paragraph 2.4.2.2 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 July 24, 2009 for a total sum granted by Bpifrance of €33,006,398.

5.7.1 Framework agreement with Bpifrance

5.7.1.1 Initial conditions of the agreement

On July 24, 2009, the Company signed a framework agreement with Bpifrance to secure aid for the CARMAT Industrial Strategic Innovation (ISI) project. Under the terms of the agreement, Bpifrance undertook to pay a total amount of €33,006,398, of which €18,499,074 as subsidies and €14,507,324 as refundable advances, payable upon achievement of the key milestones set out in the agreement, the last one being the achievement of CE marking.

The Company acts as project leader, thus receiving all of the refundable advances and €17,442,639 in subsidies, *i.e.* €31,949,963. The remaining €1,056,435 are paid to the four partners in the project: Dedienne Santé, PaxiTech, Vignal Artru Industries (VAI, Pack'Aero Group), and Ireis (former HEF R&D).

5.7.1.2 Relationships with the Partners

- PaxiTech is responsible for the work relating to development of a portable fuel cell. This agreement was entered into for a term of 2 years with effect from July 7, 2009. If PaxiTech wishes to use the results in any area outside the medical domain, it will have to obtain the prior authorization 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 Bpifrance framework, on September 13, 2011, in light of the progress realized in the first two years that allowed for the possibility of creating the first industrial prototypes.
- Dedienne Santé is responsible for the work relating to manufacture of parts in implantable PEEK. The initial term of the agreement – four years from July 7, 2009 – has been extended to June 1, 2017. If Dedienne Santé wishes to use the results in any area outside the medical domain, it will have to obtain the prior authorization of CARMAT, which may not be refused without good reason.
- Ireis (formerly HEF R&D) is responsible for the work relating to qualification of the motor pump set. This agreement was entered into for a term of six years with effect from July 7, 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 transferable usage right, free of charge and without time limit, to these results, for application outside of the medical devices domain.
- Vignal Artru Industries (Pack'Aero Group) is responsible for the work relating to construction of the motor pump set. The initial term of the agreement – four years from July 7, 2009 – has been extended to June 1, 2017. If Vignal Artru Industries wishes to use the results in any area outside the medical domain, it will have to obtain the prior authorization of CARMAT, which may not be refused without good reason.

Under the Bpifrance Innovation framework agreement, each of the partners has undertaken to provide the resources necessary to complete the development project for the bioprosthetic artificial heart and its components. In return, Bpifrance will pay its subsidies and repayable advances as certain phases and milestones described below are executed.

5.7.1.3 Milestones of the project, associated deliverables and specific conditions for continuation of the project

Milestone	Provisional date	Name of the determining deliverable	Specific conditions for continuation of the project
Milestone1	T0 + 6 months	Documentation defining prosthesis D1 Mechanical and biological Preliminary definition documentation Electronics and software	
Milestone2	T0 + 12 months	Prototypes acceptance report (two non-clinical)	Presentation of a document certifying a contribution in equity(1) and in cash at least equal to the payments by Bpifrance at milestones 2 and 3
Milestone3	T0 + 23 months	Functional trials documentation	
Milestone 4(2)	T0 + 29 months	*In vitro* pre-clinical trials documentation	Conditional authorization by the CPP to start clinical trials on human subjects. Presentation of a document certifying a contribution in equity(1) and in cash at least equal to the payments by Bpifrance at milestone 4
Milestone5	T0 + 39 months	Clinical prototypes acceptance report Clinical trials monitoring report	Conditional authorization from the AFSSAPS (ANSM) to progress to clinical trials in humans Presentation of a document certifying a contribution in equity(1) and in cash at least equal to the payments by Bpifrance up until the end of the R&D project
Milestone 6(2)	T0 + 49 months	System design documentation	Conditional authorization from the AFSSAPS (ANSM) and the CPP for the second series of clinical trials and consideration of the results
Milestone7	T0 + 54 months	CE mark documentation	

T0: effective start date of the project = June 1, 2009.

(1) In the form of capital, convertible bonds, issue premiums or current accounts of associates grouped together by the corresponding tranche of the R&D program. Payments under industrial agreements with no immediate consideration may be acceptable.

(2) However, as regards milestone 6, and although the Company can obtain CE marking without having obtained the agreement of ANSM to permit it to undertake clinical trials on humans in France, as soon as the Company has undertaken conclusive clinical tests on humans in other countries, this agreement must be obtained, under the terms of the contract as it currently stands, before it can receive the subsidies and repayable advances associated with these stages.

5.7.1.4 Maximum initial payments by type of aid, by partner and by milestone (in €) of the initial agreement

5.7.1.4.1 Subsidies (initial contract)

Maximum subsidy payment schedule for IR (Industrial Research)

		Maximum payment per milestone[1]							
(in euros)	Initial payment	Milestone 1	Milestone 2	Milestone 3	Milestone 4	Milestone 5	Milestone 6	Milestone 7[2]	Total payments
CARMAT	4,072,638	3,193,168	3,519,904	3,624,136	2,873,627	159,166	0	0	17,442,639
Ireis	177,700	235,275	170,175	5,032	34,413	59,725	29,381	0	711,700
Vignal Artru Industries	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)

		Maximum payment per milestone[1]							
(in euros)	Initial payment	Milestone 1	Milestone 2	Milestone 3	Milestone 4	Milestone 5	Milestone 6	Milestone 7[2]	Total payments
CARMAT	0	0	0	0	0	0	0	0	0
Ireis	0	0	0	0	0	0	0	0	0
Vignal Artru Industries	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

(1) Maximum amount paid for the milestone.
(2) Balance.

5.7.1.4.2 Repayable Advances (initial agreement)

		Maximum payment per milestone[1]							
(in euros)	Initial payment	Milestone 1	Milestone 2	Milestone 3	Milestone 4	Milestone 5	Milestone 6	Milestone 7[2]	Total payments
CARMAT	546,304	760,022	712,565	1,724,264	3,771,913	5,251,038	290,486	1,450,732	14,507,324

(1) Maximum amount paid for the milestone.
(2) Balance.

5.7.1.4.3 Accounting and financial conditions

The subsidies accrue to the Company as of right and so will not be repayable in the event of success of the project.

Accordingly, these are accounted for in the "Subsidies" line of the income statement.

Repayable advances will have to be repaid by CARMAT according to the arrangement set out in the paragraphs below. Repayable advances are therefore accounted for on the liabilities side of the balance sheet under the "Other equity – Conditional advances" line.

The corresponding interest is shown on the liabilities side of the balance sheet under the "Sundry loans and financial debts" line.

Once cumulative sales of €38 million have been realized from marketing the bioprosthetic artificial heart under the project, CARMAT will have to pay Bpifrance the financial returns shown in the following schedule:

- 0.5% of its turnover for two years;
- thereafter 1% of its turnover for two years;
- thereafter 2% of its turnover for two years;
- thereafter 2.5% of its turnover for one year, making a total of seven years of financial returns or maximum cumulative financial returns of €50 million if these are reached in less than seven years.

5.7.1.5 Addendum to the framework agreement and the Bpifrance (Oseo-ISI) support contract dated June 15, 2011

In order to take account of results achieved and changes in the regulatory context following discussions with the AFSSAPS resulting in a requirement to arrive at a definition of the implantable part of the prosthesis before proceeding to initial clinical trials, CARMAT asked Bpifrance if modifications could be made to the CARMAT Industrial Strategic Innovation Agreement.

As a result, in a letter dated December 29, 2010, Bpifrance issued a favorable opinion on the following modifications to the said agreement:

- the level D2 prosthesis will proceed directly to human trial (no implantation of prosthesis D1);
- the other systems (excluding the prosthesis) involved in supplying the electrical power to the prosthesis and patient monitoring will be external, initially at the hospital only, and then in a portable equipment version for use at home;
- activities linked to prosthesis D2 have been postponed to the milestones 3-4 period.

As a result, there have been modifications to the cost profile and planning of the project, with no effect on the value of the aid or on the project end date.

These modifications take account of changing conditions and ensure continuity of the project without distorting its purpose.

These modifications have been the subject of addenda dated June 15, 2011 to the CARMAT Industrial Strategic Innovation Agreement and to the contract in support of the CARMAT project.

The principal elements of the addenda relate to the individual milestones and payment of the subsidies and repayable advances.

5.7.1.6 Addendum to the framework agreement and the Bpifrance (Oseo-ISI) support contract dated September 16, 2013

Bpifrance agreed to postpone the milestone "Conditional authorization from the AFSSAPS (ANSM) and the CPP to progress to clinical trials in humans" from milestone 4 to 5.

The Parties jointly agreed to review the terms for the financial returns as follows:

The Parties agreed to calculate the amount of the financial returns due by CARMAT based on thresholds of turnover generated by the products and services created by the project (reference products and services).

Definition of thresholds

Triggering threshold S1 (cumulative sales of reference products and services) is set at €38,000,000 (thirty-eight million euros).

Triggering threshold S2 (cumulative sales of reference products and services) is set at €2,000,000,000 (two billion euros).

Reimbursement of advance payment

If threshold S1 (as defined above) is reached, CARMAT will pay Bpifrance (by June 30 of each year following the reference year), the following flat-fees:

Year 1 by June 30	€184,000 (one hundred eighty-four thousand euros)
Year 2 by June 30	€368,000 (three hundred sixty-eight thousand euros)
Year 3 by June 30	€1,472,000 (one million, four hundred seventy-two thousand euros)
Year 4 by June 30	€2,784,000 (two million, seven hundred eighty-four thousand euros)
Year 5 by June 30	€8,316,000 (eight million, three hundred sixteen thousand euros)
Year 6 by June 30	€11,300,000 (eleven million, three hundred thousand euros)

The amounts will reimbursed as indicated above, based on CARMAT's operating income from the project's products, in light of the annual income statement as set out in Article 3.1.

Should threshold S1 not be reached, CARMAT will not pay Bpifrance the amounts above.

From year 2 and for the remaining years, in case of a fall in sales exceeding 20% of the updated forecasts (in 2013), as defined in the table below, these amounts will be capped:

- for year 2: to 0.5% (zero point five percent) of yearly sales of the reference products and services in the previous year;
- for years 3 and 4: at 1% (one percent) of yearly sales of the reference products and services in the previous year;
- for years 5 and 6: at 2% (two percent) of yearly sales of the reference products and services in the previous year.

In this scenario, CARMAT will generate new forecasts allowing it to draw up a new timetable for the reimbursements to Bpifrance.

Should sales of the reference products and services be in excess of the forecasts, the flat fees defined above will not be affected.

In any case, in the event that no reimbursement is due pursuant to this Article over a period of 10 (ten) years from payment of the last subsidy as set out in the support agreement, CARMAT will be released from any obligation to pay financial returns. Moreover, this agreement will be terminated ipso jure with no other formalities, provided that CARMAT has complied with all its obligations. CARMAT will be bound to pay specific fees as defined above, should threshold S1 be reached before this date, and until said date is reached.

Reimbursement of aid

If the advance payment has been reimbursed in accordance with the provisions above, CARMAT will pay Bpifrance – during the year after the date said reimbursement is completed and provided sales of the reference products and services (excluding taxes) have reached at least

€2,000,000,000 (two billion euros) – 2.5% (two point five percent) of the yearly turnover generated the previous year by sales of the Project's products and services.

The corresponding amounts will be payable on any generated sales, up to a maximum cap of financial returns equal to €50,000,000 (fifty million euros) in present value, or if this is reached before eight years.

5.7.1.7 Dates and contents of milestones

Milestone	Date[1]	Deliverables
Milestone 1	*December 1, 2009*	*Prosthesis, mechanical and biological definition documentation* *Preliminary, electronic and software definition documentation*
Milestone 2	*November 1, 2010*	*Prototypes acceptance report (two non-clinical)*
Milestone 3	*May 1, 2011*	*Functional test report*
Milestone 4	*July 8, 2013*	In vitro *pre-clinical files documentation*
Milestone 5[1]	1st half of 2014	Conditional authorization by the ANSM to start a clinical trial and monitoring report of first trial
Milestone 6[1]	2nd half of 2014	System design documentation and conditional authorization by the ANSM to start the second round of clinical trials
Milestone 7[1]	2015	CE mark certificate

The stages achieved on the date of this registration document appear in italics.
(1) Dates in the future are provisional and correspond to the estimated completion date of the stages and not to payment of the corresponding amounts, which will take place between a few days and several months later, after review by the experts and administrative processing.

As a reminder, completion of milestone No. 6 is linked, in particular, to the ANSM agreeing to authorize a second round of human trials in France (see paragraph 5.7.1.3).

5.7.1.8 Revised maximum payments under the addendum, by type of aid and milestone (in €)

5.7.1.8.1 Subsidies (addendum)

		Maximum payment per milestone[1]							
(in euros)	Initial payment	Milestone 1 received[2]	Milestone 2 received[2]	Milestone 3 received[2]	Milestone 4 received[2]	Milestone 5	Milestone 6	Milestone 7[3]	Total payments
Date		12/1/2009	11/1/2010	5/1/2011	7/10/2013	1st half of 2014	2nd half of 2014	2015	
CARMAT	4,072,638	3,193,168	3,519,904	3,624,136	2,873,627	159,166	0	0	17,442,639

(1) Maximum amount paid for the milestone.
(2) Stages already reached at the date of registration of this registration document; the following dates are provisional.
(3) Balance.

5.7.1.8.2 Repayable advances (addendum)

		Maximum payment per milestone [1]							
(in euros)	Initial payment	Milestone 1 received[2]	Milestone 2 received[2]	Milestone 3 received[2]	Milestone 4 received[2]	Milestone 5	Milestone 6	Milestone 7[3]	Total payments
Date		12/1/2009	11/1/2010	5/01/2011	7/10/2013	1st half of 2014	2nd half of 2014	2015	
CARMAT	546,304	760,022	712,565	1,724,264	3,771,913	5,251,038	290,486	1,450,732	14,507,324

(1) Maximum amount paid for the milestone.
(2) Stages already reached at the date of this registration document; the following dates are provisional.
(3) Balance.

5.7.1.8.3 Summary of Subsidies and repayable advances at 12/31/2013

	Cumulative amount received at 12/31/2013	Cumulative amount reimbursed at 12/31/2013	To be repaid at 12/31/2013	Cumulative amount to be received at 31/12/2013 subject to stages being reached
Subsidies	17,283,473	-	-	159,166
Refundable advances	7,515,068	0	0	6,992,256
Total	**24,798,541**	**-**	**-**	**7,151,422**

5.7.1.9 Scientific and financial timetable revised by the addendum

5.7.1.9.1 Stages reached

The first milestone of the Bpifrance agreement was reached on January 1, 2010, with a delay of one month for the administrative and accounting reasons associated with the approval of the financial statements as at December 31, 2009. In this context, in the first quarter of 2010, CARMAT received repayable advances of €760,022.93 and subsidies of €3,193,166.93.

The second stage of the Bpifrance agreement, milestone 2, was reached at the end of 2010 with the construction of the first artificial hearts. In this context, CARMAT received a repayable advance of €712,565 on December 31, 2010 and a subsidy of €3,519,904 on January 3, 2011, €1,207,587 of which is shown on the assets side as accrued income as at December 31, 2010. The payment of the Bpifrance subsidy for milestone 2 is slightly less than the amount appearing in the contract, since the system design expenditure was lower than expected.

The third milestone of the Bpifrance agreement was reached in 2011 based on the functional test report. In the third quarter of 2011, CARMAT received a refundable advance of €1,724,264 and an operating expenses subsidy of €3,624,136.

The fourth milestone of the Bpifrance agreement was reached in 2012 based on the *in vitro* test report. The documentation to be delivered for milestone 4 of the Bpifrance agreement, in particular the *in vitro* pre-clinical trials documentation, was sent to Bpifrance in 2012. At the beginning of July 2013, the report on *in vivo* tests on animals was sent, marking the formal achievement of this milestone (see paragraph 5.7.1.6). In the third quarter of 2013, CARMAT received a refundable advance of €3,771,913 and an operating expenses subsidy of €2,873,627.

5.7.1.9.2 Amounts received and still to be received

After validation of the first four milestones, CARMAT received the following amounts as part of the Bpifrance-ISI project:

- net subsidies of €4,072,638 shown under income for the 2009 fiscal year;
- net subsidies of €4,297,697 shown under income for the 2010 fiscal year (of which €1,207,587 recognized in accrued income under assets at December 31, 2010 (*i.e.* total net subsidies of €10,785,710, of which €2,415,374 still to be recognized in income for 2011;
- total refundable advances of €2,018,892 for the 2010 fiscal year;
- total refundable advances of €1,724,249 and subsidy for operating expenses of €6,039,510 for the 2011 fiscal year;
- total refundable advances of €3,771,913 and subsidy for operating expenses of €2,872,627 for the 2013 fiscal year.

In summary, at the date of this registration document, the Company had received €17.3 million in subsidies and €7.5 million in refundable advances for reaching milestones 1 to 4.

The Company also expects to receive €0.16 million in subsidies and €7 million in refundable advances for reaching milestones 5 to 7.

▶ STILL TO BE REACHED AND RECEIVED

	1st half of 2014	2nd half of 2014	2015	TOTAL
Milestone	Milestone 5	Milestone 6	Milestone 7	
Contents	ANSM authorization and clinical trial follow-up report	ANSM authorization of the 2nd trial and system design documentation	Milestone mark certificate	
Subsidies	€159,166	-	-	€159,166
Repayable advances	€5,251,038	€290,486	€1,450,732	€6,992,256

5.7.2 Other important contracts

5.7.2.1 Edwards Lifesciences

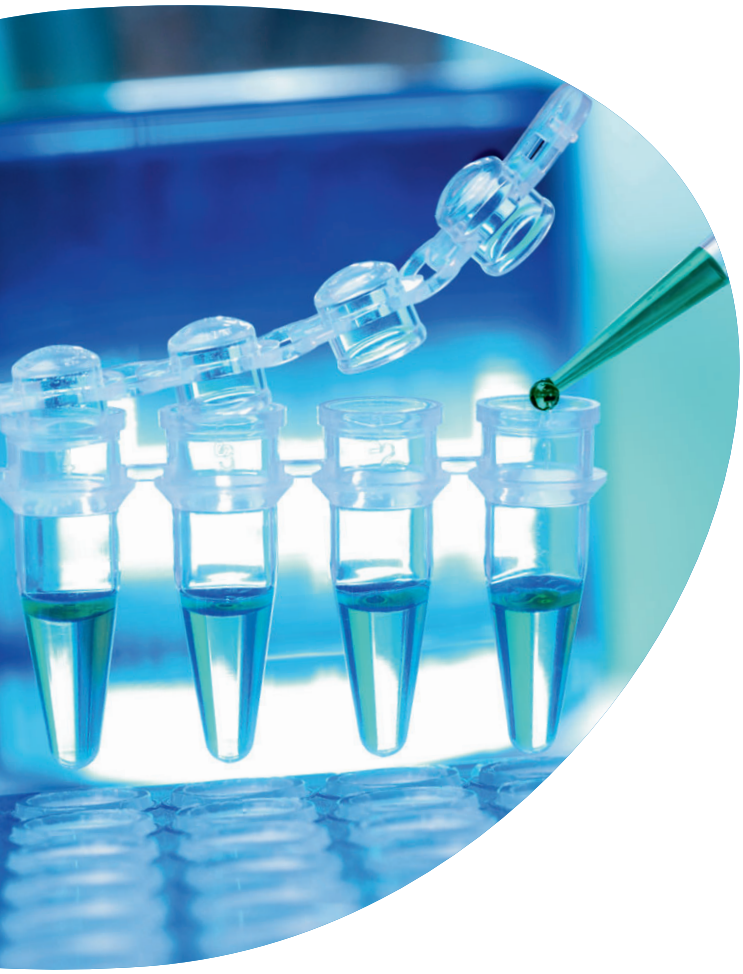
An agreement with an initial term of one year, automatically renewable annually, was entered into in the final quarter of 2010 by CARMAT and Edwards Lifesciences, the world leader in the heart valves sector and in hemodynamic monitoring, for the use and supply of Carpentier-Edwards bioprosthetic heart valves for the CARMAT total artificial heart.

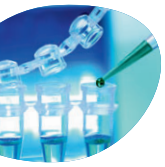
5.7.2.2 Invibio Limited

An agreement with a term of 12 years was concluded during the third quarter of 2012 between CARMAT and Invibio Limited, for the supply and use of PEEK-OPTIMA polymer materials®. This material is used by CARMAT owing to its biocompatibility characteristics, its certified long-term implantability and its mechanical properties. Subgroups.

6

FINANCIAL STATEMENTS AS AT DECEMBER 31, 2013



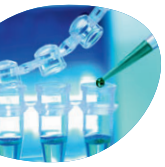


6.1 INCOME STATEMENT

Income Statement *(in euros)*	12/31/2013 France	12/31/2013 Export	12/31/2013 Total	12/31/2012 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 6.4.4.1)			2,873,627	10,500
Write-backs of amortization/depreciation and provisions, and transfer of expenditure				7,489
Other revenues				
TOTAL OPERATING INCOME(I)			**2,873,627**	**17,989**
OPERATING EXPENSES[2]				
Purchase of goods				
Inventory change (goods)				
Purchase of raw materials and other supplies				
Change in inventory (raw materials and other supplies)				
Other purchases and external expenditure[3][4]			13,376,375	16,467,584
Taxes, fees and similar payments			174,612	135,111
Wages and salaries			3,283,217	3,089,888
Social security costs			1,127,202	1,093,916
Amortization/depreciation and impairments				
Of fixed assets: amortization/depreciation (Note 6.4.4.1)			919,614	1,473,858
Of fixed assets: impairments				
Of current assets: impairments				
Provisions (Note 6.4.4.3)			68,766	45,163
Other expenses			40,466	97,984
TOTAL OPERATING EXPENSES (II)			**18,990,251**	**22,403,502**
1 – OPERATING RESULT (I-II)			**-16,116,624**	**-22,385,513**
SHARES IN RESULT FOR JOINT OPERATIONS				
Profits allocated or loss transferred (III)				
Loss or profit transferred (IV)				
FINANCIAL INCOME				
Financial income from equity interests[5]				
Income from other securities and fixed asset receivables[5]				
Other interest receivable and similar income[5]			72,444	355,793
Write-backs of impairments and provisions, and transfer of expenditure				
Positive exchange differences			2,480	276
Net proceeds from sales of marketable securities				
TOTAL (V)			**74,923**	**356,068**
FINANCIAL EXPENSES				
Amortization/depreciation, impairments and provisions			30,784	
Interest expenses and similar charges[6]			362,133	242,988
Negative exchange differences			5,618	2,981
Net expenses from sales of marketable securities				
TOTAL (VI)			**398,534**	**245,970**

Income Statement *(in euros)*	12/31/2013 France	12/31/2013 Export	12/31/2013 Total	12/31/2012 Total
2 – FINANCIAL RESULT (V-VI)			**-323,611**	**110,099**
3 – EARNINGS BEFORE INTEREST AND TAX (I-II+III-IV+V-VI)			**-16,440,235**	**-22,275,415**
EXTRAORDINARY INCOME (NOTE 6.4.4.5)				
Extraordinary income from management operations				
Extraordinary income from capital operations			90,830	104,101
Write-backs of impairments and provisions, and transfer of expenditure				
TOTAL (VII)			**90,830**	**104,101**
EXTRAORDINARY EXPENSES (NOTE 6.4.4.5)				
Extraordinary expenses from management operations			23,467	
Extraordinary expenses from capital operations			42,144	33,810
Amortization/depreciation, impairments and provisions				
TOTAL (VIII)			**65,611**	**33,810**
4 – EXTRAORDINARY RESULT (VII-VIII)			**25,219**	**70,290**
Employee profit-sharing (IX)				
Income taxes (X) (Note 6.4.4.3)			-1,770,114	-5,015,433
TOTAL INCOME (I+III+V+VII)			**3,039,380**	**478,158**
TOTAL EXPENSES (II+IV+VI+VIII+IX+X)			**17,684,282**	**17,667,849**
5 - PROFIT OR LOSS (TOTAL INCOME – TOTAL EXPENSES)			**-14,644,902**	**-17,189,691**

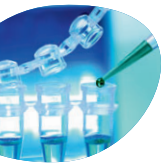
(1) Including income from previous years.
(2) Including expenses from previous years.
(3) Including: Fee from equipment leasing.
(4) Including: Fee from real-estate leasing.
(5) Including income from related enterprises.
(6) Including interest from related enterprises.



6.2 BALANCE SHEET

Assets *(in euros)*	12/31/2013 Gross	12/31/2013 Amortization/ depreciation and impairments	12/31/2013 Net	12/31/2012 Net
UNCALLED SHARE CAPITAL (TOTAL I)				
Fixed assets				
Intangible fixed assets (Note 6.4.4.1)				
Start-up costs				
Development costs				
Licenses, patents and similar rights	1,376,728	1,317,752	58,976	168,468
Goodwill(1)				
Assets under construction	66,436		66,436	
Advances and payments on account				
Property, plant and equipment (Note 6.4.4.1)				
Land				
Buildings				
Technical plant, equipment and tooling	4,378,395	4,031,699	346,696	725,017
Other property, plant and equipment	1,067,647	468,972	598,674	646,566
Assets under construction				184,621
Advances and payments on account				
Financial assets(2) (Note 6.4.4.1)				
Holdings accounted for on an equity basis				
Other holdings				
Other equity investments				
Loans				
Other financial assets	593,315	30,784	562,532	542,090
TOTAL II	**7,482,521**	**5,849,207**	**1,633,314**	**2,266,763**
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 prepayments on orders	48,060		48,060	
Debtors(3)				
▸ Trade receivables and other receivables				
▸ Other debtors (Note 6.4.4.4)	2,951,518		2,951,518	6,092,119
▸ Subscribed capital – called, not paid in				
Marketable securities				
Cash instruments (Note 6.4.4.5)	13,525,000		13,525,000	5,006,854
Cash on hand	3,358,974		3,358,974	6,127,584
Accrued charges(3) (Note 6.4.4.7.4)	467,317		467,317	203,577
TOTAL III	**20,350,868**		**20,350,868**	**17,430,133**
Accruals				
Bond issuance costs to be amortized (IV)				
Bond redemption premiums (V)				
Unrealized foreign exchange losses (VI)				
GRAND TOTAL (I+II+III+IV+V+VI)	**27,833,390**	**5,849,207**	**21,984,896**	**19,696,896**
(1) Including lease rights.				
(2) Of which of less than one year.			*472,541*	*423,855*
(3) Of which of more than one year.				

Liabilities *(in euros)*	**12/31/2013**	**12/31/2012**
Equity		
Capital (of which, paid in: 171,339) (Note 6.4.4.6)	171,339	166,312
Issue, merger and acquisition premiums (Notes 6.4.3.2.13 and 6.4.4.6)	67,791,344	52,864,118
Excess of restated assets		
Reserves		
Legal reserve		
Statutory or contractual reserves		
Regulatory reserves		
Other reserves		
Losses brought forward	-42,089,202	-25,899,511
Result for the period (profit or loss)	**-14,644,902**	**-17,189,691**
Capital grants		
Regulatory provisions		
TOTAL I	**7,228,579**	**9,941,228**
Other equity		
Proceeds of issues of participating stock		
Conditional advances (Note 6.4.4.7.1)	7,515,054	3,743,141
TOTAL II	**7,515,054**	**3,743,141**
Provisions		
Provisions for risks	39,342	
Provisions for charges (Notes 6.4.4.3 and 6.4.5.1.3)	102,758	73,334
TOTAL III	**142,100**	**73,334**
Debts[1]		
Financial debts		
Convertible bond loans		
Other bond loans		
Loans from credit institutions		
Bank loans and overdraft		
Sundry loans and financial debts (Notes 6.4.4.7.1 and 6.4.4.4)	822,187	460,054
Advances and payments on account received for current orders		
Accounts payable (Note 6.4.4.4)		
Trade accounts payable and related payables	4,786,855	4,012,870
Tax and social liabilities	1,467,400	1,313,901
Liabilities secured to property and related liabilities (Note 6.4.4.4)	22,006	148,669
Other debts (Note 6.4.4.4)		3,698
Accruals		
Accrued income[1] (Note 6.4.4.7.4)		
TOTAL IV	**7,098,449**	**5,939,193**
UNREALIZED FOREIGN EXCHANGE GAINS TOTAL V		
GRAND TOTAL (I+II+III+IV+V+VI)	**21,984,183**	**19,696,896**
(1) Debts and deferred income of less than one year.	*6,276,262*	*5,479,139*



6.3 CASH-FLOW STATEMENT

	As at 12/31/2012	As at 12/31/2012
Net result	-14,644,902	-17,189,691
Amortization/depreciation and provisions	1,018,164	1,519,021
Write-backs of amortization/depreciation and provisions		-7,489
Gains or losses on asset sales		-70,291
Investment subsidies transferred to income	0	0
Other income and expenses with no impact on cash flow	362,133	242,988
SELF-FINANCING CAPACITY	**-13,263,605**	**-15,505,462**
Tax and social liabilities	153,499	154,485
Trade accounts payable	647,322	-1,211,843
Other debts	-3,698	-2,800
Accrued income	0	0
Stocks and work in progress	0	0
Advances and prepayments on orders	-48,060	486,860
Other debtors	3,140,601	-1,971,491
Trade receivables	0	0
Accrued charges	-263,740	97,383
CHANGES IN CASH POSITION (CHANGE IN WORKING CAPITAL REQUIREMENTS)	**3,625,923**	**-2,447,406**
CASH FLOW FROM OPERATIONS	**-9,637,682**	**-17,952,868**
Acquisition of property, plant and equipment	-118,074	-310,773
Acquisition of intangible fixed assets	-147,649	-204,993
Acquisition of financial fixed assets	-51,224	-1,479,257
Proceeds from financial fixed asset disposals		1,472,636
CASH FLOW FROM INVESTMENT OPERATIONS	**-316,948**	**-522,387**
Increase in capital	5,027	1,200
ORA/BSA	0	0
Issue premium	11,927,226	238,800
Capitalization of current accounts	0	0
Loans and conditional advances	3,771,913	0
CASH FLOW FROM FINANCING OPERATIONS	**15,704,166**	**240,000**
CHANGE IN CASH AND CASH EQUIVALENTS	**5,749,536**	**-18,235,255**
OPENING CASH AND CASH EQUIVALENTS (NOTE 6.4.4.5)	**11,134,438**	**29,369,693**
OPENING CASH AND CASH EQUIVALENTS (NOTE 6.4.4.5)	**16,883,974**	**11,134,438**

6.4 ANNEX TO THE FINANCIAL STATEMENTS

Annex to the balance sheet for the year ended December 31, 2013, totalling €21,984,183, and to the income statement for the year ended December 31, 2013, presented in list form and showing zero revenue resulting in a loss of €14,644,902.

The financial year commenced on 1/1/2013 and ended on 12/31/2013, a duration of 12 months which is identical to that of the comparative period.

The notes and tables presented hereafter are an integral part of the financial statements for the period ended on December 31, 2013 as approved by the board of directors on February 11, 2014. They are presented in euros unless otherwise stated.

6.4.1 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 fiscal year, the Company carried out several capital increases:

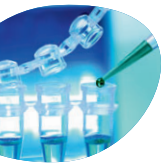
- further to the bond issue agreement with Kepler Cheuvreux on June 7, 2013, eight subscriptions were organized on June 25, June 27, September 24, September 26, October 1, November 12, November 18, and December 23 totalling 116,800 BEA, increasing share capital by €4,672 raising it from €166,311.80 to €170,983.80 through the issue of 116,800 ordinary shares with a nominal value of €0.04 at a unit value of €108.86 with a €11,938,052 issue premium.

  Given the costs related to capital increases amounting to €81,470.84, deducted from the issue premium in application of the preferential accounting method, the net amount of the issue premium in respect of capital increases is €11,856,581. Issue premiums in the balance sheet consequently rose from €52,864,118 to €64,720,699.
- nine BCE exercises, on May 15, May 22, June 12, June 13, June 15, October 9, October 18 and November 18, for a total of 305 BCE-2009-2, enabled a capital increase of €305, therefore bringing it up from €170,983.80 to €171,288.80, through the issue of 7,625 ordinary shares with a par value of €0.04, at a unit value of €8 (*i.e.* €7.96 issue premium per action). As a result, the issue premium rose from €64,720,699 to €64,781,394;
- the exercising of 50 BSA 2009-1 warrants on October 22, led to a capital increase of €50, whereby share capital rose from €171,288.80 to €171,338.80 through the issue of 1,250 ordinary shares with a nominal value of €0.04 at a unit price of €8, *i.e.* at an issue premium of €7.96 per share. As a result, the issue premium rose from €64,781,394 to €64,791,344.

The Company is maintaining the Research Tax Credit (CIR) option for 2013. This option was first exercised for the calendar year 2009 and renewed in 2010, 2011 and 2012. €5,022,922 of the Research Tax Credit pertaining to the 2012 financial year was accounted for under the Corporation taxes item of the income statement (see details in Note 4.5.3 of the annex for the 2012 financial statements) and appears under "Other debtors" in the balance sheet. The Research Tax Credit recognized as at December 31, 2012 was refunded by the taxation authorities, on April 11, 2013, in full *i.e.* 5,022,922 euros.

On July 10, 2013, the Company received 6,645,540 euros from Bpifrance, broken down as follows:

- 2,873,627 euros in respect of subsidies, recognized on the "Subsidies" line of the income statement;
- €3,771,913 in respect of the refundable advances, recognized as "Conditional advances" on the liability side of the balance sheet.



6.4.2 Significant events after the end of the reporting period

No event occurring after the closing of the reporting period is liable to change the presentation or valuation of the items in the balance sheet or the income statement as approved by the board of directors.

6.4.3 Accounting rules and methods

(French commercial code – Articles L.123-12 and L.123-28)

(Decree No. 83-1020 of 11/29/1983) (Accounting Regulation Committee Regulation No. 99-03: PCG)

The valuation methods for this period have not been changed from those used in the previous financial year.

6.4.3.1 General principles and conventions

The accounts for the period have been prepared and presented in accordance with the accounting regulations and 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 french commercial code (*code de commerce*), the Accounting Decree of 11/29/1983 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 of each year.

The board of directors has assumed that the business is a going concern, having taken the following points in particular into account:

- cash, cash instruments and liquid marketable securities totalling €16,883,974 as at December 31, 2013;
- the payment of subsidies (€159,166) and refundable advances (€6,992,256) still to be claimed between now and the end of the Bpifrance aid program signed in 2009.

6.4.3.2 Supplementary information

6.4.3.2.1 Applied research and development costs

(Decree No. 83-1020 of 11/29/1983, Article 19)

Research and development costs are accounted for under expenses for the year in which they are incurred.

6.4.3.2.2 Property, plant and equipment

(Decree No. 83-1020 of 11/29/1983, 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	Mode	Period
Licenses and software	Straight line	1 to 3 years
Patents	Straight line	15 years

6.4.3.2.3 Property, plant and equipment

(Decree No. 83-1020 of 11/29/1983, Article 24-4)

The gross value of property, plant and equipment 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	Mode	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

6.4.3.2.4 Financial assets

OTHER EQUITY INVESTMENTS

In 2010, the Company entered into a liquidity contract with Dexia Securities France (now named DSF Markets), 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 an amount of €300,000 available to this provider. Treasury shares acquired through the implementation of this liquidity agreement are recorded under financial assets at their purchase price. If necessary, a provision is made for impairments 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.

6.4.3.2.5 Receivables and payables

(Decree No. 83-1020 of 11/29/1983, Article 24-5)

Receivables and payables are shown at face value. If necessary, receivables are depreciated by making a provision to take account of difficulties with recovery that are likely to occur. Any provisions for impairments are determined by comparison between the acquisition value and the likely realization value.

6.4.3.2.6 Cash on hand in euros

Cash on hand or at the bank is entered at face value.

6.4.3.2.7 Cash instruments

These comprise the time deposit accounts shown under assets at their acquisition value, plus accrued interest at the closing date of reporting period.

6.4.3.2.8 Cash and cash equivalents

For the purposes of the cash-flow statement, cash and cash equivalents are defined as being the sum of the “Cash instruments” and “Cash on hand” items under the assets, to the extent that cash instruments are available in the very short term and do not present a 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.

6.4.3.2.9 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.

6.4.3.2.10 Subsidies

Subsidies received are recorded as soon as 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.

6.4.3.2.11 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.

6.4.3.2.12 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.

6.4.3.2.13 Share issue costs

In accordance with the preferential method, share issue costs are recorded in the balance sheet minus a deduction for the issue premium.
Supplementary information on the balance sheet

6.4.4 Supplementary information on the balance sheet

6.4.4.1 Schedule of fixed assets

	Gross value at start of period	Additions	
		Line to line transfers	Acquisitions
Licenses, patents and similar rights[1]	1,295,515		81,213
Assets under construction	0		66,436
TOTAL	**1,295,515**	**0**	**147,649**
Technical plant, equipment and industrial tooling[2]	4,141,609	160,197	76,589
General plant, sundry fixtures and fittings	731,652	24,424	29,127
Office and IT equipment, furniture	270,085		12,359
Assets under construction	184,621		
TOTAL	**5,327,967**	**184,621**	**118,075**
Other equity investments[3]	155,879		1,439,177
Other financial fixed assets[4]	386,211		
TOTAL	**542,090**	**0**	**1,439,177**
GRAND TOTAL	**7,165,572**	**184,621**	**1,704,901**

	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]			1,376,728	
Assets under construction			66,436	
TOTAL	**0**	**0**	**1,443,164**	
Technical plant, equipment and industrial tooling[2]			4,378,395	
General plant, sundry fixtures and fittings			785,203	
Office and IT equipment, furniture			282,444	
Assets under construction	184,621		0	
TOTAL	**184,621**	**0**	**5,446,042**	
Other equity investments[3]		1,309,496	285,560	
Other financial fixed assets[4]		78,455	307,756	
TOTAL	**0**	**1,387,951**	**593,316**	
GRAND TOTAL	**184,621**	**1,387,951**	**7,482,521**	

(1) This item includes a sum of €411,284, accounted for as the share of the contribution in kind made on September 30, 2008, with a total value of €960,000, relating to the contribution of patents.
(2) This item includes the commissioning of the clean room at a total cost of €943,582. The item also includes a sum of €548,716, accounted for as the share of the contribution in kind made on September 30, 2008, with a total value of €960,000, relating to the contribution of equipment and tooling.
(3) This item includes the 2,404 own shares held in connection with the liquidity contract, valued at €285,560.
(4) This item includes (i) the liquidities not invested in own shares as at the end of the period under the liquidity contract of €186,981, and (ii) obligatory deposits totalling €120,774, mainly comprising deposits under premises lease contracts.

6.4.4.2 Schedule of depreciation and amortization

Statements and movements for the period	Value at start of period	Allowances for the period	Reductions Write-backs	Value at end of period
Licenses, patents and similar rights	1,127,046	190,706		1,317,752
TOTAL	**1,127,046**	**190,706**		**1,317,752**
Technical plant, equipment and industrial tooling	3,416,593	615,106		4,031,699
General plant, sundry fixtures and fittings	242,572	80,266		322,838
Office and IT equipment, furniture	112,598	33,536		146,134
TOTAL	**3,771,763**	**728,908**		**4,500,671**
GRAND TOTAL	**4,898,809**	**919,614**		**5,818,423**

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	190,706				
TOTAL	**190,706**				
Technical plant, equipment and industrial tooling	615,106				
General plant, sundry fixtures and fittings	80,266				
Office and IT equipment, furniture	33,536				
TOTAL	**728,908**				
GRAND TOTAL	**919,614**				

6.4.4.3 Schedule of provisions

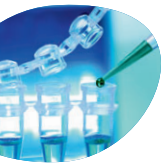
Provisions	Value at start of period	Increases Allowances	Reductions Amounts used	Reductions Amounts not used	Value at end of period
Sundry risks		39,342			39,342
Pensions and similar commitments[1]	73,334	29,424			102,758
TOTAL	**73,334**	**68,766**			**142,100**
Impairment of other equity investments		30,784			30,784
TOTAL		**30,784**			**30,784**
GRAND TOTAL	**73,334**	**99,550**			**172,884**
Including allowances and operational write-backs		68,766			
Including allowances and financial write-backs		30,784			

(1) See Note 6.4.6.1.3.

6.4.4.4 Schedule of maturities of receivables and payables

Schedule of receivables	Gross sum	1 year or more	More than 1 year
Social security and other social bodies	1,546	1,546	
Income taxes	1,778,681	1,778,681	
Value Added Tax	1,149,086	1,149,086	
Sundry debtors	22,205	22,205	
TOTAL	**2,951,518**	**2,951,518**	

Schedule of payables	Gross sum	1 year or more	1 to 5 years	More than 5 years
Sundry loans and financial debts	822,187		822,187	
Trade accounts payable and related payables	4,786,855	4,786,855		
Staff and related payables	785,561	785,561		
Social security and other social bodies	670,707	670,707		
Value Added Tax	8,374	8,374		
Other taxes and related payables	2,759	2,759		
Liabilities secured to property and related liabilities	22,006	22,006		
TOTAL	**7,098,449**	**6,276,262**	**822,187**	



6.4.4.5 Cash instruments

Cash instruments comprised certificates of deposit totalling €13,500,000. This amount was made up of six deposit agreements made with recognized financial institutions in July, October, November and December 2013, maturing respectively on January 13, 2014 (€4,000,000), January 26, 2014 (€1,000,000), February 11, 2014 (€4,000,000), March 19, 2014 (€1,000,000), April 18, 2014 (€2,000,000) and April 22, 2014 (€1,500,000). Accrued interest of €25,000 was recorded in the accounts as at December 31, 2013 in relation thereto. These investments present no risk to the invested capital, other than the unlikely default of the deposit-taking financial institutions before these very short maturities.

6.4.4.6 Capital

(Decree No. 83-1020 of 11/29/1983, Article 24-12)

6.4.4.6.1 Composition of the share capital

Categories of shares	Face value in euros	Number of shares			
		Opening	Created	Redeemed	Closing
Ordinary shares	0.04	4,157,795	125,675		4,283,470
TOTAL		**4,157,795**	**125,675**		**4,283,470**

The increases in capital through the exercise of BCE warrants in 2013 resulted in the creation of 7,625 ordinary shares with a unit face value of €0.04.

The increases in capital through the exercise of BEA warrants by Kepler Cheuvreux in 2013 resulted in the creation of 116,800 ordinary shares with a unit face value of €0.04.

The increase in capital through the exercise of BSA warrants in 2013 resulted in the creation of 1,250 ordinary shares with a unit face value of €0.04.

6.4.4.6.2 Changes in equity

EQUITY AT THE START OF THE PERIOD	**9,941,228**
Increase in capital through exercising of BCE warrants	61,000
Increase in capital through exercising of BSA warrants	10,000
Increase in capital through exercising of BEA warrants	11,861,253
Result for the period	-14,644,902
EQUITY AT THE END OF THE PERIOD	**7,228,579**

6.4.4.6.3 Stock warrants

BSA 2009-1

At the general meeting and the meeting of the board of directors of July 8, 2009 and following the board of directors' meeting of September 8, 2011, 3,096 BSA 2009-1 warrants were issued, 506 of which were cancelled following the resignation of one of the directors and 50 of which have been exercised. As at December 31, 2013, there remained 2,540 BSA 2009-1 warrants conferring subscription rights to 63,500 new shares, representing 1.48% of the existing capital as at December 31, 2013, at a unit price of €8.

SUMMARY TABLE OF BSA WARRANTS

	Issued	Subscribed	Lapsed	Exercised	Balance	Lapsing on
BSA-2009-1 GM of 07/08/2009	3,096	3,096	506	50	2,540	07/08/2019

6.4.4.6.4 Start-up Company Stock Warrants (BCE)

At the general meeting and the meeting of the board of directors of July 8, 2009 and following the board of directors' meeting of September 8, 2011, 3,108 fully assigned and subscribed BCE-2009-1 warrants were issued, 308 of which have been exercised. The 2,800 BCE-2009-1 warrants subscribed and not exercised as at December 31, 2013 confer subscription rights to 70,000 new shares, representing 1.63% of the existing capital as at December 31, 2013, at a unit price of €8.

BCE-2009-2

At the general meeting and the meeting of the board of directors of July 8, 2009 and following the board of directors' meeting of September 8, 2011, 7,566 fully assigned and subscribed BCE-2009-2 warrants were issued, 2,242 of which have been exercised and 2,435

of which have lapsed and been cancelled. The 2,889 BCE-2009-2 warrants subscribed and not exercised as at December 31, 2013 confer subscription rights to 72,225 new shares, representing 1.69% of the existing capital as at December 31, 2013, at a unit price of €8.

BCE-2012-1

In accordance with the board of directors' decision of June 27, 2012, as authorized by the combined general meeting of April 26, 2012, 56,500 fully assigned and subscribed BCE-2012-1 warrants have been issued, of which 4,000 have lapsed and been cancelled. The 52,500 BCE-2012-1 warrants subscribed and not exercised as at December 31, 2013 confer subscription rights to 52,500 new shares, representing 1.21% of the existing capital as at December 31, 2013, at a unit price of €108.483.

BCE-2012-2

In accordance with the board of directors' decision of November 8, 2012, as authorized by the combined general meeting of April 26, 2012, 6,700 fully assigned and subscribed BCE-2012-2 warrants have been issued. The 6,700 BCE-2012-2 warrants subscribed and not exercised as at December 31, 2013 confer subscription rights to 6,700 new shares, representing 0.16% of the existing capital as at December 31, 2013, at a unit price of €122.00279.

SUMMARY TABLE OF BCE WARRANTS

	Issued	Subscribed	Lapsed	Exercised	Balance	Lapsing on
BCE-2009-1 GM of 07/08/2009	3,108	3,108	0	308	2,800	09/09/2019
BCE-2009-2 GM of 07/08/2009	7,566	7,566	2,435	2,242	2,889	07/08/2019
BCE-2012-1 GM of 04/26/2012	56,500	56,500	4,000	0	52,500	06/27/2022
BCE-2012-2 GM of 04/26/2012	6,700	6,700	0	0	6,700	11/08/2022
BCE TOTAL	**73,874**	**73,874**	**6,435**	**2,550**	**64,889**	

6.4.4.7 Other balance sheet details

6.4.4.7.1 Conditional advances

The conditional advances item is comprised of repayable advances received from Bpifrance, the total amount of which as at the end of the period was €7,515,054. Note 6.4.6.1.1 below states the repayment conditions of these advances.

They are interest-bearing at the contracted rate of 5.59%. The interest accrued calculated using the capitalization method stood at €822,187 at period end and appears in liabilities under the Sundry loans and financial debts heading.

6.4.4.7.2 Accrued income

(Decree No. 83-1020 of 11/29/1983, Article 23)

Value of accrued income included in the following balance sheet items	Value
Other debtors	19,486
TOTAL	**19,486**

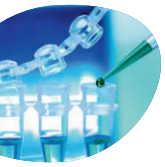
6.4.4.7.3 Accrued charges

(Decree No. 83-1020 of 11/29/1983, Article 23)

Value of accrued charges included in the following balance sheet items	Value
Sundry loans and financial debts	822,187
Trade accounts payable and related payables	3,539,948
Tax and social liabilities	1,114,966
Liabilities secured to property and related liabilities	22,006
TOTAL	**5,499,107**

6.4.4.7.4 Accrued income and charges

(Decree No. 83-1020 of 11/29/1983, Article 23)



Accrued charges	Value
Operating expenses	467,317
TOTAL	**467,317**

Accrued income	Value
Operating income	Not applicable
TOTAL	**NOT APPLICABLE**

The accrued charges item is comprised of the following:

- the share of rent for the first quarter of 2014 billed in December 2013, totalling €124,233;
- the share of software license royalties and insurance premiums for the period after December 31, 2013, for a total amount of €112,323;
- €230,761 corresponding to the difference between invoices recorded under research & development costs (research study and subcontracting costs) and the percentage of completion of the services in question as at December 31, 2013.

6.4.4.7.5 Information on related enterprises

The following balance sheet items include sums in connection with associates:

Trade accounts payable and related payables	1,027,251

6.4.5 Supplementary information on the income statement

6.4.5.1 Subsidies

In 2012, the Company did not receive any subsidies. Moreover, as the right to payment of the next contractually agreed Bpifrance subsidy had not been accrued at the end of the reporting period, the subsidy was not recorded in Accrued income on the balance sheet as at December 31, 2012 for the share corresponding to the expenses already incurred at this date, although the Company has been authorized since July 1, 2012 to begin the EC5 research phase. On receipt of the subsidy on July 10, 2013, it was recorded on the "Subsidies" line in the income statement for the period for a total of €2,873,627, representing the entirety of the EC5 advance.

6.4.5.2 Applied research and development costs

Research and development costs are accounted for under expenses. They amounted to €11,098,089 in 2013 compared to €14,450,400 the previous year.

6.4.5.3 Research Tax Credit

The income statement for the period shows a Research Tax Credit of €1,770,114, relating to the Research Tax Credit for the period from January 1 to December 2013, compared with €5,015,433 recorded for 2012.

6.4.5.4 Auditors' fees

The total amount of auditors' fees paid over the year is €55,214 excluding taxes and expenses and breaks down as follows:

- fees for the statutory auditing of the financial statements and the services provided for by law: €55,214;
- fees for consultancy and services rendered in connection with activities directly linked to the statutory audit, as defined by the professional standards referred to in Article L.822-11 (II): none

6.4.5.5 Extraordinary income and expenses

(Resolution of April 27, 1982)

Type	12/31/2013	12/31/2012
Extraordinary income		
▸ Property disposal		
▸ Disposal of own shares	90,830	104,101
TOTAL	**90,830**	**104,101**
Extraordinary expenses		
▸ Property disposal		
▸ Disposal of own shares	42,144	33,810
▸ Fines and penalties	23,467	
TOTAL	**65,611**	**33,810**

The extraordinary income results mainly from the sale of own shares under the liquidity contract described in Note 4.3.2.4.

6.4.5.6 Information on associates

The following income statement items include sums in connection with associates:

Other purchases and external expenditure	843,285

6.4.6 Financial commitments and other information

6.4.6.1 Financial commitments

6.4.6.1.1 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 €5,508,851.

In addition to the €3,743,141 received before January 1, 2013, a €3,771,913 refundable advance was received during the period, *i.e.*, a total of €7,515,054 received as at December 31, 2013. This sum is repayable subject to achieving revenue of at least €38,000,000. The Bpifrance 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 June 24, 2008 the Company signed a royalty's agreement with Professor Alain Carpentier and Matra Défense, who were 12.8% and 27.3% shareholders respectively as at December 31, 2013. 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 SA, 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 six 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 €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 €30,000,000 is index-linked to the *Indice du Prix à la Production de l'Industrie des Services aux Entreprises – Matériel médicochirurgical et d'orthopédie-exportation zone euro* [Index of Prices for the Industrial Production of Services to Businesses – Medico-surgical and orthopedic equipment – for export within the Eurozone].

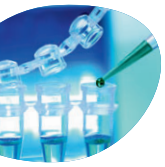
The rights allocated to Professor Alain Carpentier and to Matra Défense in this way are non-transferable.

As at December 31, 2013, since the marketing of the "CARMAT" Artificial Heart had not started, no royalty had been paid by the Company under the agreement.

6.4.6.1.2 Commitments received

The Bpifrance agreement provides for payment of a total sum of €17,442,639 by way of subsidies, of which €159,166 remain to be paid between now and the end of the program.

It also provides for payment of a total sum of €14,507,324 by way of repayable advances, €6,992,256 of which remain to be paid between now and the end of the program.



6.4.6.1.3 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 December 31, 2013.

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 3% *per annum* (identical to the rate used at 06/30/2013 and 12/31/12).

The overall amount of the provision was €102,758 at the end of the period, an increase of €29,424 on the previous period.

6.4.6.2 Other information

6.4.6.2.1 Information on the management

6.4.6.2.1.1 ADVANCES AND LOANS TO MANAGEMENT

No loans or advances were made to the management of the Company during the period, in accordance with the provisions of Article R.123-197 of the french commercial code.

6.4.6.2.1.2 MANAGEMENT REMUNERATION

The total remuneration paid to directors in the form of attendance fees amounted to €40,000 for the year (sums recorded in the income statement under "Other expenses").

The total remuneration allocated to members of the management bodies was €674,174 for the year and breaks down as follows:

Type	2013	2012
Gross salaries	576,628	502,696
Benefits in kind	10,707	9,780
Bonuses	86,839	79,994
TOTAL REMUNERATION	**674,174**	**592,469**

6.4.6.2.2 Increases and reductions in future tax liabilities

(Decree No. 83-1020 of 11/29/1983, Article 24-24)

Type of temporary differences	Value
Allowable loss carry-forwards	74,573,153

This amount comprises:

- the tax loss carried forward made during previous periods and available as at January 1, 2013, in the sum of €58,205,533;
- the tax loss made in the 2013 fiscal year in the sum of €16,367,620.

6.4.6.2.3 Average staffing levels

(Decree No. 83-1020 of 11/29/1983, Article 24-22)

Salaried staff	2013	2012
Managers	29	30
Supervisors and technicians	6	4(1)
Employees	5(3)	6(2)
TOTAL	**38**	**38**

(1) Including two trainees.
(2) Including one trainee.
(3) Including two trainees.

6.4.6.2.4 Individual right to training

In connection with the individual right to training instituted by law No.. 2004-391 of May 4, 2004 concerning ongoing professional training, on December 31, 2013 the aggregate number of hours of training in relation to rights accrued and not exercised was 2,650.71 hours.

6.5 AUDITORS' REPORT ON THE ANNUAL FINANCIAL STATEMENTS

Auditors' report on the annual financial statements

(Period ending on December 31, 2013)

To the Shareholders,

CARMAT SA
36, Avenue de l'Europe
78941 Vélizy-Villacoublay

In compliance with the assignment entrusted to us by your general shareholders' meeting on October 16, 2008, we hereby report to you, for the year ended December 31, 2013, on:

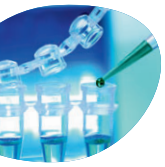
- the audit of the accompanying financial statements of CARMAT SA;
- the justification of our assessments;
- the specific verifications and information required by law.

These financial statements have been approved by the board of directors. Our role is to express an opinion on these financial statements based on our audit.

I – Opinion on the financial statements

We conducted our audit in accordance with professional standards applicable in France. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit involves performing procedures, on a test basis or by selection, to obtain audit evidence about the amounts and disclosures in the financial statements. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as the overall presentation of the financial statements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

In our opinion, the financial statements give a true and fair view of the financial position and assets and liabilities of the Company and of the results of its operations for the year elapsed in accordance with the accounting rules and principles applicable in France.



II – Justification of our assessments

In accordance with the requirements of Article L.823-9 of the french commercial code relating to the justification of our assessments, we bring to your attention that the assessments that we carried out centered on the appropriateness of the accounting principles applied.

These assessments were made in the context of our audit of the financial statements, taken as a whole, and therefore contributed to the opinion we formed which is expressed in the first part of this report.

III – Specific verifications and information

We have also performed, in accordance with professional standards applicable in France, the specific verifications required by French law.

We have no matters to report regarding the fair presentation and the conformity with the financial statements of the information given in the management report of the board of directors, and in the documents addressed to the shareholders with respect to the financial position and the financial statements.

In accordance with French law, we have verified that the required information concerning the controlling interests and the identity of the shareholders has been properly disclosed in the management report.

Signed in Neuilly-sur-Seine and Paris, March 10, 2014,

The auditors

PRICEWATERHOUSCOOPERS AUDIT
THIERRY CHARRON

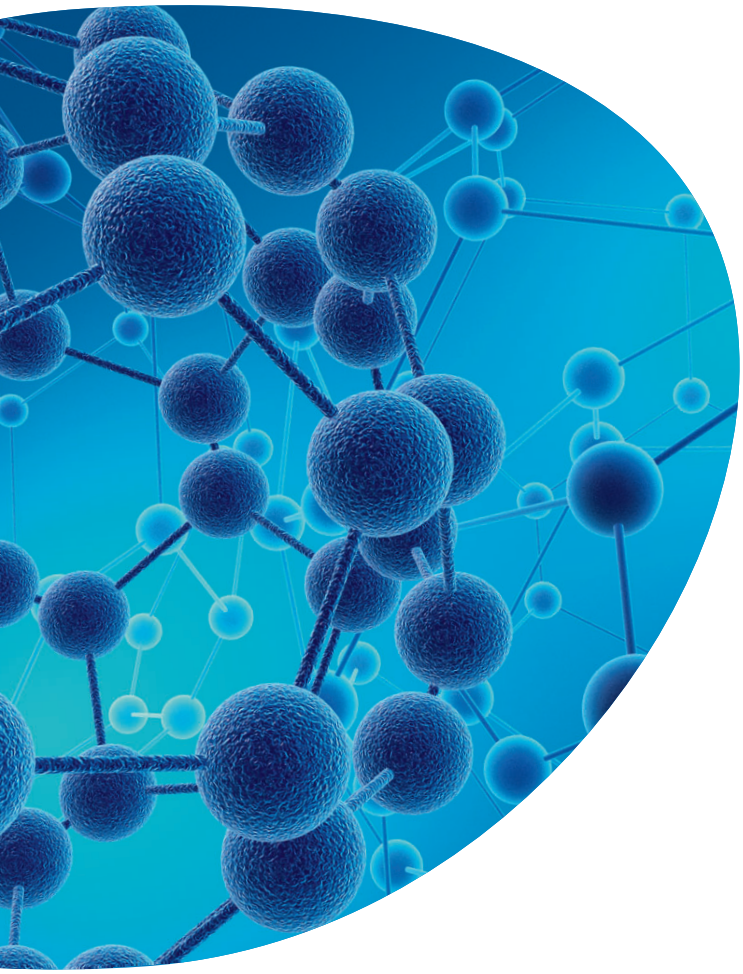
63, rue de Villiers
92208 Neuilly-sur-Seine Cedex

LISON CHOURAKI

13, rue Spontini
75016 Paris

7

INFORMATION ON THE COMPANY AND ITS CAPITAL



7.1 SHARE CAPITAL

7.1.1 Value of the share capital

As at the date of this registration document, the share capital totaled €171,338.80.

The share capital is divided into 4,283,470 ordinary shares with a nominal value of €0.04 each, all of the same category and fully paid up.

7.1.2 Securities not representing capital

As at the date of this registration document, there were no securities not representing capital.

7.1.3 Pledges, guarantees and collateral

As at the date of this registration document, and to the best of the Company's knowledge, there exist no pledges, guarantees or collateral taken on the Company's equity.

7.1.4 Acquisition by the Company of its own shares

As at February 28, 2014, the Company held 2,822 treasury shares, representing 0.07% of its share capital.

The combined general meeting of June 4, 2013, authorized the implementation by the board of directors of an 18-month program to buy back company shares, starting from the meeting, pursuant to the provisions of Article L.225-209 of the french commercial code and in compliance with the General Regulation of the French Financial Markets Authority (AMF). The main terms of this authorization are the following:

Number of shares that can be purchased: 10% of the share capital on the date of the buyback. When shares are acquired in order to promote the trading and liquidity of shares, the number of shares taken into account to determine the 10% limit referred to above corresponds to the number of shares purchased, less the number of shares sold during the period of authorization.

Objectives of the share buyback program:

- to improve the liquidity of transactions and regularize the listing of the Company's securities or prevent price differences not justified by market trends as part of a liquidity contract entered into with an investment services provider acting independently in conditions of and following procedures set by regulations and recognized market practices such as the decisions of the French Financial Markets Authority dated March 22, 2005 and October 1, 2008, and in accordance with the AMAFI code of ethics of March 8, 2011, recognized by the March 21, 2011 decision of the Financial Markets Authority;
- to deliver the shares when rights attached to transferable securities are exercised, giving the immediate or future right, by the redemption, conversion, exchange, presentation of a warrant or indirectly more than ten by any other means, to the allocation of Company shares, as well as carrying out any hedging transactions related to the issue of such securities, under conditions stipulated by the market authorities and at the times that the board of directors will chose;
- to keep the shares and deliver them at a later date as payment or in exchange in any acquisition, merger, demerger or contribution transactions, in respect of market practices allowed by the French Financial Markets Authority.

Maximum purchase price: €240, excluding any fees and commissions and adjustments in order to account for capital transactions.

It is specified that the number of shares acquired by the Company to keep and later deliver as payment or in exchange as part of a merger, demerger or contribution transaction cannot exceed 5% of its capital.

Maximum amount of funds that can be used to buy back shares: €2,000,000

The shares bought back can be cancelled.

The general meeting of April 2, 2014 is asked to renew this authorization for a new 18-month period starting from the general meeting, under the following terms:

Number of shares that can be purchased: 10% of the share capital on the date of the buyback. When shares are acquired in order to promote the trading and liquidity of shares, the number of shares taken into account to determine the 10% limit referred to above corresponds to the number of shares purchased, less the number of shares sold during the period of authorization.

Objectives of the share buyback program:

- to ensure the liquidity of the shares of the Company as part of a liquidity contract to be signed with an investment services provider, in accordance with a code of ethics recognized by the French Financial Markets Authority;
- to honor the obligations linked to stock option purchase programs, bonus share allocations, employee savings or other allocations of shares to employees and managers of the Company or affiliated Companies;
- to deliver shares when the rights attached to securities giving access to capital are exercised;
- to purchase shares for keeping and later delivery or exchange or payment as part of possible acquisitions;
- more generally, to operate for any objective that would be authorized by law or any market practice that would be authorized by market authorities, with the understanding that in such an event, the Company would inform its shareholders in a press release.

Maximum purchase price: €240, excluding any fees and commissions and adjustments in order to account for capital transactions.

It is specified that the number of shares acquired by the Company to keep and later deliver as payment or in exchange as part of a merger, demerger or contribution transaction cannot exceed 5% of its capital.

Maximum amount of funds that can be used to buy back shares: €5,000,000

The shares bought back can be cancelled.

7.1.5 Other securities giving access to capital

As of February 28, 2014, the exercise of all securities giving access to capital would allow the subscription of 348,125 new shares representing 8.13% of the current issued share capital and 7.52% of share capital after issue of these shares.

Thus, the size of the holding of a shareholder holding 1% of the current share capital would reduce to 0.92% if the rights to all these securities were exercised.

Start-up Company Stock Warrants (BCE)

Type of security	BCE-2009-1
Number of BCE options issued and assigned	3,108(1)
Number of BCE options lapsed	0
Number of BCE options exercised	308
Balance of BCE options to be exercised	2,800
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	Ten years from the date of award of the BCE options
Ratio	One 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 the date of the first anniversary of the beneficiary joining the Company over a period of three 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 €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 September 8, 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	70,000

(1) After adjustments resulting from the increase in capital with preferential subscription rights performed in August 2011.

Type of security	BCE-2009-2
Number of BCE options issued and assigned	7,566[1]
Number of BCE options lapsed	2,435
Number of BCE options exercised	2,242
Balance of BCE options to be exercised	2,889[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	Ten years starting from the date of the award of the BCE
Ratio	One BCE-2009-2 for 25 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 his/her actual and continued presence within the Company at that date; ▸ 40% of the BCE-2009-2 options may be exercised by full monthly periods in tranches of 1/48th from date of the first anniversary of the beneficiary joining the Company; ▸ 10% of BCE-2009-2 options may be exercised from the finalization and success of the initial clinical trials of the CARMAT total artificial heart before the end of the second quarter of 2012 (medical report on completion of the trial covering the safety and end point aspects), subject to his/her actual and continued presence within the Company at that date[2]; ▸ 10% of the BCE-2009-2 warrants may be exercised after the completion and success of the first clinical implantation of the CARMAT total artificial heart before the end of November 2012 (report from a third party), subject to the actual and continued presence of the beneficiary within the Company at that date; ▸ 6.5% of BCE-2009-2 options may be exercised from the success of the pivotal round of clinical trials of the CARMAT total artificial heart (report from the scientific board), subject to his/her actual and continued presence within the Company at that date; ▸ 6.5% of the BCE-2009-2 options may be exercised from the date on which the CE mark is obtained for the CARMAT total artificial heart, subject to actual and continued presence of the beneficiary within the Company at that date; ▸ 7% of BCE-2009-2 options may be exercised from the realization at December 31 of the first year of marketing of the CARMAT total artificial heart, recorded by the board of directors, of revenue and gross margin in line with the business plan established by the General Management and approved by the board of directors, subject to his/her actual and continued presence within the Company at that date.
Number of new shares that may be subscribed	72,225

(1) After adjustments resulting from the increase in capital with preferential subscription rights performed in August 2011.

(2) Using a delegation approved by the shareholders on July 8, 2009, The board of directors meeting on June 27, 2012 decided, upon recommendation of the remunerations committee of the Company and subject to (i) the approval of the owners of the BCE-2009-2 and (ii) the retroactive ratification of its decisions by the next general meeting of shareholders, to modify the timings and arrangements for exercise of the BCE-2009-2 options appearing in Article 4 of the Bylaws with reference to these BCE-2009-2 options.

Type of security	BCE-2012-1
Number of BCE options issued and assigned	56,500
Number of BCE options lapsed	4,000
Number of BCE options exercised	0
Balance of BCE options to be exercised	52,500
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	Ten years starting from the date of the award of the BCE
Ratio	One BCE-2012-1 for one new CARMAT share
General conditions of exercise	▸ 50% of BCE-2012-1 options may be exercised on the basis of monthly periods in tranches of 1/48th from the date of assignment of BCE-2012-1 options to the beneficiary for four years, subject to actual and continued presence within the Company at that date; ▸ 16.25% of BCE-2012-1 options may be exercised from the success of the pivotal round of clinical trials of the CARMAT total artificial heart (report from the scientific board), subject to his/her actual and continued presence within the Company at that date; ▸ 16.25% of the BCE-2012-1 options may be exercised from the date on which the CE mark is obtained for the CARMAT total artificial heart, subject to actual and continued presence of the beneficiary within the Company at that date; ▸ 17.5% of BCE-2012-1 options may be exercised from the realization at December 31 of the first year of marketing of the CARMAT total artificial heart, recorded by the board of directors, of revenue and gross margin in line with the business plan established by the General Management and approved by the board of directors, subject to his/her actual and continued presence within the Company at that date.
Number of new shares that may be subscribed	52,500

Type of security	BCE-2012-2
Number of BCE options issued and assigned	6,700
Number of BCE options lapsed	0
Number of BCE options exercised	0
Balance of BCE options to be exercised	6,700
Date of the general meeting	April 26, 2012
Date of the meeting of the board of directors	November 8, 2012
Exercise price per new share subscribed	€122,003
BCE option exercise deadline	Ten years starting from the date of the award of the BCE
Ratio	One BCE-2012-2 for one new CARMAT share
General conditions of exercise	▸ 50% of BCE-2012-2 options may be exercised on the basis of monthly periods in tranches of 1/48th from the date of assignment of BCE-2012-2 options to the beneficiary for four years, subject to actual and continued presence within the Company at that date; ▸ 16.25% of BCE-2012-2 options may be exercised from the success of the pivotal round of clinical trials of the CARMAT total artificial heart (report from the scientific board), subject to his/her actual and continued presence within the Company at that date; ▸ 16.25% of the BCE-2012-2 options may be exercised from the date on which the CE mark is obtained for the CARMAT total artificial heart, subject to actual and continued presence of the beneficiary within the Company at that date; ▸ 17.5% of BCE-2012-2 options may be exercised from the realization at December 31 of the first year of marketing of the CARMAT total artificial heart, recorded by the board of directors, of revenue and gross margin in line with the business plan established by the General Management and approved by the board of directors, subject to his/her actual and continued presence within the Company at that date.
Number of new shares that may be subscribed	6,700

Summary table of BCE warrants

	Issued	Subscribed	Lapsed	Exercised	Balance	Lapsing on
BCE-2009-1 GM of 07/08/2009	3,108	3,108	0	308	2,800	09/09/19
BCE-2009-2 GM of 07/08/2009	7,566	7,566	2,435	2,242	2,889	07/08/19
BCE-2012-1 GM of 04/26/2012	56,500	56,500	4,000	0	52,500	06/27/22
BCE-2012-2 GM of 04/26/2012	6,700	6,700	0	0	6,700	11/08/22
BCE TOTAL	**73,874**	**73,874**	**6,435**	**2,550**	**64,889**	

Share subscription warrants (BSA):

Type of security	BSA-2009-1
Number of BSA warrants issued and assigned	3,096(1)
Number of BSA warrants lapsed	506
Number of BSA warrants exercised	50
Balance of BSA warrants to be exercised	2,540
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	Ten years from the date of award of the BSA warrants
Ratio	One BSA-2009-1 warrant for 25 new CARMAT shares
General conditions of exercise	▸ 25% of the BSA-2009-1 warrants may be exercised on the date of the first anniversary of the beneficiary joining the Company, subject to his actual and continued presence within the Company at that date; ▸ 75% of BSA-2009-1 options may be exercised on the basis of monthly periods in tranches of 1/36th from the date of the first anniversary of the beneficiary joining the Company over a period of three 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 September 8, 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	63,500

(1) After adjustments resulting from the increase in capital with preferential subscription rights performed in August 2011.

Summary table of BSA warrants

	Issued	Subscribed	Lapsed	Exercised	Balance	Lapsing on
BSA-2009-1 GM of 07/08/2009	3,096	3,096	506	50	2,540	07/08/2019
BSA TOTAL	**3,096**	**3,096**	**506**	**50**	**2,540**	

Stock issue warrants (BEA):

Type of security	BEA (total exercisable by Kepler Cheuvreux)
Number of BEA warrants issued and assigned	200,000
Number of BEA warrants lapsed	0
Number of BEA warrants exercised	116,800
Balance of BEA options to be exercised	83,200
Date of the general meeting	June 4, 2013
Date of the meeting of the board of directors	June 5, 2013
Exercise price per new share	93% of the average volume-weighted price of the CARMAT share in the five consecutive trading days preceding the request for a draw
BEA warrant exercise deadline	June 5, 2013
Ratio	One BEA KEPLER for one new CARMAT share
Number of new shares that may be subscribed	83,200

Summary table of BEA warrants

	Issued	Subscribed	Cancelled	Exercised	Balance	Lapsing on
BEA Revenue at 06/05/2013	200,000	200,000	0	116,800	83,200	06/05/2015
BEA TOTAL	**200,000**	**200,000**	**0**	**116,800**	**83,200**	

7.1.6 Share capital authorized but not issued

Meeting of June 4, 2013

Resolution	Subject matter of the resolution	Maximum nominal amount in euros	Method of determining the issue price	Period of authorization and expiry
6th resolution of the combined general meeting of June 4, 2013	Delegation of authority allowing the board of directors to decide on the issue, with retention of the preferential subscription rights, of shares and/or transferable securities giving immediate or future access to capital or providing a right to a debt instrument	Nominal amount of increases in capital: €60,000 Nominal amount of bonds and other debt securities giving access to capital: €40,000,000	Free	August 4, 2015 (26 months)
7th resolution of the combined general meeting of June 4, 2013	Delegation of authority allowing the board of directors to decide on the capitalization of profits, reserves or premiums	Nominal amount of increases in capital: €60,000	Free	August 4, 2015 (26 months)
8th resolution of the combined general meeting of June 4, 2013	Delegation of authority allowing the board of directors to decide on the issue of shares and/or securities giving immediate or future access to the capital or providing a right to a debt instrument, with removal of the preferential subscription right of shareholders for the benefit of categories of beneficiaries (Article L.225-138)	Nominal amount of increases in capital: €60,000 Nominal amount of bonds and other debt securities giving access to capital: €40,000,000	At least equal to the average volume-weighted price of the last five stock market sessions prior to it being defined, less any discount (maximum 30%)	December 4, 2014 (18 months)
9th resolution of the combined general meeting of June 4, 2013	Delegation of authority to the board of directors to decide on the issue of shares and/or securities giving immediate or future access to capital or providing a right to a debt instrument, by private placement and up to a limit of 20% of the share capital per year (Article L.225-136 3)	Nominal amount of increases in capital: €60,000. The total amount of these capital increases will be limited to 20% of capital (as existing on the date of the transaction) per year. Nominal amount of bonds and other debt securities giving access to capital: €40,000,000	At least equal to the average volume-weighted price of the last five stock market sessions prior to it being defined, less any discount (maximum 30%)	August 4, 2015 (26 months)
10th resolution of the combined general meeting of June 4, 2013	Delegation of authority allowing the board of directors to decide on the issue of shares and/or transferable securities giving immediate or future access to capital or providing a right to a debt instrument, with removal of the preferential subscription right without indicating the beneficiary and by public offering (Article L.225-136)	Nominal amount of increases in capital: €60,000 Nominal amount of bonds and other debt securities giving access to capital:€40,000,000	At least equal to the average volume-weighted price of the last five stock market sessions prior to it being defined, less any discount (maximum 30%),	August 4, 2015 (26 months)

N.B.: the above-mentioned ceilings may if necessary be raised by the additional value of shares or securities to be issued in order to preserve the rights of holders of securities giving access to capital in accordance with the provisions of the french commercial code. The full text of the resolutions of the combined general meeting of June 4, 2013 may be viewed on the Company's website.

The combined general meeting of April 2, 2014 is asked to grant the following delegations of authority:

Resolution	Subject matter of the resolution	Maximum nominal amount in euros	Method of determining the issue price	Period of authorization and expiry
7th resolution of the combined general meeting of April 2, 2014	Delegation of authority allowing the board of directors to increase capital immediately or in the future by issuing ordinary shares or any other securities giving access to the capital, with retention of preferential subscription rights subject to the limit of an overall nominal amount of €80,000	Nominal amount of increases in capital: €80,000(1) Nominal amount of bonds and other debt securities giving access to capital: €60,000,000(1)	Free	June 2, 2016 (26 months)
8th resolution of the combined general meeting of April 2, 2014	Delegation of authority allowing the board of directors to decide on the issue of shares and/or transferable securities giving immediate or future access to capital, with removal of the preferential subscription right by way of a public offer (Article L.225-136)	Nominal amount of increases in capital: €80,000(1) Nominal amount of bonds and other debt instruments giving access to capital: €60,000,000(1)	At least equal to the average volume-weighted price of the last five stock market sessions prior to the defining of the issue price less any discount (maximum 30%)	June 2, 2016 (26 months)
9th resolution of the combined general meeting of April 2, 2014	Delegation of authority allowing the board of directors to decide on the issue of shares and/or transferable securities giving immediate or future access to capital, with removal of the preferential subscription rights, by offering to qualified investors or to a limited circle of investors in the meaning of paragraph II of Article L.411-2 of the french monetary and financial code (Article L.225-136 3)	Nominal amount of increases in capital: €80,000(1) Nominal amount of bonds and other debt instruments giving access to capital: €60,000,000(1)	At least equal to the average volume-weighted price of the last five stock market sessions prior to the defining of the issue price less any discount (maximum 30%)	June 2, 2016 (26 months)
10th resolution of the combined general meeting of April 2, 2014	Delegation of authority allowing the board of directors to decide on the issue of shares and/or securities giving immediate or future access to the capital or providing a right to a debt instrument, with removal of the preferential subscription right of shareholders for the benefit of categories of beneficiaries (Article L.225-138)	Nominal amount of increases in capital: €80,000(1) Nominal amount of bonds and other debt instruments giving access to capital:€60,000,000(1)	At least equal to the average volume-weighted price of the last five stock market sessions prior to the defining of the issue price less any discount (maximum 30%)	October 2, 2015 (18 month)
11th resolution of the combined general meeting of April 2, 2014	Subject to the listing of the Company's shares on a regulated market, the authorization allowing the board of directors, in the event of the issue of shares or of any security giving access to capital with removal of the preferential subscription right, to set the issue price at a maximum of 10% of the share capital and within the limits determined by the board of directors	Limited to 10% of the Company's capital (as existing on the date of the transaction) per 12 month period	At least equal to the average volume-weighted price of the last five stock market sessions prior to the defining of the issue price, less any discount (maximum 15%)	June 2, 2016 (26 months)
12th resolution of the combined general meeting of April 2, 2014	Delegation of authority allowing the board of directors to increase the amount of each of the issues with or without preferential subscription right which would be decided under resolutions 7 to 10.	With a limit of 15% of the initial issue*	Price identical to that of the initial issue	June 2, 2016 (26 months)
14th resolution of the combined general meeting of April 2, 2014	Delegation of authority allowing the board of directors to increase capital by incorporation of premiums, reserves, profits or other	Nominal amount of increases in capital: €80,000(1)	Free	June 2, 2016 (26 months)

(1) These amounts are not cumulative, the overall maximum nominal amount of capital increases that can be carried out under the delegations granted under resolutions 7 to 12 is set at €80,000. The maximum nominal amount of debt securities that can be issued under the above-mentioned delegations is set at €60,000,000.
(2) Separate limit for the 7th to 12th resolutions mentioned above.

The full text of the resolutions of the Company's general meetings can be consulted on the website of the *Bulletin des Annonces Légales Obligatoires*: http://www.journal-officiel.gouv.fr/balo.

7.1.7 Details of share capital subject to an option or a conditional or unconditional agreement making them subject to an option

None.

7.1.8 Table of changes in the Company's share capital since its creation

The Company was registered in the Versailles Trade and Companies Register on June 30, 2008 with an initial share capital of €40,000. The share capital has since been increased several times to reach €112,478, divided into 2,811,950 shares in July 2010.

The table below shows a summary of the changes in share capital since that date.

Date of realization of the operation	Type of operation	Increase in capital *(in €)*	Issue premium or contribution *(in €)*	Number of shares created	Nominal value of shares *(in €)*	Cumulative number of shares	Share capital following the operation *(in €)*
07/07/2010	Conversion of category A shares into ordinary shares	0.00	0,00	1,562,000	0	0.04	2,811,950
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 through the exercise of BSA warrants	1,751.00	0.00	43,775	0.04	3,682,727	147,309.08
07/07/2010	Increase in capital by cash contribution through the exercise of convertible bonds	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 through the exercise of BSA warrants	426.64	0.00	10,666	0.04	3,800,059	152,002.36
07/22/2010	Increase in capital by cash contribution	1,112.08	520,175.42	27,802	0.04	3,827,861	153,114.44
04/28/2011	Increase in capital by cash contribution through the exercise of BCE options	786.00	156,414.00	19,650	0.04	3,847,511	153,900.44
06/19/2011	Increase in capital by cash contribution through the exercise of BCE options	95.00	18,905.00	2,375	0.04	3,849,886	153,995.44
08/10/2011	Increase in capital by cash contribution	11,068.38	29,320,085.64	276,709	0.04	4,126,595	165,063.80
09/26/2011	Increase in capital by cash contribution through the exercise of BCE options	48.00	9,952.00	1,200	0.04	4,127,795	165,111.80
03/08/2012	Increase in capital by cash contribution through the exercise of BCE options	118.00	23,482.00	2,950	0.04	4,130,745	165,229.80
06/27/2012	Increase in capital by cash contribution through the exercise of BCE options	298.00	59,302.00	7,450	0.04	4,138,195	165,527.80
07/19/2012	Increase in capital by cash contribution through the exercise of BCE options	70.00	13,930.00	1,750	0.04	4,139,945	165,597.80
11/08/2012	Increase in capital by cash contribution through the exercise of BCE options	301.00	59,899.00	7,525	0.04	4,147,470	165,898.80

Date of realization of the operation	Type of operation	Increase in capital *(in €)*	Issue premium or contribution *(in €)*	Number of shares created	Nominal value of shares *(in €)*	Cumulative number of shares	Capital following the operation *(in €)*
12/13/2012	Increase in capital by cash contribution through the exercise of BCE options	413,00	82,187.00	10,325	0.04	4,157,795	166,311.80
05/17/2013	Increase in capital by cash contribution through the exercise of BCE options	116,00	23,084.00	2,900	0.04	4,160,695	166,427.80
06/20/2013	Increase in capital by cash contribution through the exercise of BCE options	121.00	24,079,00	3,025	0.04	4,163,720	166,548.80
07/08/2013	Increase in capital by cash contribution through the exercise of BEA options	368.00	1,001,144.00	9,200	0.04	4,172,920	166,916.80
09/25/2013	Increase in capital by cash contribution through the exercise of BEA options	1,400.00	3,708,600.00	35,000	0.04	4,207,920	168,316.80
10/02/2013	Increase in capital by cash contribution through the exercise of BEA options	1,400.00	3,708,600.00	35,000	0.04	4,242,920	169,716.80
11/07/2013	Increase in capital by cash contribution through the exercise of BCE options	52.00	10,348.00	1,300	0.04	4,244,220	169,786.80
11/07/2013	Increase in capital by cash contribution through the exercise of BSA warrants	50.00	9,950.00	1,250	0.04	4,245,470	168,818.80
11/25/2013	Increase in capital by cash contribution through the exercise of BEA options	624.00	1,520,844.00	15,600	0.04	4,276,070	170,442.80
12/19/2013	Increase in capital by cash contribution through the exercise of BCE options	16.00	3,184.00	400	0.04	4,276,470	170,442.80
12/24/2013	Increase in capital by cash contribution through the exercise of BEA options	880.00	2,144,780.00	22,000	0.04	4,283,470	171,338.80

7.2 PRINCIPAL SHAREHOLDERS

7.2.1 Distribution of capital and voting rights

7.2.1.1 Current distribution of capital and voting rights

The table below shows the distribution of the capital and voting rights (please refer to paragraph 7.2.2 Voting rights of this registration document, which indicates the conditions under which double voting rights may be obtained) of the Company at February 28, 2014, to the best of the Company's knowledge.

Shareholder	Number of shares	Number of voting rights	% of capital	% of voting rights
Matra Défense (Airbus Group)	**1,036,983**	**2,018,383**	**24.21**	**29.19**
Professor Alain Carpentier	**548,583**	**1,097,166**	**12.81**	**15.87**
Scientific Research Association of the Alain Carpentier Foundation	**115,000**	**230,000**	**2.68**	**3.33**
FCPI UFF Innovation 5	473,670	947,340	11.06	13.70
FCPI EUROPE Innovation 2006	195,358	390,716	4.56	5.65
FCPR Truffle Capital II	178,289	356,578	4.16	5.16
FCPI Fortune	66,110	132,220	1.54	1.91
FCPI UFF Innovation 7	67,498	134,996	1.58	1.95
FCPI Innovation Pluriel	4,575	4,575	0.11	0.07
Sub-total for funds managed by Truffle Capital	**985,500**	**1,966,425**	**23.01**	**28.44**
Treasury stock	2,822	0	0.07	0.00
Secondary offering	1,594,582	1,602,130	37.23	23.17
TOTAL	**4,283,470**	**6,914,104**	**100.00**	**100.00**

To the best of the Company's knowledge, there is no other shareholder owning more than 5% of the capital or the voting rights.

Truffle Capital

Founded in 2001 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.

With more than €550 million under management or advice in *Fonds Communs de Placements à Risques* (Mutual Funds for Risk Investment – FCPR) and *Fonds Commun de Placement dans l'Innovation* (Mutual Funds for Investment in Innovation – FCPI), under management, and Incubator Holding Companies, under advice, Truffle Capital is run by a team of four partners with successful entrepreneurial and investment backgrounds both in Europe and North America.

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 is a co-founder and shareholder of CARMAT.

Airbus Group

Airbus Group (formerly EADS), 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 defense and associated services sectors. Airbus Group holds shares in CARMAT through its wholly-owned subsidiary, Matra Défense.

Professor Carpentier

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 Biosurgical Research Laboratory at the Scientific Research Association of the Alain Carpentier Foundation. Winner of the 1998 Foundation for Medical Research Grand 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 (ARSFAC):

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.

7.2.1.2 Change in the distribution of capital and voting rights

The table below shows the change, to the best of the Company's knowledge, in the distribution of capital and voting rights in the Company as at December 31, 2013, 2012 and 2011:

	As at 12/31/2013			
Shareholder	**Number of shares**	**Number of voting rights**	**% of capital**	**% of voting rights**
Matra Défense (Airbus Group)	**1,170,040**	**2,151,440**	**27.32**	**31.10**
Professor Alain Carpentier	**548,583**	**1,097,166**	**12.81**	**15.86**
Scientific Research Association of the Alain Carpentier Foundation	**115,000**	**230,000**	**2.68**	**3.32**
FCPI UFF Innovation 5	475,133	950,266	11.09	13.74
FCPI EUROPE Innovation 2006	195,968	391,936	4.57	5.67
FCPR Truffle Capital II	178,806	357,612	4.17	5.17
FCPI Fortune	66,322	132,644	1.55	1.92
FCPI UFF Innovation 7	67,712	135,424	1.58	1.96
FCPI Innovation Pluriel	4,606	4,606	0.11	0.07
Sub-total for funds managed by Truffle Capital	**988,547**	**1,972,488**	**23.08**	**28.51**
Treasury stock	2,404	0	0.06	0.0
Secondary offering	1,458,896	1,466,413	34.06	21.20
TOTAL	**4,283,470**	**6,917,507**	**100.0**	**100.0**

	As at 12/31/2012			
Shareholder	**Number of shares**	**Number of voting rights**	**% of capital**	**% of voting rights**
Matra Défense (Airbus Group)	**1,265,382**	**2,246,782**	**30.43**	**32.46**
Professor Alain Carpentier	**548,583**	**1,097,166**	**13.19**	**15.85**
Scientific Research Association of the Alain Carpentier Foundation	**115,000**	**230,000**	**2.76**	**3.32**
FCPI UFF Innovation 5	542,546	1,085,092	13.05	15.68
FCPI EUROPE Innovation 2006	220,497	440,994	5.30	6.37
FCPR Truffle Capital II	199,872	399,744	4.81	5.78
FCPI Fortune	74,909	149,818	1.80	2.16
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**	**26.94**	**32.28**
Treasury stock	1,260	0	0.03	0.0
Secondary offering	1,107,615	1,113,350	26.65	16.09
TOTAL	**4,157,795**	**6,921,375**	**100.00**	**100.00**

Shareholder	As at 12/31/2011 Number of shares	Number of voting rights	% of capital	% of voting rights
Matra Défense (Airbus Group)	**1,265,382**	**2,140,382**	**30.66**	**34.06**
Professor Alain Carpentier	**663,583**	**1,309,833**	**16.07**	**20.84**
Scientific Research Association of the Alain Carpentier Foundation	**565,326**	**865,576**	**13.70**	**13.78**
FCPI UFF Innovation 5	238,022	400,522	5.77	6.38
FCPI EUROPE Innovation 2006	234,916	365,916	5.69	5.82
FCPR Truffle Capital II	81,043	112,293	1.96	1.79
FCPI Fortune	81,553	81,553	1.98	1.30
FCPI UFF Innovation 7	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 stock	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**

7.2.2 Voting rights

The voting right attaching to shares is proportional to the percentage of capital that they represent and each share gives an entitlement to at least one vote.

However, in accordance with Article 14 of the Articles of Association and in accordance with the provisions of the french 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 share capital that they represent.

7.2.3 Statement concerning control of the Company

As at the date of this registration document, to the best of the Company's knowledge, 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.

7.2.4 Agreements that may bring about a change in the control

As at the date of registration of this registration document, and to the best of the Company's knowledge, there are no agreements that may bring about a change in control of the Company.

7.3 MEMORANDUM AND ARTICLES OF ASSOCIATION

7.3.1 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 field of medical devices and equipment, specifically in the cardiovascular field, and in all scientific fields directly or indirectly related thereto;
- production and marketing of (i) medical devices and equipment in the cardiovascular field and (ii) all associated technologies;
- acquisition or creation of technology products and licenses connected with the cardiovascular field;
- investment in French or foreign enterprises having activities that are similar to, 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 above-mentioned purpose or likely to contribute to the development thereof.

7.3.2 Provisions of the Articles of Association, a charter or Bylaws of the Company concerning the members of the board of directors and the General Management (Articles of Association No. 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 an extraordinary general meeting. Their term of office is six (6) years. It concludes at the end of the ordinary general meeting of shareholders that approves the financial statements for the period just closed, and which is held in the year in which the term of office of the said director expires.

Any outgoing director may be re-elected subject to fulfilling the conditions of this Article.

Directors may be removed from office and replaced at any time by the ordinary general meeting.

Natural persons aged 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 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 a natural person must, at the time of their appointment and throughout their term of office, meet the legal requirements 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 natural 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 that relate to directors who are natural 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 of 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 publication 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 directors, 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 next ordinary general meeting. In the absence of ratification, resolutions passed and acts performed previously by the board will remain valid.

Article 17 – Organization and deliberations of the board

I. Chairman

The board of directors elects a chairman from among its members, who must be a natural person, failing which the appointment will be null and void. The board of directors determines the remuneration of the chairman.

The chairman of the board of directors organizes and directs the work of the latter, and reports thereon to the general meeting. 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. If the chairman of the board of directors passes this age during his term of office, he will be deemed to have officially resigned and the appointment of a new chairman will take place subject to the conditions provided for in this Article.

The chairman is appointed for a term that may not exceed that of his term of office as a director. The chairman is eligible for re-election.

The board of directors may revoke the appointment at any time.

In the event of the chairman being temporarily unavailable, 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 remains 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.

When it has not met for more than two (2) months, a minimum of one third of the members of the board of directors may ask the chairman to call a meeting with a specific agenda.

The chief executive may also ask the chairman to call 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 unavailable, 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 unavailable, the board appoints a chairman for each meeting from among the members present.

At each meeting, the board may appoint a secretary, who does not necessarily have to be a member.

A register is kept which is signed by the directors attending the board meeting.

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 *via* video-conference or 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 financial statements and the consolidated financial statements, and also for drawing up the management report and the consolidated 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 *via* video-conference or telecommunication. 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 who is 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 initialed, 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 conclude at the end of the ordinary general meeting of shareholders called to approve the financial statements for the period just closed, 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 upon the death or incapacity of an observer who is a natural person, or in the event of winding up or receivership in the case of an observer who is a legal entity.

Observers may be natural 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 duty 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 to an observer or observers prior to the meeting of the board of directors 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.

Except for the powers expressly reserved for 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 assumes an obligation, even for acts of the board of directors that do not fall within the scope of the corporate purpose, unless it can prove that the third party was aware that the act exceeded that scope, or, under the circumstances, must have been aware, although the simple publication of the Articles of Association will not suffice as 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, the general management of the Company is undertaken, on behalf of the Company, either by the chairman of the board of directors or by another natural person appointed by the board of directors and bearing the title of chief executive.

The choice between the two methods of exercising general management is made by the board of directors, which must inform the shareholders and third parties subject to the regulatory requirements.

The decision of the board concerning the choice of the method of exercising general management is taken by a majority vote of the directors present or represented, subject to the specific provisions of Article 17-III where directors attend the meeting by video-conference 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

Depending on the choice made by the board of directors in accordance with the provisions of the above paragraph, the general management of the Company is exercised by the chairman of the board of directors, or by a natural person, who may or may not be a director, who is appointed by the board of directors and bears the title of 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, define his term of office, determine 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. If a chief executive in post passes this age he is deemed to have officially resigned.

The chief executive may be removed from office 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 cause.

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, except for those which the law expressly reserves for the meetings of shareholders and the board of directors.

He represents the Company in its relations with third parties. The Company assumes an obligation, even for acts of the chief executive that do not fall within the scope of the corporate purpose, unless it can prove that the third party was aware that the act exceeded that scope, or, under the circumstances, must have been aware, although the simple publication of the Articles of Association will not suffice as 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, 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 commitments in excess of €100,000 and not provided for in the annual budget;
- hiring, laying off and amending 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, 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:

- take any decision to proceed with the transfer of any substantial asset or any intellectual/industrial property belonging to the Company;
- take any decision to acquire a holding in a listed or unlisted company.

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, who are 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 term of office as a director.

A person over the age of eighty-five (85) years may not be appointed as deputy chief executive. 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 prevented from performing his duties, the deputy chief executives will retain their functions and powers until the new chief executive is appointed, unless otherwise decided by the board.

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 defined by the meeting, without being bound by previous decisions. The amount is posted to the operating expenses.

The board of directors freely distributes among its members the total amounts allocated to the directors as directors' fees; it may in particular allocate a higher share to those directors who are members of working groups than that allocated to 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 or deputy chief executives, or a shareholder holding more than 10% of the voting rights in the Company, or in the case of a shareholding company, the Company controlling it pursuant to Article L.233-3 of the french commercial code, 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. 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 ended.

Shareholders may also be sent the list and subject-matter of these agreements.

7.3.3 Rights, privileges and restrictions attaching to shares (Articles of Association No. 9 to 14)

Article 9 – Depreciation of the share capital

The share capital may be depreciated in accordance with the provisions of Article L.225-198 *et seq.* of the french 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 acknowledgment 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 french 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, of the name or company name, nationality, year of birth or establishment, shareholders' addresses or number of shares held by each of them.

7.3.3.1 Article 12 – Transfer of shares – Rights and obligations associated with shares – Exceeding of limits

12.1 – Transfer of shares

Shares may be freely traded once issued in accordance with the procedures set out by law.

They remain negotiable following the winding up 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 natural person or legal entity acting alone or together with others who comes to possess a number of shares representing a percentage of the capital or the voting rights in excess of the limits set by law, will inform the Company within the statutory period, counting from when the holding limit is reached, of the total number of shares or voting rights held.

This information is also provided within the same time frames when the holding of share capital or voting rights drops below the limits mentioned in this paragraph.

A person required to provide this information will state the number of securities held giving access to capital and the voting rights attaching to these.

If required by the rules of a securities market other than a regulated market on which the securities of the Company are admitted for trading, this person will also inform the Financial Markets Authority within a time frame and according to the arrangements set by the general regulations of the latter, with effect from when the limit to the holding is passed. If necessary, this information is made public under

the conditions laid down by the general regulations of the Financial Markets Authority.

Failure to make a due declaration under the above conditions will result in the shares exceeding the fraction that should have been declared by law having their voting right removed for any meeting of shareholders held within a period expiring two years after the date that the notification is dealt with.

Similarly, voting rights attaching to these shares and which are not duly declared may not be exercised or delegated by the defaulting shareholder.

The commercial court having jurisdiction for the registered office, at the request of the chairman of the Company, a shareholder or the Financial Markets Authority, holds sole jurisdiction to pronounce a total or partial suspension, for a period not to exceed five years, of the voting rights of any shareholder who has not made the required declarations.

7.3.3.2 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 registered 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.

7.3.3.3 Article 14 – Double voting right

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 (5) of the Articles of Association.

This 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 bonus 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.

7.3.4 Conditions for changing shareholders' rights

The Articles of Association of the Company do not make any special provision that derogates from general company law.

7.3.5 General meetings of shareholders (Articles of Association No. 24-31)

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 who are present or represented.

Where videoconferencing or other means of telecommunication 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 registered 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 video-conference 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.

When the meeting is called upon to deliberate on changes to the economic or legal organization of the Company, in respect of which the works council has been consulted in accordance with Article L.2323-6 of the labor code, the opinion of the council is made known to the meeting.

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 timings, 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 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 group of meeting officials, 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 resolutions 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 them 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.

7.3.6 Provisions of the Articles of Association, a charter or regulations 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.

7.3.7 Passing of statutory limits (Articles of Association No. 12.3)

The reader is invited to refer to paragraph 7.3.3.1.

7.3.8 Changes to the share capital (Articles of Association No. 8)

1 - The share capital 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, and may waive this 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 share capital to below the legal minimum may only be decided subject to 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 the common stock after it has been reduced.

Failing this, any interested party may seek a legal order to wind up the Company. This may not be issued if, on the day on which the court rules on the merits of the case, the situation has been regularized.

7.4 PARTICULARS OF THE LEGAL AFFAIRS OF THE COMPANY

7.4.1 Regulated agreements

The reader is invited to refer to paragraph 7.5 Regulated agreements.

7.4.2 Particulars of company representatives and auditors

7.4.2.1 Bonus shares and stock options

The Company did not perform any bonus issues and has not set up any share purchase or subscription plan.

7.4.2.2 Share transactions by the executives

Pursuant to the provisions of Articles 223-22 A and 223-26 of the general regulations of the French Financial Markets Authority, we publish below the Company share dealings of the executives of the Company and their close relatives during the fiscal year:

Persons concerned	Type of operation	Date of transaction	Number of shares	Value of the transaction
Truffle Capital	Sale	05/14/2013	15,290	2,002,525.18
Truffle Capital	Sale	05/15/2013	9,883	1,263,229.25
Truffle Capital	Sale	05/16/2013	2,957	377,245.19
Truffle Capital	Sale	05/17/2013	992	124,442.73
Truffle Capital	Sale	05/20/2013	1,119	140,249.98
Marcello Conviti	Sale	05/20/2013	700	86,929.22
Truffle Capital	Sale	05/21/2013	2,715	345,586.38
Marcello Conviti	Sale	05/21/2013	1,000	127,280.00
Truffle Capital	Sale	05/22/2013	1,500	191,011.05
Marcello Conviti	Sale	05/22/2013	1,000	127,050.00
Truffle Capital	Sale	05/23/2013	803	100,407.44
Marcello Conviti	Sale	05/24/2013	500	62,252.20
Truffle Capital	Sale	05/24/2013	111	13,893.22
Truffle Capital	Sale	05/29/2013	50	6,251.27
Truffle Capital	Sale	05/31/2013	1,080	135,007.45
Truffle Capital	Sale	06/03/2013	565	70,696.64
Truffle Capital	Sale	06/19/2013	300	35,415.00
Marcello Conviti	Sale	06/20/2013	500	58,065.00
Truffle Capital	Sale	07/11/2013	487	57,869.77
Truffle Capital	Sale	09/24/2013	21,610	2,632,664.18
Truffle Capital	Sale	09/25/2013	5,200	603,801.12
Truffle Capital	Sale	09/25/2013	7,000	820,662.24
Marcello Conviti	Sale	10/04/2013	300	32,730.87
Marcello Conviti	Sale	10/04/2013	200	21,879.72

Persons concerned	Type of operation	Date of transaction	Number of shares	Value of the transaction
Marcello Conviti	Sale	10/07/2013	200	21,913.70
Marcello Conviti	Sale	10/08/2013	300	32,994.48
Marcello Conviti	Sale	10/09/2013	300	32,563.77
Marcello Conviti	Sale	10/10/2013	300	33,000.00
Marcello Conviti	Sale	10/11/2013	200	21,861.98
Marcello Conviti	Sale	10/14/2013	300	32,734.95
Marcello Conviti	Sale	10/15/2013	300	32,086.02
Marcello Conviti	Sale	10/15/2013	200	21,350.12
Marcello Conviti	Sale	10/15/2013	300	31,759.41
Marcello Conviti	Sale	10/17/2013	400	42,047.92
Truffle Capital	Sale	10/18/2013	2,437	261,261.02
Marcello Conviti	Sale	10/18/2013	400	43,705.44
Truffle Capital	Sale	11/01/2013	2,400	259,772.64
Patrick Coulombier	Sale	11/01/2013	497	54,059.34
Patrick Coulombier	Sale	11/01/2013	34	3,650.04
Truffle Capital	Sale	11/04/2013	1,000	106,971.00
Truffle Capital	Sale	11/05/2013	170	17,714.62
Truffle Capital	Sale	11/06/2013	1,078	114,068.03
Truffle Capital	Sale	11/07/2013	253	26,572.49
André-Michel Ballester	Sale	11/07/2013	78	8,268.00
Truffle Capital	Sale	11/08/2013	47	4,935.00
André-Michel Ballester	Sale	11/15/2013	200	21,200.00
Truffle Capital	Sale	12/04/2013	1,707	181,309.52
Truffle Capital	Sale	12/05/2013	1,204	126,034.12
Truffle Capital	Sale	12/06/2013	925	97,055.65
Truffle Capital	Sale	12/09/2013	1,650	174,736.30
Truffle Capital	Sale	12/10/2013	1,251	133,262.16
Truffle Capital	Sale	12/11/2013	3,000	324,472.80
Truffle Capital	Sale	12/12/2013	1,150	124,142.74
Truffle Capital	Sale	12/13/2013	1,100	116,077.28
Truffle Capital	Sale	12/16/2013	245	25,780.61
Truffle Capital	Sale	12/17/2013	28	2,955.03
Truffle Capital	Sale	12/20/2013	327	34,151.93
Truffle Capital	Sale	12/23/2013	900	117,900.00
Truffle Capital	Sale	12/23/2013	39,174	4,999,393.71

7.4.3 Information on the Company's securities

7.4.3.1 Shareholders

See paragraph 7.2.1.2 Change in the distribution of capital and voting rights.

7.4.3.2 Employee shareholding

In accordance with the provisions of Article L.225-102 of the french commercial code, we hereby indicate that the Company has not set up any company savings plan for the benefit of employees.

As at December 31, 2012, employees and managers held 0.45% of the Company's share capital.

7.4.3.3 Transactions by the Company in its own shares

We are also obliged to report to you on purchases and sales by the Company of its own shares for the purposes of regulating the price, in accordance with the provisions of Article L.225-209-1 of the french commercial code.

During the period that closed on December 31, 2013, the Company proceeded with the following dealings in its own shares under the liquidity agreement entered into for a period of one year with an independent financial services provider, as authorized by the general meeting of June 4, 2013 (Resolution No. 4):

- purchase of 12,672 shares at an average price of €113.5714
- sale of 11,528 shares at an average price of €117.8160

As at December 31, 2013, the Company held 2,404 treasury shares, *i.e.* 0.06% of the share capital, acquired at a total purchase price of €285,559.52.

These disposals of treasury shares performed under the liquidity agreement provided a net gain of €48,686.13.

(Note 6.4.4.5 to the 2013 Annual Financial Statements)

7.4.3.4 Securities giving access to the Company's capital

In total, these securities confer subscription rights to 348,125 new shares (8.13% of the existing capital as of December 31, 2013), which includes 205,725 shares at a unit price of €8, 52,500 shares at a unit price of €108 and 6,700 shares at a unit price of €122.

For details on the securities giving access to the Company's capital and in force at December 31, 2013, see paragraph 7.1.5 Other securities giving access to capital.

7.4.3.5 Participating and controlling interests

In accordance with the provisions of Articles L.233-6 and L.247-1 of the french commercial code, we can report that the Company has not acquired any participating or controlling interests during the reporting period.

7.4.3.6 Table of delegations of authority

In accordance with the provisions of Article L.225-100 of the french commercial code, we indicate below the delegations of authority currently in force, granted by the general meeting to the board of directors in relation to increasing the capital pursuant to Articles L.225-129-1 and L.125-129-2 of the french commercial code.

Resolution	Subject matter of the resolution	Maximum nominal amount in euros	Use of delegations during the 2013 period	Method of determining the issue price	Period of authorization and expiry
6th resolution of the combined general meeting of June 4, 2013	Delegation of authority allowing the board of directors to decide on the issue, with retention of the preferential subscription rights, of shares and/or transferable securities giving immediate or future access to capital or providing a right to a debt instrument	Nominal amount of increases in capital: €60,000 Nominal amount of bonds and other debt instruments giving access to capital: €40,000,000	N/A	Free	August 4, 2015 (26 months)
7th resolution of the combined general meeting of June 4, 2013	Delegation of authority allowing the board of directors to decide on the capitalization of profits, reserves or premiums	Nominal amount of increases in capital: €60,000	N/A	Free	August 4, 2015 (26 months)
8th resolution of the combined general meeting of June 4, 2013	Delegation of authority allowing the board of directors to decide on the issue of shares and/ or securities giving immediate or future access to the capital or providing a right to a debt instrument, with removal of the preferential subscription right of shareholders for the benefit of categories of beneficiaries (Article L.225-138)	Nominal amount of increases in capital: €60,000 Nominal amount of bonds and other debt instruments giving access to capital: €40,000,000	N/A	At least equal to the average volume-weighted price of the last five stock market sessions prior to the defining of the issue price, less any discount (maximum 30%)	December 4, 2014 (18 months)
8th resolution of the combined general meeting of June 4, 2013	Delegation of authority to the board of directors to decide on the issue of shares and/ or securities giving immediate or future access to capital or providing a right to a debt instrument, by private placement and up to a limit of 20% of the share capital per year (Article L.225-136 3)	Nominal amount of increases in capital: €60,000. The total amount of the increases in capital will be limited to 20% of the capital (as existing on the date of the operation) per annum Nominal amount of bonds and other debt instruments giving access to capital: €40,000,000	Meeting of the board of directors of June 5, 2013: Issue of 200,000 stock warrants for Kepler Cheuvreux During fiscal 2013, Kepler Cheuvreux exercised 116,800 warrants, consequently subscribing in the amount of €116.800, representing a capital increase for a nominal amount of €4,672, accompanied by an issue premium of €12,083,968.	At least equal to the average volume-weighted price of the last five stock market sessions prior to the defining of the issue price, less any discount (maximum 30%)	August 4, 2015 (26 months)
10th resolution of the combined general meeting of June 4, 2013	Delegation of authority allowing the board of directors to decide on the issue of shares and/or transferable securities giving immediate or future access to capital or providing a right to a debt instrument, with removal of the preferential subscription right without indicating the beneficiary and by public offering (Article L.225-136)	Nominal amount of increases in capital: €60,000 Nominal amount of bonds and other debt instruments giving access to capital: €40,000,000	N/A	At least equal to the average volume-weighted price of the last five stock market sessions prior to the defining of the issue price, less any discount (maximum 30%),	August 4, 2015 (26 months)

7.5 REGULATED AGREEMENTS

7.5.1 Royalties agreements

Under a royalties agreement signed on June 24, 2008 and amended by an addendum of February 5, 2010 between CARMAT, Professor Alain Carpentier and Matra Défense (a subsidiary of the Airbus 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 €30 million less the amount of royalties already paid at the time this right to royalties is repurchased. This sum of €30 million is indexed-linked to 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-chirurgical and orthopedic material for export in the eurozone PVIC Code 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).

7.5.2 Relationships between CARMAT and the subsidiaries of the Airbus Group

Because of the specific skills it requires and its historical links the Company has commercial relationships with the following Airbus 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 ended on December 31, 2013):

- Airbus Group France for €191,854 for the supply of IT and telephone services;
- MATRA ÉLECTRONIQUE for €205,878 for the production of the prothesis' integrated electronics and its testing;
- ASTRIUM for €284,108 for monitoring the manufacture of the electronics of the prosthesis and preparation of the performance support file;
- MBDA FRANCE for €4,500 for expert appraisal of electronic and electromechanical aspects and production consultancy;
- CASSIDIAN for €151,000 in respect of the staff loan agreement with CARMAT;
- Airbus Group Aeroassurances for €5,946 for personal accident insurance cover.

7.5.3 Relations between CARMAT and the Scientific Research Association of the Alain Carpentier Foundation

Owing to the specific competencies sought and historical relations, the Company maintains commercial relations with the Scientific Research Association of the Alain Carpentier Foundation (ARSFAC) in the normal conduct of its business and ordinary financial conditions for the type of services performed.

It thus signed a collaboration agreement for medical research with ARSFAC on April 30, 2013. Under the terms of this agreement, concluded for one year starting on January 1, 2013, the Company committed to repay to ARSFAC all the costs mentioned in the appendices to said agreement. For 2013, the amount of fees repaid by the Company to ARSFAC totaled €118,146.

7.5.4 Special report of the statutory auditors on the regulated agreements

(General meeting to approve the financial statements for the period ended December 31, 2013)

To the shareholders,

CARMAT SA
36, Avenue de l'Europe
78941 Vélizy-Villacoublay

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 in respect of the conclusion of these agreements and commitments for the purpose of approving them.

Furthermore, we are required, where necessary, to provide you with the information pursuant to Article R.225-31 of the french commercial code (*code de commerce*) concerning the execution of agreements, in the year just ended, previously approved by the 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 assignment. 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 the general meeting

In accordance with Article L.225-40 of the french commercial code, we have been informed of the following agreement previously authorized by your board of directors.

The Scientific Research Association of the Alain Carpentier Foundation (ARSFAC), on behalf of your company, conducted tests on animals with a view to the approval of the clinical study.

During the year ended December 31, 2013, your company recognized an expense of €118,146 as part of this agreement.

ARSFAC, a shareholder holding more than 10% of the share capital of your company, is represented by Professor. Alain Carpentier, who is also a director.

Agreement already approved by the general meeting

In accordance with Article R.225-30 of the french commercial code (*code de 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 (hereinafter referred to as "the Company"), Professor Alain Carpentier and Matra Défense

On June 24, 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 six 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 €30,000,000, less 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 €30,000,000 is index-linked to the *Indice du Prix à la Production de l'Industrie des Services aux Entreprises – Matériel médicochirurgical et d'orthopédie-exportation zone euro* [Index of Prices for the Industrial Production of Services to Businesses – Medico-surgical and orthopedic equipment – for export within the Eurozone].

The rights allocated to Professor Alain Carpentier and to Matra Défense in this way are non-transferable.

As at December 31, 2013, since the marketing of the "CARMAT" Artificial Heart had not started, no royalty had been paid by the Company under the Agreement.

Signed in Neuilly-sur-Seine and Paris, March 10, 2014

The statutory auditors

PRICEWATERHOUSECOOPERS AUDIT
THIERRY CHARRON

63, rue de Villiers
92208 Neuilly-sur-Seine Cedex

LISON CHOURAKI

13, rue Spontini
75016 Paris

8

SUPPLEMENTARY INFORMATION

8.1 AUTHOR OF THE REGISTRATION DOCUMENT

8.1.1 Name of the author of the registration document

Marcello Conviti, CARMAT's chief executive officer, is the author of the registration document.

8.1.2 Declaration of the author of the registration document

"Having taken all reasonable steps to verify the contents of this registration document, 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 registration document, and that they have read the entire registration document".

The financial information for the year ending December 31, 2013 set out in this registration document was the subject of the auditors' report which appears in paragraph 6.5 of this registration document, and which contains no observations.

The historical financial information as at December 31, 2010, December 31, 2011 and December 2012, that is incorporated by reference into this registration document was previously presented in the 2010 registration document, the 2011 registration document and the 2012 registration document, which were registered with the Financial Markets Authority on April 27, 2011 under number R.11-017, on September 12, 2012 under number R.12-044 and May 30, 2013 under number R.13-027 respectively, and was the subject of reports by the auditors which contained no observations.

Vélizy, March 17, 2014

Marcello Conviti

Chief executive officer, CARMAT

8.2 AUDITORS

8.2.1 Statutory auditors

PricewaterhouseCoopers Audit, member of the Regional auditors' Association of Versailles.

Represented by Mr. Thierry Charron

63, rue de Villiers – 92200 Neuilly-sur-Seine

Date of commencement of duties: appointed upon the incorporation of the Company on June 25, 2008

Duration of current term: six financial periods from the date the Company was incorporated.

Expiry of current term: at the end of the general shareholders' meeting to approve the accounts for the year ending December 31, 2014.

Ms. Lison CHOURAKI, member of the auditors' Association of Paris

13, rue Spontini – 75016 Paris

Date of commencement of duties: October 16, 2008.

Duration of current term: six financial periods from October 16, 2008.

Expiry of current term: at the end of the general shareholders' meeting to approve the accounts for the year ending December 31, 2014.

8.2.2 Alternate auditors

Mr. Étienne BORIS, member of the Regional auditors' Association of Versailles

63, rue de Villiers – 92200 Neuilly-sur-Seine

Date of commencement of duties: appointed upon the incorporation of the Company on June 25, 2008.

Duration of current term: six financial periods from the date the Company was incorporated.

Expiry of current term: at the end of the general shareholders' meeting to approve the accounts for the year ending December 31, 2014.

Ms. Soulika BENZAQUEN, member of the auditors' Association of Paris

5, rue de Prony – 75017 Paris

Date of commencement of duties: October 16, 2008.

Duration of current term: six financial periods from October 16, 2008.

Expiry of current term: at the end of the general shareholders' meeting to approve the accounts for the year ending December 31, 2014.

8.2.3 Statutory auditors who resigned, were dismissed or were not reinstated

Since their appointment, the statutory auditors and their substitutes have not been dismissed from their positions, nor have they resigned.

8.2.4 Auditors' fees

	PricewaterhouseCoopers Audit				Lison Chouraki			
In euros (excl. VAT)	**2013**	**%**	**2012**	**%**	**2013**	**%**	**2012**	**%**
Auditing, certification, examination of individual accounts – Issuer	27,314	100	24,450	91.7	27,900	100	20,450	90.3
Other activities and services directly linked to the audit task – Issuer	0	0	2,200	8.3	0	0	2,200	9.7
TOTAL	27,314	100	**26,650**	**100**	27,900	100	**22,650**	**100**

8.3 INFORMATION FROM THIRD PARTIES, DECLARATIONS BY EXPERTS AND DECLARATIONS OF INTEREST

None.

8.4 PUBLICLY ACCESSIBLE DOCUMENTS

Copies of this registration document 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 [AMF] (www.amf-france.org).

All documents which must be made available to shareholders (such as by-laws, minutes of general meetings, historical financial information and the valuations and declarations made by an expert at the Company's request included or referred to in this registration document) may be consulted at the Company's registered office at 36 avenue de l'Europe – 78140 Vélizy Villacoublay.

All the regulatory information, as defined in Article 221-1 of the general regulations of the AMF, is available on the Company's website.

8.5 INFORMATION ON HOLDINGS

As at the date of this registration document, the Company did not have any holdings in the share capital of other companies.

8.6 RECENT EVENTS

On March 4, 2014, the Company published the following release:

Continuation, in France, of the clinical trial on the first bioprosthetic artificial heart.

CARMAT (FR0010907956, ALCAR), the designer and developer of the world's most advanced total artificial heart project, providing an alternative for people suffering from end-stage heart failure, today announces the continuation of the initial first-in-man clinical trial of its bioprosthetic artificial heart, in accordance with the applicable regulatory agreements.

Following the announcement of the death, two and a half months after the implantation of the artificial heart, of the first patient, aged 76, CARMAT first and foremost wishes to pay tribute to the courage and the pioneering role of this patient and his family, and to thank the medical team's dedication and their contribution to this world first.

The Company would like to point out that this first implantation is part of an approved feasibility study involving four patients in an immediate life threatening situation. Given these specific conditions, the clinical monitoring of a patient for 30 days or more after the artificial heart is implanted is considered to be encouraging.

The first bioprosthetic heart, designed by Professor Alain Carpentier and developed in collaboration with CARMAT, beat for 74 days, *i.e.* some 7 million times, following its implantation on December 18, 2013 at the Georges Pompidou European Hospital in Paris.

An analysis of the data is being carried out in accordance to the clinical trial's protocol. The Company stresses that it is too soon to draw any conclusions from the data of a single patient, whatever the duration of the implantation.

Subject to regulatory obligations or specific circumstances, CARMAT is not planning to publish any information on the results of the feasibility study until a global analysis of the trial's data has been completed.

On March 17, 2014, the Company published the following release:

CARMAT is continuing to analyze the first prosthesis, implanted for 74 days

- The results of this analysis are not yet known.
- This analysis is being carried out in accordance with the customary clinical trial monitoring rules, under the supervision of independent monitoring committees.

CARMAT (FR0010907956, ALCAR), the designer and developer of the world's most advanced total artificial heart project, providing an alternative for people suffering from end-stage heart failure, today confirms that it is continuing to analyze the data from the first implanted prosthesis, and will continue the clinical trial once it has obtained the results of the data from this first implantation.

The prosthesis, its control console, their respective power supplies and above all the interactions between the weakened organism of a patient with end-stage heart failure and the prosthesis are very complex issues. More than 4,000 pieces of data are recorded every second. Detailed analysis is still being carried out, but at the current time there is no single explanation, only hypotheses that will be substantiated or not in the coming weeks by in-house and external experts.

The results of the analyses of the first implantation, like the following implantations, will notably be reviewed by the Data and Safety Monitoring board (DSMB).

From the Company's point of view, the first implantation was positive, with the patient surviving for 74 days within the framework of a trial where the benchmark for success was 30 days. The approved medical centers are continuing to assess the next patients for the ongoing clinical trial.

As stated in the Company's 2012 registration document and the press release of March 4, 2014, CARMAT is not planning to publish any interim results, subject to regulatory obligations or specific circumstances.

CARMAT does not accept any responsibility or liability for information released beyond its control.

8.7 CROSS-REFERENCE TABLES

In application of Article 28 of Regulation No. 809/2004 of the European Commission, the following information is included by reference in this registration document:

- the 2012 annual financial statements and corresponding audit report shown respectively in paragraphs 20.1 and 20.3 of the registration document for the fiscal year 2012 recorded by the AMF on May 30, 2013 under No. R. 13-027; and
- the 2011 annual financial statements and the corresponding audit report shown respectively in paragraphs 20.1 and 20.3 of the registration document for the fiscal year 2011 recorded by the AMF on September 12, 2012 under No. R. 12-044.

The two registration documents cited above are available on the Company's website (www.carmat.fr) and that of the AMF (www.amffrance.org).

8.7.1 Cross-reference table of the registration document

The cross-reference table below refers to the main headings required by Regulation No. 809/2004 in application of Directive 2003-1971/EC and to the pages of this registration document.

	Numbers	
Headings of Appendix 1 of Regulation No. 809/2004	**Pages**	**Paragraphs**
1. PERSONS RESPONSIBLE	168	8.1
2. STATUTORY AUDITORS	169	8.2
3. SELECTED FINANCIAL INFORMATION		
3.1. Historical financial information	10	1.1
3.2. Interim financial information	N/A	N/A
4. RISK FACTORS	55-77	3
5. INFORMATION CONCERNING THE ISSUER		
5.1. History and development of the Company	11-13	1.2; 1.2.5
5.2. Investments	16	1.6
6. OVERVIEW OF ACTIVITIES		
6.1. Main activities	14; 18-38	1.3; 2.1; 2.2
6.2. Main markets	38-51	2.3
6.3. Exceptional events	N/A	N/A
6.4. Degree of dependency on patents, licenses, manufacturing, sales or financial contracts or new manufacturing processes	67-68	3.3.6
6.5. Competitive position	41; 56-57	2.3.2; 3.1.2
7. ORGANIZATION CHART		
7.1. Summary description of the Group	15; 97	1.4; 4.7.1.1
7.2. List of major subsidiaries 15	15	1.4.2
8. PROPERTY, PLANT AND EQUIPMENT		
8.1. Main property, plant and equipment and significant expenses related thereto	15	1.5.1
8.2. Environmental issues that can influence the use of property, plant and equipment	15	1.5.2
9. REVIEW OF THE COMPANY'S FINANCIAL SITUATION AND PERFORMANCE		
9.1. Financial situation	104-105	5.2.1; 5.2.2
9.2. Operating result	10; 102; 109	1.1; 5.1.1; 5.5.1
10. CASH AND CAPITAL		
10.1. Information on the capital	105	5.2.3.1
10.2. Cash flow	10; 105; 126; 129	1.1; 5.2.3.2
10.3. Borrowing conditions and financing structure	105-106	5.2.3.3
10.4. Restrictions on the use of capital	106	5.2.3.4
10.5. Anticipated sources of finance	106	5.2.3.5
11. RESEARCH AND DEVELOPMENT, PATENTS AND LICENSES	51; 104	2.4; 5.1.6

Headings of Appendix 1 of Regulation No. 809/2004	Numbers	
	Pages	Paragraphs
12. TRENDS		
12.1. Main trends since the end of the previous financial year	108; 170	5.4.2; 5.4.3; 8.6
12.2. Known trend or event likely to influence the outlook of the issuer	107	5.4.1
13. PROFIT FORECASTS OR ESTIMATES	108	5.4.4
14. ADMINISTRATIVE, MANAGEMENT AND SUPERVISORY BODIES AND SENIOR MANAGEMENT		
14.1. Administrative bodies	80-83	4.1.1; 4.1.2
14.2. Conflicts of interest	85	4.2
15. REMUNERATION AND BENEFITS		
15.1. Remuneration and benefits in kind	92-96	4.6.1; 4.6.3
15.2. Total amount of sums provisioned or recognized for payment of pensions, retirement or other benefits	96	4.6.2
16. OPERATION OF THE ADMINISTRATION AND MANAGEMENT BODIES		
16.1. Date of expiration of current terms	86	4.3.1
16.2. Service contracts binding the members of the administrative, management and supervisory bodies	86	4.3.2
16.3. Board of Auditors and Compensation board	86-87	4.4
16.4. Compliance with the corporate governance recommendations effective in France	89	4.5.1
17. EMPLOYEES		
17.1. Number of employees	97	4.7.1.2
17.2. Investment and stock options	99-100	4.7.2
17.3. Employee involvement in issuer's capital	100; 162	4.7.3; 7.4.3.2
18. PRINCIPAL SHAREHOLDERS		
18.1. Shareholders holding more than 5% of the capital	149-151	7.2.1
18.2. Existence of different voting rights	151	7.2.2
18.3. Control of the issuer	151	7.2.3
18.4. Agreements that could bring about a change in control	151	7.2.4
19. RELATED PARTY TRANSACTIONS	160; 164-167	7.4.1; 7.5
20. FINANCIAL INFORMATION ON THE ASSETS, FINANCIAL POSITION AND PERFORMANCE OF THE ISSUER		
20.1. Historical financial information	10; 104-108; 110; 171	1.1; 5.2; 5.5.3; 8.7
20.2. *Pro-forma* financial information	N/A	N/A
20.3. Financial statements	119-134	6
20.4. Checks on the annual historical financial information	135-136	6.5
20.5. Date of the most recent financial information	119	6
20.6. Financial information on intermediaries and others	N/A	N/A
20.7. Dividend distribution policy	112	5.6
20.8. Legal and arbitration proceedings	77	3.7
20.9. Significant changes in the financial or commercial position	108	5.4.2
21. SUPPLEMENTARY INFORMATION		
21.1. Share capital	138-148; 162	7.1; 7.4.3.4
21.2. Memorandum and Articles of Association	152-159	7.3
22. IMPORTANT CONTRACTS	112-118	5.7
23. INFORMATION FROM THIRD PARTIES, DECLARATIONS BY EXPERTS AND DECLARATIONS OF INTEREST	170	8.3
24. PUBLICLY ACCESSIBLE DOCUMENTS	170	8.4
25. INFORMATION ON HOLDINGS	170	8.5

8.7.2 Cross-reference table of the annual financial report

To facilitate the reading of the annual financial report, the following thematic table refers the reader to the main information in this registration document stipulated by Article L. 451-1-2 of the french monetary and financial code.

	Number	
	Pages	**Paragraphs**
1. CORPORATE FINANCIAL STATEMENTS	**119-134**	**6**
2. CONSOLIDATED FINANCIAL STATEMENTS	**N/A**	**N/A**
3. MANAGEMENT REPORT (IN THE MEANING OF THE FRENCH MONETARY AND FINANCIAL CODE)		
3.1. Information contained in Article L. 225-100 of the french commercial code		
Analysis of the change in turnover	10; 109	1.1; 5.5.1.1
Analysis of results	10; 109-110	1.1; 5.5.1
Analysis of the financial position	10; 104-106	1.1; 5.2
Key human resources and environmental indicators	15; 97-100	1.5.2; 4.7
Main risks and uncertainties	55-77	3
Summary table of currently valid delegations made by the Shareholders' General Meeting to the Board of Directors concerning capital increases	162-163	7.4.3.6
3.2. Information contained in Article L. 225-100-3 of the french commercial code		
Elements likely to have an influence in the case of a public offering	N/A	N/A
3.3. Information contained in Article L. 225-211 of the french commercial code		
Acquisition by the Company of its own shares	138-139; 162	7.4.3.3; 7.1.4
4. DECLARATION BY THE PERSON RESPONSIBLE FOR THE 2012 ANNUAL FINANCIAL REPORT	**168**	**8.1**
5. STATUTORY AUDITORS' REPORT ON THE CORPORATE FINANCIAL STATEMENTS AND CONSOLIDATED FINANCIAL STATEMENTS	**135-136**	**6.5**
6. COMMUNICATION ON THE AUDITORS' FEES	**169**	**8.2.4**
7. INTERNAL CONTROL	**91-92**	**4.5.5**
8. STATUTORY AUDITORS' REPORT ON THE CHAIRMAN'S REPORT ON INTERNAL CONTROL	**N/A**	**N/A**

8.8 GLOSSARY OF TERMS

Actuator	A device that controls the movement of a fluid or a solid.
Acute heart failure	Sudden incapacity of the heart to ensure sufficient blood flow to meet the oxygen needs of the various organs. The symptoms are severe at the outset. It occurs either following a heart attack (see myocardial infarction) which caused damage to a region of the heart, or following a sudden inability of the body to compensate for a chronic cardiac failure (see Decompensation).
AFSSAPS	*Agence Française de Sécurité Sanitaire des Aliments et Produits de Santé* (French Agency for the Safety of Health Products). This agency evaluates and oversees the safe use of health products, examines their quality in the laboratory and inspects the manufacturing, distribution and trial sites, and also produces information campaigns regarding the correct usage of health products. It was replaced by the ANSM (see corresponding entry) by law No. 2011-2012 of December 29, 2011.
Angiotensin-converting enzyme inhibitors (ACE)	Drug reducing vascular resistance.
Annuloplasty	Surgery intended to correct mitral insufficiency linked to a dilatation of the mitral annulus.
ANSM	*Agence nationale de sécurité du médicament et des produits de santé* (French national agency for medicines and health products safety) (ANSM). It is a French public institution whose aim is to assess the health risks of health products destined for use in humans. It has authority over the regulatory field of biomedical research.
Anticoagulant	Drug limiting the coagulation of blood in order to avoid the formation of clots and acting on clotting factors other than platelets (see preceding entry). Their dosage is complex: too much could cause a hemorrhage and not enough could result in a thromboembolic accident. Their use at high doses is necessary for all implantable devices made out of metal or plastic which are not hemocompatible and are the source of numerous complications.
Aorta	The aorta is the largest artery in the body and allows oxygenated blood to be carried to all parts of the body from the left ventricle.
Atrium	One of the two small upper chambers of the heart that receive blood before it is passed into the corresponding ventricle. Each atrium communicates with the corresponding ventricle by an atrioventricular valve, the tricuspid valve on the right, the mitral valve on the left.
Betablockers	Drug which reduces the cardiac rhythm and output to decrease blood pressure.
Bioprosthetic (valve) or bioprosthesis	Artificial valve manufactured from animal tissue in order to replace an inadequate cardiac valve. By extension a medical device containing biological components.
Bpifrance	French Public Investment Bank (which incorporated the activities of Oseo Innovation, previously known as ANVAR aimed at promoting innovation through financial guarantees and partnerships).
Cardiogenic shock	Failure of the myocardial pump to generate a sufficient blood flow for the peripheral organs.
CE marking	Declaration made by the manufacturer certifying that the product meets the applicable legal provisions and the European directives (compliance with a certain number of conditions relating to safety, therapeutic value, production traceability...).
Cerebrovascular accident (CVA)	Sudden neurological deficit of vascular origin caused by a heart attack or a hemorrhage in the brain.
Chemically treated animal pericardium	Double walled sac found in animals (cows, pigs or horses) that contains the heart and roots of large blood vessels treated with a sterilized fixative, glutaraldehyde. It is known as the least thrombogenic biomaterial and does not cause rejection.
Chronic cardiac insufficiency	The incapacity of the heart to provide sufficient blood flow to deal with the oxygen needs of the various organs. The main causes of chronic cardiac insufficiency are angina and myocardial infarction, arterial hypertension, valvular diseases and degenerative diseases of the myocardium. In all cases, the result is a progressive destruction of the cardiac muscle linked to a loss of its contractile force.
Clean room	Room or series of rooms where the particulate concentration is controlled in order to minimize the introduction, generation, retention of particles inside, generally for a specific industrial or research purpose. Parameters such as temperature, humidity and relative pressure are also maintained at a specific level.
Clinical Trial Authorization (CTA)	Authorization granted by the ANSM. It is one of two authorizations required in France to carry out biomedical research on humans, the other being that granted by the *Comité de Protection des Personnes* (CPP: see corresponding entry).
Coagulation (blood)	Phenomenon of blood clot formation. It is the normal reaction of the body to stop a hemorrhage. Nevertheless, when these clots form in the heart, in a vessel or a device, they can obstruct a blood vessel and can cause a pulmonary embolism or a cerebrovascular accident (stroke).
Comité de Protection des Personnes (CPP)	Ethical research committee whose role is to assure that all biomedical research projects on humans carried out in France respect various considerations (medical, ethical, and legal) aiming to ensure the protection of the people that participate in that research.
Compliance	In medicine, the ability of an organic cavity to change volume under the influence of changes in pressure.
Coronary heart disease	Decrease in the capacity of one or more arteries of the heart (or coronary arteries) and leads to angina and myocardial infarction (or heart attack).
Critical events committee (CEC)	Committee composed of members who are totally independent from the promoter and the investigators of the study, set up in accordance with ISO 13485 and to Good Clinical Practices (GCP): Its role is to review all adverse events, whether they are serious or not, and establish causality with the device under investigation.
Data and Safety Monitoring Board (DSMB)	DSMB: Data Safety and Monitoring Board Committee composed of members which are totally independent from the promoter and the investigators of the study, set up in accordance to ISO 13485 and to Good Clinical Practices (GCP): its role is to review all the data referring to the study and give the promoter its opinion on whether to continue with the pursuit of the inclusions in the clinical study.

Destination therapy	Permanent implementation – Destination Therapy, as opposed to being on a transplant waiting list.
Diastole	Relaxation phase of the muscle of a cardiac cavity that allows it to be filled.
Diuretic	Drug which eliminates excess fluids and, in this way, lightens the load on the heart and prevents pulmonary edema.
Erythrocytes (red blood cells)	Red blood corpuscle.
Etiology	Medical field that studies and analyzes the causes of diseases.
Ex vivo	Refers to tests that take place on cadavers (see *In vivo*).
FDA – Food and Drug Administration	American agency that authorizes marketing approval for drugs and medical devices in the USA.
French Order of Physicians	Professional, administrative and legal body for the defense and regulation of the medical profession.
Fuel cell	Cell in which electricity is generated by means of the oxidation of an electrode of a reducing fuel (for example hydrogen) coupled with the reduction on another electrode of an oxidant, such as oxygen in the air.
HDE – Humanitarian Device Exemption	Authorization procedure of the FDA which allows a device to be commercialized without any performance evidence (security is the only criteria taken into account). The FDA uses the term HUD (Humanitarian Use Device). This authorization limits the number of devices that can be commercialized on the American market to 4,000 per year.
Hemocompatibility	Quality of the biological compatibility of non-living materials, used in a medical device, in contact with blood and other biological organs.
Hemolysis	Destruction of red blood cells releasing hemoglobin into the blood plasma, thus reducing their ability to transport oxygen.
High blood pressure	Cardiovascular disease characterized by an arterial pressure superior to normal and resulting in an increase in the volume of the left ventricle.
HUD	See HDE.
Hyperlipidemia	Pathology showing dysfunctions caused by a high level of fat in the blood.
Hypertrophy	Excessive enlargement of an organ or element of the body.
IDE (Investigational Device Exemption)	Authorization procedure which allows a device to be used within the scope of clinical trial during which it must show a high level of safety and efficiency in order to receive PMA approval.
Immunosuppressant	Agent restricting immune responses of the body in order to reduce the risk of rejection following organ transplantation. The most well-known is cyclosporine.
In silico	Refers to tests that are performed on computers and/or by digital simulation.
In vitro	Refers to tests performed outside of the organism, in the laboratory or on a test bench. These tests were originally conducted in test tubes.
In vivo	Refers to tests performed in a living organism. (also see *ex vivo*).
Incidence	Number of new cases of a disease observed during a given period and for a defined population. It is different from prevalence which counts all cases (new or not) at a given time.
Inotrope	Drugs increasing contractility of the cardiac muscle. The dependency on inotropes signals end-stage heart failure.
Ischemia	Decrease in the arterial blood supply to an organ.
ISO standard	Standard created by the International Organization for Standardization (ISO) in order to ensure reliable, good quality products and services.
Mitral (valve)	Cardiac valve that separates the left atrium from the left ventricle.
Myocardial infarction	Necrosis (death) of a part of the cardiac muscle. In ordinary language, heart attack. It occurs when one or more coronary arteries become blocked. The myocardial cells (the muscle making up the heart) supplied with blood by this (or these) artery(ies) are no longer oxygenated, which causes their suffering (pain experienced) and can lead to their death.
New York Heart Association (NYHA)	A scale based on symptoms used to quantify and monitor the functional impact (on the activity) of heart failure in an individual.
Orthotopic	Transplantation of an organ to its normal anatomical location.
Orthotopic "total" artificial heart	Artificial cardiac prosthesis (or Total Artificial Heart – TAH) intended to totally replace the native heart. It is distinct from ventricular assistance which functions in parallel with the diseased heart.
Platelet anti-aggregate	Drug preventing blood platelets, partly responsible for the phenomenon of blood coagulation (see corresponding entry), from aggregating and forming the start of a clot. The most well-known is aspirin.
PMA – Pre Market Approval	Authorization procedure before a device is put on the market. It requires measured and concrete information on safety and efficiency mainly based on a clinical trial IDE.
Polyetheretherketone (PEEK)	A high performance plastic with a unique combination of properties, used for its strength in the medical, aeronautical, automobile, electronics, food and industrial sectors.
Polyurethane	Plastic material used in varnishes, paints, synthetic rubbers, obtained by polymerization.
Prevalence	Measurement of the state of health of a population at a given time; can be expressed as a percentage. For a given pathology, the prevalence is obtained by dividing the number of sufferers at a given time by the size of the total population.

Product Lifecycle Management (PLM)	Literally the “management of the product lifecycle”, software dealing with the creation and maintenance of product definitions throughout their lifecycle, from the creation of the initial offer to the end of life. PLM covers the management of the definition of products, including configuration management, development management and project management.
Proteic	Concerning proteins.
Pulmonary artery	Arteries that transport blood from the heart to the lungs.
Pulmonary edema	Invasion of the pulmonary alveoli by blood plasma that has passed through the wall of the capillaries (small vessels). APE (acute pulmonary edema) is an absolute emergency and a frequent result of cardiac decompensation.
Pulmonary embolism	Situation where a blood clot blocks a pulmonary artery.
Pulsating	Pulsed animation to the rhythm of the heart beat.
Research Tax Credit (RTI)	Tax incentive created to encourage businesses to undertake research and development.
Septicemia	Serious generalized infection of the body due to the discharges of pathogenic bacteria in the blood.
Simulator HIL	Real time simulator allowing the computers used to believe that they drive the real system (principal of the Hardware In The Loop test).
Stasis	In medicine the term refers to the abnormal stagnation of blood in the organ.
Systole	Phase of contraction of the muscle of a cardiac cavity allowing ejection of the blood it contains.
Telemetry	Means of following certain biological parameters, in particular cardiorespiratory or technical parameters, from a distance.
Thromboembolic	Disease characterized by the formation of coagulated blood clots (thrombus) in the veins that, when detached, risk provoking embolisms (sudden obstruction of a blood vessel).
Thrombogenic, thrombogenicity	Refers to the cause of a thrombus (blood clot).
Thrombosis	Obstruction, by the formation of a clot (thrombus), of a blood vessel, artery or vein, or a cardiac cavity (embolism). The blood no longer flows and the organs are no longer irrigated.
Total human blood	This is blood with all its constituents, in particular plasma, red corpuscles, white corpuscles and platelets.
Transplantation	Surgical operation consisting of replacing a diseased organ with a healthy one.
Vasodilator	Drug that relaxes the blood vessels to increase the flow of blood and oxygen to the heart without increasing its effort.

8.9 BIBLIOGRAPHY AND REFERENCES

Note	Page	Référence
1	14	Carpentier A. Cardiac valve surgery - the French correction. J Thorac Cardiovasc Surg.1983 Sep; 86(3):323-37.
2	18	Adamopoulos S et al. ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012. European Heart Journal (2012) 33, 1787–1847.
3	18	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.
4	18	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.
5	18	Boyle AJ et al. Predictors of poor RV function following LVAD implantation. J Heart Lung Transplant 2003 ; 22 : S205
6	18	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.
7	18	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.
8	19	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.
9	19	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.
10	19	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.
11	19	Gorodeski EZ et al. Prognosis on chronic dobutamine or milrinone infusions for stage D heart failure. Circ Heart Fail. 2009 Jul;2(4):320-4
12	19	Cowie MR et al. The epidemiology of heart failure. Eur Heart J 1997 ; 18 : 208–225.
13	19	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.
14	19	Remme WJ et al. Public awareness of heart failure in Europe: first results from SHAPE. Eur Heart J 2005 ; 26 : 2413–2421.
15	19	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).
16	19	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.
17	19	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.
18	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.
19	19	Tendera M. Epidemiology, treatment, and guidelines for the treatment of heart failure in Europe. European Heart Journal Supplements (2005) 7 (Supplement J), J5–J9.
20	19	Croft JB et al. Heart failure survival among older adults in the United States: a poor prognosis for an emerging epidemic in the Medicare population. Arch Intern Med 1999 ; 159 : 505–510.
21	20	Go A et al. Heart Disease and Stroke Statistics – American Heart Association 2014. Circulation. 2014 ; 129 : e28-e292.
22	20	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.
23	20	Heart Disease and Stroke Statistics – American Heart Association 2010.
24	20	Régime général de l'Assurance Maladie www.ameli.fr/l-assurance-maladie/statistiques-et-publications
25	20	McMurray, JJ Stewart S. Epidemiology, aetiology, and prognosis of heart failure. Heart 2000 ; 83 : 596–602.
26	20	Clegg AJ et al. Clinical and cost effectiveness of LVAD for end stage heart failure – Health Technology Assessment NHS – 2005.
27	20	American Heart Association – Heart Failure Medications - http://www. heart.org/HEARTORG/Conditions/HeartFailure/PreventionTreatmentofHeartFailure/Heart-Failure-Medications_UCM_306342_Article.jsp.
28	20	Benner JS et al. Long-term persistence in use of statin therapy in elderly patients. JAMA. 2002 ; 288 : 455-61.
29	21	Strickberger SA et al. Patient Selection for Cardiac Resynchronization Therapy, Circulation. 2005 ; 111 : 2146-2150.
30	21	Marwick TH. Restrictive Annuloplasty for Ischemic Mitral RegurgitationToo Little or Too Much. J Am Coll Cardiol. 2008 ; 51(17):1702-1703.
31	21	Garbern J et al. Cell Stem Cell, Volume 12, Issue 6, 689-698, 6 June 2013.
32	21	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.
33	21	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.
34	21	Latrémouille C et al. Transplantation cardiaque. EMC - ©Elsevier, Techniques chirurgicales - Thorax, 42-748, 2006.
35	21	Agence de la biomédecine - Synthèse nationale de prélèvement et de greffe 2012 et annexe au bilan 2012.
36	21	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.

Note	Page	Référence
37	22	Agence de la biomédecine – Rapport d'information au Parlement et au Gouvernement – septembre 2013
38	22	Lindenfeld JA et al. Drug Therapy in the Heart Transplant Recipient. Circulation.2005 ; 111 : 113-117
39	22	Milliman Report 2011 - Table 2 : Estimated U. S Average 2011 Billed Charges Per Transplant (the 2014 report is not yet available at the date of drafting this document).
40	22	Agence de Biomédecine - Modalités de financement 2013 des activités de prélèvement et de greffe d'organes, de tissus et de cellules souches hématopoïetiques - www.agence-biomedecine.fr
41	25	Shareholder Newsletter n° 3 - January 2013.
42	26	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.
43	26	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.
44	27	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.
45	28	Information presented at the 64th convention of the French Society of Thoracic and Cardiovascular Surgery (SFCTCV) in Lyon, 26-27 May 2011.
46	29	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.
47	31	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.
48	34	FDA Panel review Summary of Safety and Probable Benefit - H040006 - AbioCor® Implantable Replacement Heart. http://www. accessdata.fda.gov/cdrh_docs/pdf4/H040006b.pdf.
49	34	Acker MA et al. Statement regarding the pre and post market assessment of durable, implantable ventricular assist devices in the United States. Ann Thoracic Surg 2012; 94(6): 2147-58.
50	34	Latremouille C et al. Sub-Acute Implantation of a Novel Bioprosthethic Artificial Heart. J Heart Lung Transplant 2012 ; 32(4) : S174-S175.
51	35	Shareholder Newsletter n° 4 - July 2013.
52	36	Shareholder Newsletter CARMAT - January 2014.
53	37	Paragraphes 3.13 p. 3 et 5.11 p. 16 de la norme Européenne ISO 14155 : 2012-05.
54	38	ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2008. European Heart Journal (2008) 29, 2388–2442 (out of approximately 900 million inhabitants in the 51 countries member of the European Society of Cardiology).
55	38	Heart Disease and Stroke Statistics – 2010 Update at a glance – American Heart Association and American Stroke Association.
56	38	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.
57	38	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.
58	38	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.
59	39	ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012 - European Heart Journal (2012) 33, 1787–1847.
60	39	Haute Autorité de la Santé website - La HAS s'attaque à l'infarctus du myocarde – Mai 2007.
61	39	Heart Disease and Stroke Statistics – 2010 Update at a glance – American Heart Association and American Stroke Association.
62	39	Yeh RW et al. Population Trends in the Incidence and Outcomes of Acute Myocardial Infarction. N Engl J Med 2010 ; 362 : 2155-2165.
63	39	Perspectives de la population mondiale - Révision de 2006, Organisation des Nations unies - Département des affaires économiques et sociales, 2007.
64	39	Haute Autorité de la Santé website - La HAS s'attaque à l'infarctus du myocarde - Mai 2007.
65	39	Roger VL. Epidemiology of myocardial infarction. Med Clin North Am. 2007 July ; 91(4): 537–ix.
66	39	http://www.cdc.gov/dhdsp/atlas/2010_heart_atlas/docs/Executive_Summary.pdf - page 16.
67	39	Yeh RW et al. Population Trends in the Incidence and Outcomes of Acute Myocardial Infarction. N Engl J Med 2010 ; 362 : 2155-2165.
68	39	http://www.cdc.gov/dhdsp/atlas/2010_heart_atlas/docs/Executive_Summary.pdf - page 16.
69	39	Roger VL. Epidemiology of myocardial infarction. Med Clin North Am. 2007 July ; 91(4): 537–ix- Table 1.
70	39	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.
71	39	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.

Note	Page	Référence
72	40	51 pays adhérents de la Société Européenne de Cardiologie, incluant notamment l'Europe de l'Est, la Russie et les pays du Golfe (se reporter à la note bibliographie n° 54).
73	41	Kirklin JK et al. The Fifth INTERMACS Annual Report. J Heart Lung Transplant 2012 ; 32 : 141–56 - February 2013 http://www.uab.edu/medicine/intermacs/images/Federal_Quarterly_Report/Federal_Partners_Report_2013_Q3.pdf 9,791 patients at September 30, 2013. (data only for the United -States and only for the devices marketed, outside clinical trials. A EUROMACS registry will be available shortly – www.euromacs.org – it does not yet display public statistics.
74	42	Kirklin JK et al. The Fifth INTERMACS Annual Report. J Heart Lung Transplant 2012;32:141–56 - Février 2013 http://www.uab.edu/medicine/intermacs : 9 791 patients au 30 septembre 2013. (Données uniquement pour les États-Unis et uniquement pour les dispositifs commercialisés – hors essais cliniques, Un registre EUROMACS est en cours de création – www.euromacs.org – mais ne met pas encore à disposition de statistiques publiques).
75	42	Najjar S et al. An analysis of pump thrombus events in patients in the HeartWare ADVANCE bridge to transplant and continued access protocol trial. J Heart Lung Transplant. 2014 Jan ; 33(1):23-34.
76	42	Devices indicated in waiting for recovery (Bridge to Recovery: BTR) are not mentioned here. Indeed, their indications and their technologies are very different. They can provide only a limited assistance (around 2 liters/minute vs. 9 liters/minute for the CARMAT heart) for a very limited time (from a few hours to a few days) and are intended for patients without permanent ventricular deterioration, who need temporary hemodynamic support, for example after surgical intervention or post-traumatic hemorrhage.
77	42	Presentation by Dr J. Teutenberg (University of Pittsburgh, Pennsylvania) at the International Society for Heart and Lung Transplantation (ISHLT) - Montreal, Quebec, Canada-April 24-27, 2013.
78	42	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.
79	42	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.
80	42	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.
81	42	Boyle AJ et al. Predictors of poor RV function following LVAD implantation. J Heart Lung Transplant 2003 ; 22 : S205.
82	42	Fitzpatrick JR et al. Risk score derived from pre-operative data analysis predicts the need for biventricular mechanical circulatory support. J Heart Lung Transplant 2008 ; 27 : 1286–92.
83	42	Fitzpatrick JR et al. Early planned institution of biventricular mechanical circulatory support results in improved outcomes compared with delayed conversion of a left ventricular assist device to a biventricular assist device. J Thorac Cardiovasc Surg 2009 ; 137 : 971-977.
84	43	HeartWare® website HeartWare International 2013 Fourth Quarter and Year-End Results Conference Call - Thursday, February 27, 2014.
85	43	Hetzer R et al. Long-term biventricular support with the HeartWare implantable continuous flow pump. J Heart Lung Transplant 2010 ; 29 : 822-4. Loforte A et al. Biventricular support with the HeartWare implantable continuous flow pump: An additional contribution. J Heart Lung Transplant 2010 ; 29 : 1443-4.
86	43	Loforte A et al. Biventricular support with the HeartWare implantable continuous flow pump: An additional contribution. J Heart Lung Transplant 2010 ; 29:1443-4.
87	43	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/.
88	43	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.
89	43	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.
90	43	Brenyo A et al. Risk of mortality for ventricular arrhythmia in ambulatory LVAD patients. J Cardiovasc Electrophysiol. 2012 May ; 23(5):515-20.
91	43	Backes D et al. Cerebrovascular complications of left ventricular assist devices. Eur J Cardiothorac Surg (2012). doi : 10.1093/ejcts/ezs320.
92	43	Starling R et al. Unexpected abrupt increase in left ventricular assist device thrombosis. N Engl J Med 2014 ; 370 : 33-40.
93	44	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.
94	44	The reader is invited to carry out his or her own research and to form his or her own opinion in this domain. For example, Jarvik 2000 (www.jarvikheart.com), Sunshine Heart (www.sunshineheart.com), etc.
95	44	www.syncardia.com – all the information concerning Syncardia is taken from their website, unless specifi cally stated otherwise.
96	44	Historical information on Jarvik 7 is available on Jarvik Heart's website: www.jarvikheart.com.
97	44	www.intermacs.org – Statistical updates - Quarterly Statistical Report 2013 3rd Quarter.
98	44	FDA (2004) – Summary of Safety and Effectiveness Data – PO30011 – disponible sur le site de Syncardia ou sur celui de la FDA.
99	45	Slepian MJ et al. The SynCardia total artificial heart: in vivo, in vitro, and computational modeling studies. Journal of Biomechanics 46 (2013) 266-275
100	45	Adapted from 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.

Note	Page	Référence
101	45	Dowling RD et al. Initial experience with the AbioCor Implantable Replacement Heart System. J Thorac Cardiovasc Surg 2004 ; 127 : 131-41.
102	45	www.abiomed.com – all information concerning Abiomed® is taken from their website, unless otherwise mentioned.
103	45	Laumen M et al. Projekt ReinHeart : Lebensretter Kunstherz. Dtsch Arztebl 2013 ; 110(46): [11] (article in German).
104	46	Adapted from European Heart Network – Cardiovascular statistics 2008 - www.ehnheart.org.
105	46	Translated from 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.
106	46	Eurotransplant (register of donor organs and transplants for Germany, Belgium, the Netherlands, Austria, Croatia and Slovenia). www.eurotransplant.org.
107	46	Activité de prélèvement et de greffe : organes, tissus et cellules. Synthèse nationale 2010 - Édition octobre 2011 - Data extraction as at March 2011 - Agence de biomédecine website.
108	46	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.
109	46	Beyersdorf F. Heart Transplant and Artificial Heart Systems. Dtsch Arztebl Int. 2009 July ; 106(28-29): 469–470.
110	47	Liste des Produits et Prestations remboursables – LPP (ameli.fr) : the regulated unit price of a monoventricular HeartMate II® is fixed at €87,565 (11/29/2012 decree).
111	48	Shareholder Newsletter n° 5 - January 2014.
112	48	Shareholder Newsletter n° 2 - July 2012.
113	48	Shareholder Newsletter n° 3 - January 2013.
114	65	http://ec.europa.eu/health/medical-devices/files/revision_docs/citizen_summary_20120926_en.pdf.
115	66	http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ucm310927.htm.

Designed & published by Labrador +33 (0)1 53 06 30 80

CARMAT SA | Immeuble l'Etendard | CS 40533 | 36, avenue de l'Europe | 78941 Vélizy-Villacoublay cedex | FRANCE
téléphone | +33 1 39 45 64 50 — télécopie | +33 1 39 45 64 51
siret | 504 937 905 00025 — No. TVA intra | FR35 504 937 905