Annual Shareholders' Meeting of 4 June 2013

Written questions put to the Board of Directors of CARMAT SA, received by 29 May 2013

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The annual shareholders' meeting originally scheduled for 25 April 2013 was postponed until 4 June 2013 due to an error made by the BALO (*Bulletin d'Annonces Légales Obligatoires*), officially acknowledged by the BALO in a letter dated 22 April 2013.

For the record, written questions are only acceptable if they are related to matters tabled on the agenda for the annual shareholders' meeting. They must also be addressed to the Chairman of the Board of Directors and sent to the Company's registered office by registered mail return receipt requested no later than the fourth business day before the date of the meeting (i.e. 29 May 2013), accompanied by a certificate evidencing the asker's share ownership.

Article L. 225-108 indent 4 of the French Commercial Code permits the Board of Directors to answer written questions put by shareholders without repeating them at the shareholders' meeting provided they have been posted on the company's website in a special Q&A section.

The Board of Directors has therefore decided to publish on the company's website, prior to the shareholders' meeting of 4 June 2013, a single document containing its answers to all written questions received before both the original and the postponed meeting to take account of developments between 25 April and 4 June 2013.

Thirty written questions were received by the Company from two shareholders, in accordance with the terms and conditions and within the timeframe required by law.

These questions are reproduced below in full in their original form.

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Questions from Mr. Cyrille Goulard (162 shares) received on 25 March 2013

CARMAT has put back the scheduled date for its first human implant several times: "end 2011", then "1st or 2nd quarter 2012", then "in 2012" (source: press releases and shareholder newsletters 1 to 3).
What are the main reasons for this?
Given the information in the company's possession to date, is the technical file to be submitted to the ANSM (French national health authority) in order to obtain authorisation for the first implant now complete?
If not, when do you expect to have the final data?
When does CARMAT think it will be able to perform the first human implant?
Has CARMAT taken or will it take measures to catch up part of the delay?

> *The timing delays were due partly to difficulties in setting up the industrial process in 2012 and partly to the additional pre-clinical activities required by the ANSM in the 1st quarter of 2013. The reasons are detailed in the Company's 2011 and 2012 Registration Documents[1] (registered by the Autorité des Marchés Financiers French stock exchange authority respectively on 12 September 2012 under number R.12-044 and on 30 May 2013 under number R.13-027), and in the Company's Annual Financial Report for the year ended 31 December 2012, published on 4 April 2013.*
> *The "technical" file comprising all the bench tests is complete. Only the animal trials are still ongoing.*
> *The adjusted expected timetable is set out in sections 6.1 and 6.4.7 of the Company's 2012 Registration Document registered by the Autorité des Marchés Financiers on 30 May under number R.13-027, where it is specified that "The timing difference between the above timetable and the one published in the previous registration document is principally due to the continuation of animal trials required by the ANSM in the 1st quarter of 2013 (see section 6.3.3.1 on page 59 onwards) …".*
> *In line with the previous timetable, we have also set up a clinical trial programme in other countries (see press release dated 14 May 2013).*

In its business plan, CARMAT said it envisaged obtaining agreement from the patient protection committees in other countries (or regions) of the European Union to perform implants there. Has CARMAT applied for or obtained authorisation to carry out a first implant outside France?

> *The implementation of an international clinical trial programme was in fact announced in the timetable appearing on pages 36 and 73 of the 2011 Registration Document registered by the Autorité des Marchés Financiers on 12 September 2012 under number R.12-044. The requisite procedure was therefore implemented in parallel with our entirely French activities and resulted in the agreement of 4 cardiothoracic surgery centres to perform the first implants (see press release dated 14 May 2013). It is actually good clinical practice to conduct a multicentre international study as this not only helps avoid the procedural bias specific to a single country or centre, but also provides a global basis for a product that is not intended only for the domestic market.*

In its press release of 4 March 2013 on 2012 financial results, CARMAT said: "The Company has also set up a clinical trial programme in other countries, in order to be able to count on other centres to initiate or extend trials as quickly as possible." Does this mean that CARMAT could perform its first implant outside France?

> *The agreements with 4 centres abroad, under the regulations prevailing in each country and particularly those concerning the compassionate use of a device not yet available on the market, could result in an initial implant in some countries as soon as the training process ends. In France, three teams have already been trained and the patient protection committee has given its agreement: the first implant could therefore take place in France as soon as we have completed the animal trials enabling us to make formal application to the ANSM for authorisation to conduct clinical trials. We will therefore have 7 fully trained centres.*
> *All options therefore remain open as to where the first implant will be performed.*

In an interview given to Reuters in October 2012, Mr. Conviti talked about negotiations with a view to potential partnerships. At which milestone could such a partnership or partnerships be implemented (ANSM agreement, first human implant, end of phase 1 or 2 clinical trials, CE marking, etc.)? What form could they take (shareholding, industrial partnership, etc.)?

[1] Registration documents are avalable on the Company's website (www.carmatsa.com) in the Investors section, heading Documentation/Registration Documents.

As indicated in the interview: "When it comes to the marketing stage, CARMAT plans to enter into partnerships […]. But the company […] intends to remain independent, he stressed."
It would be premature to speculate on the type of partnerships that might be possible in the future, as some major scientific and regulatory milestones have yet to be successfully completed.

Questions from Mr. Fabrice Jordan (2 shares) received on 5 April 2013

Have you filed an application with the ANSM for authorisation for phase 1 implants? If so, when?

As indicated in the Company's Annual Financial Report for the year ended 31 December 2012, published on 4 April 2013 (page 8), "As a result, in-vitro pre-clinical tests were finalized during the 4th quarter of 2012." These data have been included in the pre-submission file opened with the ANSM. The "technical" part of the file is therefore complete. In addition, as indicated in sections 6.1 and 6.4.7 of the Company's 2012 Registration Document registered by the Autorité des Marchés Financiers on 30 May under number R.13-027, "the Company is continuing the requisite pre-clinical activities and hopes to make a formal application to the ANSM for authorisation to conduct clinical trials at the end of the 1st half of 2013."

Will you announce that you have obtained ANSM authorisation before performing the first implant?

We have promised many times to make a public announcement as soon as we receive authorisation. We have already announced our agreements with the international centres and will announce the ANSM's decision as soon as it is known.

Will you give information about phase 1 implants during rollout or will we have to wait for the end of the phase for details of each implant?

Patients taking part in biomedical research are, rightly, protected by a very strict regulatory and legislative framework. This includes data protection and review by a panel of experts who have no connection with the study's sponsor. The panel includes a biostatistician. In view of these requirements and the profile of phase one patients, who have a very limited life expectancy prior to the operation, it is not possible from a regulatory or ethical point of view to give details of individual patients, nor would it have any statistical or scientific value. The normal practice is therefore to release results in a report drawn up by the principal investigator on all the study's subjects, published in a peer-reviewed publication. Note that the protocol for phase one requires monitoring of each patient for 30 days before being able to make a judgment on the success criteria (see page 61 of the 2012 Registration Document registered by the Autorité des Marchés Financiers on 30 May under number R.13-027).

If you haven't already applied to the ANSM for authorisation, when do you plan to do so?

As indicated in sections 6.1 and 6.4.7 of the Company's 2012 Registration Document registered by the Autorité des Marchés Financiers on 30 May under number R.13-027, "the Company is continuing the requisite pre-clinical activities and hopes to make a formal application to the ANSM for authorisation to conduct clinical trials at the end of the 1st half of 2013."

EADS will not use a lithium-ion battery in its new aircraft; do you plan to use it? Do you have a backup solution? What's the difference between your lithium-ion battery and Boeing's?

Lithium-ion batteries are very widely used in portable devices (telephones, laptops, etc.) and especially in medical devices because of their high energy density. This is particularly the case for ventricular assist devices where the patient's mobility is crucial and for patients who will have a CARMAT heart. Lithium-ion batteries are also used in many life support systems, including implantable ventricular assist devices.
Although the technology is the same, there are many differences compared with the batteries used by Boeing, such as power (several tens of watts for CARMAT, several Kilowatts for Boeing) and environmental conditions.
Lithium-ion batteries can be safe and reliable when used in a life support system. In addition, their use is only envisaged for the initial devices. CARMAT is, in fact, also developing a fuel cell battery in association with PaxiTech.[2]

If the implant is marketed, will the price fall? What annual volumes will be needed before prices can fall?

Commercial strategy is dealt with in section 6.4.3 of the Company's 2012 Registration Document registered by the Autorité des Marchés Financiers on 30 May under number R.13-027, and price assumptions are discussed more specifically on page 72. No new developments have changed this. The Registration Document states that "price target for CARMAT's bioprosthetic artificial heart project is still between €140,000 and €180,000. This price range is in line with current reimbursement practices for existing devices. For example, reimbursement levels in Europe for a single left ventricular assist device currently range from €60,000 to €110,000. For a system that includes an implantable device plus external parts and associated pre- or post-operative services, the adjustment variables are numerous and will enable us to adapt to volume and reimbursement conditions specific to each centre or market."
Prices are set in each country by the social security system or private health insurers and take account of the medical service provided compared with existing alternatives and the annual volume of patients. If an increase in the volume of implants were to lead to a price cut, we can assume that the number of implanted patients requiring post-operative care would be higher. A fall in the price of the implant could thus be offset by the revenue generated by these services. They would also be reimbursed by the social security systems or private health insurers on the basis of a monthly fixed sum per patient (for example, in France, in the region of €7,200 a year for a left ventricular assist device).

[2] See CARMAT's Shareholder Newsletter no. 2, avalable on the Company's website (www.carmatsa.com) in the Investors section, heading Documentation/Shareholder Newsletter.

Questions from Mr. Fabrice Jordan (2 shares) received on 17 April 2013

Are you still conducting tests at the ANSM's request?

As indicated in the Company's Annual Financial Report for the year ended 31 December 2012, published on 4 April 2013, the bench tests have been completed and the results included in the file in the 4th quarter of 2012. As indicated in the Company's 2012 Registration Document registered by the Autorité des Marchés Financiers on 30 May under number R.13-027, particularly in sections 6.1, 6.3.3.1 D and 6.4.7, the only trials still ongoing are the animal trials requested by the ANSM in the 1st quarter of 2013.

Do you plan to make a new capital increase in the next three months?

We had about €11 million of cash at end April 2013, including a €5 million research tax credit received in April 2013 (see press release dated 23 April 2013). We also expect to receive about €6.7 million from Oseo during 2013, once we have completed milestone 4, which is contingent on receiving the ANSM's conditional authorisation to begin clinical trials. We will then have more than twelve months' cash at the current rate of consumption and, therefore, sufficient resources to conduct our clinical trial programme. We are, of course, always on the look out for financing opportunities compatible with our strategy that would consolidate or accelerate the pre-marketing stages.

Questions from Mr. Cyrille Goulard (162 shares) received on 14 May 2013

N.B.: This section only contains different or supplementary questions from those received on 25 March 2013, which have been dealt with above.

Questions about the delays compared with the initial business plan:

If the ANSM requires additional tests, what are the minimum expected results?

As explained in the Company's 2012 Registration Document registered by the Autorité des Marchés Financiers on 30 May under number R.13-027 (page 59 onwards), the ANSM asked for a further animal trial over longer periods than the 48 hours in the initial trials.[3] The new protocol aims to confirm the return to normal of clinical indicators (standing, spontaneous feeding, normal renal and digestive function) as well as haemodynamic and biological indicators, particularly the absence of haemolysis, over the longest possible period without causing suffering to the animal. The post-mortem examination must show the absence of thrombosis in the device and the animal's organs.
These trials are complex to conduct as the device is designed specifically for the human anatomy and physiology and is not adapted to animals (see pages 58 and 59 of the Company's 2012 Registration Document registered by the Autorité des Marchés Financiers on 30 May under number R.13-027). The pre-operative cardiac output for these animals, which weigh about 100 to 120 kg, is between 11 and 15 litres a minute, whilst the device designed for a human adult has a maximum output of 9 litres a minute. The device has therefore demonstrated its ability to function at its maximum output. However, this maximum output only just covers the metabolic needs of a calf aged 2 to 4 months weighing 100 to 120 kg and gaining weight at a rate of more than 15 to 20 kg a week: the trial therefore cannot be continued for very long to avoid suffering to the animal. However, many regulatory agencies, including the ANSM and the FDA, continue to request chronic animal trials before authorising human trials. These animal trials are therefore in progress and are on track with our expectations.

A presentation made at an investors' meeting held in June 2012 in New York, which was available on the website for a while but has since been removed, could, unless I am mistaken, imply that the phase 2 timetable requires more time than was indicated in the registration documents. What is the situation?

[3] Sub-Acute Animal Implantation of a Novel Bioprosthethic Artificial Heart. Latremouille C. et al, The Journal of Heart and Lung Transplantation Vol. 32, Issue 4, Supplement, Pages S174-S175.

The adjusted expected timetable set out in the 2012 Registration Document registered by the Autorité des Marchés Financiers on 30 May under number R.13-027 envisaged a phase 2 start in the 2nd half of 2013 with marketing in 2014 at the earliest.

Questions about the first implants in France or in other countries

The 2011 Registration Document refers to obtaining authorisation for phase two clinical trials. This element does not appear to have been included in the overall timetable. Does this mean that agreement can be obtained at the end of phase one clinical trials without any further delay?

Subject to the feasibility study giving satisfactory results, phase two trials will be the subject of a different protocol including patients with a better prognosis and monitored over a period of 180 days. We have always planned for the time required to submit this new protocol to the competent authorities, in France or elsewhere. The adjusted timetable in the 2012 Registration Document registered by the Autorité des Marchés Financiers on 30 May under number R.13-027 also includes this time period.

Furthermore, what is the event that marks the end of phase one clinical trials? (6 months after implantation in the final phase one patient?)

The feasibility study protocol provides for 30-day monitoring or successful bridging to a heart transplant within the 30 days. The end of the trial is therefore 30 days after the final patient's implantation or successful bridging to a heart transplant. 6-month monitoring (180 days) is for phase two trials.

Questions about industrial development

Has the company been able to fully implement its second supply source plan for critical components, announced to shareholders at the time of the July 2011 rights issue?

We have made progress in implementing second supply sources, but it is an ongoing iterative process. Depending on the complexity of the component or subassembly, it takes several months to several years. We have to identify which sub-contractors have the right expertise, select one of them and deal with the contractual aspects of the agreement, then have the sub-contractor manufacture several parts to our quality standards and check their conformity to the first supply source parts. We also have to implement quality controls, make sure the manufacturing process is properly documented and then begin manufacturing. We have therefore not yet finished assessing all the various second supply sources envisaged since 2011, but we believe we have made significant progress in that direction. The process has also enabled us in some cases to renegotiate the terms of our agreement with first supply sources.

How long does it currently take on average to assemble a full artificial heart (assuming that all the components are available)?

Once all the components are available, it takes about 12 weeks on average to obtain an artificial heart and all its accessories in sterile packaging ready for clinical use. This includes the mandatory "quarantine" periods required for regulatory sterility testing, periods during which the device and its accessories are stored in a controlled environment for a precise period pending biological tests and analyses.

How many assembled devices does the company currently have for conducting clinical trials on humans?

Several devices intended for clinical trials are currently being manufactured, each one at a different assembly stage, some in the final test or sterilisation phase. On the day of the operation, two full sets of the device and accessories are required for each implant, in case of accidental contamination in the operating theatre.

Question about investor communications

With its innovative artificial heart project, CARMAT is obviously invited to take part in various scientific events during which presentations may be made about progress (for example during European Days held by the

Société Française de Cardiologie (SFC) in January 2013). According to the public interview given in October 2012 to Reuters, the company was envisaging a first implant in January 2013. Yet during the SFC's European Days, the specialist press talked about a new timetable of "six weeks to six months" (source: "Theheart.org" among others).
Do you plan to take any particular measures to make sure that all shareholders obtain the same information – whether or not they are health professionals (for example, a press release following a scientific event when comments made, even verbally, have not previously been made public)?

We release our expected timetable regularly as and when new developments occur. In October 2012, therefore, in line with the timetable published several weeks prior to that in the 2011 Registration Document, we envisaged filing the latest data with the ANSM, particularly those resulting from endurance tests and short-term animal implants, in the 4th quarter of 2012. This was done in December and enabled us to envisage authorisation and a first implant in early 2013. We had no other information in October 2012.
Similarly, in January 2013, during the Société Française de Cardiologie's European Days, we had already filed those data but had not yet been asked by the ANSM to conduct further animal trials and could therefore not unveil any details about a new timetable. That is also why, in our Annual Financial Report published on 4 March 2013, we said that we were in the process of reviewing our expected scientific and regulatory timetable.
An adjusted expected timetable therefore appears in the 2012 Registration Document registered by the Autorité des Marchés Financiers on 30 May under number R.13-027, following new events that have occurred since then and which were made public in a press release. We would remind you that only those press releases made by official representatives of the Company are binding. Private comments made by people involved in or external to the project, rumours, opinions, articles, titles or reports of interviews or meetings, analyses, blogs or comments on forums simply reflect the opinions of their authors, on which the Company does not comment.

Questions from Mr. Fabrice Jordan (2 shares) received on 17 May 2013

You announced that 3 hospitals in 3 European countries could perform implants. These 3 countries are subject to the same conditions as those imposed by the ANSM in France, so presumably the 3 hospitals have to submit a file to the medical authorities in their country?

We announced in our press release of 14 May last that we had obtained authorisation to perform the first implants in four internationally renowned cardiothoracic surgery centres. These clinical collaboration agreements with highly reputed centres and surgeons bear witness to the international scientific community's interest and validate the maturity of our project. It goes without saying that CARMAT and those centres will comply with all the local and national rules and regulations that apply to implantation of the devices.

Have applications for authorisation been submitted in the 3 countries to an authority equivalent to the ANSM? If so, has the authority granted authorisation? Which countries are they? If the applications have not yet been submitted, when will they be? What is the timeframe for each country?

The process required for the first implants includes validation of the protocol by the ethics committees, all requisite translations, taking out insurance contracts, notifying the supervisory organisations, drawing up contracts, etc. The process is being undertaken with support from the centres and is at various stages of progress depending on practices in each country. For example, all the ethics committees have issued a favourable opinion.
The training process is being carried out in parallel. This not only involves the surgeons, but also everyone else involved in selecting the patient, in the operation itself and in post-operative care. So we are not training individuals but teams of surgeons, cardiologists, anaesthetists/reanimators, perfusionists, biomedical engineers and nursing staff, both in the operating theatre and in reanimation and intensive care units. Then, a patient who fits the protocol has to be identified and his or her anatomical compatibility with the device verified using our 3D virtual simulation tool. Finally, and most

importantly, the patient has to give his or her consent. The ethical aspect of obtaining informed consent from the patient or his or her family is fundamental.
We could therefore very soon have 7 trained centres, 4 abroad and 3 in France. Depending on how quickly the other stages develop in their respective countries, these centres could take part in the feasibility study (the first 4 patients) and/or the pivot study (the next twenty or so patients).

Questions about Saudi Arabia

Has an application for authorisation been submitted to the Saudi medical authority? Has authorisation been obtained?

An application for authorisation has been filed with and approved by the hospital; there is no central national authority.

Who serves as the "external assessment organisation" for Saudi Arabia? In other words, whom will Saudi Arabia ask to review the application?

The Prince Sultan Cardiac Center is autonomous in its decisions to authorise clinical trials. It consults international experts to review and give an opinion on applications submitted.

Question from Mr. Fabrice Jordan (2 shares) received on 28 May 2013

Why did you bench test horizontally for 5 years rather than vertically as on an upright human being?

The devices were tested in various positions including horizontally and vertically. We developed several types of benches so that we could test the device in different environments reflecting human activity: for example, physiologies of various patients even including extreme or pathological conditions, life cycles reproducing a daytime and night-time activity, different positions simulating various postures during a human activity, etc.