

# **ASIT BIOTECH**

Société anonyme

Avenue Ariane 5

B-1200 Brussels

RPM Brussels 460.798.795

Management report of the Board of Directors for the financial year ended 31 December 2015





# Report of the board of directors

Dear Shareholders, in accordance with the legal requirements and those laid down in the Company's Articles of Association, we are pleased to present you our report on the activities of our Company during the financial year and submit to you, for your approval, the annual accounts for the financial year ended on 31 December 2015. More extended information on the Company and its activities can be found in our annual report or in the IPO prospectus available on the website of the Company (www.asitbiotech.com).

# 1. Strategic highlights

# Current operations and principal activities of the Company and the principal markets in which it competes

The Company is a clinical-stage biopharmaceutical company, focused on the research, development and future commercialisation of a range of immunotherapy products for the treatment of allergies, but has to date no product approved or commercialised. The Company believes that its breakthrough immunotherapy product candidates, based on the Company's innovative technology, ASIT+TM, have the potential to address the risks and limitations of current allergy immunotherapy treatments. Whole allergen immunotherapy is the only current therapy available on the market that targets the cause of allergy. However, it often causes significant side-effects and requires a lengthy and inconvenient course of treatment resulting in limited real-life effectiveness. The Company therefore believes that there is a large and attractive market for its immunotherapy product candidates.

### ASIT+TM platform

The ASIT+<sup>TM</sup> platform allows the production, characterisation and quality control of truly new active ingredients consisting of highly purified natural allergen fragments, in an optimal size selection. In the framework of phase I and phase II clinical studies, it has been demonstrated that the grass pollen ASIT+<sup>TM</sup>:

- triggers a rapid immune response without the need for an adjuvant, leading to the potential for at least one-year protection;
- induces minimal side-effects;
- reduces the reactivity to an allergen provocation test; and
- allows for a faster injection regimen of higher doses, compared to treatments with whole allergens, resulting in a reduced course of treatment with four doctor visits over 3 weeks.

# Therefore, the Company believes that:

- the absence of an adjuvant improves the overall safety profile and represents a real advantage with respect to long-term safety; and
- the reduced course of treatment will improve patient compliance and, therefore, real-life clinical effectiveness.

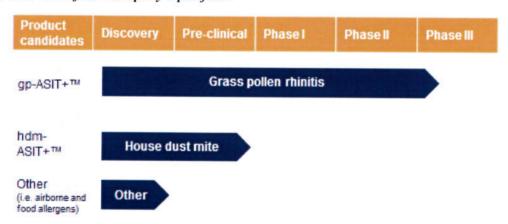
### 1.1. Portfolio

The Company has demonstrated clinical proof-of-concept for its candidate lead product, gp-ASIT+TM with compelling and statistically significant phase IIa and phase IIb clinical study results. The Company currently performs the phase III clinical study for the same and it expects to have results available for this phase III clinical study by Q1 2017. Subject to the results of such study, the Company intends to file a first marketing authorisation application for gp-ASIT+TM in Germany (to the Paul Ehrlich Institute, the "PEI") by Q2 2017 and obtain it one year later (Q2 2018) in order to launch the product immediately thereafter.

The Company intends to start clinical development in the United States as soon as possible. A meeting with the Food and Drug Administration ("FDA") will be requested during the first semester of 2016. The Company intends to start the clinical studies in the United States according to the outcome of this meeting and to have the second phase III clinical study completed by the end of 2018. The Company believes that this timing allows for the performance of a Phase II study in 2016-2017 if such study would be required by the FDA. The completion of the clinical development in the United States will require additional funding as from Q4 2017. The precise timing and quantum of the additional funding are dependent upon (i) the proceeds of the Offering and (ii) the progress the Company will make in the further clinical and preclinical development of its product candidates post-Offering.

In addition, the Company intends to start a phase I/II study with hdm-ASIT+TM for the treatment of house dust mite allergy at the beginning of Q3 2016 and to pursue the clinical development with a phase IIb study for which results are expected at the end of 2017. The Company is also developing product candidates for the treatment of other respiratory and food allergies which are currently in discovery phase.

### 1.2. Overview of the Company's portfolio



### 1.3. Commercialisation

To date, none of the product candidates of the Company has been approved or commercialised. The Company believes that, if approved, the attractive product profile of its immunotherapy product candidates will increase the number of patients (i) to whom the treatment is offered, (ii) accepting treatment and (iii) completing the course of therapy. The Company has retained all commercial rights to its product candidates.

Germany is currently the first worldwide market in terms of sales of subcutaneous immunotherapy products and the United States are currently the first worldwide market in terms of patients treated with

subcutaneous immunotherapy products. Therefore, these two markets are the first markets targeted by the Company. Given the limited number of allergists in these first target markets, the Company intends to build or acquire its own sales and marketing infrastructure to commercialise these product candidates. The Company may also consider alternative ways of commercialising its product candidates in these countries, including partnering with or acquiring other companies that have the requisite infrastructure. In the rest of the world, the Company plans to market its product candidates via licensing or other forms of partnership.

### Major events during the financial year 2015 2.

#### 2.1 Phase III clinical study with gpASIT+TM

Early 2015, the Company has decided to launch a Phase III clinical study to confirm the safety, the tolerability and the clinical efficacy of gpASIT+TM in real-life during the grass pollen season. To face the challenge of the further development of gpASIT+TM, about 10 new scientific collaborators have been hired. Agreements sere entered intod with GMP CMO's for the manufacturing of clinical batches of the drug substance and the drug products. CRO's have been recruited for the launch and the followup of the Phase III clinical study. The clinical trial documentation of the Phase III has been filed in July 2015 in six European countries. The investigator meeting was held in Brussels by the end of October and the approvals by the Regulatory Authorities and the Ethical Committees were obtained by mid-November 2015. All the clinical centres have been open early 2016 and 549 patients have been recruited before the start of the pollen season.

#### 2.2 New name for the Company

On 5 August 2015 the shareholders' meeting approved the modification of the name of the Company, from Biotech Tools to ASIT biotech.

#### 2.3 Issuance of convertible bonds

On 5 August 2015, the Company issued 413 convertible bonds with a nominal value of EUR 10,000 each (the "Convertible Bonds"). The Convertible Bonds were in registered form and bear an interest of 6% p.a. Interest was computed on the basis of a 360-day basis and the actual number of days that have lapsed since the issuance of the Convertible Bonds. The conversion of the Convertible Bonds into Shares took place automatically on the date of the initial public offering (12 May 2016).

### 2.4 Winding-up of Biotech Tools Factory SA

On 26 June 2015, the Company approved the liquidation of its subsidiary Biotech Tools Factory SA, which was an empty shell.

### 2.5 Modification of the articles of association of the Company

On 26 June 2015 the shareholders' meeting approved a modification of the articles of association of the Company with a view to implement the standards of listed companies. Some modifications took effect immediately and others were adopted under the condition of the IPO.

### 2.6 Preparation of the IPO

During the accounting year 2015 a lot of actions were taken with a view to preparing the listing of the Company on Euronext Paris and Euronext Brussels. Amongst other things Corporate governance principles were implemented and IFRS accounts were adopted.

### 3. Financial review 2015

	2015	2014	2013	
	(in thousand euros)			
IFRS Loss for the year	7,715	4,429	2,319	
BGAAP Loss for the year	4,042	1,384	2,315	
IFRS Equity	(858)	7,432	42	
BGAAP Equity	6,199	10,241	6	
IFRS Cash and cash equivalent	4,621	8,441	1,245	
Bgaap Cash and cash equivaler	nt 4,621	8,410	1,211	
Staff	20	10	10	

It is to be noted that due to the fact that the Company is mostly engaged in research activities, over 80% of the IFRS loss of the year is related to research costs (EUR 6,691 K, as of December 2015) with the balance being general and administrative expenses.

The amount of research costs incurred on a yearly basis is quite variable as the bulk of these expenses are related to amounts spent on outside contracts depending of the type of study the Company intends to perform. As the Company does not generate any revenue, its spending level is directly related to its ability to raise funds.

Therefore as the Company's funding improved between 2013 and 2015, its spending on research and development has also increased in parallel from EUR 1,670 K in 2013, to EUR 3,541 K in 2014 to reach EUR 6,691 K as of December 2015. Research spending is allocated up to 60% to gp-ASIT+TM, the Company's most developed product. Hdm-ASIT+TM represents up to 20% of the spending, the residue is allocated to other product candidates (eg. ragweed, egg white).

The Company has always had a very low level of investments. Acquisitions made in prior years amounted respectively to EUR 26,000 in 2013 and EUR 182,000 in 2014. In 2014, acquisitions mainly related to manufacturing and laboratory equipment (EUR 160,000) such as Chromatography

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columns/Holder/Jacketed vessels and tanks used to produce and/or test the drug substance for the product candidates.

Per 31 December 2015, the main investments made for manufacturing and laboratory equipment amounted to EUR 328,000. In addition, the Company invested EUR 14,000 in IT equipment and EUR 30,000 in furniture.

The net Investments as of December 2015, amounted to EUR 494,000 in IFRS (EUR 422,000 in BGAAP).

At the date of this Annual Report, the Company has no investment commitments outstanding.

It is to be noted that in BGAAP, during the years 2014 and 2015, the Company was allowed to capitalize research costs and production for its own. As of 31 December 2015 the net amount capitalized as intangible asset was EUR 7,128,000. This explains why as of December 2015, IFRS Equity attributable to shareholders amounted only to EUR 858,000, compared to a BGAAP net Equity of EUR 6,199,000.

As of December 2015, the Company's cash amounted to EUR 4,621,000, compared to a financial debt of EUR 4,130,000 (convertible bonds) and accounts payable of EUR 1,611,000.

# 4. Corporate governance statement

The Corporate Governance Statement (including the Remuneration Report) is included in the Annual Report. This report can be found on the website of the Company (www.asitbiotech.com).

### 5. Internal control

The role of the executive Directors and of the management team is to develop and maintain an adequate control system to assure:

- The realization of the Company objectives;
- The reliability of financial information;
- The adherence to applicable laws and regulations;
- Monitor the internal and external impact of the risks identified by its Committees, and the management of the risks identified.

The Audit Committee has a guiding, supervisory and monitoring role with respect to the executive Directors and the management team, as regards the development, maintenance and execution of internal controls and:

- Assists the Board of Directors in respect of control issued in general;

 Acts as the interface between the Board of Directors and the external auditors of the Company.

An internal audit role has been assigned to M. Gregory Nihon that was appointed by the Company a few months before the Offering. He works in strict collaboration with the CFO and the CEO. M. Nihon has also been appointed as compliance officer of the Company.

## 6. Statutory auditors

RSM InterAudit BV ovve CVBA, with registered office at 1151 chaussée de Waterloo, 1180 Brussels, Belgium, member of the *Institut des Réviseurs d'Entreprises/Instituut der Bedrijfsrevisoren*, represented by Luis Laperal, auditor and Mazars Réviseurs d'Entreprises SC SCRL, with registered office at avenue Marcel Thiry, 1200 Brussels, Belgium, member of the *Institut des Réviseurs d'Entreprises/Instituut der Bedrijfsrevisoren*, represented by Xavier Doyen, auditor, are the current auditors of the Company, for a term ending immediately following the adjournment of the annual general shareholders' meeting of the Company to be held in 2018, resolving upon the financial statements for the fiscal year ended on 31 December 2017.

# 7. Group Structure

At the date of the present report, the Company does not have any subsidiaries nor branches. The Company had a subsidiary named Biotech tool factory, but such subsidiary was liquidated on 26 June 2015.

# 8. Statements required by article 34 of Royal decree of 14 November 2007

According to Article 34 of the Royal decree of 14 November 2007, the Company hereby discloses the following items:

Elements which by their nature would have consequences in case of a public take-over bid on the Company

- The share capital of the Company amounts to 17,438,592.81 EUR and is fully paid-up. It is represented by 12,756,800 shares.
- The shares existing before the Offering as well as the shares issued further to the conversion of the bonds issued on 5 August 2015 are subject to a lock-up period of 12 months since the IPO. The new shares issued in the framework of the Offering are not subject to such lock-up provision.
- Other than the lock-up period mentioned above the Company's articles of association do not contain any other restriction on the transfer of shares.
- There are no agreements between the shareholders which are known by the Company and may result in restrictions on the transfer of securities and/or the exercise of voting rights.



- There are no holders of any shares with special voting rights.
- There is no external control over the employee incentive plans; warrants are granted directly to the beneficiary.
- Each shareholder of the Company is entitled to one vote per share. Voting rights may be suspended as provided in the Company's articles of association and the applicable laws.
- The rules governing the appointment and replacement of board members and amendment to articles of association are set out in the Company's articles of association.
- The powers of the board of directors, more specifically with regard to the power to issue or redeem shares are set out in the Company's articles of association. The board of directors was not granted the authorization to purchase its own shares to "avoid imminent and serious danger to the Company". The Company's articles of association do not provide for any other specific mechanisms against public takeover bids.

# 9. Transactions within the authorized capital

There has been no transaction within the authorized capital in 2015.

# 10. Acquisition of own securities

Neither ASIT biotech SA nor any direct affiliate or any nominee acting in his own name but on behalf of the Company or of any direct affiliate, have acquired any of the Company's shares. ASIT biotech SA has not issued profit-sharing certificates or any other certificates.

## 11. Use of financial instruments

The Company did not use any financial instruments.

### 12. Risk factors

The risk factors relating to the Company and its activities are detailed in the Annual Report. This report is available on the website of the Company (<a href="www.asitbiotech.com">www.asitbiotech.com</a>).

# 13. Financial instruments, risks of credit, risks of liquidity and risks of treasury

This information is detailed in the Annual Report. This report is available on the website of the Company (www.asitbiotech.com).

### 14. R&D

Research and development IFRS costs can be summarised as follows:



(in EUR 000)	31/12/2015	31/12/2014	31/12/2013
Staff costs	(1,135)	(638)	(478)
Share-based payment	(17)	(84)	S <b>T</b> S
Studies & analyses	(4,498)	(2,276)	(794)
Laboratory supplies	(450)	(254)	(210)
Depreciation and amortisation	(72)	(16)	(18)
Rent	(67)	(26)	(22)
Patents	(154)	(153)	(106)
Facilities	(82)	(41)	(33)
External advice	(156)	(44)	558
Other	(60)	(9)	(9)
	# Total Control of the Control of th	g	A
Total research and development costs	(6,691)	(3,541)	(1,670)

Staff costs include payroll expenses of people dedicated to the R&D activities of the Company. Payroll expenses are allocated to research and development activities based on an analysis of the function of the employees. They are more or less attributable on a 50/50 ratio basis between the 2 main products of the Company, gp-ASIT+<sup>TM</sup> and hdm-ASIT+<sup>T</sup>.

Studies & analyses and laboratory supplies are directly attributable to research & development activities, whereas other indirect costs such as rent are allocated to the different activities based on an allocation key reflecting the headcount dedicated to the different activities.

Costs booked as Studies & analysis are sub-contracted to an outside source. In 2015, the EUR 4,498,000 were mainly related to the costs incurred by the CMO for the GMP production of the drug substance and drug product required for the launch early 2016 of the phase III pivotal study for gp-ASIT+<sup>TM</sup> (60

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% ) as well as for the preparation of the phase I/II clinical study for hdm-ASIT+  $^{TM}$  ( 20% ) to be launched in H2 2016 .

## 15. Conflicts of interest of directors

The Directors report that during the financial year four decisions have been taken that fall within the provisions of Art. 523 BCC.

As required by Art. 523 BCC, the relevant extracts of the minutes of the relevant meetings of the Board of Directors relating to such conflict of interests are reproduced hereunder.

During the financial year 2015, no transaction or other agreement between the Company (or its affiliates) and a Director other than the decisions reproduced hereunder was declared, which could be considered a conflict of interests within the meaning of Art. 523 BCC. Furthermore, during the financial year 2015, there have been no transactions or other contractual relationships between the Company on the one hand, and a Director or executive manager, on the other hand, other than those that fall within the provisions of Art. 523 BCC or that have been disclosed under "related party transactions" set out in the Annual Report.

## Board of directors dated 13 January 2015

### Statement:

"(...) Two directors of the company declare to the Board that they are personally in a potential conflict of interest situation in the sense of article 523 of the BCC with respect of the decisions to be adopted under point 1 of the agenda, *i.e.* those relating to, on the one hand, the granting of an exceptional bonus of the amount of 210,000€ to the managing director and, on the other hand, the conclusion of a service agreement with the service company of which the share capital is held by Mr. François Meurgey.

The Board of Directors acknowledges this declaration and considers that the declaration made in accordance with article 523 BCC is not of that nature to undermine the decision making process with respect to the relevant point of the agenda.(...)"

### Decisions:

"As a result of the Company's exceptional results for the year 2014, the CR proposes to grant an exceptional bonus of the amount of 210,000€ to Mr. Thierry Legon. The CR proposes to split the payment of this bonus into two instalments: the first, of an amount of 140,000€ payable immediately and the second, an amount of 70,000€ payable in January 2015 to the extent that M. Legon has not resigned as the Company's managing director by this date.

The Board of Directors is in favour of attributing this bonus and in general, a higher amount to Mr. Legon. The Board of Directors, however, questions the appropriateness to grant Mr. Legon with such a high variable amount in comparison with Mr. Legon's normal fixed remuneration. In this context, the Board of Directors requests the CR to propose a new remuneration scheme including a revaluation of

the managing director's fixed remuneration. This new proposition will be submitted to the Board of Directors at its next meeting.

Furthermore, for the coming years it is contemplated to set goals for the managing director in the beginning of the year (and this as from 2015). The granting of exceptional bonuses will then depend on achieving these goals. These goals will be set at the next board meeting with respect to the fiscal year 2015.(...)

Proposition of market intelligence and investor communication mission between François Meurgey and the Company:

In order to assure the choice of strategic marketing assignment in the best interest of the company, the Board of Directors wishes that Mr. Meurgey submits a financial proposition prior to the next meeting of the Board of Directors (...)

### Board of directors dated 11 February 2015

### Statement:

"(...) Two directors of the company declare to the Board that they are personally in a potential conflict of interest situation in the sense of article 523 of the BCC with respect of the decisions to be adopted under point 1 of the agenda, *i.e.* those relating to, on the one hand, the re-evaluation of the managing director's remuneration and the granting of the exceptional bonus of the amount of 210,000€ to the managing director and, on the other hand, the conclusion of a service agreement with the service company of which the share capital is held by Mr. François Meurgey.

The Board of Directors acknowledges this declaration and considers that the declaration made in accordance with article 523 BCC is not of that nature to undermine the decision making process with respect to the relevant point of the agenda."

### **Decisions**:

"Review of the Report of the Remuneration Committee

1. Remuneration and goals of the Managing Director for the fiscal year 2015

As a result of the Company's exceptional results for the year 2014, the remuneration committee proposes to grant an exceptional bonus of the amount of 210,000€ to Mr. Thierry Legon. This proposition has already been accepted by the Board of Directors during its meeting of 13 January 2015. The payment of this bonus will be divided in two different installments: the first instalment will be paid during the first quarter of 2015 and the second instalment, amounting to an amount of 70,000€ will be paid in January 2016, insofar to the extent that Mr. Legon has not resigned as the Company's managing director by this date.

Insofar as necessary, the Board of Directors approves the attribution of this exceptional bonus.

Furthermore, the Remuneration Committee proposes (i) to increase the amount of the annual fixed remuneration of the managing director from 134,720 to 161.000€ and (ii) to limit the attribution of the variable remuneration to 50,000€ depending of the achievement of the annual goals set by the Board of Directors. The Board of Directors unanimously approves this proposal.

(...) Finally, the Board of Directors unanimously decides to foresee in the payment of an exceptional bonus of 30,000 EUR for the managing director in the event the IPO will be realized in the course of 2015.

## Marketing mission of François Meurgev

(...) Mr. Meurgey proposes to commence with a retro planning and to take it from there in order to establish a marketing team for a price of 1,250€/jour. The Board of unanimously accepts this proposal."

### Board of directors dated 21 September 2015

### Statement:

"(...) Mr. Everard van der Straten informs the Board that he is personally in a potential conflict of interest situation in the sense of article 523 of the BCC with respect of the decisions to be adopted under point 2 of the agenda, *i.e.* the entering into of a services agreement between the Company and the company Espad Services NV. The purpose of this agreement is to substantiate the mission of the CFO, and this for 5 to 8 days per month for a daily fee of  $1,000 \in$ .

Mr. Everard van der Straten informs the Board that he holds the majority of the share capital of Espad Services NV and that he is the manager thereof.

The Board acknowledges this declaration and considers that the declaration made in accordance with article 523 BCC is not of that nature to undermine the decision making process with respect to the relevant point of the agenda."

### **Decisions:**

"The Board entrusts the company Espad Services NV, represented by Mr. Everard van der Straten, with the function of CFO. Espad Services NV agrees to engage into this function. The task shall be carried out 5 to 8 days per month for a flat fee of 1,000 EUR per day. A service agreement similar to the one entered into with the previous CFO will be entered into as soon as possible.

In this context, the Board gives a power of attorney to Espad Services NV to represent the Company towards stakeholders and subcontractors involved in the IPO. No commitment for an amount higher than 25,000 EUR can be made and no strategic decision can be made before prior approval of the Board."

### Board of directors dated 20 November 2015

### Statement:

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"Mr. Everard van der Straten informs the Board that he is personally in a potential conflict of interest situation in the sense of article 523 of the BCC with respect of the decisions to be adopted under point 2 of the agenda, *i.e.* the entering into of a services agreement between the Company and the company Espad Services NV. The purpose of this agreement is to substantiate the mission of the CFO, and this for 5 to 8 days per month for a daily fee of 1,200 €.

Mr. Everard van der Straten informs the Board that he holds the majority of Espad Services NV's share capital and that he is the manager thereof.

Mr. Legon equally informs the Board that he is personally in a potential conflict of interest situation in the sense of article 523 of the BCC with respect of the decisions to be adopted under point 3a of the agenda, *i.e.* the approval of his remuneration following the completion of the IPO.

The Board acknowledges these declarations and considers that the declarations made in accordance with article 523 BCC is not of that nature to undermine the decision making process with respect to the relevant point of the agenda."

### **Decisions:**

Point 2

"Mr. Zettlmeissl explains and reads the minutes of the Remuneration Committee's meeting held on 19 November, which remain attached to the present minutes.

The Board approves the proposal of the Remuneration Committee to fix the remuneration of the companies Oukelos and Espad Services at 1,250€ per day.

The Board requests the secretary to prepare the draft service agreements on that basis."

(...)

Point 3a

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"As proposed by the Remuneration Committee, the Board unanimously approves (with the exception of Mr. Legon, abstaining) the remuneration of the CEO, following the IPO. The remuneration is fixed at 250,000 EUR per year, with a 33% variable bonus. The Board observes that the amount of the remuneration can evolve according to the results of Phase III.

# 16. Independence and expertise of at least one member of the audit committee

The audit committee consists of at least three directors. As provided by article 526bis of the BCC all members of the audit committee are non-executive directors. According to the BCC, at least one member

of the audit committee must be independent and must have the necessary competence in accounting and auditing. At the date of this report the following directors have been appointed as members of the audit committee: Yves Désiront (chairperson), Gerd Zettlmeissl and Bruservices SA (represented by Henri De Meyer). The audit committee of the Board of Directors is composed exclusively of non-executive directors, of which two are independent directors.

The tree members of this committee have a very good expertise in audit and finance. Their profile and professional experience are summarised in the Annual Report.

### 17. Justification of the valuation rules

The current cash position of the Company will allow it to keep up with the financial obligations for at least the following 12 months. Consequently, the annual accounts have been prepared on the assumption that the Company is a going concern.

# 18. Appropriation of results

Results have always been carried forward as per Statement of changes in equity (in EUR 000) below

	Capital	Share premium	Share-based Payment reserve	Accumulated deficit	Total equity attributable to the owners of the Company
As at 31 December 2014	11,625		573	(4,766)	7,432
Loss of the year			ধর	(7,715)	(7,715)
Share-based payment		:4:	18	÷	18
Costs of capital increase	15	-		(593)	(593)
As at 31 December 2015	11,625	820	591	(13,074)	(858)

The appropriation of the result in BGAAP per 31 December 2015 is as follows (000):

Loss of the year	4, 042
Loss carried over previous year	1,384
Loss to carry over current year	5,426



# 19. Important events subsequent to the accounting reference date.

# Launch of the initial public offering

The Company successfully completed its initial public offering on 11 May 2016 on Euronext Brussels and Euronext Paris. The final offer price has been set at EUR 7.00 per share, giving the Company a market capitalization of approximately EUR 93.1 million, or EUR 95.4 million assuming the exercise in full of the over-allotment option. Gross proceeds from the Offering will amount to EUR 23.5 million, or EUR 25.8 million assuming the exercise in full of the over-allotment option.

## Conversion of bonds

Further to the realization of the initial public offering, the convertible bonds issued on 5 August 2015 were converted into share capital on 12 May 2016 for a total amount of EUR 4,130,000 divided into 902,700 shares (EUR 1,233,994 was included in the capital and EUR 2,896,006 was treated as issue premium).

Brussels, 27 May 2016,

Thierry Legon

Chief Executive Officer

François Meurgey

Directors