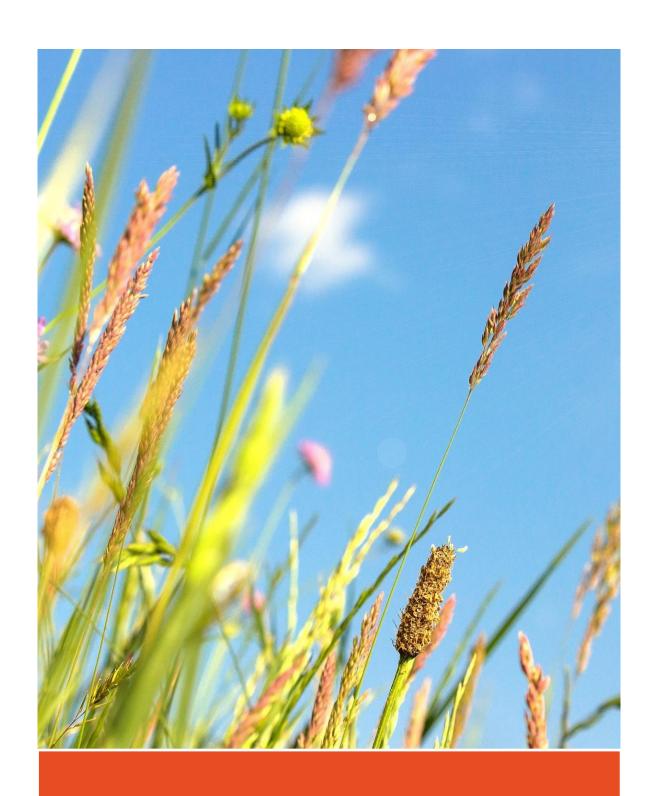


ANNUAL REPORT

2015





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Schedule 1 : Management Report

# 1 INTRODUCTION

#### 1.1. LANGUAGE OF THIS ANNUAL REPORT

ASIT biotech SA (the "Company") published the annual report (the "Annual Report") in English. The Company has also prepared a French translation of this Annual Report and is responsible for the consistency between the French and English version of this Annual Report.

In the event of differences of interpretation between English and French versions of the document, the original English version shall prevail.

#### 1.2. PERSONS RESPONSIBLE FOR THE CONTENTS OF THE ANNUAL REPORT

The Board of Directors of ASIT biotech SA, assumes responsibility for the content of this Annual Report.

The Board of Directors declares that, having taken all reasonable care to ensure that such is the case, the information contained in this Annual Report is, to the best of its knowledge, in accordance with the facts and contains no omission likely to affect its content.

#### 1.3. STATUTORY AUDITOR

RSM InterAudit 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.

#### 1.4. FORWARD-LOOKING STATEMENTS

Certain statements in this Annual Report are not historical facts and are forward-looking statements. Forward-looking statements include statements concerning the Company's plans, objectives, goals, strategies, future events, future revenues or performance, capital expenditure, research and development, financing needs, plans or intentions relating to partnership or acquisitions, competitive strengths and weaknesses, business strategy and the trends which the Company anticipates in the industries and the political, economic, financial, social and legal environment in which it operates and other information that is not historical information. Words such as "believe", "anticipate", "estimate", "expect", "intend", "predict", "project", "could", "may", "will", "plan" and similar expressions are intended to identify forward-looking statements, but are not the exclusive means of identifying such statements. By their very nature, forward-looking statements involve inherent risks and uncertainties, both general and specific, and risks exist that the predictions, forecasts, projections and other forward-looking statements will not be achieved. These risks, uncertainties and other factors include, amongst other things, those listed in the Section "Risk Factors".

#### 1.5. MARKET AND INDUSTRY INFORMATION

Information relating to markets and other industry data pertaining to the Company's business included in this Annual Report has been obtained from internal surveys, scientific publications, section association studies and government statistics. The Company accepts responsibility for having correctly reproduced information obtained from publications or public sources, and, in so far as the Company is aware and has been able to ascertain from information published by those industry publications or public sources, no facts have been omitted which would render the reproduced information inaccurate or misleading. However, the Company has not independently verified information obtained from industry and public sources. Certain other



information in this Annual Report regarding the industry reflects the Company's best estimates based on information obtained from industry and public sources. Information from the Company's internal estimates and surveys has not been verified by any independent sources.

#### 1.6. OTHER AVAILABLE INFORMATION

The Company has filed its deed of incorporation and must file its restated articles of association and all other deeds and resolutions that are to be published in the Belgian Official Gazette (*Moniteur Belge*) with the clerk's office of the French speaking commercial court of Brussels (Belgium), where such documents are available to the public. The Company is registered with the register of legal entities of Brussels under company number 0460.798.795. A copy of the most recent restated articles of association, the reports of the Boards of Directors and the minutes of the shareholders' meeting are also available on the Company's website (www.asitbiotech.com) or can be provided upon request to ASIT biotech SA, Mr. Albert Vicaire, 5, Avenue Ariane, 1200 Woluwe-Saint-Lambert, Belgium (Tel: +322 264 03 90, Fax: + 322 264 03 99 and e-mail: info@biotech.be).

The Company completed its initial public offering on Euronext Brussels and Paris on 10 May 2016 (the "Offering"), for which the Company has issued a prospectus, which contains in-depth information about the Company and its business (the "Offering Prospectus"). The Offering Prospectus can be accessed through the Company's website (www.asitbiotech.com).

The Company prepares annual audited and consolidated financial statements. All financial statements, together with the reports of the Board of Directors and the statutory auditor are filed with the National Bank of Belgium, where they are available to the public. Furthermore, as a Company with shares listed and admitted to trading on Euronext Brussels and Paris, the Company publishes an annual financial report (included its financial statements and the reports of the Board of Directors and the statutory auditor) and an annual announcement prior to the publication of the annual financial report, as well as a half-yearly financial report on the first six months of its financial year. Copies of these documents will be made available on the Company's website (www.asitbiotech.com) and STORI, the Belgian central storage platform which is operated by the FSMA and can be accessed via its website (www.fmsa.be).

The Company must also disclose price sensitive information and certain other information relating to the public. In accordance with the Belgian Royal Decree of 14 November 2007 relating to the obligations of issuers of financial instruments admitted to trading on a Belgian regulated market (*Arrêté royal relative aux obligations des émetteurs d'instruments financiers admis à la négociation sur un marché reglementé*), such information and documentation will be made available through the Company's website (www.asitbiotech.com), press releases and the communication channels of Euronext Brussels.

#### 1.7. AVAILABILITY OF THE ANNUAL REPORT

The Annual Report is available in English and in French. The Annual Report will be made available, free of charge, for the public upon request to:

ASIT biotech SA To the attention of Mr. Albert Vicaire Avenue Ariane 5 1200 Woluwe-Saint-Lambert Belgium

Tel: +322 264 03 90 Fax: + 322 264 03 99 E-mail: info@biotech.be



#### 1 INTRODUCTION

An electronic version of the Annual Report is also available on ASIT biotech SA's website (www.asitbiotech.com). The posting of this Annual Report on the internet does not constitute an offer to sell or a solicitation of an offer to buy any of the shares to any person in any jurisdiction in which it is unlawful to make such offer or solicitation to such person. The electronic version may not be copied, made available or printed for distribution. Other information on the website of the Company or on another website does not form part of the Annual Report.



#### RESPONSIBILITY STATEMENT

We hereby certify that, to the best of our knowledge, the consolidated financial statements as of 31 December 2015, prepared in accordance with the International Financial Reporting Standards, as adopted by the European Union, and the legal requirements applicable in Belgium, give a true and fair view of the assets, liabilities, financial position and loss of the Company and the undertakings included in the consolidation taken as a whole, and that the management report and the Annual Report include a fair view of the development and the performance of the business and the position of the Company and the undertakings included in the consolidation taken as a whole, together with a description of the principal risks and uncertainties that it faces.

On behalf of the Board of Directors

Thierry Legon

Chief Executive Officer

Everard van der Straten-Ponthoz Chief Financial Officer

# 2 BUSINESS SECTION

#### 2.1. LETTER FROM THE CEO

Dear shareholders,

In December 2014, the Company obtained positive and statistically significant results for the phase IIb clinical study with gp-ASIT+<sup>TM</sup>, its lead product candidate targeting grass pollen rhinitis. These results confirmed that the administration of gp-ASIT+<sup>TM</sup> in four doctor visits over a period of three weeks reduces the reactivity score to a conjunctival provocation test and induces allergen specific blocking antibodies. These results allowed the optimal size selection of the natural allergen fragments for gp-ASIT+<sup>TM</sup> and the design of its phase III clinical study, being the last phase of clinical studies before filing marketing authorisation applications.

Early 2015, the Company decided to launch this critical phase III clinical study to confirm the safety, the tolerability and the clinical efficacy of gp-ASIT+<sup>TM</sup> in real life over one grass pollen season. To face the challenge of the further development of gp-ASIT+<sup>TM</sup>, about 10 new scientific collaborators were hired and CRO's were recruited for the launch and the follow-up of the phase III clinical study. In addition, the Company entered into agreements with Good Manufacturing Practices ("*GMP*") contract manufacturing organisations ("*CMO*") for the manufacturing of clinical batches of the drug substance and the drug products.

The clinical study was performed in six European countries as from early 2016 and was completed in May 2016. 549 patients had been recruited before the start of the pollen season and 516 have completed the study. The results of the study are expected for H1 2017. A second product candidate for the house dust mite rhinitis, hdm-ASIT+<sup>TM</sup>, has been designed on the basis the ASIT+<sup>TM</sup> technology platform. The first phase of the regulatory required preclinical development of this product candidate was completed and a first GMP clinical batch was produced in November 2015. This second product candidate will now enter its clinical development stage. The clinical trial documentation for the first clinical trial was filed with the Paul Ehrlich Institute (the German Regulatory Authority) in April 2016.

The Company has set-up a financing plan for short and medium term development of its activities. In August 2015, the Company issued convertible bonds for a total amount of  $\in$ 4.13 million combined to an irrevocable commitment from the bond holders to subscribe to a capital increase for a total amount of  $\in$ 8.26 million. At the same time the Company changed its name into ASIT biotech in reference to Allergen Specific ImmunoTherapy. Different financing strategies among which a private placement, a partnership and an IPO were explored at the time.

I would like to thank all the people and in particular the team, the partners, the board members and the shareholders for their commitment and their support to achieve the Company's objectives.

The next months will be very important for the development of the Company. The clinical development team closely follows-up the phase III clinical study with gp-ASIT+<sup>TM</sup> in Europe. A meeting will be held with the US authorities to define the clinical development plan of gp-ASIT+<sup>TM</sup> in the United States. The first clinical trial with hdm-ASIT+<sup>TM</sup> is expected to start during the summer, and the development of the production process of the third product candidate for ragweed rhinitis is on track.

I warmly welcome you to read more about us, our vision and our products on our website. I will continue to share with you our strategy for growth and how we believe our promising therapy will make a difference in providing a relief for the growing number of allergy sufferers around the globe.

Thank you for your support to ASIT biotech that will help us to become one of the world leader in the field of allergy immunotherapy.

Thierry Legon, CEO



#### 2.2. OPERATIONAL REVIEW

#### ASIT+TM technology platform

The ASIT technology 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. The first product candidate designed on the basis of ASIT+<sup>TM</sup> technology platform, gp-ASIT+<sup>TM</sup>, is intended to treat grass pollen rhinitis. gp-ASIT+<sup>TM</sup> has been tested successfully in allergic patients from phase I to phase II clinical study.

#### Two consecutive clinical trials with consistent clinical and immunological results

In December 2014, the phase IIb results confirmed that gp-ASIT+<sup>TM</sup> allows a reduced course of treatment with four doctor visits over three weeks. It reduces the reactivity to a conjunctival provocation test and induces allergen specific antibodies with the capacity to block in vitro allergic reactions, both in a statistically significant way.

#### The first ASIT+TM product candidate in phase III clinical study

These phase IIb results have paved the way for the first phase III clinical study with gp-ASIT+<sup>TM</sup>. These results also demonstrated the proof of concept of the ASIT+<sup>TM</sup> technology platform to be applied to the development of several innovative drug candidates for respiratory and food allergies.

Early 2015, the Company decided to launch the first phase III clinical study with gp-ASIT+<sup>TM</sup> in Europe (a second phase III clinical study will be performed later in the United States) to confirm the real life clinical effectiveness during grass pollen natural challenge, as well as the safety and the clinical tolerability of gp-ASIT+<sup>TM</sup>.

The clinical trial documentation was filed in July in six different countries: Germany, Italy, Spain, France, Czech Republic and Belgium. Approval by the different Regulatory Authorities and Ethical Committee were obtained in the course of mid-November 2015, allowing the opening of the sites in the different countries. The results of this trial are expected for H1 2017.

#### Securing the manufacturing of gp-ASIT+TM at the commercial scale

In 2015, ASIT biotech entered into agreements with two GMP contract manufacturing organisations: the first one for the manufacturing of the active ingredients and the second one for the manufacturing of the drug products. The validation of the production processes at the commercial scale are on track in order to be able to file a marketing authorisation application in Germany in 2017, subject to compelling statistically significant results from the first phase III clinical study.



#### A second ASIT+TM product in the pipeline soon in clinical development

In 2015, a second product for house dust mite rhinitis hdm-ASIT+<sup>TM</sup> has been designed out of the ASIT technology platform. The technology transfer for the production of the clinical batches according to the Good Manufacturing Practicies has been successfully completed. The preclinical development of hdm-ASIT+<sup>TM</sup> was also successfully completed by the end of 2015 allowing the filing of the clinical documentation for a phase I/II clinical study to be performed in 2016.

#### Settlement of an office in Liège

The Company has settled an office in Liège that hosts the R&D team in charge of the product development, the preclinical development and the quality control. The Company has hired 10 people over 2015, including MDs and PhDs.



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#### 2.3. MISSION AND STRATEGY

The Company aims at becoming a key global player in allergy immunotherapy. Its product pipeline currently consists of two novel ASIT+TM product candidates targeting the respiratory allergies with the highest prevalence. The key elements of the Company's strategy are as follows:

## 2.3.1. COMPLETE THE CLINICAL DEVELOPMENT OF ITS INNOVATIVE LEAD PRODUCT CANDIDATE, GP-ASIT+TM, FOR GRASS POLLEN RHINITIS

The Company has received all approvals from the Competent Regulatory Authorities and Ethical Committees in Europe to start its phase III pivotal study (BTT-gpASIT009) and has finalised patient screening and recruitment, with 549 randomised patients. The study is performed in 67 sites spread over Belgium, Czech Republic, France, Germany, Italy and Spain. The results of the study are expected at the end of Q1 2017. Under the condition of compelling clinical data, the Company will seek marketing authorisation in Germany shortly by Q2 2017 to obtain it one year later (Q2 2018) in order to launch the product immediately thereafter. Besides, the Company has the objective to plan a meeting with the Food and Drug Administration ("FDA") before filing an Investigational New Drug application (a pre-IND meeting) in order to define the US clinical development plan including a second phase III clinical study in the United States with results expected by the end of 2018. The Company believes that such timing allows for the performance in 2016-2017 of a possible phase II study, should such study be required by the FDA.

# 2.3.2. PERFORMING CLINICAL STUDIES FOR ITS SECOND DRUG CANDIDATE FOR HOUSE DUST MITE RHINITIS, HDM-ASIT+TM, FOR HOUSE-DUST MITE RHINITIS, AND ADVANCING OTHER PRODUCT CANDIDATES THROUGH THE PIPELINE

The Company has completed the first phase of required regulatory preclinical development of hdm-ASIT+TM in order to start clinical studies in Europe at the beginning of Q3 2016. Results of the phase I/II study, having as primary endpoint the assessment of the maximum tolerated dose, are expected by the end of 2016. If results are positive a phase IIb study, having as primary endpoint the determination of the dose and administration schedule with the optimal safety and efficacy profile based on individual allergen provocation test will be conducted in 2017.

Furthermore the Company will seek to further leverage on its innovative and flexible ASIT+<sup>TM</sup> technology platform by advancing other product candidates into clinical development (ragweed-induced allergic rhinitis and food allergens) which are currently in their discovery phase and for which the Company has already obtained first evidence of applicability of the ASIT+<sup>TM</sup> production platform. According to first estimates from the Company, launching a product for a new indication in Europe and the United States would require funding for a minimum amount of EUR 25 million.



## 2.3.3. INDEPENDENTLY COMMERCIALISE ITS PRODUCT CANDIDATES IN GERMANY AND THE UNITED STATES

The Company has retained global commercialisation rights for all of its product candidates and intends to establish its own sales and marketing capabilities in Germany and in the United States, focusing on allergy specialists. The Company believes that the relatively low number of allergy specialists (approximately 5,000 in Germany/80 million inhabitants and 5,500 in the United States/345 million inhabitants, Internal report, AVOS Consulting, 2015) should enable the effective promotion of its product candidates with a focused marketing strategy and a limited sales force. The Company may also consider alternative ways of commercialising its product candidates in these markets, including partnering with other companies that have the required infrastructure and expertise.

Given its attractive market characteristics, the Company selected Germany as its first target market for gp-ASIT+TM under the condition of marketing authorization granted on the basis of very compelling positive results of the first phase III clinical study. Subject to successful completion of a second phase III clinical study in the United States, the Company will target subsequently the United States and other key European countries (France, Spain and Italy). Germany represents about 39% of the European allergy immunotherapy ("AIT") market in terms of sales, followed by France (31%), Spain (10%) and Italy (10%) (ALK-Abelló IR presentation 6 December 2014).

#### 2.4. MARKET OPPORTUNITIES AND COMPETITIVE ADVANTAGE

The Company believes that a number of strengths have helped its development so far, and will enable it to achieve its strategic goals:

# 2.4.1. FOCUS ON DEVELOPING IMMUNOTHERAPY TREATMENTS FOR ALLERGIES - A LARGE MARKET OPPORTUNITY WITH SIGNIFICANT UNMET MEDICAL NEED

Allergies to grass pollen and house dust mites, for which the Company develops its two lead product candidates, affect a significant part of the population in Europe and the United States. It is estimated that 22 million adults suffer from physician-diagnosed allergic rhinitis in the four biggest European immunotherapy markets (Germany, France, Italy, Spain) and 25 million in the United States (Bauchau & Durham 2004, Nathan et al 2008). Despite a \$ 10 billion yearly symptomatic drug consumption, there is still an important unmet medical need in the allergic patient population. The target population for respectively gp-ASIT+TM and hdm-ASIT+TM are those patients with a poor control of their disease and who are looking for new effective treatment. They are estimated at 25% of the physician-diagnosed allergic rhinitis patients, representing today 6 and 5 million adult patients respectively in the United States and in the four biggest European immunotherapy markets (Germany, France, Spain and Italy). Most of these patients are probably sensitised to both grass pollen and house dust mite allergens. These patients could be satisfied by products that:

- improve compliance and real life effectiveness;
- offer patients and health care payers better cost efficiency;
- tackle the root causes of the disease; and



• reduce the duration of the treatment and the number of treatment visits.

The only current treatment available on the market tackling the cause of allergic disease is whole allergen immunotherapy (EUR 900 million market in 2014 – Stallergènes, Document de Référence 2014). However, the numerous drawbacks of this treatment (weekly or biweekly injections and a long course of therapy of up to three years in order to achieve desensitisation to specific allergens and consequently high cost obligation) limit its acceptance and compliance to it. This offers a real opportunity for safe and efficacious short-course AIT products that reduce both the overall number of visits and associated patient costs.

On the basis of the clinical results obtained to date for its grass-pollen ASIT+TM, the Company believes that its product candidates have the potential to become the best-in-class immunotherapy products for the relevant allergens and overcome the limitations of current treatments. In addition, the Company believes that its product candidates represent a step change to a new generation of immunotherapy treatments that could significantly expand the immunotherapy market. The short-course approaches, the fast onset of action, as well as adjuvant-free products are among the features that resonate the most in that target group.

### 2.4.2. GP-ASIT+<sup>TM</sup> VERY PROMISING PRODUCT CANDIDATE FOR GRASS POLLEN RHINITIS WITH SHORT TIME TO MARKET

The Company's lead product candidate has successfully completed early stage clinical development. The phase IIa and phase IIb clinical studies generated compelling proof of concept with statistically significant results demonstrating that, after 4 treatment visits within 3 weeks, gp-ASIT+TM:

- induces a significant reduction of the reactivity to a standardised conjunctival provocation test, used to assess the clinical efficacy;
- has a positive and significant impact on the immune system as evidenced by the production of protecting antibodies; and
- has a favourable benefit-risk profile.

In consequence, gp-ASIT+<sup>TM</sup> is the first adjuvant free short course treatment AIT product with 4 doctor visits over 3 weeks with clear phase IIb clinical safety and efficacy data. The Company therefore believes that this breakthrough product can address the significant unmet need by inducing a protective immune response in a quickly, convenient and safely manner.

The Company has launched a first phase III clinical study in Europe with gp-ASIT+<sup>TM</sup>. As such, gp-ASIT+<sup>TM</sup> is well-positioned to become the first short course treatment subcutaneous immunotherapy ("*SCIT*") product without adjuvant targeting grass pollen rhinitis to be authorised in Germany on the basis of a marketing authorisation based on a fully documented file.

The Company believes that the short duration of the AIT treatment with gp-ASIT+ $^{TM}$  can be considered by both physicians and payers as obvious benefits for patients in terms of convenience and Quality of Life (QoL) aspects.

## 2.4.3. INNOVATIVE AND FLEXIBLE ASIT+TM PLATFORM APPLICABLE TO A BROAD RANGE OF ALLERGIES

The ASIT+<sup>TM</sup> platform allows the production, characterisation and quality control of active ingredients consisting of highly purified natural allergen fragments with an optimal size selection. In contrast with the current immunotherapy products including whole allergens, ASIT+<sup>TM</sup> allergen fragments have been demonstrated in vitro to induce less allergic reactions, as shown by a reduction by 100 times of the blood



basophil degranulation of allergic patient induced by gp-ASIT+TM compared to placebo (according to BTT-gpASIT001 preclinical study UZ Gent). The mechanism of action allows for the fast induction of protecting antibodies while limiting the allergic reaction and thus resulting in an improved safety profile. This innovation results in a short course of treatment, expected improved patient compliance and clinical efficacy. The Company is currently the only developer of product candidates consisting of a unique mixture of highly purified peptides produced from natural sources of allergens.

The Company believes that its innovative ASIT+TM technology platform is very flexible and would be applicable across a range of other allergens. The know-how collected at industrial scale during the validation of the production process of gp-ASIT+TM can be applied to the development of allergen fragments from other natural allergens such as house dust mite, ragweed and food allergens like egg white and peanut. The second product candidate, hdm-ASIT+TM, is expected to enter its clinical testing phase at the beginning of Q3 2016. In addition there are product candidates in discovery phase, for some of which (ragweed and food allergens) the Company has already obtained first evidence of applicability of the ASIT+TM production platform, following the production of small scale batches of allergen fragments. According to first estimates from the Company, launching a product for a new indication in Europe and the United States would require funding for a minimum amount of EUR 25 million.

#### 2.4.4. STRONG IP PROTECTION

The Company has multiple levels of intellectual property protection for its allergy product candidates and has a robust patent filing and maintenance programme in place which is intended to offer protection until at least 2027 (for both gp- and hdm-ASIT+TM's most relevant patents, that are BTT04 (expiration date 2027) and BTT07 (expiration date 2032)). The Company may be eligible for extensions of up to five years for each product through supplementary protection certificates (SPCs) in the European Union and certificates extending patent term in the United States. In addition, the Company's product candidates could benefit from data/market exclusivity (between ten to twelve years depending on the territory) after marketing authorisation approval.

#### 2.4.5. POTENTIAL FURTHER UPSIDE

- Other ASIT+TM products: the discovery process for the development of allergen fragments from other allergens such as ragweed and food allergens like egg white and peanut on the basis of the ASIT+TM technology platform is ongoing.
- Geographic expansion: the Company believes that in addition to its 5 key target markets for both gp- and hdm-ASIT+TM, which it plans to address in the first instance, there could be potential to envisage targeting other European and emerging markets with similar product propositions. The potential of the Chinese market is very large as approx. 7% of the Chinese population has been reported as suffering from allergic rhinitis (Zheng et al., "Prevalence of Allergic Rhinitis Among Adults in Urban and Rural Areas of China: A Population-Based Cross-Sectional Survey", Allergy Asthma Immunol Res. 2015; 7(2):148-157).
- Additional indications: new therapeutic options targeting both allergic rhinitis and allergic asthma would offer clear advantages in terms of the diseases cost and management, especially since the socio-economic impact of allergic asthma is high, as demonstrated by surveys in the United States and extensive evidence for European countries. As a growing body of evidence points out to the potential of AIT to be the only treatment to prevent the onset of allergic asthma, there is potential for the Company to conduct further research to assess the potential impact and efficacy of gp-ASIT+TM and hdm-ASIT+TM on allergic asthma.



#### **2.5. OUTLOOK FOR 2016**

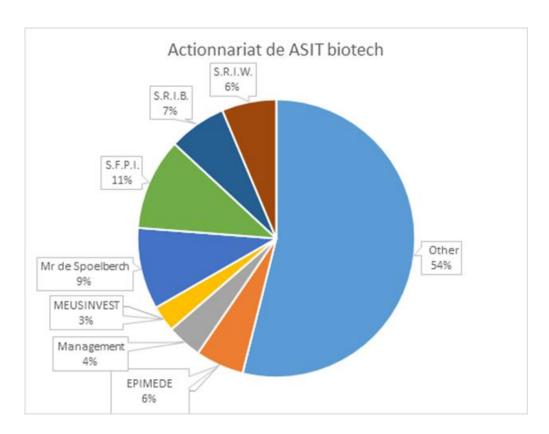
A long development has taken place in 2015. The next objectives for gp-ASIT+<sup>TM</sup> are the feedback of the pre-IND meeting with the FDA and the results of the European phase III. The outcome of this pre-IND meeting will determine the gp-ASIT+<sup>TM</sup> clinical development path in the United States. In case of positive statistically and clinically compelling results of the European phase III clinical study for gp-ASIT+<sup>TM</sup>, a market authorization could be granted in Germany on the basis of these results.

The next objective for hdm-ASIT+<sup>TM</sup>, the second product candidate, is the launch of the first clinical trial (phase I/II clinical study).

#### 2.6. FINANCIAL KEY FIGURES

	2015	2014	2013
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 equivalent	4,621	8,410	1,211

#### 2.7. SHAREHOLDERS STRUCTURE





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#### 2.8. EVENTS THAT OCCURRED SINCE 31 DECEMBER 2015

#### Launch of the initial public offering

The Company successfully completed its initial public offering on 10 May 2016 on Euronext Brussels and Euronext Paris. The final offer price was 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 completion of the Offering, the convertible bonds issued on 5 August 2015 were converted into share capital 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).

#### Gp-ASIT+TM phase III clinical study status

The first objective of this phase III clinical study (BTT009) is to demonstrate the clinical efficacy of gp-ASIT+TM during one grass pollen season when administered subcutaneously prior to the grass pollen season in patients suffering from hay fever. The primary endpoint will be the reduction (in the treated group compared to the placebo group) of the Combined Symptom and Medication Score (*CSMS*) taking into account the daily Rhinoconjunctivitis Total Symptom Score (*RTSS*) and the daily Rescue Medication Score (*RMS*) over the peak of grass pollen season subsequent to treatment.

The study is performed in 67 sites spread over Belgium, Czech Republic, France, Germany, Italy and Spain. As of mid-May 2016, 549 patients were randomised among which 516 patients have completed the treatment.

A sample of 516 patients at the start of the pollen season should allow to show a statistically significant CSMS reduction of minimum 25%, in case of a patient drop-out rate of 20% (including patients excluded from the statistical analysis) by the end of the study.

The drop-out rate reported for the clinical studies leading to the marketing authorisation of Oralair and Grazax were comprised between 10% and 15% (Oralair 100 IR & 300 IR SLIT-tablets and Oralair 300 IR SLIT-tablets, Summary of Products Characteristics (*SmPC*) (lastly updated on 12/2015); Grazax 75,000 SQ-T oral lyophilisate, SmPC (lastly updated in 07/2015)).

The safety assement is particularly focused on the adverse events occuring at the site of injection and the adverse events of allergic origin. Systemic allergic reactions (*SAR*) are classified according a five-point grading system of the World Allergy Organization to classify subcutaneous immunotherapy systemic reactions. Each grade is based on both the organ system involved and the severity. Briefly, grade 1 SAR comprise reactions from a single organ system such as cutaneous, conjunctival, or upper respiratory, but not asthma, gastrointestinal, or cardiovascular. A SAR will belong to grade 2 or 3 whenever symptoms/signs are detected in more than 1 organ system or asthma, gastrointestinal, or cardiovascular. Grade 4 is defined by a respiratory failure or hypotension (with or without loss of consciousness), and grade 5 by death (Cox L., Larenas-Linnemann D., Lockey R., Passalacqua G., et al., "Speaking a Common Language in Grading Subcutaneous Immunotherapy Systemic Reaction Grading System", Journal of Allergy Organization Subcutaneous Immunotherapy Systemic Reaction Grading System", Journal of Allergy and Clinical Immunology, 2010(3); 125:569-574). The severity of SAR is afterwards reported within each different grade as mild, moderate or severe.

The occurrence of systemic allergic reactions in the clinical study BTT009 until 31 March 2016 is described in the Offering Prospectus under section 9.6.2 (iii). Since 31 March, no grade 3, grade 4 or grade 5 SAR have



occurred, and 21 grade 1 SAR (18 mild and 3 moderate) and 9 grade 2 SAR (6 mild, 2 moderate and 1 severe) were reported until the end the treatement. Although study BTT009 is not completed yet, a preliminary descriptive analysis of the blinded data seems to show that systemic allergic reactions reported at this stage of the study are in line with what was observed during previous gp-ASIT+<sup>TM</sup> clinical studies, and with what is described in the literature for other products.

At the most recent meeting on 2 May 2016, the Data and Safety Monitoring Board (*DSMB*), an independent group of experts that advises the Company and the study investigators on among others participant safety, concluded that there were no safety concerns and that the study could continue. The DSMB was also pleased with the reporting process, the meeting format and the good efficiency of the safety physician and the Company's team in providing promptly the necessary information to assess the study safety.

The next objective is the follow-up of the patients and their reporting during the pollen season. The last patient visit is planned for the end of September 2016. The lock of the database and the results of the statistical analysis are expected by the end of Q1 2017.

#### 2.9. FINANCIAL CALENDAR 2016

31 May 2016 Publication Annual Report 2015

30 June 2016 Annual shareholders meeting

23 September 2016 Publication of half-year results



# FINANCIAL INFORMATION (INCLUDING STATUTORY ACCOUNTS)

#### IFRS audited financial information of the company for the last 3 years

#### **Consolidated statement of financial position (in EUR 000)**

		3	1 December		1
	Note	2015	2014	2013	January 2013
ASSETS					
Non-current assets					
Intangible assets		-	-	-	-
Property, plant and equipment	7	494	202	39	35
Other long term receivables	8	12	13	3	3
		506	215	42	38
Current assets					
Inventories	9	11	14	13	10
Trade receivables	10	2	18	2	4
Other receivables	11	277	84	59	46
Other current assets	12	57	8	7	16
Cash and cash equivalents	13	4,621	8,441	1,245	2,520
		4,968	8,565	1,326	2,596
Total assets		5,474	8,780	1,369	2,634
Capital and reserves Capital	14 14 15	11,625 591 (13,074) (858)	11,625 573 (4,766) <b>7,432</b>	14,293 5,413 374 (20,038) <b>42</b>	14,293 5,413 767 (18,112) <b>2,361</b>
LIABILITIES					
Non-current liabilities	16			885	
Financial debt Other non-current liabilities	16 18	-	70	003	-
Other non-current habilities	16			-	
			70	885	
Current liabilities					
Financial debt	16	4,232			
Trade payables	17	1,611	858	351	187
Other payables	18	489	421	92	86
		6,332	1,279	443	273
Total liabilities		6,332	1,349	1,328	273
Total equity and liabilities		5,474	8,780	1,369	2,634

#### Consolidated income statement and other comprehensive income (in EUR 000)

		3	31 December	
	Note	2015	2014	2013
Revenue	19	4	5	7
Other operating income / (expenses)		(3)	3	6
Cost of goods sold		(3)	-	3
Research and development expenses	20	(6,691)	(3,541)	(1,670)
General and administrative expenses	21	(947)	(785)	(644)
Operating loss for the period		(7,640)	(4,318)	(2,298)
Financial income	24	33	6	13
Financial expense	25	(108)	(117)	(32)
Loss for the period before taxes		(7,715)	(4,429)	(2,319)
Taxes	26	-	-	-
Loss for the period		(7,715)	(4,429)	(2,319)
Other comprehensive income				
Comprehensive loss for the period		(7,715)	(4,429)	(2,319)
Loss for the year				
Attributable to owners of the Company		(7,715)	(4,429)	(2,319)
Losses per share (in EUR per share)				
- basic and diluted	31	(90,72)	(75.73)	(40.11)

#### **Statement of changes in equity (in EUR 000)**

	Capital	Share premium	Share-based Payment reserve	Accumulated deficit	Total equity attributable to the owners of the Company
As at 1 January 2013	14,293	5,413	767	(18,112)	2,361
Loss of the year	_	_		(2,319)	(2,319)
Share-based payment	<u> </u>	<u> </u>	(393)	393	
As at 31 December 2013	14,293	5,413	374	(20,038)	42
Loss of the year	_	_	-	(4,429)	(4,429)
Share-based payment	-	-	199	-	199
Conversion of convertible bonds	4,531	-	-	-	4,531
Capital decrease	(19,700)	0	0	19,700	0
Capital increase	12,500	(5,413)	-	-	7,087
As at 31 December 2014	11,625	_	573	(4,766)	7,432
Loss of the year	-	-	-	(7,715)	(7,715)
Share-based payment	-	-	18	-	18
Costs of capital increase	-	-	-	(593)	(593)
As at 31 December 2015	11,625		591	(13,074)	(858)

#### **Statement of cash flows (in EUR 000)**

	Note	2015	2014	2013
Loss of the period	:	(7,715)	(4,429)	(2,319)
Adjustments	•			
Depreciation on property, plant and equipment	7	80	20	22
Share-based payments	15	18	199	-
Financial (income) / expense		75	111	19
Changes in working capital				
Inventories		3	(1)	(3)
Trade receivables, other receivables and other current assets		(819)	(42)	(2)
Other non-current liabilities, trade payables and other payables		751	764	170
Cash flow from operating activities		(7,606)	(3,377)	(2,112)
Investing activities				
Purchase of property, plant and equipment	7	(372)	(182)	(26)
(Increase) / Decrease of long-term receivables		1	(10)	-
Cash flow from investing activities	•	(371)	(192)	(26)
Financing activities				
Capital increase	14	-	7,087	-
Issuance of convertible loan		4,130	3,678	854
Interests received		33	6	13
Interests paid		(6)	(6)	(2)
Cash flow from financing activities		4,157	10,765	865
Net increase / (decrease) in cash and cash equivalents		(3,820)	7,196	(1,273)
Cash and cash equivalents at the beginning of the period	13	8,441	1,245	2,520
Cash and cash equivalents at the end of the period	13	4,621	8,441	1,245

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

#### 1. General information

ASIT biotech SA, a company incorporated in Belgium with corporate address 5, Avenue Ariane, 1200 Woluwe-Saint-Lambert in Belgium is a clinical-stage biopharmaceutical company focused on the development and commercialisation of a range of immunotherapy products for the treatment of allergies. The lead product candidate gp-ASIT+TM is designed for treatment of grass pollen allergy. Besides this lead investigational product, the Company's product pipeline includes another product, hdm-ASIT+TM, intended for treatment of house dust mite allergy.

These product candidates are being developed using the Company's innovative technology, ASIT+TM, allowing the production, the characterisation and the quality control of truly new active ingredients. These new active ingredients are highly purified natural allergen fragments allowing faster injection regimen with higher doses resulting in short course treatment improving patient compliance and clinical efficacy.

ASIT biotech SA incorporated a subsidiary under the name Biotech Tools Factory SA, which was liquidated in June 2015. For the purpose of these notes, ASIT biotech SA and Biotech Tools Factory SA will be referred to together as the Company. The Company has so far been funded by a combination of private investors and funds from regional and national authorities. Several grants have been awarded to the Company to support its R&D activities.



The financial statements have been authorised for issue on 27 May 2016 by the board of directors of the Company.

#### 2. First time adoption of IFRS - summary of significant accounting policies

#### • Basis of preparation of IFRS Financial information

The Company's annual report for the year ended 31 December 2015 is the First annual consolidated financial statements that comply with IFRS. The consolidated Financial Statements have been prepared in accordance with the significant accounting policies described in note 2. The Company has applied IFRS 1, "First-time adoption of International Financial Reporting Standards" in preparing these statements.

#### • IFRS 1 Exemptions

IFRS 1 sets out the procedures that the Company must follow when it adopts IFRS for the first time as the basis for preparing its consolidated Financial Statements. The Company is required to establish its IFRS accounting policies as at 31 December 2015 and, in general, apply these retrospectively to determine the IFRS opening balance sheet at its date of transition 1 January 2013. This standard provides a number of optional exemptions to this general principle. These are set out below, together with a description in each case of the exemption adopted by the Company.

Share-based payments (IFRS 2, "Share-based payments")

The Company has elected to apply IFRS 2 to all relevant share-based payment transactions granted but not fully vested at 1 January 2013.

Fair value or revaluation as deemed cost (IAS 16, "Property, Plant and Equipment" and IAS 38, "Intangible assets")

The Company has not elected to measure any item of property, plant and equipment or intangible asset at the date of transition to IFRS at its fair value.

#### • Principal accounting policies

The principal accounting policies for preparing the consolidated financial statements are summarised below.

#### **Statement of compliance**

The consolidated financial statements of the Company for the year ended 31 December 2015 have been prepared in accordance with the International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and as adopted by the European Union. Annual accounts have been prepared in accordance with IFRS for the first time for the accounting period ending 31 December 2015.

#### **Basis of preparation**

The consolidated financial statements have been prepared on the historical cost basis. Historical cost is generally based on the fair value of the consideration given in exchange for assets or liabilities. All entries are made at historical cost, with the exception of the share based payments (not accounted for in Belgian GAAP), booked at fair value.

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on



the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability or in the absence of a principal market, in the most advantageous market for the asset or liability. The principal or the most advantageous market must be accessible by the Company. The fair value of an asset or liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that the market participants act in their economic best interest.

All assets and liabilities for which fair value is measured or disclosed in the consolidated financial statements are categorised within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- i. **Level 1** Quoted (unadjusted) market prices in active markets for identical assets or liabilities:
- ii. **Level 2** Valuation techniques for which the lowest level input that is significant to the fair value measurement is directly or indirectly observable;
- iii. **Level 3** Valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable.

The consolidated financial statements are presented in Euro (EUR) and all values are rounded to the nearest thousand (k EUR), except when otherwise indicated.

The following standards and interpretations are published, issued but are not yet effective and have not been applied to the first IFRS financial statements of the Company. Some may or may not affect the preparation of future annual reports. The Company will assess full impact of these standards in due course:

- a) IFRS 9 Financial instruments and subsequent amendments. The standard will replace the majority of IAS 39 and covers the classification, measurement, recognition and de-recognition of financial assets and financial liabilities, impairment of financial assets and provides a new hedge accounting model. It will normally be applicable for annual periods beginning on or after 1 January 2018, but it is not yet endorsed in the EU. Its impact on the Company's financial statements will be analysed in due course;
- b) IFRS 14 Regulatory Deferral Accounts. The purpose of this standard is to specify the financial reporting requirements for 'regulatory deferral account balances' that arise when an entity provides goods or services to customers at a price or rate that is subject to rate regulation. The standard is normally applicable for annual periods beginning on or after 1 January, 2016, but has not yet been endorsed in the EU. This should not impact the Company as it is not involved in regulated activities;
- c) IFRS 15 Revenue from Contracts with Customers. This standard provides a single principle based approach to the recognition of revenue from all contracts with customers. It focuses on the identification of the performance obligations in a contract and requires that revenue be recognised when such obligations are satisfied. The standard will be applicable for annual periods beginning on or after 1 January 2018, but it has not yet been endorsed in the EU. This standard shall impact the Company when it will generate revenue:
- d) IFRS 16 Leases. This standard provides a basis for the accounting of leasing contracts by lessees and lessors. Considering the nature of the lease agreements in which the Company is involved, this standard shall not significantly impact the Company. The standard will be applicable for annual periods beginning on or after 1 January 2019.
- e) Amendments to IFRS 10, IFRS 12 and IAS 28 Investment entities applying the consolidation exception (normally applicable for annual periods beginning on or after



- 1 January 2016, but not yet endorsed in the EU). The Company is not an investment entity and it shall not be impacted by these amendments;
- f) Amendments to IAS 1 Disclosure initiative (applicable for annual periods beginning on or after 1 January 2016). As per analysis performed these amendments shall not significantly impact the Company;
- g) Amendments to IAS 27 Equity method in separate financial statements (applicable for annual periods beginning on or after 1 January 2016). The Company does not prepare separate IFRS financial statements and it will therefore not be impacted by these amendments;
- h) Amendments to IAS 12 Recognition of deferred tax assets for unrealised losses (normally applicable for annual periods beginning on or after 1 January 2017, but not yet endorsed in the EU). As per analysis performed the Company shall not be impacted by this amendment.
- i) Amendments to IAS 7 Disclosure initiative (normally applicable for annual periods beginning on or after 1 January 2017, but not yet endorsed in the EU);
- j) Improvements to IFRS (2012-2014) (applicable for annual periods beginning on or after 1 January 2016). As per analysis performed these improvements should not impact the Company's financial statements;
- k) Amendments to IAS 16 and IAS 38 Clarification of acceptable methods of depreciation and amortisation (applicable for annual periods beginning on or after 1 January 2016). As per analysis performed these amendments should not impact the Company's financial statements;
- 1) Amendments to IFRS 11 Accounting for acquisitions of interests in joint operations (applicable for annual periods beginning on or after 1 January 2016). This should not impact the Company as it does not have interest in joint operations;
- m) Amendments to IAS 16 and IAS 41 Bearer plants (applicable for annual periods beginning on or after 1 January 2016). The Company is not involved in agricultural activities and will therefore not be impacted by these amendments.

It is not expected that the initial application of the above mentioned IFRS standards, interpretations and amendments will have a significant impact on the consolidated financial statements.

The Company consistently used the same accounting policies in its opening IFRS statement of financial position and throughout all periods presented in its first IFRS financial statements. There is no impeding change in accounting policy.

#### **Consolidation principles**

The consolidated financial statements comprise the financial statements as at 31 December 2015 of the Company and its subsidiary, which was liquidated in June 2015. A subsidiary is an entity controlled by the Company. Control is achieved when the Company is exposed or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee. The Company controls an investee if, and only if, the Company has:

- i. Power over the investee i.e., existing rights that give it the current ability to direct the relevant activities of the investee;
- ii. Exposure, or rights, to variable returns from its involvement with the investee;
- iii. The ability to use its power over the investee to affect its returns.



All transactions between group companies have been eliminated upon consolidation.

#### **Foreign currency translations**

The consolidated financial statements are presented in Euro, which is the Company's functional and presentation currency.

Transactions in foreign currencies are recorded at the foreign exchange rate prevailing at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies at the balance sheet date are translated at the foreign exchange rates prevailing at that date. Exchange differences arising on the settlement of monetary items or on reporting monetary items at rates different from those at which they were initially recorded during the period or in previous periods, are recognised in the consolidated income statement.

#### **Intangible assets**

#### > Research and development costs

Research costs are expensed as incurred. Developments cost are recognised as intangible assets, if and only if, all of the following conditions are met:

- the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- the intention to complete the intangible asset and use or sell it;
- the ability to use or sell the intangible asset;
- how the intangible asset will generate future economic benefits;
- the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- the ability to measure reliably the expenditure attributable to the intangible asset during its development.

At this stage, the Company is of the opinion that none of the projects currently undergone meet the recognition criteria.

#### ➤ Research and development costs

Purchased intangible assets such as patents and licenses and purchased IT, are capitalised if it can be demonstrated that such assets will generate future economic benefits for the Company.

Intangible assets are amortised in accordance with the expected pattern of consumption of future economic benefits derived from each asset. Specifically, intangible assets are amortised on a straight line basis over their estimated useful life.

The Company has at this stage no intangible asset carried on the statement of financial position.

#### Property, plant and equipment

Property, plant and equipment are initially recorded in the statement of financial position at their acquisition cost, which includes the costs directly attributable to the acquisition and installation of the asset. Property, plant and equipment are recorded at their historical cost less accumulated depreciation and impairment, if any.



Property, plant and equipment are depreciated on a straight line basis over their estimated useful life. The estimated useful life of each category of property, plant and equipment is as follows:

IT and laboratory & manufacturing equipment	3 to 10 years				
Leasehold improvements	The shorter of rent duration and 10 years				
Other	10 years				

Property, plant and equipment are derecognised upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss arising on de-recognition of the asset, which is the difference between the net disposal proceeds and the carrying amount of the asset, is included in the income statement when the asset is derecognised.

The residual values, useful lives and methods of depreciation of property, plant and equipment are reviewed at each financial year end and adjusted prospectively, if appropriate.

#### Impairment of intangible assets and property, plant and equipment

At each reporting date, the Company assesses whether there is an indication that an asset may be impaired. If an indication of impairment exists, or when annual impairment testing is required (in the case of goodwill and intangible assets with an indefinite useful life), the Company estimates the asset's recoverable amount. The recoverable amount of an asset is the higher of the assets or cash-generating units (CGU) fair value less costs of disposal and its value in use.

The recoverable amount is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or group of assets. When the carrying amount of an asset or CGU exceeds its recoverable amount, the asset is considered as impaired and is written down to its recoverable amount.

In assessing value in use, the estimated future cash flows are discounted to their present value using a pretax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset.

A previously recognised impairment loss is reversed only if there has been a change in the assumptions used to determine the asset's recoverable amount since the last impairment loss was recognised. The reversal is limited so that the carrying amount of the asset does not exceed its recoverable amount, nor exceeds the carrying amount that would have been determined, net of depreciation, had no impairment loss has been recognised for the asset in prior years. Such reversal is recognised in the consolidated income statement.

As the Company currently does not generate significant cash-inflows, it is to be noted that the recoverable amount of an asset is determined on basis of its fair value less cost of disposal.

#### > Inventory

Inventories are valued at the lower of cost and net realisable value. The cost of inventories is determined on a first in, first out basis (FIFO method).

Net realisable value is the estimated selling price in the ordinary course of business, less estimated costs of completion and estimated costs necessary to make the sale.



#### > Financial instruments

Financial assets and financial liabilities are recognised when the Company becomes a party to the contractual provisions of the instruments.

Financial assets and financial liabilities are initially measured at fair value. Transactions costs that are directly attributable to the acquisition or issue of financial assets and liabilities are added or deducted from the fair value of the financial assets or financial liabilities, as appropriate, on initial recognition.

#### A) Financial assets

The Company has only loans and receivables which are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. Loans and receivables include trade receivables and other receivables which are measured at amortised cost using the effective interest method, less any impairment. Interest income is recognised by applying the effective interest rate, except for short-term receivables when the effect of discounting is immaterial.

#### o Derecognition

A financial asset is derecognised when the contractual rights to receive cash flows from the asset have expired or when the Company transferred its rights to receive cash flows and substantially all risks and rewards of ownership of the financial asset to another party. If the Company neither transfers nor retains substantially all the risks and rewards of ownership and continues to control the transferred asset, the Company recognises its retained interest in the asset and an associated liability for amounts it may have to pay. If the Company retains substantially all the risks and rewards of ownership of a transferred financial asset, the Company continues to recognise the financial asset and also recognised a collateralised borrowing for the proceeds received.

#### o Impairment of financial assets

The Company assesses, at each reporting date, whether there is objective evidence that a financial asset or a group of financial asset is impaired. An impairment exists if one or more events that has occurred since the initial recognition of the asset (an incurred "loss event"), has a negative impact on the estimated future cash flows of the financial asset or the group of financial assets that can be reliably estimated.

The carrying amount of the asset is reduced through the use of an allowance account and the loss is recognised in the income statement.

#### B) Financial liabilities

All financial liabilities are initially recorded at fair value, net of directly attributable transaction costs, if any.

After initial recognition, financial liabilities are subsequently measured at amortised cost using the effective interest rate method. Amortised cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective interest rate. The effective interest rate amortisation is included as financial cost in the consolidated income statement.

The Company's financial liabilities include non-current liabilities (financial debt and other non-current liabilities) and current liabilities (trade and other payables).



#### Derecognition

The Company derecognises financial liabilities when, and only when, the Company's obligations are discharged, cancelled or they expire. The difference between the carrying amount of the financial liability derecognised and the consideration paid and payable is recognised in income statement.

#### > Equity instruments

Equity instruments issued by the Company are recorded at the fair value of the proceeds received, net of transaction costs.

#### Cash and cash equivalents

Cash and cash equivalents include cash in hand, deposits held at call with banks, other short-term deposits with a maturity of or less than 3 months, and which are subject to an insignificant risk of changes in value.

#### ➤ Income taxes

Income taxes include current income tax and deferred income tax.

#### Current income tax

Current income tax assets and liabilities are measured at the amount expected to be recovered from or paid to the tax authorities. Tax rates and tax laws that are considered to determine the amount of tax assets or liabilities are those that are enacted or substantially enacted, at the reporting date.

#### Deferred income tax

Deferred tax is provided using the liability method on temporary differences between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes at reporting date. Deferred tax liabilities are recognised for all taxable temporary differences, except when the deferred tax liability arises from the initial recognition of an asset or liability in a transaction that at the time of the transaction affects neither the accounting profit nor taxable profit or loss.

Deferred tax assets are recognised for all deductible temporary differences, the carry forward of unused tax credits and any unused tax losses. Deferred tax assets are recognised to the extent that is probable that taxable profit will be available against which the deductible temporary differences, and the carry forward of unused tax credits and unused tax losses can be utilised, except when the deferred tax asset relating to the deductible temporary differences arises from the initial recognition of an asset or liability in a transaction that at the time of the transaction affects neither accounting profit nor taxable profit or loss.

The carrying amount of deferred tax assets is reviewed at each reporting date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilised. Unrecognised deferred tax assets are re-assessed at each reporting date and are recognised to the extent that it has become probable that future taxable profits will allow the deferred tax asset to be recovered.



Deferred tax assets and tax liabilities are measured at the tax rates that are expected to apply in the year when the asset is realised or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantially enacted at the reporting date.

Deferred tax assets and deferred tax liabilities are offset if a legally enforceable right exists to set off current tax assets against current tax liabilities and the deferred taxes relate to the same taxation authority.

#### > Employee benefits

#### A) Short-terme employee benefits

Short-term employee benefits include salaries and social security taxes, paid vacation and bonuses. They are recognised as expenses for the period in which employees perform the corresponding services. Outstanding payments at the end of the period are presented within current liabilities (other payables).

#### B) Post-employment benefits

Post-employment benefits include pensions and retirement benefits for employees, which are covered by defined contribution plans.

Under defined contribution plans, the Company pays contributions based on salaries to an insurance company responsible for paying out pensions and social security benefits, in accordance with the laws and agreements applicable in Belgium.

The defined contribution plans are by law subject to minimum guaranteed rate of return, which was until recently 3.25% on employer contributions. This rate has recently been modified to 1.75% and applies to the future contributions as from the date of modification.

Contributions are recognised as expenses for the period in which employees perform the corresponding services. Outstanding payments at the end of the period, if any, are presented within current liabilities (other payable).

#### Share-based compensation

There are several equity-settled share-based compensation plans in place. The fair value of the employee services received in exchange for the grant of stock options or warrants is determined at the grant date using a Black & Scholes valuation model.

The total amount to be expensed over the vesting period, if any, with a corresponding increase in the « share-based payment reserve » within equity, is determined by reference to the fair value of the stock options or warrants granted, excluding the impact of any non-market vesting conditions. At each balance sheet date, the entity revises its estimates of the number of stock options that are expected to become exercisable. It recognises the impact of the revision of original estimates, if any, in the income statement, and a corresponding adjustment to equity over the remaining vesting period.

The proceeds received net of any directly attributable transaction costs are credited to share capital when the stock options or the warrants are exercised.



#### > Provisions

A provision is set up by the Company if, at the reporting date, the Company has a present obligation, either legal or constructive, as a result of past events, when it is probable that an outflow of resources will be required to settle the obligation and when a reliable estimate of the amount can be made.

#### ▶ Grants

Government grants are recognised if there is reasonable assurance that the Company will comply with the conditions attached to them and that the grants will be received.

A grant relating to assets is presented by deducting the grant from the asset's carrying amount. A grant relating to income is reported separately as other income.

#### > Leases

A financial lease is a lease which transfers substantially all risks and rewards of ownership to the lessee. All other leases are operating leases. The Company is only involved in operating leases as a lessee. For such agreements payments made are expensed on a straight-line basis over the period of the lease.

#### ➤ Borrowing costs

Borrowing costs are expensed as incurred as there is no qualifying asset for which capitalisation of borrowing costs may be required.

#### Revenue

As of today the Company has only incidental revenue. The Company will develop accounting policies when it will begin to generate material revenues.

#### Segments

To date, all Company's activities relate to research & development and as a consequence, there is only one operating segment. The reporting to the decision maker is currently done at the global level.

Assets of the Company are located in the country of domicile per 31 December 2015, except some items of manufacturing equipment purchased in 2014 and 2015 and located in the premises of the CMO in Europe.

The net book value of these assets as at 31 December 2015 is EUR 316,000 compared with EUR 155,000 as at 31 December 2014 (and nihil as at 31 December 2013).

#### 3. Capital Management

Capital comprises equity attributable to shareholders, borrowings and cash and cash equivalents. The Company's policy is to maintain a strong capital base in order to maintain investor confidence in its capacity to support the future development of its operations. The Company's objectives when managing capital are to maintain sufficient liquidity to meet its working capital requirements and fund capital investment in order to safeguard its ability to continue operating as a going concern.

The Company monitors capital regularly to ensure that the legal capital requirements are met and may propose capital increases to the Shareholders' Meeting to ensure the necessary capital remains intact.



#### 4. Management of Financial Risks

#### • Financial risk factors

The Company's activities expose it to a variety of financial risks such as liquidity risk. The Company's finance department identifies and evaluates the financial risks in co-operation with the operating units.

#### ➤ Market risk

Market risk is the risk that the fair value of future cash flows of a financial instrument will fluctuate because of changes in market prices. The Company's activities may expose it to changes in foreign currency exchange rates and interest rates. The Company is not exposed to any equity price risk or commodity price risk as it does not invest in these classes of investments.

#### > Foreign exchange risk

The Company may be exposed to foreign currency risks through its operating activities. To date, certain purchase transactions are undertaken in Swiss francs (CHF), in British Pounds (GBP), in US Dollars (USD) and in Swedish crowns (SEK). However, the magnitude of purchases in foreign currencies is currently limited; meaning that the Company's exposure to fluctuation of the exchange rate of the concerned currencies into Euro is limited. In the future, as the developments progress and particularly in view of the commercialisation of the product candidates, the foreign exchange risk may significantly increase, especially the foreign exchange risk linked to the USD.

#### Interest rate risk

The Company issued convertible borrowings. The interest rate risk of such operations was however limited as such borrowings were concluded with a fixed interest rate. Accordingly, a change in the market interest rates does not impact the cash-flow and the profit or loss of the Company.

#### ➤ Liquidity risk

The Company's main sources of cash inflows are obtained through capital increases, convertible loans and grants. Cash is invested in low risk investments such as short-term bank deposits or savings accounts. The Company mainly makes use of liquid investment in current accounts (in Euro) or short-term deposit accounts.

The ability of the Company to maintain adequate cash reserves to support its activities in the medium term is highly dependent on the Company's ability to raise additional funds. As a consequence, the Company is exposed to significant liquidity risk in the medium term.

Analysis of contractual maturities of financial liabilities at 31 December is as follows:

	2015			2014			2013		
(in EUR 000)	Financial Debt	Trade Payables	Other Payables	Financial Debt	Trade Payables	Other Payables	Financial Debt	Trade Payables	Other Payables
Less than 1 month		1,611	489		858	353	-	351	24
1-3 months	-	-	-	-	• -	-	-	-	-
3 months to 1 year	4,232	-	-	-		68	-	-	68
1-5 years	-	-	-	-	-	70	-	-	-
5+ years					<u> </u>		885		
TOTAL	4,232	1,611	489		858	491	885	351	92



#### > Fair value

The carrying amount of cash and cash equivalents, trade receivables, other receivables and other current assets approximate their value due to their short term character.

The carrying value of current liabilities approximates their fair value due to the short term character of these instruments.

The fair value of non-current liabilities (financial debt and other non-current liabilities) is evaluated based on their interest rates and maturity date. These instruments have fixed interest rates or no interest rate and their fair value measurements are subject to changes in interest rates. The fair value measurement is classified as level 2.

#### A) Faire value hierarchy

The Company uses the following hierarchy for determining and disclosing the fair value of financial instruments by valuation techniques:

Level 1: quoted (unadjusted) market prices in active markets for identical assets or liabilities;

Level 2: valuation techniques for which the lowest level input that is significant to the fair value measurement is directly or indirectly observable; and

Level 3: valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable.

(in EUR 000)		Carrying value		Fair value			
	31/12/2015	31/12/2014	31/12/2013	31/12/2015	31/12/2014	31/12/2013	
Financial Assets							
Other long term receivables	12	13	3	12	13	3	
Loans and receivables measured at amortised cost	-	-	-	-	-	-	
Trade and other receivables.	279	102	61	279	102	61	
Other current assets	57	8	7	57	8	7	
Cash and cash equivalents	4,621	8,441	1,245	4,621	8,441	1,245	
Financial liabilities							
Financial liabilities measured							
at amortised cost	4,232	-70	885	4,232	-70	885	
Trade and other payables	2,100	1,279	443	2,100	1,279	443	

#### 5. Critical accounting estimates and assumptions

When preparing the consolidated financial statements, judgments, estimates and assumptions are made that affect the carrying amount of certain assets, liabilities and expenses. These include the going concern assessment, the accounting for defined contribution plans, the share-based payment transactions, the accounting for research and development expenses and deferred taxes. These judgments, estimates and assumptions have been reviewed for each year and are reviewed on a regular basis, taking into consideration past experience and other factors deemed relevant under the then prevailing economic conditions. Changes in such conditions might accordingly result in different estimates in the Company's future consolidated financial statements.

#### > Critical judgments

#### Going concern



The financial statements have been prepared on a going concern basis.

Taking into consideration the cash and cash equivalents as at 31 December 2015 and the net proceeds of more than 20 Millions euros raised during the IPO finalize on May  $12\ 2016$ , going concern is assured for at least 12 months from the date of the present report.

#### Critical accounting estimates and assumptions

#### Share-based payments

The Company has several equity-settled share based payment plans in place. Estimating fair value for share-based payment transactions requires determination of the most appropriate valuation model, which is dependent on the terms and conditions of the option plan. This estimate also requires determination of the most appropriate inputs to the valuation model including the expected life of the share option, volatility and dividend yield and making assumptions about them.

#### Research & Development expenses

In line with market, the Company is of the opinion that research and development expenditures do not meet the capitalisation criteria until successful completion of phase III is achieved. Accordingly, no research and development asset has been recognised in the financial statements of the Company.

#### Deferred tax assets

As a result of significant losses incurred by the Company, the Company enjoys tax losses that can be carried forward. However, no deferred tax asset has been recognised as at this stage it cannot be demonstrated that the tax losses will be compensated by future taxable income in the foreseeable future.

#### 6. Subsidiary

The Company owned 100% of the shares of Biotech Tools Factory SA, a Belgian Company that was incorporated on April 8, 2009. Corporate address of Biotech Tools Factory was Rue des Chasseurs Ardennais 3 - B4031 Angleur. The Company was registered under number BE 0811.028.777 and had a share capital of EUR 181,926. Biotech Tools Factory was liquidated on 26 June 2015.

#### 7. Property Plant and Equipment

	ICT Equipment	Equipment	Furniture and fixtures	Leasehold improvement	Total
			(in EUR 000)		
As at 1st January 2013					
Cost	63	135	35	10	243
Accumulated depreciation	(52)	(112)	(32)	(10)	(206)
Net book value	11	23	3	<u>-</u>	37
2013					
Acquisitions	22	4	-	-	26
Depreciation	(12)	(10)	(1)	-	(23)
Net book value	21	17	2		40
2014					
Acquisitions	17	162	-	3	182



	ICT Equipment	Equipment	Furniture and fixtures	Leasehold improvement	Total
Depreciation	(5)	(14)	(1)	-	(20)
Net book value	33	165	1	3	202
2015					
Acquisitions	14	328	30	-	372
Depreciation	(11)	(64)	(5)	<u> </u>	(80)
Net book value	36	429	26	-3	494
As at 31 December 2015					
Cost	116	629	65	13	823
Accumulated depreciation	(80)	(200)	(39)	(10)	(329)
Net book value	36	429	26	3	494

In 2015, acquisitions were mainly related to manufacturing equipment (EUR 328,000) for the manufacturing of the drug substance for the product candidates.

The yearly depreciation charge amounts to EUR 80,000 in 2015, EUR 20,000 in 2014 and EUR 23,000 in 2013.

#### 8. Other Long Term Receivables

Other long term receivables are summarised hereafter:

	31/12/2015	31/12/2014	31/12/2013
		(in EUR 000)	
Other deposit	12	13	3
Total other long term receivables	12	13	3

#### 9. <u>Inventories</u>

Inventories are as follows:

	31/12/2015	31/12/2014	31/12/2013
		(in EUR 000)	
Inventories	11	14	13
Total inventories	11	14	13

Income statement has been impacted as follows by inventories:

	2015	2014	2013
		(in EUR 000)	
Net increase / (decrease) in inventories	(3)	-	3

#### 10. Trade Receivables



	31/12/2015	31/12/2014	31/12/2013
		(in EUR 000)	
Trade receivables (gross)	2	2	2
Credit notes to be received	-	16	-
Allowance for doubtful receivables	<u>-</u> _	<u>-</u> _	
Trade receivables	2	18	2

2014 Trade receivables include credit notes to be received for EUR 16,000.

#### 11. Other receivables

Other receivables are summarised in the following table:

	31/12/2015	31/12/2014	31/12/2013
		(in EUR 000)	
VAT receivable	265	73	38
Current tax receivable	10	5	13
Other	2	6	8
Other receivables	277	84	59

#### 12. Other Current Assets

Other current assets relate to prepaid expenses and accrued income (creditor bank interests) which amount to EUR 57,000 as at 31 December 2015, EUR 8,000 as at 31 December 2014 and EUR 7,000 as at 31 December 2013.

#### 13. Cash and Cash Equivalents

	31/12/2015	31/12/2014	31/12/2013
		(in EUR 000)	
Short term deposit	7	7	7
Savings accounts	26	1,327	1,190
Current accounts	4,588	7,107	48
Petty Cash	-	-	-
Total cash and cash equivalents	4,621	8,441	1,245

#### 14. Capital and Share Premium

On 31 December 2015 the share capital of the Company amounted to EUR 11,625,136.35 and has evolved as follows.

As at 31 December 2013 the share capital amounted to EUR 14,292,747.03 and was represented by 57,812 ordinary shares. As a consequence of capital increases which took place before 2012, a share premium amounting to EUR 5,413,000 was accounted for.

At the extraordinary Shareholders' Meeting of the Company held on 23 December 2014, the following operations were decided:

• A capital increase without issuance of new Shares of EUR 5,412,968.81 through the incorporation of the share premiums;



- A capital decrease by absorption of the accumulated deficit of EUR 19,699,539.49 by way of absorption of carried forward losses;
- A capital increase of EUR 7,086,960 through a contribution in cash and the creation of 13,124 new Shares:
- A capital increase of EUR 854,100 as a result of the conversion into shares of convertible bonds issued in April 2013, and the creation of 3,275 new Shares;
- A capital increase of EUR 2,596,800 as a result of the conversion into shares of convertible bonds issued in May 2014, and the creation of 7,648 Shares; and
- A capital increase of EUR 1,081,100 as a result of the conversion into shares of convertible bonds issued in October 2014, and the creation of 3,182 Shares.

Following these transactions, the share capital of the Company amounts to EUR 11,625,136.35 at 31 December 2015, represented by 8,504,100 shares without nominal value.

#### 15. <u>Share Based Compensation</u>

The Company has currently four outstanding stock based incentive plans, including (i) the 2008 warrants plan (the 2008 Plan), (ii) the 2011 warrants plan (the 2011 Plan), (iii) the 2014 warrants plan (the 2014 Plan) and (iv) the 2015 warrants plan (the 2015 Plan) (collectively the Stock Based Plans).

#### > 2008 Plan

The Board of Directors proposed on 27 September 2007 to issue and grant to employees/directors/shareholders 5,459 subscription rights (warrants) in the framework of the provisions of Belgian law of 26 March 1999 on stock options. Such proposal made by the Board of Directors was approved by the Shareholders' Meeting on 8 January 2008.

The exercise price of each warrant was EUR 267 for the ones granted in 2008 and EUR 523.4 for the ones granted in 2011 and 2012.

The key features of the warrants granted under the 2008 Plan are as follows (i) each warrant could be exercised for one share, it being understood that further to the stock-split approved on 8 January 2016 the exercise of a warrant after that date will give right to one hundred shares instead of one share, the conversion price of the warrant remaining unchanged, (ii) the warrants are granted for free, i.e. no consideration is due upon the grant of the warrants, (iii) the warrants have a term of five years since the grant, (iv) no vesting conditions, and (v) the warrants can be exercised between the first day of the fourth civil year following the grant and the last day of the fifth civil year following the grant.

Out of these 5,459 issued warrants, 4,319 warrants were offered in 2008, according to the following distribution: 3,992 were accepted by employees, directors and members of the scientific committee, and 327 warrants were accepted by three shareholders for anti-dilution purposes.

All these warrants have expired on 31 December 2013.

On the remaining portion, 1,100 warrants were offered and accepted in 2011. As of the date of these financial statements, 1,100 warrants granted in 2011 under the 2008 Plan are still outstanding. 40 warrants have not been offered and became void.



#### > 2011 Plan

On 20 October 2011, the Shareholders' Meeting of the Company approved the issuance and the award of warrants as follows: (i) 49 warrants were issued and offered to shareholders who were the beneficiaries of the allocation decided in 2008, (ii) 770 warrants were offered to employees and directors who were the beneficiaries of the allocation decided in 2008, (iii) 350 warrants were issued and offered to independent directors, (iv) 500 warrants were issued for the benefit of employees but have never been offered and (v) 200 warrants were issued and offered to 3 Shareholders (Creafund, SRIW and SRIB). The warrants were offered to these three shareholders for anti-dilution purposes.

The exercise price of each warrant is EUR 523.40.

The key features of the warrants granted under the 2011 Plan are as follows: (i) each warrant could be exercised for one share, it being understood that further to the stock-split approved on 8 January 2016 the exercise of a warrant will after that date give right to one hundred shares instead of one share, the conversion price of the warrant remaining unchanged, (ii) the warrants are granted for free, i.e. no consideration is due upon the grant of the warrants, (iii) the warrants have a term of five years since the grant, (iv) no vesting conditions and (v) the warrants can be exercised between the first day of the fourth civil year following the grant and the last day of the fifth civil year following the grant (31 December 2016 or 31 December 2017 depending on the date at which the grants occurred).

848 warrants have been offered to and accepted by employees, directors and members of the scientific committee, under the 2011 Plan. 249 warrants were offered to and accepted by three shareholders for anti-dilution purposes.

At the date of these financial statements, 848 warrants granted under the 2011 Plan to employees, directors and members of the scientific committee are still outstanding, entitling the holders to subscribe to 84,800 shares of the Company. 135 warrants granted under the 2011 Plan to shareholders are still outstanding entitling the holders to subscribe to 13,500 shares of the Company.

#### > 2014 Plan

On 15 October 2014 the Shareholders' Meeting of the Company approved the issuance of 5,300 warrants. These warrants are valid until 30 October 2024. The Shareholders' Meeting granted a special proxy to the Board of Directors of the Company in order to (i) identify the beneficiaries, (ii) offer the issued warrants to workers of the Company (employees, managers or directors) and (iii) to determine the exercise price of the concerned warrants before each offer with the approval of the auditor. It being understood that the beneficiaries shall be workers of the Company, the exercise price shall be equal to the real value of the underlying shares at the time of the offer and that a maximum of 2,000 warrants will be offered to beneficiaries who are not employees of the Company but exercise their services as self-employed people.

On 15 October 2014 the Board of Directors decided to offer 2,400 warrants to beneficiaries, and approved a warrants plan.

The exercise price of each warrant is EUR 300.

The key features of the warrants granted under the 2014 Plan are as follows (i) each warrant could be exercised for one share, it being understood that further to the stock-split approved on 8 January 2016 the exercise of a warrant after that date will give right to one hundred shares instead of one share, the conversion price of the warrant remaining unchanged, (ii) the warrants are granted for free, i.e. no consideration is due upon the grant of the warrants, (iii) the warrants have



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a term of five years since the grant, (iv) no vesting conditions, and (v) the warrants can be exercised between 1 November 2014 and 30 October 2019.

2,145 warrants have been accepted by employees, directors and members of the scientific committee.

At the date of these financial statements, 2,145 subscription rights are still outstanding under the 2014 Plan entitling the holders to subscribe 214,500 Shares of the Company.

#### > 2015 Plan

On 10 March 2015, 14 April 2015 and 19 May 2015 the Board of Directors decided to offer 1,700 subscription rights (issued on 15 October 2014) to beneficiaries and approved a warrants plan. The exercise price of each subscription right is EUR 540.

The key features of the subscription rights granted under the 2015 Plan are as follows (i) each subscription right can be exercised for one share, it being understood that further to the stock-split approved on 8 January 2016 the exercise of a warrant will give right to one hundred shares instead of one share, the conversion price of the warrant remaining unchanged (ii) the subscription rights are granted for free, i.e. no consideration is due upon the grant of the subscription rights, (iii) the subscription rights have a term of five years since the grant, (iv) the subscription rights can only be exercised if the holder still exercise his professional activity in favour of the Issuer, and (v) the subscription rights can be exercised between 1 June 2017 and 30 April 2020.

Contrary to the previous plans, the 2015 plan foresees an employment condition. Accordingly, the fair value of the plan is expensed over the vesting period.

At the date of these financial statements 1,160 subscription rights are still outstanding under the 2015 Plan, entitling the holders to subscribe 116,000 shares of the Company.

#### Accounting for share-based payment

The share-based compensation expense recognised in the income statement is EUR 0 for 2013, EUR 199,000 for 2014 and EUR 18,000 for 2015.

The fair value of each option or subscription right is estimated on the date of grant using the Black & Scholes model and the following assumptions:

2007 granting of warrants	
Number of warrants granted*:	3,992
Exercise price	EUR 267
Expected dividend yield	0%
Expected stock price volatility	35%
Risk-free interest rate:	3,61%
Expected duration	5 years
Forfeiture rate:	0%
Fair Value	EUR 393,000

These warrants expired on 31 December 2013.



2011 granting of warrants	
Number of warrants granted*:	1,948
Exercise price	EUR 523.40
Expected dividend yield	0%
Expected stock price volatility	35%
Risk-free interest rate:	3,50%
Expected duration	5 years
Forfeiture rate:	0%
Fair Value	EUR 374,000
Plan 2014	2145
Number of warrants granted*:	2,145
Exercise price	EUR 300
Expected dividend yield	0%
Expected stock price volatility	35%
Risk-free interest rate:	0,30%
Expected duration	5 years
Forfeiture rate:	0%
Fair Value	EUR 199,000
* to employees, Directors and members of the scientific committee	
2015 granting of warrants	
Number of warrants granted**:	1,700
Exercise price	EUR 540
Expected dividend yield	0%
Expected stock price volatility	35%
Risk-free interest rate:	-0,01%
Expected duration	4 years
Forfeiture rate:	0%
Fair Value	EUR 251,000

<sup>\*\* 1,160</sup> warrants accepted and outstanding as at December 31,2015

As at the date of these financial statements, and considering the 2015 plan, there are 5,388 warrants entitling the holders to subscribe to 538,800 new Shares or 6.5% of the existing Shares of the Company.

#### 16. Financial Debts

The Company issued several convertible loans, which were all converted into capital on 23 December 2014:

- Convertible loan of EUR 854,000 issued on April 28, 2013;
- Convertible loan of EUR 2,597,000 issued on May 23, 2014; and
- Convertible loan of EUR 1,081,000 issued on October 15, 2014.

The 2013 convertible loan included a contractual obligation for the Company to deliver a variable number of shares and accordingly has been classified as a financial debt as at 31 December 2013.

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 is 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 maturity date of the Convertible Bonds was 15 May 2016. As of 31 December 2015, accrued interest on such bonds amounted to EUR 102,000.

As the Offering was completed and the book fully subscribe at 7 €/share on May 2016, the number of new Shares issued upon conversion of one bond equals to 153% of EUR 10,000 divided by the Offer Price of 7€ per share. The 413 convertible bond gave therefore right to 902.700 new shares representing a total value of 4,130,000 €.

The corresponding capital increase was officialised by an act from notary van Halteren on May 12 2016 for an amount of 1,233,994 €, the remaining 2,896,006 € were booked as share premium.

#### 17. Trade Payables

Trade payables as at the end of each financial year can be presented as follows:

	31/12/2015	31/12/2014	31/12/2013
		(in EUR 000)	
Payables	335	671	116
Invoices to be received	1,276	187	235
Total	1,611	858	351

The strong increase of trade payables in 2015 is related to the significant increase of the Company's research activity and more specifically to the productions of the drug substance and drug product batches to be used in the forthcoming phase III clinical study with its gp-ASIT+<sup>TM</sup> product candidate.

#### 18. Other Non-Current Liabilities & Other Payables

Other non-current liabilities and other payables can be presented as follows:

_	31/12/2015	31/12/2014	31/12/2013
		(in EUR 000)	
Other non-current liabilities			
Bonus to be paid (long term part)	-	70	-
Total other other non-current liabilities	<u>-</u>	70	-
Other payables			
Withholding taxes	4	17	14
Social security	28	51	8
Bonus to be paid (short term part)	-	140	-
Holiday pay accrual	142	68	68
Advance received on grant	314		
Accrued expenses & interests	0	144	2
Total other payables	489	421	92
Total	489	491	92

The other non-current liability and other payables as at 31 December 2015 comprise an amount received of EUR 314,000 from the Walloon Region with respect to a grant recently signed.



#### 19. Revenue

Revenue is incidental and represents sales of Lupus' diagnostics.

(in EUR 000)	31/12/2015	31/12/2014	31/12/2013
Revenue	4	5	7
Total revenue	4	5	7

#### 20. Research and development costs

Research and development 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)	-	
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)	-	
Other	(60)	(9)	(9)	
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. 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 headcount dedicated to the different activities.

#### 21. General and Administrative Expenses

General and administrative expenses can be summarised as follows:

	31/12/2015	31/12/2014	31/12/2013
		(in EUR 000)	
Staff costs	(405)	(426)	(227)
Share-based payment	(1)	(116)	-
External advice	(429)	(178)	(359)
Facilities	(25)	(21)	(16)
ICT	-	-	-
Depreciation and amortisation expense	(8)	(4)	(4)
Laboratory supplies	(5)	(5)	-
Rent	(6)	(10)	(12)
Other	(67)	(25)	(26)
Total general and administrative expenses	(947)	(785)	(644)



#### 22. Defined Contribution Plans

The post-employment benefits of the employees of the Company are defined contribution plans with minimum guaranteed rates of return which was until recently of 3,25% on employer contributions and has been modified to 1.75%. The minimum guaranteed rates apply as an average over the entire career, may be modified by a Royal Decree in which cases the new rates apply to the future contributions as from the date of modification onwards.

The Company funds the plans by paying a fixed percentage of the monthly salary of the employee to the external insurance company. There is an employee contribution. There is a risk that the Company may have to pay additional contributions related to past services. However, in the case at hand, the Company has taken up insurance to cover any potential shortfall. Therefore, the risk of any liability is considered remote by the Company.

In accordance with the Company's accounting policy, the Company accounts for those plans as defined contribution plans and compare the "walk away liability" or the vested rights at reporting date with the fair value of the plan assets. If the vested rights are higher as compared to the fair value of the plan asset, a liability is recognised for the shortage at the reporting date.

At 31 December 2015, 2014 and 2013, no such net liability was recognised in the balance sheet as the minimum guaranteed reserves equal the fair value of the plan assets or the underfunding is immaterial.. At the date of the Offering Prospectus, and according to actuarial calculation from the Company's insurer, the Company would have to recognise an unaccrued liability for an aggregate amount of EUR 1,606.62.

The total expense recognised in the consolidated income statement for contributions made under these plans amount to EUR 38,000 in 2015, EUR 27,000 in 2014 and EUR 20,000 in 2013.

#### 23. Employee Benefits

Employee benefits can be summarised as follows:

_	31/12/2015	31/12/2015 31/12/2014	
_		(in EUR 000)	
Salaries	(1.372)	(902)	(585)
Social charges	(13)	(63)	(42)
Fringe benefits	(11)	(40)	(23)
Defined contribution plan	(38)	(27)	(20)
Share-based payment	(18)	(150)	-
Holiday pay accrual	(74)	-	(14)
Other	(32)	(32)	(22)
Total employee benefits	(1,558)	(1,214)	(705)

The decrease of the share-based payment charge in 2015 is due to the fact that the 2015 plan has vesting conditions whereas the 2014 plan was fully vested at grant date.

#### 24. <u>Financial Income</u>

Financial income can be summarised as follows:



_	31/12/2015	31/12/2014	31/12/2013
_		(in EUR 000)	
Interests	31	6	13
Other	2	-	-
Total financial income	33	6	13

#### 25. Financial Expense

Financial expense can be summarised as follows:

<del>-</del>	31/12/2015	31/12/2014	31/12/2013
_		(in EUR 000)	
Interests on convertible loan	(102)	(112)	(31)
Exchange differences	(4)	(3)	-
Other	(2)	(2)	(1)
Total financial expense	(108)	(117)	(32)

#### 26. Taxes

Tax expense for the year can be reconciled to the accounting loss as follows:

_	31/12/2015	31/12/2014	31/12/2013
_		(in EUR 000)	
Loss before taxes	(7,715)	(4,429)	(2,319)
Income tax credit calculated at 33,99%	2,622	1,505	788
Effect of unused tax losses not recognised as deferred tax asset	(2,622)	(1,505)	(788)
Income tax expense (profit) recognised in income statement	<u>-</u>	-	-

The tax rate used in the reconciliation is the corporate tax rate of 33,99 % applicable in Belgium.

#### Unrecognised deferred tax assets

Due to the uncertainty surrounding the Company's ability to realise taxable profit in the future, the Company has not recognised any deferred tax assets on tax losses that can be carried forward and on notional interest deductions.

Tax losses of the Company that can be carried forward amount to EUR 24,500,000 as at 31 December 2015 and EUR 20,501,000 as at 31 December 2014. The corresponding amount as at 31 December 2013 was EUR 19,318,000. Tax losses that can be carried forward are determined on the basis of the statutory financial statements and local Belgian tax rules. Accordingly, the yearly variations in tax losses carried forward cannot be compared to the IFRS results for the same period. In Belgium, tax losses can be carried forward indefinitely. Notional interest deductions prior to 2012 can be carried forward for a limited period of seven years. Notional interest that can be carried forward amount to EUR 552,000 as at 31 December 2015. These notional interests will expire in 2016 for EUR 248,000, in 2017 for EUR 149,000 and in 2018 for the remaining EUR 154,000. The corresponding amount as at 31 December 2014 is EUR 848,000. The decrease is explained by the fact that as at 31 December 2015 some notional interests previously carried forward expired. After 2012 notional interests deduction has to take place within the tax year and it is not possible anymore to carry them forward.



#### 27. Contingenies

#### • Legal claims:

The Company is currently not involved in any litigation that might have an adverse significant impact on the Company's financial position.

#### • Grants:

The Company benefited between 1998 and 2007 from operation subsidies granted by the Brussels-Capital Region for an aggregate amount of EUR 2,167,000 for its research project in the field of grass pollen-induced allergic rhino conjunctivitis. These subsidies were accounted for as investment grants and no amount has been recognised with respect to these grants in the financial statements for financial years 2013, 2014 and 2015.

In order to continue satisfying the conditions for the maintenance of the grant of these subsidies, i.e. ensuring the industrial and commercial development in the interest of the economy, employment and the environment in the Brussels-Capital Region, the Company agreed to pursue activity on the territory of the Brussels-Capital Region in the 10 years following the end date of the agreements granting subsidies (i.e., until March 2018).



#### 28. Commitments

#### > Capital commitments

There are no commitments related to capital expenditures at the balance sheet date.

#### > Operating leases

The Company has entered into operating leases in relation to its offices as well as in relation to employee cars for which the average lease term is 48 months.

The Company's future payments as per 31 December 2015 under its leasing contracts are summarised in the table below:

	31/12/2015	31/12/2015 31/12/2014	
	<del></del>	(in EUR 000)	
Within 1 year	129	74	12
Between 1 and 5 years	228	52	-
More than 5 years	-	-	-
Total	357	126	12

Payments under operating leases recognised as an expense:

	31/12/2015	31/12/2014	31/12/2013
		(in EUR 000)	
Expense	130	41	41
Total	130	41	41

#### 29. Related party transactions

Transactions between the Company and its subsidiary have been eliminated on consolidation and are not disclosed in the notes.

#### > Remuneration of the key management

The remuneration of the senior management consists of the remuneration of the CEO of the Company:

	31/12/2015	31/12/2015 31/12/2014	
		(in EUR 000)	
Short-term remuneration & compensation*	282	328	180
Long-term remuneration & compensation	-	70	-
Share based payment	-	70	-
Total	282	468	180

<sup>\*</sup> In 2014 it Included the short term remuneration of EUR 188,000 effectively charged and paid in 2014, and a guarantee bonus for an amount of EUR 140,000 to be paid in 2015

No loans or other guarantees have been given to a member of the executive management team.



#### > Transactions with non-executive directors and shareholders

Subscription rights have been granted to non-executive directors, shareholders and members of the scientific Committee. The share based payment expense relating to these related is nihil in 2015, EUR 49,000 in 2014 and nihil in 2013.

#### 30. Events after the balance-sheet date

The other non-current liability and other payables as at 31 December 2015 comprise an amount received of EUR 314,000 from the Walloon Region with respect to a grant agreement.

On 2 December 2015 the agreement relating to the granting of a subsidy taking the form of a refundable advance related to the development of the house dust mite treatment was signed with the Walloon Region for a total amount of EUR 1,254,000 (of which EUR 314,000 has already been received in December 2015 and the balance of EUR 940,000 is to be received in the coming months as expenses will be incurred). The agreement was entered into subject to the execution of a covenant, which was eventually signed by the Company on 5 February 2016.

This contract will be accounted for in the 2016 accounting year of the Company.

The Company successfully launch its Offering on 10 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.

Further to the realization of the Offering, the convertible bonds issued on 5 August 2015 were converted into share capital 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).

#### 31. Earnings per Share

The Company has warrants plans and Convertible Bonds that may be settled in common shares of the Company which are anti-dilutive considering the loss of the year. As such the basic and diluted earnings per share are equal.

The basis for the basic and diluted earnings per share is the net loss for the year attributable to the owners of the Company.

or the company.	31/12/2015	31/12/2014	31/12/2013
		1. (in EUR 000)	
Loss for the year attributable to the owners of the Company	(7,715)	(4,429)	(2,319)
Weighted average number of shares for basic and diluted loss per share (in number of shares)	85,041	58,482	57,812
Losses per share basic and diluted (in EUR per share)	(90,72)	(75.73)	(40.11)

#### 32. First time adoption of IFRS – impact of transition to IFRS

#### > Impact of transition to IFRS



The following table is a summary of the effects of the differences between IFRS and Belgium GAAP on the Company's total equity shareholders' funds and loss for the financial year for the years previously reported under Belgium GAAP following the date of transition to IFRS.

	Note	01/01/2013	31/12/2013	31/12/2014	31/12/2015
			(in EUR	000)	
Total shareholders' equity (Belgium GAAP)		2,321	6	10,241	6,199
Measurement and recognition differences					
Consolidation of Biotech	a.				
Tools Factory		40	36	31	
Depreciation charge of	b.				
tangible assets		-	-	32	72
- Intangible assets	c.	-	-	(2,662)	(7,128)
- salaries accruals	d.	-	-	(210)	
Total shareholders' equity (IFRS)		2,361	42	7,432	(858)
		Note	31/12/2013	31/12/2014	31/12/2015
				(in EUR 000)	
Loss for the year ended (Belgium GAAP)		<b></b>	(2,315)	(1,385)	(4,041)
-Consolidation of Biotech		a.			
Tools Factory			(4)	(4)	(31)
- Share-based payments		e.	-	(199)	(18)
- Depreciation charge of tangible assets	s	b.	-	32	40
- Intangible assets		c.	-	(2,662)	(4,466)
- Salaries accruals		d.	-	(210)	210
- Offerings costs		f.			593
Loss for the year ended (IFRS)			(2,319)	(4,429)	(7,715)

#### > Measurement and recognition differences

#### a) Consolidation of Biotech Tools Factory

Under IFRS, the fully owned subsidiary of ASIT biotech SA has been consolidated. No consolidated financial statements have been prepared in accordance with Belgium GAAP as the quantitative criteria of the BCC were not met.

#### b) Depreciation charge of tangible assets

Under Belgium GAAP, a full annuity of depreciation is accounted for on the acquisitions of the period, whereas under IFRS depreciation starts when the asset is ready for its intended use. No deferred tax (neither asset, nor liability) has been recognised on the temporary difference arising from this restatement as these amounts would have been immaterial.

#### c) Intangible assets



The Company recognised intangible assets under Belgium GAAP. On the other hand, IFRS recognition criteria are not met (potential revenue generated by the research costs incurred occurred in a too far away period to allow recognition for capitalisation). No deferred tax asset has been recognised on the deductible temporary difference arising from this restatement because the Company is in a loss position and will stay so in the near future.

#### d) Salaries accruals

Management bonuses are expensed at the date of granting under Belgium GAAP whereas it is accrued for under IFRS.

#### e) Share-Based payments

IFRS 2, "Share-based payment" requires that an expense for equity instruments granted be recognised in the financial statements based on their fair value at the date of grant. This expense, which is primarily in relation to subscription rights offered, held by employees, managers, directors and beneficiaries who are not employees of the Company but exercise their services as self-employed people, is recognised over the vesting period of the scheme.

#### f) Offerings costs

Costs incurred with respect to the Offering are expensed as incurred under Belgian GAAP. Under IFRS, these costs will be deducted from the net proceeds of the Offering, if the Offering takes place and is successful.

Reconciliation of the Belgium GAAP profit and loss account to the IFRS consolidated income statement

#### Year ended 31 December 2013

Belgium GAAP format	Belgium GAAP	Measurement and recognition differences	Presentation differences	IFRS	IFRS Format
		(in EUR 000)	)		
Revenue	5			5	Revenue
Other operating income	0		6	6	Other operating income
Cost of sales	3			3	Cost of sales
Sundry expenses	(1,772)			(1.670)	Research & development
Payroll expenses	(514)	(4)		(1,670)	expenditures
Depreciation charge	(22)	(4)		(614)	General & administrative
Other operating charges	(3)			(644)	expenses
Operating loss for the period	(2,302)			(2,299)	Operating loss for the period
Financial income	13			13	Financial income
Financial charge	(32)			(32)	Financial expense
Loss for the period before taxes and exceptional result	(2,321)			(2,319)	Loss for the period before taxes
Exceptional income	10		(10)	-	
Exceptional charges	(3)		3	-	
Taxes					Taxes
Loss for the period	(2,315)	(4)	_	(2,319)	Loss for the period



#### Year ended 31 December 2014

Belgium GAAP format	Belgium GAAP	Measurement and recognition differences	Presentation differences	IFRS	IFRS Format
		(in EUR 000	9)		
Revenue	5			5	Revenue
Own production*	558	(558)		0	
Other operating income	3			3	Other operating income
Cost of sales	-			-	Cost of sales
Sundry expenses	(483)			(3,525)	Research & development
Payroll expenses	(636)	(2.497)		(3,323)	expenditures
Depreciation charge	(718)	(2,487)		(901)	General & administrative
Other operating charges	(2)			(801)	expenses
Operating loss for the period	(1,273)			(4,318)	Operating loss for the period
Financial income	6			6	Financial income
Financial charge	(117)			(117)	Financial expense
Loss for the period before taxes and exceptional result	(1,384)			(4,429)	Loss for the period before taxes
Exceptional income	-			-	
Exceptional charges	-			-	
Taxes					Taxes
Loss for the period	(1,384)	(3,045)	_	(4,429)	Loss for the period

<sup>\*</sup> The own production relates to the capitalisation (under the Belgian GAAP) of payroll costs incurred for research and development activities. Research and development salaries are accounted among payroll costs as an expense and the part that is capitalised is accounted as an income and an intangible asset.



#### Year ended 31 December 2015

Belgium GAAP format	Belgium GAAP	Measurement and ecognition differences	Presentation differences	IFRS	IFRS Format
		(in EUR 000	<b>9</b> )		
Revenue	4			4	Revenue
Own production*	820	(820)		0	
Other operating income	-	(2)	(1)	(3)	Other operating income / (expenses)
Cost of sales	(3)			(3)	Cost of sales
Sundry expenses	(1.656)			(6,601)	Research & development
Payroll expenses	(1.088)	(2.026)		(6,691)	expenditures
Depreciation charge	(2.069)	(2,826)	1	(0.47)	General & administrative
Other operating charges	(1)		1	(947)	expenses
Operating loss for the period	(3,992)			(7,640)	Operating loss for the period
Financial income	33			33	Financial income
Financial charge	(108)			(108)	Financial expense
Loss for the period before taxes and exceptional result	(4,066)			(7,715)	Loss for the period before taxes
Exceptional income	25	(25)		-	
Exceptional charges	-			-	
Taxes	-			-	Taxes
Loss for the period	(4,041)	(3,673)	=	(7,715)	Loss for the period

<sup>\*</sup> The own production relates to the capitalisation (under the Belgian GAAP) of payroll costs incurred for research and development activities. Research and development salaries are accounted among payroll costs as an expense and the part that is capitalised is accounted as an income and an intangible asset.

## Reconciliation of the Belgium GAAP Balance sheet to the IFRS Statement of financial position $1\,\mathrm{January}\,2013$

Belgium GAAP format	Belgium GAAP	Measurement and ecognition differences	Presentation differences	IFRS	IFRS Format
		(in EUR 00	<b>0</b> )		
Fixed assets					Non-current assets
Intangible assets	-			-	Intangible assets
Property, plant and equipment	35			35	Property, plant and equipment
Other long-term receivables	3			3	Other long-term receivables
Current assets					Current assets
Inventories	10			10	Inventories
Trade receivables	4			4	Trade receivables
Other current receivables	45	1		46	Other receivables
Investments	7		(7)	-	
Cash and cash equivalents	2,475	38	7	2,520	Cash and cash equivalents
Deferred charges/Accrued income	16			16	Other current assets
Total assets	2,595	39	0	2,634	Total assets
Shareholders' equity					Equity
Capital	14,293			14,293	Capital
Share premium	5,413			5,413	Share premium
Other Reserves					Other reserves
		767		767	Share-based payment reserve



Retained losses	(17,385)	(728)	(18,112)		Retained losses
Non-current liabilities				-	
Financial debt	-			-	
Other non-current liabilities	-				
Current liabilities					
Trade payables	187			187	Trade payables
Social and tax related liabilities	85		1	86	Other payables
Other current liabilities	1		(1)	-	
Accrued charges	1		(1)	-	
Total equity and liabilities	2,595	39		2,634	Total equity and liabilities

## Reconciliation of the Belgium GAAP Balance sheet to the IFRS Statement of financial position 31 December 2013

Belgium GAAP format	Belgium GAAP	Measurement and recognition Differences	Presentation differences	IFRS	IFRS Format	
		(in EUR 000)				
Fixed assets					Non-current assets	
Intangible assets	-			-	Intangible assets	
Property, plant and equipment	39			39	Property, plant and equipment	
Other long-term receivables	3		-	3	Other long-term receivables	
Current assets					Current assets	
Inventories	13			13	Inventories	
Trade receivables	2			2	Trade receivables	
Other current receivables	58	1		59	Other receivables	
Investments	7		(7)	-		
Cash and cash equivalents	1,204	34	7	1,245	Cash and cash equivalents	
Deferred charges/Accrued income	7			7	Other current assets	
Total assets	1,334	35		1,369	Total assets	
Shareholders' equity				-	Equity	
Capital	14,293			14,293	Capital	
Share premium	5,413			5,413	Share premium	
Other Reserves						
		374		374	Share-based payment reserve	
Retained losses	(19,700)	(338)		(20,038)	Retained losses	
Non-current liabilities						
Financial debt	885			885		
Other non-current liabilities						
Current liabilities						
Trade payables	351			351	Trade payables	
Social and tax related liabilities	89		2	91	Other payables	
Other current liabilities	1		(1)			
Accrued charges	2		(2)			
Total equity and liabilities	1,334	35		1,369	Total equity and liabilities	



## Reconciliation of the Belgium GAAP Balance sheet to the IFRS Statement of financial position 31 December 2014

Belgium GAAP format	Belgium GAAP	Measurement and recognition Differences	Presentation differences	IFRS	IFRS Format
		(in EUR 000)		_	
Fixed assets		,			Non-current assets
Intangible assets	2,662	(2,662)		-	Intangible assets
Property, plant and equipment	170	32		202	Property, plant and equipment
Other long-term receivables	13			13	Other long-term receivables
Current assets					Current assets
Inventories	14			14	Inventories
Trade receivables	18			18	Trade receivables
Other current receivables	84			84	Other receivables
Investments	7		(7)	0	
Cash and cash equivalents	8,403	31	7	8,441	Cash and cash equivalents
Deferred charges/Accrued income	8			8	Other current assets
Total assets	11,379	(2,599)		8,780	Total assets
Shareholders' equity				-	Equity
Capital	11,625			11,625	Capital
Share premium	-			-	Share premium
Other Reserves	-			-	
	-	573		573	Share-based payment reserve
Retained losses	(1,384)	(3,382)		(4,766)	Retained losses
Non-current liabilities					
Financial debt					
Other non-current liabilities		70		70	Other non-current liabilities
Current liabilities					
Trade payables	858			858	Trade payables
Social and tax related liabilities	137	140	145	421	Other payables
Other current liabilities	1		(1)	-	
Accrued charges	144		(144)	-	
Total equity and liabilities	11,379	(2,599)		8,780	Total equity and liabilities



### Reconciliation of the Belgium GAAP Balance sheet to the IFRS Statement of financial position 31 December 2015

Belgium GAAP format	Belgium GAAP	Measurement and recognition Differences	Presentation differences	IFRS	IFRS Format
		(in EUR 00	<b>(</b> )		
Fixed assets					Non-current assets
Intangible assets	7,128	(7,128)		-	Intangible assets
Property, plant and equipment	422	72		494	Property, plant and equipment
Other long-term receivables	12			12	Other long-term receivables
Current assets					Current assets
Inventories	11			11	Inventories
Trade receivables	2			2	Trade receivables
Other current receivables	277			277	Other receivables
Investments	7		(7)	-	
Cash and cash equivalents	4,614		7	4,621	Cash and cash equivalents
Deferred charges/Accrued income	57			57	Other current assets
Total assets	12,531	(7,056)		5,474	Total assets
Shareholders' equity				_	Equity
Capital	11,625			11,625	Capital
Share premium	-			-	Share premium
Other Reserves	-			_	1
	-	591		591	Share-based payment reserve
Retained losses	(5,426)	(7,648)		(13,074)	Retained losses
Non-current liabilities					
Financial debt					
Other non-current liabilities					Other non-current liabilities
Current liabilities					
Financial debt	4,130		102	4,232	Financial debt
Trade payables	1,611			1,611	Trade payables
Social and tax related liabilities	175		314	489	Other payables
Other current liabilities	314		(314)	-	• •
Accrued charges	102		(102)	-	
Total equity and liabilities	12,531	(7,056)		5,474	Total equity and liabilities

#### **AUDITOR'S REPORT**

STATUTORY AUDITOR'S REPORT TO THE GENERAL SHAREHOLDERS' MEETING ON THE CONSOLIDATED FINANCIAL STATEMENTS OF THE COMPANY ASIT BIOTECH SA AS OF AND FOR THE YEAR ENDED 31 DECEMBER 2015

As required by law, we report to you on the performance of our mandate of statutory auditor. This report includes our opinion on the consolidated financial statements, as well as the required additional statement. The consolidated financial statements comprise the consolidated statement of financial position as at 31st December 2015, and the consolidated statement of comprehensive income, the consolidated statement of



changes in equity and the consolidated statement of cash flows for the year ended 31st December 2015 and the explanatory notes.

#### Report on the consolidated financial statements – Unqualified opinion

We have audited the consolidated financial statements of the company ASIT BioTech SA for the year ended 31st December 2015, prepared in accordance with the International Financial Reporting Standards (IFRS) as adopted by the European Union, which show a consolidated statement of financial position total of KEUR 5.474 and a consolidated income statement showing a consolidated loss for the year of KEUR 7.715.

Responsibility of the board of Directors for the preparation of the consolidated financial statements

The board of Directors is responsible for the preparation of consolidated financial statements that give a true and fair view in accordance with the International Financial Reporting Standards as adopted by the European Union, and for such internal control as the board of Directors determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

Responsibility of the statutory auditor

Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We conducted our audit in accordance with International Standards on Auditing (ISAs). Those standards require that we comply with the ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the statutory auditor's judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, the statutory auditor considers the company's internal control relevant to the preparation of consolidated financial statements that give a true and fair view, in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the board of Directors, as well as evaluating the overall presentation of the consolidated financial statements.

We have obtained from the board of Directors and company officials the explanations and information necessary for performing our audit.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

#### Unqualified opinion

In our opinion, the consolidated financial statements of the company ASIT BioTech SA give a true and fair view of the group's equity and financial position as at 31st December 2015, and of its results and its cash flows for the year then ended, in accordance with the International Financial Reporting Standards as adopted by the European Union.

#### Report on other legal and regulatory requirements

The board of Directors is responsible for the preparation and the content of the Director's report on the consolidated financial statements.



In the framework of our mandate and in accordance with the Belgian standard which is complementary to the International Standards on Auditing (ISAs) as applicable in Belgium, our responsibility is to verify, in all material respects, compliance with certain legal and regulatory requirements. On this basis, we provide the following additional statement, which does not modify the scope of our opinion on the consolidated financial statements:

 The Director's report on the consolidated financial statements includes the information required by law, is consistent with the consolidated financial statements and is free from material inconsistencies with the information that we became aware of during the performance of our mandate.

Brussels, 27 May 2016

Mazars Réviseurs d'Entreprises SCRL Statutory auditor Represented by RSM InterAudit SCRL Statutory auditor Represented by

**Xavier DOYEN** 

Luis LAPERAL

#### STATUTORY ACCOUNTS (BGAAP) FOR THE LAST 3 YEARS

According to article 105 of the BCC, the short version of statutory accounts is presented hereunder. These financial statements have been drawn up in accordance with the accounting, legal and regulatory requirements applicable to financial statements in Belgium.

This short version of the statutory accounts is included without the attached audit report (clean opinion). Full statutory accounts under BNB format will be filed with the Belgian National Bank in July 2016.

ASSETS (thousands €)	31/12/2015	31/12/2014	31/12/2013
Non-current assets	7.562	2.845	42
Intangible assets	7.128	2.662	-
Property, plant and equipment	422	170	39
Other long term receivables	12	13	3
Current assets	4.969	8.534	1.292
Inventories	11	14	13
Short term receivables	280	102	61
Cash and cash equivalents	4.621	8.411	1.211
Other current assets	57	8	7
TOTAL ASSETS	12.531	11.379	1.334



EQUITY AND LIABILITIES (thousands €)	31/12/2015	31/12/2014	31/12/2013
Capital and reserves	6.199	10.241	6
Capital	11.625	11.625	14.293
Share premium	-	-	5.413
Accumulated deficit	-5.426	-1.384	-19.700
LIABILITIES	6.332	1.139	1.328
Long term debt	-	-	885
Short term debt	4.130	-	-
Trade payables	1.611	858	351
Advance payment	314	-	-
Social debts	175	137	89
Other payables	1	1	1
Period adjustment account	102	144	2
TOTAL EQUITY AND LIABILITIES	12.531	11.379	1.334

PROFIT AND LOSS			
(thousands €)	2015	2014	2013
Operating income	824	566	7
R&D capitalized expenses	820	558	-
Other operating income	4	8	7
Operating expenses	-4.816	-1.839	-2.309
Cost of good sold	-3	1	2
General and administrative expenses	-1.656	-483	-1.772
Payroll expenses	-1.088	-636	-514
Depreciation	-2.069	-717	-22
Other operating expenses	-1	-2	-3
Operating result	-3.992	-1.273	-2.302
Financial income	33	6	13
Financial expenses	-108	-117	-32
Bénéfice (Perte) courant de l'exercice avant			
impôts	-4.066	-1.384	-2.321
Exceptional income	25	-	10
Exceptional expenses	-	-0	-3
Result before taxes	-4.041	-1.384	-2.315
Taxes	-0	-0	-
Result for the period	-4.042	-1.384	-2.315



## 4 RISK FACTORS

#### 4.1. RISK FACTORS RELATED TO THE COMPANY'S BUSINESS

#### 4.1.1.FINANCIAL RISK FACTORS

#### The Company's profitability is not assured

The Company has incurred significant operating losses since it was founded in 1997. Its accumulated deficit as at 31 March 2016 amounts to EUR 15.8 million. These losses have resulted principally from costs incurred in research and development, preclinical testing, clinical development of research programmes and product candidates and from general and administrative costs associated with the Company's operations. As a result of the completion of the Offering on 10 May 2016, the Company however, is no longer in the scope of article 633 BCC.

In the future, the Company intends to continue to conduct research and development, preclinical testing, clinical trials, regulatory compliance activities and start sales and marketing activities that, together with anticipated general and administrative expenses, will likely result in the Company incurring further significant losses for the next several years. In particular, the Company expects that the cash burn will increase since phase III clinical studies and commercialisation efforts involve higher costs.

There can be no assurance that the Company will earn revenues or achieve profitability, which could impair the Company's ability to sustain operations or obtain any required additional funding. If the Company achieves profitability in the future, it may not be able to sustain profitability in subsequent periods. It is likely that the Company will experience fluctuating revenues, operating results and cash flows. As a result, period-to-period comparisons of financial results are not necessarily meaningful and results of operations in prior periods should not be relied upon as an indication of future performance.

#### • Requirement of additional funding

The net proceeds of the Offering will in any case not be sufficient to finance the full completion of the phase III clinical study in the United States, in particular in the event a phase II clinical study would be required by the FDA, and they will not be sufficient to finance all sales and marketing efforts associated with the commercialisation of any of its products, including gp-ASIT+TM in Germany, the United States and other European countries, as well as the performance of a likely phase IV clinical study for gp-ASIT+TM in Germany and the preparation and completion of phase III clinical study for hdm-ASIT+TM in Europe and the United States.

At the date of this Annual Report, the Company cannot precisely estimate the costs associated with the completion of the phase III clinical study with gp-ASIT+<sup>TM</sup> in the United States (with the exception of the direct costs of subcontracted activities, which it expects will amount to 12 million EUR) and the completion of a likely phase IV clinical study with gp-ASIT+<sup>TM</sup> in Germany (the costs of which will depend on the number of patients involved in the study and the protocol required by the Paul Ehrlich Institute, *PEI*).

As the Company expects that its product candidates will not generate revenue before a relatively long period (at least 3 years), it anticipates that it will have to raise new funds before the commercialisation of its lead product candidate. The Company's ability to raise additional funds will depend on financial, economic and market conditions and other factors, over which it may have no or limited control, and the Company cannot guarantee that additional funds will be available to it when necessary on commercially acceptable terms, if at all. If the necessary funds are not available, the Company may need to seek funds through partnership arrangements that may require it to reduce or relinquish significant rights to its research programmes and product candidates, to grant licences on its technologies to partners or third parties or enter into new types of collaboration agreements. The terms and conditions of these arrangements and agreements could be less favourable to the Company than those it might have obtained in a different context.



If adequate funds are not available on commercially acceptable terms when needed, the Company may be forced to delay, reduce or terminate the development or commercialisation of all or part of its research programmes or product candidates or it may be unable to take advantage of future business opportunities.

#### 4.1.2.COMMERCIALISATION AND MARKET RISK FACTORS

#### The Company's future commercial potential

Currently, the Company does not have marketing authorisation for any of its product candidates. The Company has invested a significant portion of its financial and other resources in the development of its lead product candidate gp-ASIT+<sup>TM</sup>. The Company has launched a phase III clinical study for gp-ASIT+<sup>TM</sup> in Europe and the Company 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+<sup>TM</sup> in Germany to the PEI by Q2 2017 and obtain it one year later (Q2 2018) in order to launch the product immediately thereafter.

The inability of the Company to replicate safety and efficacy data obtained in controlled phase II clinical studies when transitioning to large, less well controlled phase III studies could impair the development of the lead product candidate of the Company.

The success of gp-ASIT+TM will depend on a number of factors, including those generally affecting biopharmaceutical products, and the following:

- successful completion of the phase III clinical study and supporting studies;
- demonstrating efficacy after transitioning from ocular provocation testing to field studies;
- randomness of the patients' natural exposure to allergens responsible for allergy targeted product candidates:
- absence of homogeneity of the allergic patient groups;
- intensity of the grass pollen season during the phase III field clinical studies;
- validation of the production process;
- stability of the commercial product;
- marketing authorisation by Competent Regulatory Authority;
- launching commercial sales, if and when approved, whether alone or in collaboration with others;
- acceptance of gp-ASIT+TM, if and when approved, by patients, the medical community and third-party payers;
- effectively competing with other allergy therapies; and
- a sustained acceptable safety profile of gp-ASIT+TM following approval and commercial use.

Any delay in the commercialisation of gp-ASIT+<sup>TM</sup> or the failure of gp-ASIT+<sup>TM</sup> in phase III clinical studies could negatively affect the development and commercialisation of the Company's other product candidates, which in turn would have a material adverse effect on the Company's business, results of operations and/or financial condition.



#### The Company's future commercial success

The future commercial success of the Company's products is connected with the following commercial, operational, regulatory and market risks:

- The phase III clinical study with gp-ASIT+TM could fail to reach the required endpoints if the grass pollen season is not strong enough;
- To date, none of the product candidates of the Company has been approved or commercialised and its lead product candidate is still in clinical development;
- The Company has a pipeline of two product candidates focused on respiratory allergies. If the Company is unable to obtain marketing authorisation for such product candidates, or experiences significant delays in doing so, this would have a material adverse effect on its business;
- Clinical studies are highly uncertain and any failure or delay in completing such studies for any of the Company's product candidates may prevent it from obtaining regulatory marketing authorisation or commercialising product candidates on a timely basis, or at all, which would require the Company to incur additional costs and would delay the generation of any product revenue;
- The ongoing phase III clinical study with gp-ASIT+TM could be stopped as a result of the occurrence of 3 DSMB confirmed grade 3 (or superior) systemic reactions at the same dose;
- The Company relies on one supplier for certain clinical trial testing materials;
- The commercial success of the Company's product candidates could be negatively affected if the allergy immunotherapy market does not develop as foreseen by the Company;
- The commercial success of the Company's product candidates will depend on the degree of market acceptance of its products among physicians, patients, healthcare payers and the medical community;
- The Company currently relies on one CMO to supply and manufacture its product candidates at a single manufacturing facility, and could consider relying on further third parties to manufacture its products. The development and commercialisation of such product candidates could be stopped or delayed if such third party fails to provide the Company with sufficient quantities of product candidates or fails to do so at acceptable quality levels or prices or fails to maintain or achieve satisfactory regulatory compliance;
- The Company may not be able to purchase specific raw material and process media such as natural sources of allergens provided by third party suppliers for the manufacturing of the product candidates;
- The Company relies upon collaborative partners for the execution of most aspects of its development programmes. Failure of these third parties to provide services of a suitable quality and within acceptable timeframes may cause the delay or failure of its development programmes
- The Company could need to rely on partners for the commercialisation and distribution of its products in certain regions;
- If serious adverse side effects are identified for any product candidate, the Company may need to abandon or limit its development of that product candidate, which may delay or prevent marketing approval, or, if approval is received for the product candidate, require it to be taken off the market, require it to include safety warnings or otherwise limit its sales;
- Failure to successfully identify, develop and commercialise additional products could impair the Company's ability to grow. In particular, the Company may not be successful in its efforts to use and expand its technology platform, ASIT+TM, to build a pipeline of product candidates and develop marketable products;



- If the Company experiences delays or difficulties in the enrolment of patients in clinical studies, its receipt of necessary regulatory approvals could be delayed or prevented;
- The Company may face significant competition and technological change which could limit or eliminate the market opportunity for its product candidates;
- The price setting and the availability and level of adequate reimbursement by third parties, such as insurance companies, governmental and other healthcare payers is uncertain and may impede on the Company's ability to generate sufficient operating margins to offset operating expenses;
- The Company has limited experience in sales, marketing and distribution;
- The Company could fail to achieve or maintain high standards of manufacturing in accordance with Good Manufacturing Practices and other manufacturing regulations;
- The Company has obtained significant funding from the Brussels-Capital and Walloon Regions. The terms of the agreements signed with the Regions may hamper the Company to partner part or all its products and restrict the Company's ability to determine the location of its premises;
- Failure to attract and retain senior management and skilled personnel could impair the Company's development and commercialisation efforts;
- Growth may trigger significant demands on the Company's management and resources;
- The Company's employees, principal investigators, consultants and collaborative partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards;
- If any product liability lawsuits are successfully brought against the Company or any of its partners, the Company may incur substantial liabilities and may be required to limit commercialisation of its product candidates.

#### 4.1.3.INTELLECTUAL PROPERTY

■ The Company may not be able to obtain, maintain, defend or enforce its intellectual property rights

The Company's commercial success depends, to a large extent, on its ability to obtain, maintain, defend and enforce its patents and other intellectual property rights covering its product candidates. The Company's research programmes and product candidates are covered by several patents and patent applications, which are owned by the Company. The Company cannot guarantee that it will be in a position in the future to develop new patentable inventions or that the Company will be able to obtain patent rights from patent offices or maintain these patent rights against third-party challenges to their validity, scope and/or enforceability.

The Company cannot guarantee that it is or has been the first to conceive an invention and to file a patent or a patent application, notably given the fact that patent applications are not published in most countries before an 18-months period from the date of the filing. Because patent law in the biopharmaceutical industry is highly uncertain, there can be no assurance that the technologies used in the Company's research programmes and product candidates are patentable, that patents will be granted from pending or future applications, or that patents will be broad enough to provide adequate and commercially meaningful protection against competitors with similar technologies or products, or that patents granted will not be successfully challenged, circumvented, invalidated or rendered unenforceable by third parties, hence enabling competitors to circumvent or use them and depriving the Company from the protection it may expect against competitors. If the Company does not obtain patents in respect of its technologies or if the patents of the Company are invalidated (for example, as a result of the discovery of prior art), third parties may use the technologies



without payment to the Company. In addition, a third party's ability to use unpatented technologies is enhanced by the fact that the published patent application contains a detailed description of the relevant technology. The Company cannot guarantee that third parties, contract parties or employees will not claim ownership rights over the patents or other intellectual property rights owned or held by the Company.

Finally, the enforcement of patents and other intellectual property is costly, time consuming and highly uncertain. The Company cannot guarantee that it will be successful in preventing the misappropriation of its patented inventions, know-how and other intellectual property rights, and failure to do so could significantly impair the ability of the Company to effectively compete.

## The Company may not be able to protect and/or enforce its intellectual property rights in all jurisdictions

Filing, prosecuting and defending patents on all of the Company's product candidates throughout the world would be prohibitively expensive to the Company. Competitors may use the Company's technologies in jurisdictions where the Company has not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where the Company has patent protection but where enforcement is not as well developed as in the United States or the European Union. These products may compete with the Company's products in jurisdictions where the Company does not have any issued patents and the Company's patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing. Proceedings to enforce the Company's patent rights in foreign jurisdictions could result in substantial cost and divert the Company's efforts and attention from other aspects of its business. The inability of the Company to protect and/or enforce its intellectual property rights throughout the world could have a material adverse effect on its business, prospects, financial condition and results of operations.

#### • Intellectual property rights do not necessarily address all potential threats to the Company's competitive advantage

The degree of future protection afforded by the Company's intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect the Company's business or permit it to maintain its competitive advantage. The following examples are illustrative:

- the Company relies on proprietary know-how to protect its research programmes, product candidates and ASIT+TM platform; know-how does not benefit from intellectual property rights protection and is difficult to maintain; the Company uses reasonable efforts to maintain its know-how, but it cannot assure that its partners, employees, consultants, advisors or other third parties will not wilfully or unintentionally disclose proprietary information to competitors;
- others may be able to make products that are similar to the Company's product candidates but that are not covered by the claims of the Company's patents;
- others may independently develop similar or alternative technologies or duplicate any of the Company's technologies without infringing the Company's intellectual property rights;
- pending patent applications may not lead to issued patents;
- issued patents may not provide the Company with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by the Company's competitors;
- the Company's competitors might conduct research and development activities in countries where the Company does not have patent rights and then use the information learned from such activities to develop competitive products for sale in its major commercial markets;



- the Company may not develop or in-license additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on the Company's business.

Should any of these events occur, they could significantly harm the Company's business, prospects, financial condition and results of operation.

#### Intellectual property infringement claims from third parties would be timeconsuming and costly to defend and may result in liability for damages, or prevent the Company from commercialising its products

The Company's success will depend in part on its ability to operate without infringing on or misappropriating the intellectual property rights of others. The Company cannot guarantee that its activities will not infringe on the patents or other intellectual property rights owned by others. The Company may expend significant time and effort and may incur substantial costs in litigation if it is required to defend against patent or other intellectual property right suits brought against the Company regardless of whether the claims have any merit. If the Company is found to infringe on the patents or other intellectual property rights of others, it may be subject to substantial claims for damages, which could materially impact the Company's cash flow and financial position. The Company may also be required to cease development, use or sale of the relevant research programme, product candidate or process or it may be required to obtain a licence on the disputed rights, which may not be available on commercially reasonable terms, if at all. Even if the Company is able to obtain a licence, it could be non-exclusive, thereby giving its competitors access to the same technologies licensed to the Company, and could require the Company to make substantial royalty payments. The Company may be unable to develop or commercialise a product, product candidate or research programme, or may cease some of its operations, which may have a material adverse effect on the Company's business.

There can be no assurance that the Company's efforts to search for existing proprietary rights before embarking on a research and development programme with respect to a particular product candidate, method, process or technology will uncover all relevant third party rights relating to such product, method, process or technology. The Company may spend significant time and effort and may incur substantial costs if required to defend against any infringement claims or to assert its intellectual property rights against third parties. The risk of such a procedure by a third party may increase in view of the Company making public announcements regarding one or more of its research programmes and product candidates. The Company may not be successful in defending its rights against such procedures or claims and may incur as a consequence thereof significant losses, costs or delays in its intended commercialisation plans as a result thereof.

#### Preservation of trade secrets

The Company relies on trade secret protection to protect its interests in its know-how or other proprietary information and processes for which patents are difficult to obtain or enforce or which are difficult to reverse engineer, all of which constitute confidential information. The Company may not be able to protect its confidential information adequately. The Company has a policy of requiring its consultants, employees, contract personnel, advisers and third-party partners to enter into invention transfer, non-disclosure and non-compete agreements. In particular, the Company has entered into a confidentiality and non-compete agreement with its CMO pursuant to which the CMO is prohibited to perform any project in the Company's field until 31 December 2027. However, no assurance can be given that the Company has entered into appropriate agreements with all of its consultants, contract personnel, advisers, third-party partners or other parties that have had access to the Company's confidential information. There is also no assurance that such agreements will provide for a meaningful protection of confidential information in the event of any unauthorised use or disclosure of information. Furthermore, the Company cannot provide assurance that any of its employees, consultants, contract personnel or third-party partners, either accidentally or through wilful



misconduct, will not cause serious damage to its programs and/or its strategy, by, for example, disclosing confidential information to its competitors. It is also possible that confidential information could be obtained by third parties as a result of breaches of physical or electronic security systems of the Company, its consultants, advisers, third-party partners or other parties that have had access to its confidential information. Any disclosure of confidential data into the public domain or to third parties could allow the Company's competitors to learn confidential information and use it in competition against the Company. In addition, others may independently discover the Company's confidential information. Any action to enforce the Company's rights against any misappropriation or unauthorised use and/or disclosure of confidential information is likely to be time-consuming and expensive, and may ultimately be unsuccessful, or may result in a remedy that is not commercially valuable.

#### 4.2. RISK FACTORS RELATED TO THE SHARES

## 4.2.1. THE MARKET PRICE OF THE SHARES MAY FLUCTUATE WIDELY IN RESPONSE TO VARIOUS FACTORS

A number of factors may significantly affect the market price of the Shares including changes in the operating results of the Company and its competitors, divergence in financial results from stock market expectations, changes in earnings estimates by analysts, changes in the general conditions in the pharmaceutical industry and general economic, financial market and business conditions in the countries in which the Company operates. Other factors which could cause the price of the shares to fluctuate or could influence the reputation of the Company include, amongst other things: (i) announcements of technological innovations or new commercial products or collaborations by the Company's competitors or the Company itself, (ii) developments concerning intellectual property rights, including patents, (iii) public information regarding actual or potential results relating to product candidates under development by the Company's competitors, (iv) actual or potential results relating to products and product candidates under development by the Company itself, (v) regulatory and medicine pricing and reimbursement developments in Europe, the United States and other jurisdictions, and (vi) any publicity derived from any business affairs, contingencies, litigation or other proceedings, the Company's assets (including the imposition of any lien), its management, or its significant Shareholders or collaborative partners.

In addition, stock markets have from time to time experienced extreme price and volume volatility which, in addition to general economic, financial and political conditions, could affect the market price for the Shares regardless of the operating results or financial condition of the Company.

## • Future sales of substantial amounts of Shares, or the perception that such sales could occur, could adversely affect the market value of the Shares

Sales by the Shareholders of a substantial number of Shares in the public markets following the Offering, or the perception that such sales might occur, could cause the market price of the Shares to decline. Furthermore, there is no commitment on the part of any of the existing Shareholders to remain a shareholder or to retain a minimum interest in the Company after the expiry of the lock-up period set out in the articles of association of the Company (the *Articles of Association*). For more information regarding the lock-up, see "*Plan of distribution—Lock-up*".

## The future issue of securities may affect the price or value of the shares and could dilute the interests of the Shareholders

The future issue of shares or warrants could affect the price of the shares of the Company or the value of the shares to be issued by the Company and could dilute the shareholdings of the existing Shareholders. The



dilution resulting from the exercise of outstanding warrants or issue and exercise of new warrants could adversely affect the price of the shares.

Additionally, the Company may decide to raise capital in the future through public or private convertible debt or equity securities, or rights to acquire these securities, and exclude or limit the preferential subscription rights pertaining to the then outstanding securities basis. If the Company raises significant amounts of capital by these or other means, it could cause dilution for the holders of its securities and could have a negative impact on the share price, earnings per share and net asset value per share.

#### Certain significant shareholders of the Company may have different interests from the Company and may be able to control the Company, including the outcome of shareholder votes

Currently, the Company is not aware that any of its current Shareholders have entered or will enter into a Shareholders' agreement with respect to the exercise of their voting rights in the Company.

Nevertheless, they could, alone or together, have the ability to elect or dismiss directors, and, depending on how broadly the Company's other shares are held, take certain other Shareholders' resolutions that require, or require more than, 50%, 75% or 80% of the votes of the Shareholders that are present or represented at Shareholders' meetings where such items are submitted to voting by the Shareholders. Alternatively, to the extent that these Shareholders have insufficient votes to impose certain Shareholders' resolutions, they could have the ability to block proposed Shareholders' resolutions that require, or require more than, 50%, 75% or 80% of the votes of the Shareholders that are present or represented at Shareholders' meetings where such items are submitted to voting by the Shareholders. Any such voting by these Shareholders may not be in accordance with the interests of the Company or the other Shareholders of the Company.

#### ■ The Company does not intend to pay dividends for the foreseeable future

The Company has never paid any dividends in the past. The Board of Directors expects to retain all earnings, if any, generated by the Company's operations for the development and growth of its business and does not anticipate paying any dividends to the Shareholders in the near future. Payment of future dividends to Shareholders will be subject to a decision of the annual Shareholders meeting of the Company and subject to legal restrictions contained in Belgian Company law. Furthermore, financial restrictions and other limitations may be contained in future credit agreements.

#### Certain transfer and selling restrictions may limit Shareholders' ability to sell or otherwise transfer their shares

The Company has applied for an admission of all of its existing and New Shares to public trading in Belgium and in France (through a listing on Euronext Brussels and Euronext Paris), but has not registered the Shares under the US Securities Act or securities laws of other jurisdictions, including Canada, Australia and Japan, and it does not expect to do so in the future. The shares may not be offered or sold in the United States, Canada, Australia, Japan or in any other jurisdiction in which the registration or qualification of the shares is required but has not taken place, unless an exemption from the applicable registration or qualification requirement is available or the offer or sale of the shares occurs in connection with a transaction that is not subject to such provisions.

## Any future sale, purchase or exchange of shares may become subject to the Financial Transaction Tax

On 14 February 2013, the European Commission published a proposal (the **"Draft Directive"**) for a Directive for a common FTT in Belgium, Germany, Estonia, Greece, Spain, France, Italy, Austria, Portugal,



Slovenia and Slovakia (the "Participating Member States"). However, Estonia has since stated that it will not participate.

Pursuant to the Draft Directive, the FTT will be payable on financial transactions provided at least one party to the financial transaction is established or deemed established in a Participating Member State and there is a financial institution established or deemed established in a Participating Member State which is a party to the financial transaction, or is acting in the name of a party to the transaction. The FTT shall, however, not apply to (inter alia) primary market transactions referred to in article 5(c) of Regulation (EC) No 1287/2006, including the activity of underwriting and subsequent allocation of financial instruments in the framework of their issue.

The rates of the FTT will be fixed by each Participating Member State but for transactions involving financial instruments other than derivatives shall amount to at least 0.1% of the taxable amount. The taxable amount for such transactions shall in general be determined by reference to the consideration paid or owed in return for the transfer. The FTT will be payable by each financial institution established or deemed established in a Participating Member State which is either a party to the financial transaction, or acting in the name of a party to the transaction or where the transaction has been carried out on its account. Where the FTT due has not been paid within the applicable time limits, each party to a financial transaction, including persons other than financial institutions, shall become jointly and severally liable for the payment of the FTT due.

Investors should therefore note, in particular, that following implementation any future sale, purchase or exchange of Shares will be subject to the FTT at a minimum rate of 0.1% provided the above mentioned prerequisites are met. The investor may be liable to pay this charge or reimburse a financial institution for the charge, and/or the charge may affect the value of the Shares. The issuance of New Shares should not be subject to the FTT.

The Draft Directive is still subject to negotiation among the Participating Member States and therefore may be changed at any time. Moreover, once the Draft Directive has been adopted (the "FTT Directive"), it will need to be implemented into the respective domestic laws of the Participating Member States and the domestic provisions implementing the FTT Directive might deviate from the FTT Directive itself.

Investors should consult their own tax advisers in relation to the consequences of the FTT associated with subscribing for, purchasing, holding and disposing of the Shares.

#### ■ The Speculation Tax may affect the liquidity of the Shares

For Shares acquired as of 1 January 2016, a newly introduced 'speculation tax' of 33 % may be withheld on capital gains on the Shares realised by Belgian resident and non-resident individuals within six months from the date of acquisition of the Shares. The introduction of this speculation tax may deter certain investors from actively trading the Shares and ultimately result in a reduction of the liquidity of the Shares.



# 5 BUSINESS OVERVIEW

#### 5.1. ASIT Biotech ACTIVITIES

ASIT Biotech 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.

As of today, the Company has no product approved or commercialised to date, but the Company's lead product candidate, gp-ASIT+<sup>TM</sup>, is currently in its first phase III clinical study, being the last clinical stage before the filing of a marketing authorisation application. This first phase III clinical study in Europe follows successful results in phases I and II clinical studies, and the likelihood of success of a clinical trial increases with the progression of the clinical development from the phase I to the phase III clinical studies (Nature Biotechnology, 32, 40–5, (2014) Clinical development success rates for investigational drug, Michael Hay et al). The Company's second product candidate, hdm-ASIT+<sup>TM</sup>, is due to enter clinical development in Q3 2016.

The Company believes that its 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 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 Company's lead product targeting grass pollen rhinitis, gp-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 artificial allergen challenge; 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.

#### Portfolio

The Company has demonstrated clinical proof-of-concept for gp-ASIT+<sup>TM</sup> with compelling and statistically significant phase IIa and phase IIb clinical study results. The Company has launched the first phase III clinical study with gp-ASIT+<sup>TM</sup> in Europe and has finalised patient screening and recruitment for the same. The Company expects to have its first results by the end of Q1 2017. Subject to positive results of this phase III clinical study, the Company intends to submit by the end of Q2 2017 a marketing authorisation application to the Paul Ehrlich Institute for commercialisation of gp-ASIT+<sup>TM</sup> in Germany.



The Company intends to start clinical development in the United States as soon as possible. A pre-IND meeting with the 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 such timing allows for the performance of a phase II study in 2016-2017 if such study would be required by the FDA.

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 by 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. The Company has already obtained first evidence of applicability of the ASIT+TM production platform to ragweed and some food allergens.

Overview of the Company's portfolio



#### 5.2. COMPANY MISSION AND STRATEGY

Allergy is a global issue according to the World Allergy Organization. Approximately 30% to 40% of the world population suffers from allergic diseases. Allergy is a major public health problem that impairs the patient quality of life and require a symptomatic drug consumption over \$ 10 billion each year. Allergy is one of the principal causes of missed work or school days. Allergy immunotherapy is theoretically the best available treatment because it targets the root cause of the disease and provides the patients with a sustained therapeutic effect. It is however currently underused due to the length and heaviness of the existing treatments. The mission of ASIT biotech is to commercialise worldwide short course allergy immunotherapy treatment improving patient acceptance and compliance in order to reduce the allergic symptoms and the drug consumption as well as to improve the quality of life of the allergic patients.

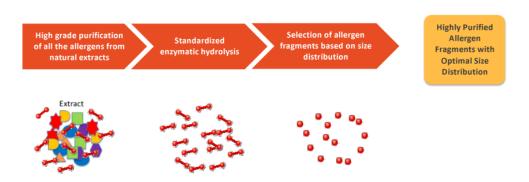
#### 5.3. TECHNOLOGY

In order to propose an immunotherapy product with both a superior safety and real life effectiveness profile and no or shorter dose escalation phase, the Company has developed the ASIT+<sup>TM</sup> technology platform.

The ASIT+TM technology platform allows the development, the characterisation, the manufacturing, and the quality control of truly innovative active pharmaceutical ingredients consisting of highly purified natural allergen fragments, in an optimal size selection.



#### ASIT+™ platform: technology scalable & applicable to various allergens

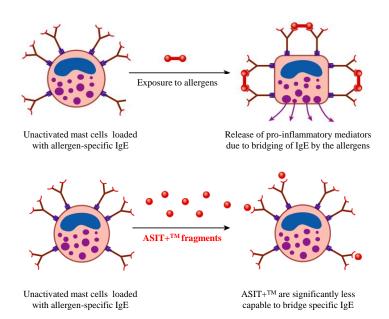


The ASIT+TM technology platform is based on a well-defined and reproducible production process including:

- extraction of soluble components from natural sources of allergens;
- purification of all the proteins from allergen extracts and the elimination of non-protein components; and
- standardised enzymatic hydrolysis of the purified proteins resulting in highly purified natural allergen fragments.

The Company believes that the use of natural sources leads to product candidates with a very broad panel of antigens stimulating the immune system with the optimal complexity.

Cross-linking of IgE antibody on mast-cells leads to rapid release of inflammatory mediators by the mast cells with intact whole allergens but not allergen fragments



The upper part of the above figure shows the bridging of mast cell bound IgE antibodies by whole intact allergens leading to the release of inflammatory mediators which cause the allergis reaction. Mast cells are large cells found in connective tissue with secretory granules containing many inflammatory mediators. Mast cells bind stably to IgE antibodies through specific receptors. Intact whole allergens bridge efficiently the mast cell bound IgE antibodies. Such bridgings trigger rapid degranulation and release of inflammatory mediators resulting in acute allergic reaction.

The lower part of the figure shows that allergen fragments are less capable to bridge mast cell bound IgE antibodies. ASIT+<sup>TM</sup> products are allergen fragments that are less able to bridge the mast cell bound IgE antibodies and therefore reduce the patient's allergic reaction at the time of administration of the ASIT+<sup>TM</sup> product.

It has been demonstrated with the grass pollen ASIT+TM product candidate (gp-ASIT+TM) in the framework of phase I and phase II clinical studies that the ASIT+TM selection of highly purified natural allergen fragments triggers a rapid immune response without the need for an adjuvant.

The Company believes that ASIT+TM products have a superior safety profile due to:

- the lack of adjuvant;
- the use of highly purified natural allergen fragments with
  - no impurities, therefore reducing the risk of side-effects and the induction of unwanted reactions;
  - reduced risk for the induction of immediate allergic reactions. As shown in Figure 7, allergen fragments are significantly less capable to cross-link the IgE antibodies present on the surface of mast cells and therefore to trigger the release of proinflammatory mediators such as histamine.

Almost all competitors of the Company's product candidates use adjuvants, which are non-specific stimulators of the immune system. Competitors therefore inject adjuvants with the active pharmaceutical



ingredients in order to increase the latter's immunogenicity. Adjuvants however also increase the frequency and the severity of the side-effects related to higher local and general reactogenicity. As the Company has demonstrated in a phase II study performed in 2011-2013 that the addition of an adjuvant did not show a consistent advantage of gp-ASIT+TM with an adjuvant, the Company has therefore focused its clinical development on adjuvant-free and thus safer gp-ASIT+TM.

The safety, the immunogenicity and the potential clinical efficacy of gp-ASIT+TM using subcutaneous delivery have been confirmed in phase I, phase IIa and phase IIb clinical trials in patients with grass pollen rhinitis.

In addition, the Company has also demonstrated for its first product candidate the reproducibility of its production process at the commercial scale leading to the batch to batch consistency. At this stage of process validation, one GMP batch of drug substance would allow the treatment of about 20,000 patients. On the basis of these results, the Company is confident that it would be able to supply the market.

#### 5.4. PRINCIPAL MARKET

The Company commissioned a strategic market access review by an independent third party organisation (Internal report, AVOS Consulting, 2015, please refer to the Offering Prospectus for more information from the report) that principally focused on the opportunities in the United States and four key EU countries - Germany, France, Spain and Italy. These countries have established AIT markets. An exploratory review was also conducted for China, providing an insight into potential expansion opportunities.

Based on numerous sources (VacZine Analytics - MarketVIEW: Allergic immunotherapy vaccines – Report VAMV012 (July-2014), various ALK-Abelló, Stallergènes and Allergy Therapeutics investor presentations), the value of the global allergy immunotherapy is estimated at about EUR 900 million in 2014, of which Europe represents EUR 700 million. Germany represents about 39% of the European AIT market in terms of sales, followed by France (31%), Spain (10%) and Italy (10%) (ALK-Abelló IR presentation 6 December 2014).

The United States are estimated to represent about EUR 100 to 120 million in sales of AIT products (total revenues related to the allergy immunotherapy are estimated at USD 2 to 3 billion, bust most revenues stem from the billing of US allergists for self-prepared solutions, see below), and the rest of the world (essentially Latin America, Japan, Russia, China) less than EUR 100 million.

In terms of patients, circa 1.3 million patients (ALK-Abelló IR presentation January 2014) are currently treated in Europe with immunotherapy for allergic rhinitis while more than 6 million patients are not satisfied with their current treatment. The geographic distribution is as follows: 560,000 in Germany, 350,000 in France, 188,000 in Spain, 135,000 in Italy, and about 40,000 each in Austria, the Netherlands and Nordic countries (according to ALK-Abelló, and in particular their investor presentations of Dec-2012 and Jan-2014).

In the United States, it is estimated by ALK-Abelló (see their investor presentations of Dec-2012 and Jan-2014) that there are about 3 million AIT-treated patients, while more than 6 million patients are eligible for this therapy. The market is dominated by products self-prepared by the allergists before their injection representing more than 95% of the prescriptions.

A distinction between AIT products can be made according to their administration route: (i) subcutaneous immunotherapy (*SCIT*), which consists in the injection of the drug under the skin, and (ii) sublingual immunotherapy (*SLIT*), which consists of the administration of the active principle on the oral mucosa. SLIT-tablets that have been registered in Europe in 2006 (Grazax, ALK-Abelló) and 2008 (Oralair, Stallergènes) still represent less than 10% of the total sales. The two market leaders are ALK-Abello and



Stallergènes with respectively 33% and 31% of the total market. SLIT-tablets (Grastek and Ragwitek from ALK-Abelló and Oralair, from Stallergènes/Greer) have been registered in the United States as from 2014. Their market penetration is very low, with 500 prescriptions each week for Grastek, and even lower figures for Ragwitek (300) and Oralair (less than 100) (ALK-Abelló Investors Relations presentation Sep-2015). The immunotherapy treatments are associated with a low acceptance rate of 50% and a high drop-out rate of 80%.

First-line treatments only alleviate symptoms and there is presently no gold standard for AIT. It was hoped for some time that SLIT-tablet therapy would completely change the treatment paradigm. However, mainly due to compliance and patient convenience problems, SLIT-tablet sales still represent less than 10% of the current allergy immunotherapy market, despite numerous years on the market, SCIT remains the preferred administration form, presenting a genuine opportunity for a short-course treatment that improves the ease of administration and thus competes very aggressively with oral treatments.

In Europe, the most frequently detected allergen in diagnosed allergic rhinitis patients is grass pollen (60 %) followed by house dust mite (52.5 %) and tree (40.4%) (Bauchau V & Durham SR. Prevalence and rate of diagnosis of allergic rhinitis in Europe. Eur Respir J. 2004 Nov 24 (5):758-64).

In the United States, the most frequently detected allergen in diagnosed allergic rhinitis patients is grass pollen (56%) followed by ragweed (49%) and house dust mite (45%) (ALK-Abelló, investors' briefing, Dec-2012).

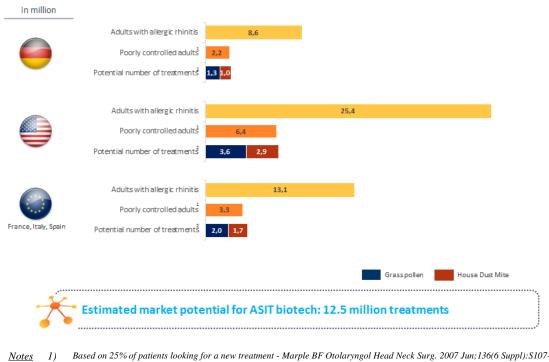
Germany, which is the largest and most established AIT market in Europe, will be the first market targeted by the Company. The prevalence of allergic rhino-conjunctivitis is estimated at 21% of the population: 16.2% of the population has received a physician diagnosis of allergic rhinitis, among whom about 75% (12.3% of the population) are using medications (Bauchau V & Durham SR. Prevalence and rate of diagnosis of allergic rhinitis in Europe. Eur Respir J. 2004 Nov 24 (5):758-64). About 25% of the patients taking medication for allergic rhinitis are not satisfied by their treatment and have poor disease control (Marple et al, Otolaryngol Head Neck Surg, 2007, 136, 107-24). This translates into nearly 6.8 million and 5.7 million unsatisfied patients for grass pollen and house dust mite allergic rhino-conjunctivitis, respectively.

The United States market is the largest potential commercial opportunity for the ASIT+TM product portfolio. Allergic rhinoconjunctivitis was the third leading chronic disease in the United States among those aged 45 and younger, and the fifth leading chronic disease across all ages (Chronic conditions – a challenge for the 21st century. National Academy on an Aging Society Washington DC, 1999, p. 2; The American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF), Press release announcing a Clinical Practice Guideline on Allergic Rhinitis, Feb. 2015).

The prevalence of allergic rhinitis in the United States is estimated at 22%. Among responders with a higher burden of nasal symptoms (≥ 30 days in the last 12 months), the prevalence of physician-diagnosed hay fever, allergic rhinitis, or nasal allergies was 11.9% of the total population (Nathan et al., Allergy Asthma Proc. 2008; 29: 600-8). The use of medication for allergic rhinitis in the American population is 7.5% (U.S. Department of Health and Human Services - Centers for Disease Control and Prevention National Center for Health Statistics: Summary Health Statistics for U.S. Adults: National Health Interview Survey, 2012). The most frequently detected allergen in allergic rhinitis patients in the United States is grass pollen (56%) followed by ragweed (49%), house dust mite (45%) and tree (23%) (ALK-Abelló Investors' Briefing on December 6 2012). An estimated 6 million patients with grass pollen and house dust mite allergic rhinoconjunctivities each year are reported to be candidates for AIT, as symptomatic treatment alone is inadequate.



#### Allergic rhinitis: a large addressable market



- Based on 25% of patients looking for a new treatment Marple BF Otolaryngol Head Neck Surg. 2007 Jun; 136(6 Suppl): S107-1) 24; Didier A et al Rev. Fr Allergol. 1999; 39: 171-185; and
- 2) Based on the prevalence of the sensitization by allergen - EU: Bauchau & Durham 2004; US: Nathan 1997 & 2008.

#### 5.5. REGULATORY FRAME WORK

#### 5.5.1. OVERVIEW

As for any company involved in human research, in each country where the Company conducts its research and intends to market its products, it has to comply with regulatory laws and regulations (hereinafter, collectively the Regulatory Regulations), including regulations laid down by national or supra-national Competent Regulatory Authorities, as well as industry standards incorporated by such Regulatory Regulations, that regulate nearly all aspects of the Company's activities.

The Competent Regulatory Authorities notably include the EMA in the EU or the individual national Competent Regulatory Authorities in Europe (i.e.; PEI, FAMHP; etc.) and the FDA in the United States.

#### 5.5.2. PRECLINICAL AND CLINICAL DEVELOPMENT PLANS

Competent Regulatory Authorities are aware of the specificities of biological product candidates, and give much attention to their upfront characterisation, including the development of assays to measure their biological activity. The preclinical and clinical development paths are broadly similar in the EU and in the United States. Initially, preclinical studies are conducted to evaluate the mode of action (pharmacology) and safety (toxicology) either in vitro or in vivo. Upon successful completion of non-clinical studies, a request for a Clinical Trial Authorisation (*CTA*, in the EU) or an Investigational New Drug application (*IND* in US) must be approved by the relevant Competent Regulatory Authorities for studies in humans to be allowed to start. Clinical trials are typically conducted sequentially from phase 1, phase 2 and phase 3, to phase 4 studies



conducted after marketing approval. These phases may be compressed, may overlap or may be omitted in some circumstances.

#### (a) Phase 1 clinical studies

After a Clinical Trial Authorisation (CTA) in Europe or an Investigational New Drug (IND) application in the United States, has been approved, a human clinical study may start.

Phase 1 clinical studies are initially conducted in a limited population to evaluate a drug candidate's safety profile. These studies may provide preliminary evidence of efficacy.

#### (b) Phase 2 clinical studies

These studies are conducted in a limited patient population to evaluate the efficacy of a drug candidate in specific indications, determine its optimal dosage and further describe the safety profile. The initial phase 2 studies of a development program, which is sometimes referred to as phase 2a, may be conducted in few patients to demonstrate safety and preliminary efficacy. Additional phase 2 studies, which may be termed phase 2b, may be conducted in a larger number of patients to confirm the safety and efficacy data generated in the phase 2a studies and to select the optimal dosing.

#### (c) Phase 3 clinical studies

These studies, which are sometimes referred to as registration or pivotal studies, are usually undertaken once phase 2 clinical trials suggest that the drug candidate is effective and has an acceptable safety profile and an effective dosage has been identified. The goal of phase 3 studies is to demonstrate evidence of clinical benefit, usually expressed as a positive benefit-risk assessment, of the new drug in a patient population with a given disease and stage of illness.

### 5.5.3. MARKETING AUTHORISATION APPLICATION AND MARKETING APPROVAL

Although different terminology is used, the data requirements, overall compliance to GMP, Good Clinical Practices ("GCP") and other regulatory requirements and the assessment and decision making process for marketing approval are similar in the EU and in the United States. Upon availability of initial efficacy data from phase 2 clinical trials and confirmatory phase 3 clinical trial data, the Company may submit a request for marketing authorisation to the Competent Regulatory Authorities (a Marketing Authorisation Application (MAA) to EMA in the EU, a Biologics License Application to FDA in the United States). Competent Regulatory Authorities may grant approval, deny the approval or request additional studies or data. Following favorable assessment and/or decision, the products may be commercially launched in the relevant territory. There can be no guarantee that such approval will be obtained or maintained. In practice, effective market launch is often further conditioned upon completion of pricing and reimbursement negotiations with Competent Regulatory Authorities involved in healthcare and pharmaceutical expenditure at the national or regional level.

#### 5.5.4. PRICING AND REIMBURSEMENT

In Europe, pricing and reimbursement for pharmaceuticals are not harmonised and fall within the exclusive competence of the national authorities, provided that basic transparency requirements defined at the European level are met as set forth in the EU Transparency Directive 89/105/EEC, which is currently under revision. As a consequence, reimbursement mechanisms by private and public health insurers vary from country to country. In public health insurance systems, reimbursement is determined by guidelines established by the legislator or a competent national authority. In general, inclusion of a product in



reimbursement schemes is dependent upon proof of the product efficacy, medical need, and economic benefits of the product to patients and the healthcare system in general. Acceptance for reimbursement comes with cost, use and often volume restrictions, which again vary from country to country.

In the United States and markets in other countries, sales of any products for which the Company receives regulatory approval for commercial sale will depend in part on the availability of coverage and adequate reimbursement from third party payers. Third party payers include government payer programs at the federal and state levels, including Medicare and Medicaid, managed care providers, private health insurers and other organisations. The process for determining whether a payer will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payer will pay for the drug product. Third-party payers may limit coverage to specific drug products on an approved list or formulary, which might not include all of the FDA-approved drug products for a particular indication. Third party payers are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. A payer's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realise an appropriate return on our investment in product development.

The price and reimbursement level for the Company's products will depend on the strength of the clinical data set and, as for most novel therapies, restrictions may apply. In most countries, authorities in charge of pricing and reimbursement ensure that the prices of registered medicinal products sold in their territory are not excessive. In making this judgment, they usually compare the proposed national price either to prices of existing treatments and/or prices in other countries also taking into account the type of treatment (preventive, curative or symptomatic), the degree of innovation, the therapeutic breakthrough, volume of sales, sales forecast, size of the target population and/or the improvement (including cost savings) over comparable treatments. Given the growing burden of medical treatments on national health budgets, reimbursement and insurance coverage is an important determinant of the accessibility of medicines. The various public and private plans, formulary restrictions, reimbursement policies, patient advocacy companies, and cost-sharing requirements may play a role in determining access to products marketed by the Company. The national authorities may also use a range of policies and other initiatives intended to influence pharmaceutical consumption. To address the above, the Company integrates as part of its clinical development programs the collection of data aimed at facilitating the evaluation of therapeutic benefit, in terms of efficacy and/or reduction in side effect profile, and of its cost. Concomitantly with marketing authorisation applications, the Company will engage in a dialogue with key decision makers at different payers in order to identify unique preferences and concerns by payer type and to obtain insight in the perceived value drivers, reimbursement barriers and price elasticity for its products.

#### 5.6. COLLABORATION & MATERIAL AGREEMENTS

#### 5.6.1. CONTRACTS WITH CMO'S

The Company has entered into contracts with CMO's in view of the outsourcing of the manufacturing, packing and labelling of its active pharmaceutical ingredients and of the necessary products to carry out its clinical trials. In this framework the Company has granted free licenses over its IP rights for a scope limited to the execution of the contracts by the CMO's and subject to IP rights clauses preserving the Company's IP rights.

The Company has entered into a framework service agreement (the *FSA*) dated 28 April 2015 with a CMO for the production of its novel APIs, and for the production process validation relating to the APIs.



The FSA has been entered into for a fixed period of six years, and it can only be terminated without cause subject to a two-year prior written notice. Under the FSA, the Company provides the CMO with a detailed description of the process as well as the list of equipment, raw materials and disposable equipment with their specifications, to enable the CMO to produce the APIs.

Considering the important exchange of know-how required for the execution of the agreement, the FSA includes the following clauses:

- (i) a confidentiality clause whereby the CMO is refrained from disclosing and using for any other purpose than the execution of the FSA any information which is confidential; this clause shall remain in force for a period of ten years after the termination of the FSA;
- (ii) an intellectual property rights clause reserving to the Company all the proprietary rights with respect to the products and the results of the execution of the contract;
- (iii) an exclusivity clause preventing the CMO to perform any project in the Company's field as defined in the FSA for its own or any third party benefit; this prohibition shall remain in force until 31 December 2027;
- (iv) restrictions with regard to subcontracting whereby the CMO's option to subcontract all or part of its obligations under the contract with the Company is subject to the Company's prior written approval; and
- (v) a change of control clause that grants the Company the right to put an end to the contract in case of change of control on the CMO, subject to a three-month notice.

Under the FSA, the CMO is granted, during the term of the FSA, an exclusive right to deliver (i) the services with respect to the API's developed and commercialised by the Company in Europe and (ii) services that are similar to those performed under the FSA for any other biological active ingredients developed and commercialised by the Company in Europe, unless the CMO is not capable of delivering these services against normal market conditions.

The Company has also entered into an agreement with another CMO for the transfer of its technology and under which the CMO will provide full scale registration/process validation of the batches and the commercial supply of the Company's drug product in vials. The contract has been entered into on 20 August 2015, and shall be supplemented by a quality agreement.

This contract has no explicit duration, and the Company can terminate the contract for any business reason by giving the CMO thirty days prior written notice. The CMO can only terminate the agreement in case of material breach or in case of re-scheduling by the Company beyond 120 days.

The contract contains confidentiality and intellectual property rights clauses. The confidentiality clause incorporates a confidentiality agreement previously entered into between the parties, and provides that its terms shall at least govern the parties' obligations for the duration of the agreement.

The intellectual property clause distinguishes between the intellectual property generated during the contract that is specific to the development, manufacture, use and sale of the Company's product that is the subject of the agreement, and the intellectual property which is not. The former shall be the exclusive property of the Company.

The contract is subject to the laws of England.



#### 5.6.2. CONTRACTS WITH CRO'S

The Company has entered (and will further enter) into several contracts with Contract Research Organisations ("*CRO*") in view of the performance of the different clinical studies with its product candidates for the treatment of grass pollen- and house dust mite—induced allergic rhinoconjunctivitis.

These contracts with CRO's are most generally entered into for the duration of completion of the clinical study, with early termination options for the Company, even for convenience (but subject to the payment of some or part of the costs already, or to be, incurred by the CRO in view of the complete performance of the contract). The counterparties' early termination options are often limited to termination for cause.

All the contracts with CRO's contain confidentiality and intellectual property rights clauses. The confidentiality clause remains applicable at least five years after termination of the contract, and in some cases 10 years, with a lump sum penalty in case of breach of the confidentiality clause. The intellectual property rights clause grants the Company all proprietary rights with respect to the results of the study or the execution of the agreement (with, for some agreements, an obligation for the CRO to provide its cooperation in obtaining patents to the benefit of the Company for the results of the research).

#### 5.7. FINANCIAL AGREEMENT

NA

#### **5.8. GRANTS AND SUBSIDIES**

The Company benefited between 1998 and 2007 from subsidies granted by the Brussels-Capital Region for an aggregate amount of EUR 2,166,690.85 for its research project in the field of grass pollen-induced allergic rhinoconjunctivitis. Each of the Brussels Grants was awarded through several subsidies agreements, which all contained a condition to the effect that the Brussels-Capital Region should benefit from the results of the study projects on an economic, employment-related and environmental level. Grants and subsidies are subject to certain obligations. In case such obligations are not complied with, the grants and subsidies could be suspended, reviewed or reclaimed.

According to the latest official letters from the Brussels-Capital Region authorities dated 4 June 2014, the Company is considered to comply with its obligations under the subsidies agreements from the relevant authorities. The risk of reimbursement of the grants is therefore considered as remote by the Company.

The Company has recently been awarded funding from the Walloon Region. The Walloon Grant consists of a refundable advance for an amount of EUR 1,254,000 for the Company's research project relating to the treatment of house dust mite and the development of hdm-ASIT+<sup>TM</sup>. The Company has already received EUR 314,000 under the Walloon Grant and the outstanding balance of EUR 940,000 is to be received in the coming months as expenses will be incurred in relation to the research project.

The Walloon Grant is subject to certain terms and conditions. The Company will have to start reimbursing the advance on an annual basis during the phase of use of the results arising from the research project, which is to start in 2017. The reimbursement is divided into a fixed part (for an amount of EUR 13,000 for 2017) and a variable part dependent upon the Company's turnover. The Walloon Grant also sets forth that the exploitation activities relating to the subsidised research have to be performed within the European Union until the end of the phase of use.



The Company owns the results of the research project subsidised by the Walloon Grant, but the Company will need to obtain the consent of the Walloon Region for any transfer, out-licensing or sale to a third party of any or all of the research project related results. Also, the Walloon Grant is dedicated to support a specific research project, and its terms may limit the Company's ability to conduct research with third parties in the field of such research project and prohibit the granting of any other rights relating to the Company's findings of such research programme to third parties.

In case the Company would decide not to use the results of the research project, it will have to transfer its rights over the results (including the patents relating to the results of the research project and which were filed or obtained during or following the research phase) to the Walloon Region. Furthermore, the Company would be prohibited from conducting any research on behalf of a third party relating to the research project during 72 months. The results of the research project will also become the property of the Walloon Region in case of bankruptcy of the Company.

#### 5.9. INTELLECTUAL PROPERTY

The Company has filed 10 patent families in the field of allergy. The table below provides an overview of the Company's allergy-related patents as well as detail on patent applications.

The expiration dates mentioned below are based on the usual 20 years of patent protection and take into account the patent term adjustment used in the United States to compensate for delays at the US Patent Office. The expiration dates assume the payment of renewal and annuity fees. There are different possibilities to extent the patent protection (*e.g.* a supplementary protection certificate for maximum five years) and/or a period of so-called "data exclusivity" of five to eight years from initial marketing authorisation. This could be extended with two years, which is a period of so called "market protection". It is only after this protection ends that generic products are authorised on the market.

Patent family	Description of the patent	Jurisdictions where patent is granted or where application has been made (pending)	Maximum term
BTT01 Vaccine HSP	The patent is directed to a pharmaceutical or food composition comprising a stress protein and an epitope of an antigenic structure related to graft rejection or allergic	Major European countries US Canada Japan	March 5, 2018
BTT02 Epitope Composition	reaction or autoimmune reaction  The patent is directed to a pharmaceutical composition for	Major European countries	June 23, 2023
Zpriope composition	sublingual, buccal or enteric administration comprising at least one substance obtainable by hydrolysis with chymotrypsin or any other protease of an antigenic structure which induces graft rejection, allergic reaction or autoimmune disease	Pending application in the US	
BTT03 Peptide Complex	The patent is directed to a complex comprising a heat shock protein and certain peptides	Major European countries US  Pending divisional patent application in Europe	May 18, 2024 (Europe) September 22, 2025 (US)
BTT04 Allergen Purification	The patent family is directed to a special way of purifying and denaturing extracts of natural allergens and a special way of hydrolysing allergens.	Pending patent application in Europe, China, USA, Japan, India, and Brazil	June 28, 2027 (expected)



Patent family	Description of the patent	Jurisdictions where patent is granted or where application has been made (pending)	Maximum term
		Divisional application pending in Japan.	
BTT05 Purified Heat Shock Proteins	The patent family covers a special way of producing ultra pure heat shock proteins	Major European countries USA Japan China	October 12, 2027 (Europe, Japan, China) April 19, 2031 (US).
		Pending patent application in Brazil and India	
BTT06 Allergen Preparation (starch based pellets)	This is an amendment of BTT04	Pending patent application in Europe	December 30, 2028 (expected)
BTT07 Production of Hydrolysed Allergens (peanut)	The patent family covers an improved method for the production of hydrolysed allergen, especially applicable to peanut allergens	Pending patent application in Europe, USA, Japan, China, Brazil, India, Canada and Australia	June 15, 2032 (expected)
BTT08 Dosage of DnaK	The patent family is covering a pharmaceutical preparation of HSP70	Pending patent application in Europe, USA, Japan, China, Brazil, India, Canada and Australia	July 19, 2032 (expected)
BTT09 Allergen Preparation	The patent family covers a special formulation of an allergen	Pending patent application in Europe, USA, Japan, China, Brazil, India, Canada and Australia	March 19, 2034 (expected)
BTT10 Allergen Preparation	This is a PCT application covering a further special formulation of an allergen	PCT application (decision on the countries to be taken by October 10, 2016)	April 9, 2035 (expected)

#### 5.10. MANUFACTURING

The Company does not own any land or facilities. It carries out its activities on two sites, one in Brussels and one in Liège. The offices located in Brussels and where the Company's registered seat is located, are leased under a (non-commercial) lease agreement.

The offices in Liège are the subject matter of a services agreement between the Company and the SPI (the Agency for economic development in the province of Liège). The new offices in Liège as from July 2016 are already the subject matter of a lease agreement between the Company and the SPI.

The Company does not own any production plant.

The Company intends to produce drug substance and drug product through subcontracting agreements whilst maintaining active control over the production process and quality control. This will result in a reduction of the time to the market and an acceleration of the further product development.

The Company does not manufacture any of the components of its novel active pharmaceutical ingredients but has outsourced such manufacturing to its CMO. The Company has also outsourced the manufacturing of the products required for its clinical testing, such as resin, and solution of pollen-peptide.



#### 5.11. INSURANCE

The Company has subscribed to several insurance policies to cover its potential exposure for a number of claims and losses, including fire insurance for the premises it leases, civil liability insurance and work accident insurance.

The Company is currently insured for its civil liability, capped at an amount of EUR 5,000,000 for claims arising from the operation of its business, and at an amount of EUR 1,500,000 for damages suffered after the delivery of its products or the performance of work orders.

The Company has contracted insurance policies for the civil liability insurance in the framework of the clinical studies. Insurance coverage is guaranteed for 3 years after the end of the study:

- BTT-gpASIT007: capped at an amount of EUR 10.000.000 for the study (coverage until 09/12/2016)
- BTT-gpASIT008: capped at an amount of EUR 50.000.000 for the study (coverage until 11/11/2017)
- BTT-gpASIT009: capped at an amount of EUR 23.800.000 for the study (EUR 3.000.000 for the study in Belgium, EUR 2.300.000 in Czech Republic, EUR 6.000.000 in France, EUR 5.000.000 in Germany, EUR 5.000.000 in Italy and EUR 2.500.000 in Spain)

The company also contracted travel accident insurances for the travel home/clinical centre of the patients during the BTT-gpASIT009 study period. The sum insured is EUR 50.000 for death and EUR 100.000 for disability (for patients between 18 and 64).

The Company also operates a defined contribution occupational pension plan which is financed by the employee (with 2% of 13.92 x monthly salary of the month May or of the subscription month, if the subscription occurs in the course of the year) and the employer (with 4% of 13.92 x monthly salary of the month May or of the subscription month, if the subscription occurs in the course of the year). The plan provides for retirement, death in service and disability coverage.

Under Belgian law, defined contribution plans are subject to a statutory minimum return on the contributions. Hence, any shortfall between the statutory minimum return and the actual return may have to be made up by the Company. On 31 December 2015, the shortfall amounted to approx. EUR 1,606.62.

However, in the case at hand, the Company has taken up insurance to cover any potential shortfall.

Therefore, the risk of any liability is considered as remote by the Company.

Since the IPO the Company has also subscribed to a specific IPO insurance with a coverage capped at EUR 15 million as well as a D&O insurance with same coverage.



### 6 ORGANISATIONAL STRUCTURE



The Company is not part to a group of companies and does not have ownership stake in a subsidiary. The Company incorporated the subsidiary Biotech Tools Factory SA in 2009 but this subsidiary was liquidated on 26 June 2015.



# PROPERTY, PLANT AND EQUIPMENT

#### 7.1. ENVIRONMENT AND HEALTH & SAFETY

In accordance with the Walloon Decree of 11 March 1999 regarding environmental permits, the laboratory of the Company in Liège is of class 3. Class 3 facilities are facilities with the lowest environmental impact and, as a result, their operation does not require the granting of an environmental permit but requires the filing of an application with the municipality on whose territory the facility is located.

On 2 September 2015, the Company electronically filed an environmental declaration for its laboratory with the municipality of Liège. On 10 September 2015, the declaration was deemed inadmissible and rectifications of pure form were required (e.g. not all chemical products referred to in the declaration are classified under the prescribed category). The Company filed an amended declaration on 27 October 2015 with the municipality of Liège. Given that the municipality did not oppose to the declaration within the 15-day period starting with the filing of the declaration, the declaration has become final and the Company can validly exercise its activities in the Liège premises.

All the waste rejected by the Company is managed by a specialised company and does not raise any environmental or health and safety concerns.

#### 7.2. PROPERTIES AND FACILITIES

The Company does not own any land or facilities. It carries out its activities on two sites, one in Brussels and one in Liège, leased under (non-commercial) lease agreements.

The Company does not own any production plant.

#### 7.3. INVESTMENTS

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

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

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



# 8 CAPITAL RESOURCES

On the date of this Annual Report, the share capital of the Company amounts to EUR 17.438.592,81 and is fully paid-up. It is represented by 12.756.800 Shares without nominal value and representing the same pro rata fraction of the share capital.

The changes in the Company's share capital since its incorporation can be summarised as follows:

Date	Transaction	Increase or reduction of share capital (EUR)	Resulting share capital (EUR)	Outstanding shares
23 May 1997	Incorporation	29,747.22	29,747.22	1,200
30 September 1998	Capital increase through contribution in cash	278,880	308,627.43	5,460
24 October 2000	Capital increase through contribution in cash	2,032,736.82	2,341,364.26	12,529
20 May 2005	Capital increase through conversion of bonds	123,936.85	2,465,301.11	12,960
20 May 2005	Capital increase through contribution in cash	1,107,272.73	3,572,573.87	16,545
8 June 2006	Capital increase through contribution in cash	664,502.00	4,237,075.84	18,698
31 May 2007	Capital increase through contribution in cash	5,210,000.00	9,447,075.84	38,212
19 November 2009	Capital increase through contribution in cash	1,417,110.82 + 1,583,017.98 (issue premium)	10,864,186.66 + 1,583,017.98 (issue premium)	43,944
7 March 2011	Capital increase through contribution in cash	2,082,393.02 + 2,326,205.18 (issue premium)	12,946,579.68 + 3,909,391.84 (issue premium)	52,367
18 January 2012	Capital increase through contribution in cash	1,346,167.35 + 1,503,745.65 (issue premium)	14,292,747.03 + 5,412,968.81 (issue premium)	57,812
23 December 2014	Capital increase through incorporation of the issue premiums	5,412,968.81	19,705,715.84	57,812
23 December 2014	Capital reduction by way of absorbing carried forward losses	19,699,539.49	6,176.35	57,812
23 December 2014	Capital increase through contribution in cash	7,086,960.00	7,093,136.35	70,936
23 December 2014	Capital increase through conversion of 3,275 bonds issued on 28 April 2013	854,100.00	7,947,236.35	74,211
23 December 2014	Capital increase through conversion of 7,648 bonds issued on 23 May 2014	2,596,800.00	10,544,036.35	81,859
23 December 2014	Capital increase through conversion of 3,182 bonds issued on 15 October 2014	1,081,100.00	11,625,135.35	85,041
8 January 2016	Stock-split			8,504,100
12 May 2016	Capital increase through contribution in cash	4,579,462.46	16,204,598.81	3,350,000
•	- -	+ 18,870,537.54 (issue premium)		
12 May 2016	Capital increase through conversion of 413 bonds issued on 5 August 2015	1,233,994 + 2,896,006 (issue premium)	17,438,592.81	12,756,800



### 9 R&D

#### 9 R&D

Research and development 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)	-
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)	-
Other	(60)	(9)	(9)
Total research and development costs	(6,691)	(3,541)	(1,670)

Staff costs include payroll expenses for people assigned 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 and HDM .

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 outside sources. In 2015, the EUR 4,498 K 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 (60%) as well as for the preparation of the phase I/II clinical study for HDM (20%) to be launched in H2 2016.



### 10 CORPORATE GOVERNANCE

#### 10.1. GENERAL

This section summarizes the rules and principles by which the corporate governance of the Company is organized. Those rules and principles are based on the Corporate Governance Charter (the "Charter") of the Company which has been approved by the Board of Directors on 27 November 2015. This Charter can be obtained free of charge at the registered office of the Company and is available on the Company's website (www.asitbiotech.com).

#### 10.2. COMPLIANCE WITH THE CORPORATE GOVERNANCE CODE

Pursuant to the Belgian Act of 6 April 2010 on the reinforcement of the corporate governance of listed companies and autonomous government enterprises and the amendment of the rules on the exclusion of employment in the bank and financial sector (*loi visant à renforcer le gouvernement d'entreprise dans les sociétés cotées et les entreprises publiques autonomes et visant à modifier le régime des interdictions professionnelles dans le secteur bancaire et financier)*, as implemented by the Royal Decree of 6 June 2010 regarding the designation of the corporate governance code on listed companies, Belgian listed companies should comply with the Belgian Code for Corporate Governance issued on 12 March 2009 by the Belgian Corporate Governance Code" or "CGC"), unless it discloses the justification why it has decided to deviate from the provisions of the Corporate Governance Code (the rule of comply or explain).

The Company has adopted a Charter that is in line with the Corporate Governance Code and entered into force upon the Offering. The Charter describes the main aspects of the corporate governance of the Company, including its governance structure, the terms of reference of the Board of Directors and its committees and other important topics. The Charter must be read together with the Articles of Association.

The Company applies the nine corporate governance principles contained in the Corporate Governance Code except in relation to the following matters:

- the severance pay to be awarded to Mr Thierry Legon, as CEO of the Company, in the event of early termination of his contract which exceeds the 12 months' basic and variable remuneration limitation set forth in Article 7.18 of the Corporate Governance Code. The Company justifies such derogation by the fact that the service agreement of Mr Thierry Legon has been negotiated and signed a long time before the decision of the Company to comply with the Corporate Governance Code. The Company does not intend to force the amendment of the existing service agreement but will consider such modification if the service agreement of Mr Thierry Legon is renegotiated in the future;
- the Company intends to award stock based incentives to the non-executive directors, upon advice of the Remuneration and Nomination Committee. This is contrary to provision 7.7 of the Corporate Governance Code that provides that non-executive directors should not be entitled to performance-related remuneration such as (amongst others) stock related long-term incentive schemes. The Company justifies this as it allows to limit the portion of remuneration in cash that it would otherwise need to pay to attract or retain (internationally) renowned experts with the most relevant skills, knowledge and expertise, and as it is customary for directors active in companies in the biotech and life industry, and as the portion of the remuneration payable in warrants is limited.

What constitutes good corporate governance will evolve with the changing circumstances of a company and with the standards of corporate governance globally, and must be tailored to meet those changing circumstances. The Board of Directors intends to update the Charter as often as required to reflect changes to the Company's corporate governance.



The Articles of Association and the Charter are made available on the Company's website and can be obtained free of charge at the Company's registered office.

#### 10.3. BOARD OF DIRECTORS

#### 10.3.1. COMPOSITION OF THE BOARD

The Company has opted for a "one tier" governance structure whereby the Board of Directors is the ultimate decision making body, with the overall responsibility for the management and control of the Company, and is authorised to carry out all actions that are considered necessary or useful to achieve the Company's purpose. The Board of Directors has all powers except for those reserved to the Shareholders' Meeting by law or the Articles of Association.

Pursuant to the Charter, the role of the Board of Directors is to pursue the long term success of the Company by providing entrepreneurial leadership and enabling risks to be assessed and managed. The Board of Directors decides on the Company's values and strategy, its risk appetite and key policies.

The Board of Directors is assisted by a number of committees in relation to specific matters. The committees advise the Board of Directors on these matters, but the decision making remains with the Board of Directors as a whole (see also "—Committees of the Board of Directors" below).

The Board of Directors appoints and removes the chief executive officer (CEO). The role of the CEO is to implement the mission, strategy and targets set by the Board of Directors and to assume responsibility for the day-to-day management of the Company. The CEO reports directly to the Board of Directors.

Pursuant to the BCC the Board of Directors must consist of at least three directors. Pursuant to the Articles of Association the Board of Directors must consist of a maximum of nine directors. The Charter provides that the composition of the Board of Directors should ensure that decisions are made in the corporate interest. It should be determined on the basis of diversity, as well as complementary skills, experience and knowledge. Pursuant to the Corporate Governance Code, at least half of the directors must be non-executive and at least three directors must be independent in accordance with the criteria set out in the BCC and in the Corporate Governance Code. Pursuant to Article 518bis of the BCC by 1 January 2022, at least one third of the members of the Board of Directors must be of the opposite gender.

The directors are appointed for a term of no more than four years by the Shareholders' Meeting. They may be re-elected for new terms. Proposals by the Board of Directors for the appointment or re-election of any director must be based on a recommendation by the Remuneration and Nomination Committee. In the event the office of a director becomes vacant, the remaining directors can appoint a successor temporarily filling the vacancy until the next Shareholders' Meeting. The Shareholders' Meeting can dismiss the directors at any time.

Pursuant to the Company's Articles of Association, the Shareholders owning, individually or jointly, at least 15% of the share capital of the Company have the right to propose the names of two candidates for a position of director. Unless recommended otherwise by the remuneration and nomination committee of the Company (the Remuneration and Nomination Committee), the Shareholders' Meeting shall appoint one of those two candidates as director.

As of the date of this annuel report, the Board of Directors is composed of 9 directors. The table below gives an overview of the members of the Company's Board of Directors:



NAME	POSITION	START OR RENEWAL OF MANDATE	TERM OF MANDATE	NATURE OF MANDATE
Béatrice De Vos	Director	13 June 2013	OGM 2016	Chairwoman
Thierry Legon	Managing Director	13 June 2013	OGM 2016	Executive
Jean Duchâteau	Director	28 June 2013	OGM 2016	Independant
Gerd Zettlmeissl	Director	13 June 2013	OGM 2016	Independant
François Meurgey	Director	13 June 2013	OGM 2016	Executive
Everard van der Straten-Ponthoz	Director	13 June 2013	OGM 2016	Executive
Yves Désiront	Director	10 July 2015	OGM 2018	Independant
Bruservices SA (Henri De Meyer)	Director	13 June 2013	OGM 2016	Non independant
Meusinvest SA (Marc Foidart)	Director	23 December 2014	OGM 2017	Non independant

The profile and professional experience of each of the Directors is summarised hereafter:

**Béatrice De Vos** is the chairman of the Board of Directors. Mrs. De Vos has MD, PhD and BCPM degrees. She is a physician, specialist in pharmaceutical medicine and member of the Belgian College of Pharmaceutical Medicine. Mrs. De Vos has been awarded a Doctor in Medical Sciences' degree at the University of Antwerp (UIA). For the past 25 years, she worked in leading positions of clinical research and medical affairs departments of major international pharmaceutical companies: Regional Director Benelux at Wyeth-Ayerst R&D (Belgium), VP Global Medical Affairs at GSK Biologicals (Belgium), VP Global Medical & Scientific Affairs at Sanofi Pasteur (France). She was in charge of the clinical development programs of multiple drug candidates and several viral vaccine candidates. She succeeded to develop a paediatric rotavirus vaccine, from bench to bed, that is currently used globally. She is author or co-author of multiple publications in international peer-reviewed journals and books, lecturer and speaker at several congresses, and advisor to several national and international companies and NGO's.



**Thierry Legon** is the CEO. Ir. Agronomy, MBA, Thierry Legon was in charge for ten years of the management of the intellectual property and technology transfer of the University of Brussels (ULB). Mr. Legon was also a member of the board of directors of Euroscreen (a drug discovery biotech company) for eight years. In May 1997, Mr. Legon founded the Company as a spin-off company of the ULB. As Company' CEO since 2000, Mr. Legon has demonstrated his capacity to design business plan, to raise the required funds and to lead the team to achieve the goals of the Company.

Gerd Zettlmeissl is holding a doctoral degree in biochemistry of the University of Regensburg and did a post-doctoral fellowship at the Institut Pasteur Paris in virology. Mr. Zettlmeissl has been working in various R&D and general management positions in the biopharmaceutical and vaccine industry since 1985. His last positions were managing director of Chiron Behring, a leading vaccine manufacturer in Germany, and until May 2011 CEO of Intercell in Austria. During his career, he made major contributions to the discovery, development and registration of a number of biologicals and vaccines. In 2010, he was named Vaccine Biotech CEO of the Year at the World Vaccine Congress. He currently serves as non-executive director of Aeras (USA). Until early 2015 he was chairman of GlycoVaxyn (Switzerland), an innovative vaccine company acquired by GlaxoSmithKline.

**Jean Duchâteau**. MD PhD, graduated in Internal Medicine and Clinical Biology, Honorary Professor of Mucosal Immunology at Université Libre de Bruxelles, Head Department of Clinical Biology at CHU-Brugmann and Hopital Universitaire des Enfants - Reine Fabiola (ULB) Professor Duchateau is one of the inventor of the first patents on tolerance induction to allergy and graft rejection, new LED tests, owned by Company. Professor Duchateau was cofounder of Company and he is now Honorary President.

**Yves Désiront** obtained a master degree as Ingénieur Commercial in Business Administration and Technology Interface from I.C.H.E.C. Brussels in 1994. He is the managing partner of a private equity fund based in Luxembourg and is acting, since October 2015, as group CFO of BGP Investment, a Luxembourg real estate group. Previously he acted as group CFO of Orco Property Group. Prior to this, he served in various functions at Groupe Bruxelles Lambert and Générale de Banque.

François Meurgey is working as independent consultant in pharmaceutical product strategic marketing. He has spent more than twenty-five years in the biopharmaceutical industry, almost equally divided between Europe and the United States, and between operational and staff functions. He has held important sales and marketing positions at Eli Lilly (Director of Global Marketing for Prozac®), Merck & Co. (Senior Director of Asia-Pacific Marketing) and UCB (Vice-President of Global Marketing), among others. He also teaches regularly at ESSEC in Paris, the ULB in Brussels, the Scandinavian International Management Institute (SIMI) in Copenhagen, and Columbia University Graduate Schools of Business and Public Health in New York. French national, he is a graduate of Reims Management School, received an MS in International Relations from Université de Paris-Sorbonne and holds an MBA from the Stern School of Business at New York University.

**Everard van der Straten Ponthoz** holds a Master in applied economics from Solvay Business School. Everard van der Straten Ponthoz started a short career as auditor with Arthur and Anderson & Co, he has been the managing director of Metallo-chimique Group until March 2007 and then member of the Board of Metallum Group until December 2008. Since that time Mr. van der Straten acts as a business angel for SME's.

**Henri De Meyer** holds two Master Degrees, both from Solvay Business School (in Management and Taxation Management) and a post grade from Université Libre de Bruxelles (in Human Resources Management). He has been working for 18 years in the Venture Capital Sector as Investment Manager and, since 2000, as Crisis Manager in charge of restructuring companies and M&A assignments.



**Marc Foidart** obtained a Master in Business Engineering from the University of Liège. He is founder of Cide-Socran ASBL and has more than 15 years' experience in financial and management consulting for small and medium enterprises. Mr. Foidart is Vice-President of Meusinvest SA and CEO of Spinventure SA.

At the date of the Annual Report, all the Directors and the members of the executive management have confirmed the absence of (i) any convictions in relation to fraudulent offenses during the past five years or (ii) any official public incrimination and/or sanctions of such members by statutory or regulatory authorities (including designated professional bodies), or disqualification by a court from acting as a member of the administrative, management or supervisory body of an issuer or from acting in the management or conduct of the affairs of any issuer during the past five years.

In the five years preceding the date of the present Annual Report, the Directors and members of the executive management have held the following directorships and memberships of administrative, management or supervisory bodies and/or partnerships (apart from their functions within the Company):

Director	Current mandate	Past mandate	
Thierry Legon	N/A	Biotech Tools Factory SA Thierry Legon BVBA	
Gerd Zettlmeisl	Themis Bioscience GmbH Aeras Foundation Hilleman Laboratories Pvt. Ltd	GlycoVaxyn AG	
Jean Duchâteau	Jean Duchâteau SPRL	N/A	
Yves Désiront	FYP SA D&R Cambre SA RE Finance Consulting SA BGP AM GmbH Nabul Construmat SL Subsidiaries of Orco Property Group		
François Meurgey	Oukelos SPRL	N/A	
Everard van der Straten	Espad-Services SA Strafer SA Teck Finance SA LBI Investissements SA REM 624 Recymet SA Chawiti SCI Altro SA Wilink SA Unijep SA	N/A	
Henri De Meyer	Maison de la Radio Flagey SA MDG SA Bruservices SA Tumor Growth Control ASBL Bruservices SA GX Holding SPRL Gogolplex SPRL	Labima SA Autocab SA Polygone International SA Hello Agency SA Primo SA Weghsteen Capital Advice SA Sushi Factory SA	
Marc Foidart	Imcyse SA Mithra Pharmaceuticals SA Uteron Pharma SA Centre d'Innovation Médicale SA Wallonia Biotech Coaching SA Cide-Socran ASBL Spinventure SA Lasea SA	Arlenda SA Métal Déployé SA MDB Holding SA Epimède SPRL Gambit Financial Solutions SA Uteron Pharma SA Themis Holding SA Pastificcio della Mamma SA	



Director	Current mandate	Past mandate	
	Amos SA Spacebel SA Pierre et Nature SARL Notger Invest SPRL Ousia SPRL Ousia Operations SPRL Samtech SA Science Park Services SA Leansquare SA	Propac SAFS Majocepi SPRL Faxim SPRL	
Albert Vicaire	N/A	Biotech Tools Factory	

#### > Activity Report

The Board of Directors met 19 times during 2015 to discuss and decide on specific matters. Below is the detail of the attendance:

Member of the board	Number of attendances
Béatrice De Vos	19/19
Thierry Legon	19/19
Jean Duchâteau	18/19
Gerd Zettlmeissl	14/19
François Meurgey	11/19
Everard van der Straten-Ponthoz	18/19
Yves Désiront	7/9
Bruservices SA (Henri De Meyer)	17/19
Meusinvest SA (Marc Foidart)	16/19

#### Committees within the Board of Directors

The Board of Directors has established two board committees which are responsible for assisting the Board of Directors and making recommendations in specific fields: the Audit Committee (in accordance with article 526bis of the BCC and provision 5.2 of the Corporate Governance Code) and the Remuneration and Nomination Committee (in accordance with article 526quater of the BCC and provision 5.3 and 5.4 of the Corporate Governance Code). The terms of reference of these board committees are primarily set out in the Charter.

#### **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 Annuel 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 members of the Audit Committee must have sufficient expertise in financial matters to discharge their functions. The chairperson of the Audit Committee is competent in accounting and auditing as evidenced by his previous and current roles. According to the Board of Directors, the other members of the Audit Committee also satisfy this requirement, as evidenced by the different senior management and director mandates that they have held in the past and currently hold.

The role of the Audit Committee is to supervise and review the financial reporting process, the internal control and risk management systems and the internal audit process of the Company. The Audit Committee monitors the audit of the statutory and consolidated financial statements, including the follow-up questions and recommendations by the statutory auditors. The Audit Committee also makes recommendations to the Board of Directors on the selection, appointment and remuneration of the external auditors and monitors the independence of the external auditor.

In principle, the Audit Committee meets as frequently as necessary for the efficiency of the operation of the Audit Committee, but at least four times a year.

#### 10.3.2. REMUNERATION AND NOMINATION COMMITTEE

The Remuneration and Nomination Committee consists of at least three directors. All members of the Remuneration and Nomination Committee are non-executive directors. In line with the BCC, the Remuneration and Nomination Committee consists of a majority of independent directors. The Remuneration and Nomination Committee is chaired by the person appointed by the Board of Directors. At the date of this Annual Report the following directors have been appointed as members of the Remuneration and Nomination Committee: Gerd Zettlmeissl (chairperson), Jean Duchâteau and Meusinvest SA (represented by Marc Foidart). Pursuant to the BCC, the Remuneration and Nomination Committee must have the necessary expertise on remuneration policy, which is evidenced by the experience and previous roles of its current members.

The role of the Remuneration and Nomination Committee is to make recommendations to the Board of Directors with regard to the appointment of directors, make proposals to the Board of Directors on the remuneration policy and individual remuneration for directors and members of the executive management, and to submit a remuneration report to the Board of Directors. In addition, the Remuneration and Nomination Committee each year submits the remuneration report to the annual Shareholders' Meeting.

In principle, the Remuneration and Nomination Committee meets as frequently as necessary for the efficiency of the operation of the committee, but at least three times a year.

#### 10.4. MANAGEMENT TEAM

The executive management of the Company is led by Thierry Legon, the CEO, assisted by the chief financial officer, the marketing director and the secretary. No executive management board (comité de direction) has been established by the Board of Directors of the Company.

**Albert Vicaire** is the secretary of the Company. As an industrial engineer, MBA, he uses his twenty years in human resources experience to manage the administrative aspects of the Company. His pragmatic problem solving approach and influence management skills help the members of the scientific team to focus on their own tasks. Mr. Vicaire is an employee of the Company.

**Everard van der Straten Ponthoz**, through his management company Espad-Services SA, has been appointed on 21 September 2015 by the Board of Directors as chief financial officer ad interim. His profile and professional experience are detailed above.



**François Meurgey**, through his management company Oukelos SPRL, has been appointed by the Board of Directors as marketing director of the Company with effect as from 1 December 2015. His profile and professional experience are detailed above.

#### 10.5. INTERNAL CONTROL MECHANISM

The role of the executive Directors and of the management team is to develop and maintain 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 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.

#### 10.6. MARKET ABUSE REGULATION

The Company established several rules to prevent illegal use of inside information by Directors, Shareholders, Management members and employees, or the appearance of such use.

The Company keeps a list of all persons (employees or persons otherwise working for the Company) having (had) access, on a regular or occasional basis, to inside information. The Company will regularly update this list and transmit it to the FSMA whenever the FSMA requests the Company to do so.

#### 10.7. FEES PAID TO AUDITORS FOR AUDIT AND OTHER ACTIVITIES

Here is the detail of the audit and non-audit fees for the year 2015

Detail for Y 2015	Amount in €
Total audit fees	12,756
Total non-audit fees	57,250



#### 10.8. REMUNERATION REPORT

#### 10.8.1. PROCEDURE

#### > Directors

Prior to the Offering, the Remuneration and Nomination Committee made recommendations in respect of the remuneration of the Board members. Such remuneration to be made applicable only in case the Company got listed. For this purpose the Remuneration and Nomination Committee made a bench-marking exercise with other peer companies to ensure to offer a fair, reasonable and competitive remuneration sufficient to attract, retain and motivate the Directors of the Company.

This proposal shall be submitted to and approved by the Shareholders Meeting.

#### > Executive Directors and Management Team

The remuneration of the Executive Directors and of the members of the Management Team are determined by the Board of Directors on recommendations made by the Nomination and Remuneration Committee. The Company strives to offer a competitive remuneration within the sector.

#### 10.8.2. REMUNERATION POLICY

#### > Director's remuneration

Since the first of January 2015, no remuneration or compensation was paid to the Directors (excluding the CEO), other than EUR 32,657.70 paid to Bejamad SPRL, the management company of Béatrice De Vos for services relating to (i) advices and recommendations on the clinical development of the Company products in order to get their registration by the competent authority and (ii) business development provided in favour of the Company and EUR 4,537.50 paid to Oukelos SPRL, the management company of François Meurgey for services relating to pharmaceutical marketing services provided in favour of the Company.

The proposal made by the Nomination and Remuneration Committee, as from the closing of the Offering, and with respect to the remuneration and compensation of the non-executive directors is as follows:

- Annual fixed fees of :
- · EUR 30,000 for the chairperson of the Board of Director;
- EUR 15.000 for the non-executive Directors:
- EUR 5,000 for the chairperson of the Audit Committee;
- EUR 3,000 for the chairperson of the Remuneration and Nomination Committee
- Share based awards: award stock based incentives to the non-executive directors, upon advice of the Remuneration and Nomination Committee, subject to shareholders' approval.

There are currently no plans to change the remuneration policy or remuneration of non-executive directors. However, the Company will permanently review the remuneration of non-executive Directors against market practice. The Company also reimburses reasonable out of pocket expenses of directors (including travel expenses) incurred in performing the mandate of Director.



#### > Remuneration of the CEO

The remuneration of the CEO prior to the Offering consisted of the following main remuneration components:

- annual base fee (fixed at EUR 161,000.00);
- licensing for know-how and assignment of IP right: on the basis of an agreement signed on 14 July 2014 the Company pays annually a lump sum amount of EUR 55,000 to Mr. Thierry Legon for the licensing of scientific know-how as well as the transfer of his IP rights. Pursuant to such agreement Mr. Thierry Legon makes available to the Company its scientific expertise and assigns to the Company all intellectual property rights, including copyrights that may result from his daily activities to the benefit of the Company;
- annual variable remuneration (linked to scientific performance (such as the finalisation of the phase III clinical studies or the development of new indications) and economic performances (new subsidies, financing and commercial income) and capped at EUR 50,000.00);
- exceptional and non-recurring bonus; and
- participation in stock option plans, depending on the final decision of the Remuneration and Nomination Committee to implement new stock option plans in the future. No decision has yet been taken for the future at this stage.

The Company decided to increase, further to the Offering, the level of remuneration and compensation of the CEO to align it with the remuneration paid to CEO's in comparable listed companies. Upon a decision of the Board of Directors, the following remuneration has been decided for the CEO subject to closing of the Offering:

- annual base fee (fixed at EUR 195,000.00);
- licensing for know-how and assignment of IP right (together with the annual base fee, the annual fee): on the basis of an agreement signed on 14 July 2014 the Company pays annually a lump sum amount of EUR 55,000 to Mr. Thierry Legon for the licensing of scientific know-how as well as the transfer of his IP rights. Pursuant to such agreement Mr. Thierry Legon makes available to the Company its scientific expertise and assigns to the Company all intellectual property rights, including copyrights, that may result from his daily activities to the benefit of the Company;
- annual variable remuneration (linked to performance and capped at 33% of the annual fee, ie. EUR 83,300.00);
- exceptional and non-recurring bonus for the completion of the Offering of an amount between EUR 70,000 and EUR 120,000, depending on the proceeds of the Offering; and
- participation in stock option plans.

Pursuant to Article 520ter of the Company Code "Unless provided otherwise in the articles of association or approved by the annual general shareholders' meeting, (a) variable remuneration for leader must be base, at least for 25%, on performance criteria measured over a period of a least two years and for (another) 25% on performance criteria measured over a period of a least three years and (b) shares may only be definitively acquired by Directors and leaders and stock-options or other rights to acquire shares may only be exercised by leaders at the earliest three years after they have been granted to them". It is expressly proposed to the annual shareholders' meeting to approve a full derogation to this provision regarding the grants (of variable remuneration or stock-options) to occur for the benefit of Directors or the CEO until the annual shareholders' meeting to be held in 2017.

#### > Remuneration of the Executive Management



#### 10 CORPORATE GOVERNANCE

Espad-Services SA, a company controlled by Everard van der Straten Ponthoz, is the chief financial officer of the Company since 21 September 2015. A service agreement has been executed in that respect on 16 December 2015. The services are invoiced at a daily rate of EUR 1,250.

Oukelos SPRL, a company controlled by François Meurgey, is the marketing director of the Company since 1 December 2015. A service agreement has been executed in that respect on 5 January 2015. The services are invoiced at a daily rate of EUR 1,250.

Mr. Albert Vicaire is employee of the Company. His yearly gross annual compensation is EUR 75,168.00. The employment agreement of Mr. Vicaire was entered into for an indefinite period of time and can be terminated by either Mr. Vicaire or the Company at any time subject to a prior notice (or the payment of an indemnity in lieu of notice) in accordance with the provisions of the Belgian Act of 3 July 1978 concerning Employment Contracts.



# 11 RELATED PARTY TRANSACTIONS

#### 11 RELATED PARTY TRANSACTIONS

The Company has not entered into transactions with its principal Shareholders.

The following service agreements have been executed between the Company and companies relating to directors:

- the service agreement executed with JEAN DUCHATEAU SPRL on 4th July 2003, a company linked to Mr. Jean Duchâteau, relating to services on research program in the field of the diagnosis and treatment of autoimmune diseases, allergies and transplant rejection; the consideration for the services is a yearly fee of EUR 15,000;
- a first service agreement was executed with OUKELOS SPRL on 16 June 2009, a company linked to Mr. François Meurgey, relating to pharmaceutical marketing services; this first agreement was replaced by a second one, effective as of 1 December 2015 and relating to the position of marketing director of the Company. The consideration for these services is a daily fee of EUR 1,250; and
- the service agreement executed with ESPAD-SERVICES SA, a company controlled by Everard van der Straten Ponthoz, relating to services of chief financial officer of the Company since 21 September 2015: the consideration for these services is a daily rate of EUR 1,250.

A service agreement had been executed with BEJAMAD SPRL on 22 March 2013, company linked to Mrs. Béatrice De Vos (chairman of the board), relating to (i) advices and recommendations on the clinical development of the Company products in order to get their registration by the competent authority and (ii) business development; the consideration for the first mission consisted in a daily fee of EUR 1,120 up to 50 days/year and the consideration for the business development was a monthly fee of EUR 2,500. This service agreement has been terminated with effect on 31 August 2015.

The Company has not entered into any related party transactions with any Shareholders or directors or any persons or entities affiliated with any of the Shareholders or directors.



## 12 EMPLOYEES

#### 12 EMPLOYEES

The Company currently employs 19 employees and relies on the services of three self-employed contractors (the CEO, the CFO and the Chief Marketing Director).

The headcount of the Company has evolved from 10 employees in 2012, 8 employees in 2013 and 10 employees in 2014. During the same period, he Company relied on the services of one self-employed contractor (the CEO).

The Company has created a pool of warrants to grant to employees. Reference is made to section 10.7.4 of the Offering Prospectus for more detailed information on the warrants plans (available on <a href="https://www.asitbiotech.com">www.asitbiotech.com</a>).



# 13 SHARES AND SHAREHOLDERS

### 13.1. SHARES AND SHAREHOLDERS

### 13.1.1. HISTORY OF CAPITAL

On the date of this Annual Report, the share capital of the Company amounts to EUR 17.438.592,81 and is fully paid-up. It is represented by 12.756.800 Shares without nominal value and representing the same pro rata fraction of the share capital.

The changes in the Company's share capital since its incorporation can be summarised as follows:

Date	Transaction	Increase or reduction of share capital (EUR)	Resulting share capital (EUR)	Outstanding shares
23 May 1997	Incorporation	29,747.22	29,747.22	1,200
30 September 1998	Capital increase through contribution in cash	278,880	308,627.43	5,460
24 October 2000	Capital increase through contribution in cash	2,032,736.82	2,341,364.26	12,529
20 May 2005	Capital increase through conversion of bonds	123,936.85	2,465,301.11	12,960
20 May 2005	Capital increase through contribution in cash	1,107,272.73	3,572,573.87	16,545
8 June 2006	Capital increase through contribution in cash	664,502.00	4,237,075.84	18,698
31 May 2007	Capital increase through contribution in cash	5,210,000.00	9,447,075.84	38,212
19 November 2009	Capital increase through contribution in cash	1,417,110.82 + 1,583,017.98 (issue premium)	10,864,186.66 + 1,583,017.98 (issue premium)	43,944
7 March 2011	Capital increase through contribution in cash	2,082,393.02 + 2,326,205.18 (issue premium)	12,946,579.68 + 3,909,391.84 (issue premium)	52,367
18 January 2012	Capital increase through contribution in cash	1,346,167.35 + 1,503,745.65 (issue premium)	14,292,747.03 + 5,412,968.81 (issue premium)	57,812
23 December 2014	Capital increase through incorporation of the issue premiums	5,412,968.81	19,705,715.84	57,812
23 December 2014	Capital reduction by way of absorbing carried forward losses	19,699,539.49	6,176.35	57,812
23 December 2014	Capital increase through contribution in cash	7,086,960.00	7,093,136.35	70,936
23 December 2014	Capital increase through conversion of 3,275 bonds issued on 28 April 2013	854,100.00	7,947,236.35	74,211
23 December 2014	Capital increase through conversion of 7,648 bonds issued on 23 May 2014	2,596,800.00	10,544,036.35	81,859
23 December 2014	Capital increase through conversion of 3,182 bonds issued on 15 October 2014	1,081,100.00	11,625,135.35	85,041
8 January 2016	Stock-split			8,504,100
12 May 2016	Capital increase through contribution in cash	4,579,462.46 + 18,870,537.54 (issue premium)	16,204,598.81	3,350,000
12 May 2016	Capital increase through conversion of 413 bonds issued on 5 August 2015	1,233,994 + 2,896,006 (issue premium)	17,438,592.81	12,756,800

# 13.1.2. AUTHORISED CAPITAL

On 26 June 2015, the Company's Shareholders' Meeting authorised, subject to and with effect as of the closing of the IPO, the Board of Directors to increase the share capital of the Company within the framework of the authorised capital with a maximum of EUR 11,625,000.

The Company's Shareholders' Meeting decided that the Board of Directors, when exercising its powers under the authorised capital, is authorised to restrict or cancel the statutory preferential subscription rights of the Shareholders (within the meaning of article 592 and following of the BCC). This authorisation includes the restriction or suppression of preferential subscription rights for the benefit of one or more specific persons (whether or not employees of the Company). The authorisation is valid for a term of five years as from the date of the publication of the authorisation in the Annexes to the Belgian State Gazette.



### 13.1.3. WARRANTS PLANS

At the date of this Annual Report the warrants plans implemented by the Company can be summarised as below. More information on these plans can be found in the Offering Prospectus uploaded on the website of the Company:

	Number of outstanding warrants	Exercise price (EUR)*	Date of expiration
2008 Plan	1,100	523.4	31/12/2016
2011 Plan	983	523.4	31/12/2016
2014 Plan	2,145	300	30/10/2019
2015 Plan	1,160	540	30/04/2020

Each outstanding warrant allows the holder to acquire 100 shares of the Company.

More information about Warrants plans can be found on section 10.7.4 of the Offering prospectus (available on www.asitbiotech.com).

# 13.1.4. 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.



### 13.1.5. TRANSPARENCY

The articles of association of the Company do not impose any additional notification obligations other than the notification obligations required in accordance with Belgian law.

### 13.1.6. SHAREHOLDERS

Te share capital of the Company amounts to EUR 17.438.592,81 and is fully paid-up. It is represented by 12.756.800 Shares without nominal value and representing the same pro rata fraction of the share capital. The total number of outsanding warrant at the date of this Annual Report is 5,388 allowing the holders to subscribe to a total of 538,800 new shares.

The identification of the shareholders that have notified the Company of their ownership of securities of the Company is on the website of the Company (www.asitbiotech.com).



# 14 ARTICLES OF ASSOCIATION

### 14.1. ARTICLES OF ASSOCIATION

This section contains the memorandum of the articles of association of the Company. The complete set of the articles of association can be found on the website of the Company (www.asitbiotech.com).

### 14.1.1. CORPORATE PURPOSE

The corporate purpose of the Company is set forth in Article 3 of its Articles of Association. The corporate purpose reads (in translation from the French original text) as follows:

"The purpose of the Company is, as well in Belgium as abroad, as well in its own name and for its own accounts as in the name or for the account of third parties:

to develop new medical technologies, including researches and development of products and process in the pharmaceutic and biotechnology fields, including immunotherapy, allergy and autoimmune diseases;

- the production and manufacturing of the results obtained by the researches and development activities;
- the marketing of products and process in the above mentioned fields;
- the development, sale, exploitation, use of results, marketing, license grant, licensing and management of all intellectual rights directly or indirectly related to the activities of the Company;
- training, information, publication, communication and edition on any supports relating to the above mentioned activities.

The Company can perform all so-called financial, movable and immovable transactions that, directly or indirectly, relate to the Company's corporate purpose or which may benefit this corporate purpose.

The Company can participate directly or indirectly to any business, company, association or institutions with a similar or related purpose or which may benefit this corporate purpose or the development of its operations.

The Company can grant guarantees to any related company or event to third parties."

### 14.2. DESCRIPTION OF THE RIGHTS ATTACHED TO THE SHARES

# 14.2.1. PREFERENTIAL SUBSCRIPTION RIGHTS

In the event of a capital increase in cash with issue of new Shares, or in the event of an issue of convertible bonds or warrants exercisable in cash, the Shareholders have a preferential right to subscribe for the new Shares, convertible bonds or warrants, pro rata to the part of the share capital represented by the Shares that they already hold. The Shareholders' Meeting may decide to limit or cancel such preferential subscription right, subject to specific substantive and reporting requirements. Such decision must satisfy the same quorum and majority requirements as the decision to increase the Company's share capital.

The Shareholders can also decide to authorise the Board of Directors to limit or cancel the preferential subscription right within the framework of the authorised capital, subject to the terms and conditions set forth in the BCC. In principle, the authorisation of the Board of Directors to increase the share capital of the Company through contributions in cash with cancellation or limitation of the preferential right of the existing Shareholders is suspended as of the notification to the Company by the FSMA of a public takeover bid on the Shares. The Shareholders' Meeting can, however, authorise the Board of Directors to increase the share



capital by issuing further Shares, not representing more than 10% of the Shares of the Company at the time of such a public takeover bid.

### 14.2.2. VOTING RIGHTS ATTACHED TO SHARES

Each Shareholder of the Company is entitled to one vote per Share.

Voting rights can be mainly suspended in relation to Shares:

- which are not fully paid up, notwithstanding the request thereto of the Board of Directors of the Company;
- to which more than one person is entitled, except in the event a single representative is appointed for the exercise of the voting right;
- which entitle their holder to voting rights above the threshold of 5%, 10%, 15%, 20% and any further multiple of 5% of the total number of voting rights attached to the outstanding financial instruments of the Company on the date of the relevant Shareholders' Meeting, in the event that the relevant Shareholder has not notified the Company and the FSMA at least 20 days prior to the date of the Shareholders' Meeting in accordance with the applicable rules on disclosure of major shareholdings; and
- of which the voting right was suspended by a competent court or the FSMA.

Pursuant to the BCC, the voting rights attached to Shares owned by the Company, as the case may be, are suspended.

Generally, the Shareholders' Meeting has sole authority with respect to:

- the approval of the annual financial statements of the Company;
- the distribution of profits (except interim dividends (see "Rights attached to the Shares—Dividends");
- the appointment and dismissal of directors and the statutory auditor of the Company;
- the granting of release from liability to the directors and the statutory auditor of the Company;
- the determination of the remuneration of the directors and of the statutory auditor for the exercise of their mandate:
- the approval of the remuneration report included in the annual report of the Board of Directors and the determination of the following features of the remuneration or compensation of directors, members of the executive management and certain other executives (as the case may be): (i) in relation to the remuneration of executive and non-executive directors, members of the executive management and other executives, an exemption from the rule that share based awards can only vest during a period of at least three years as of the grant of the awards, (ii) in relation to the remuneration of executive directors, members of the executive management and other executives, an exemption from the rule that (unless the variable remuneration is less than a quarter of the annual remuneration) at least one quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least two years and that at least another quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least three years, (iii) in relation to the remuneration of independent directors, any variable part of the remuneration, and (iv) any provisions of service agreements to be entered into with executive directors, members of the executive management and other executives providing for severance payments exceeding twelve



# 14 ARTICLES OF ASSOCIATION

months' remuneration (or, subject to a motivated opinion by the Remuneration and Nomination Committee, 18 months' remuneration);

- the filing of a claim for liability against directors;
- the decisions relating to the dissolution, merger and certain other reorganisations of the Company; and
- the approval of amendments to the Articles of Association.

# 14.2.3. RIGHTS REGARDING LIQUIDATION

In the event of dissolution of the Company, for any reason or at any time, the liquidation shall be effected by liquidators appointed by the Shareholders' Meeting, and in the absence of such appointment, the liquidation shall be effected by the Board of Directors, acting as a liquidation committee. Unless decided otherwise, the liquidators shall act jointly. To this end, the liquidators have the broadest powers under articles 186 and following of the BCC, subject to restrictions imposed by the Shareholders' Meeting. The Shareholders' Meeting determines the remuneration of the liquidators.

After settlement of all debts, charges and expenses, the net assets are first used to, in cash or in kind, repay the fully paid and not yet repaid amount of the Shares. Any surplus shall be divided equally among all Shares.

If the net proceeds are not sufficient to repay all the Shares, the liquidators shall pay the Shares that have been paid to a greater extent until they are on a par with the Shares paid up to a lesser extent or they make an additional call for capital at the expense of the latter.

### 14.2.4. RIGHT TO ATTEND AND VOTE AT SHAREHOLDERS' MEETINGS

# Annual meetings of Shareholders

The annual Shareholders' Meeting is held at the registered office of the Company or at the place determined in the notice convening the Shareholders' Meeting. The meeting is held every year on the second Thursday of the month June at 3 p.m. (Brussels time). If this date is a legal holiday the meeting is held the next business day at the same time. At the annual Shareholders' Meeting, the Board of Directors submits the audited annual financial statements and the reports of the Board of Directors and of the statutory auditor with respect thereto to the Shareholders.

The Shareholders' Meeting then decides on the approval of the statutory annual financial statements, the proposed allocation of the Company's profit or loss, the release from liability of the directors and the statutory auditor, the approval of the remuneration report included in the annual report of the Board of Directors and, when applicable, the (re-)appointment or dismissal of the statutory auditor and/or of all or certain directors.

# > Special and extraordinary Shareholders' Meetings

The Board of Directors or the statutory auditor (or the liquidators, if appropriate) may, whenever the interest of the Company so requires, convene a special or extraordinary Shareholders' Meeting. Such Shareholders' Meeting must also be convened every time one or more Shareholders holding, alone or together, at least 20% of the Company's share capital so request. Shareholders that do not hold at least 20% of the Company's share capital do not have the right to have the Shareholders' Meeting convened.

# Right to put items on the agenda of the Shareholders' Meeting and to table draft resolutions

Shareholders who hold alone or together with other Shareholders at least 3% of the Company's share capital have the right to put additional items on the agenda of a Shareholders' Meeting that has been convened and



to table draft resolutions in relation to items that have been or are to be included in the agenda. This right does not apply to Shareholders' Meetings that are being convened on the grounds that the quorum was not met at the first duly convened meeting. Shareholders wishing to exercise this right must prove on the date of their request that they own at least 3% of the outstanding share capital. The ownership must be based, for dematerialised shares, on a certificate issued by the applicable settlement institution for the shares concerned, or by a certified account holder, confirming the number of Shares that have been registered in the name of the relevant Shareholders and, for registered Shares, on a certificate of registration of the relevant Shares in the share register book of the Company. In addition, the Shareholder concerned must register for the meeting concerned with at least 3% of the outstanding share capital. A request to put additional items on the agenda and/or to table draft resolutions must be submitted in writing, and must contain, in the event of an additional agenda item, the text of the agenda item concerned and, in the event of a new draft resolution, the text of the draft resolution. The request must reach the Company at the latest on the twenty second day preceding the date of the Shareholders' Meeting concerned. If the Company receives a request, it will have to publish at the latest on the fifteenth day preceding the Shareholders' Meeting an update of the agenda of the meeting with the additional agenda items and draft resolutions.

# Notices convening the Shareholders' Meeting

The notice convening the Shareholders' Meeting must state the place, date and hour of the meeting and must include an agenda indicating the items to be discussed. The notice needs to contain a description of the formalities that Shareholders must fulfil in order to be admitted to the Shareholders' Meeting and exercise their voting right, information on the manner in which Shareholders can put additional items on the agenda and table draft resolutions, information on the manner in which Shareholders can ask questions during the Shareholders' Meeting, information on the procedure to participate to the Shareholders' Meeting by means of a proxy or to vote by means of a remote vote, and, as applicable, the registration date for the Shareholders' Meeting. The notice must also mention where Shareholders can obtain a copy of the documentation that will be submitted to the Shareholders' Meeting, the agenda with the proposed resolutions or, if no resolutions are proposed, a commentary by the Board of Directors, updates of the agenda if Shareholders have put additional items or draft resolutions on the agenda, the forms to vote by proxy or by means of a remote vote, and the address of the webpage on which the documentation and information relating to the Shareholders' Meeting will be made available. This documentation and information, together with the notice and the total number of outstanding voting rights, must also be made available on the Company's website at the same time as the publication of the notice convening the meeting, for a period of five years after the relevant Shareholders' Meeting.

The notice convening the Shareholders' Meeting has to be published at least 30 days prior to the Shareholders' Meeting in the Belgian Official Gazette (*Moniteur Belge/Belgisch Staatsblad*) and in a newspaper that is published nation-wide in Belgium and in media that can be reasonably relied upon for the dissemination of information within the EEA in a manner ensuring fast access to such information on a non-discriminatory basis.

# Formalities to attend the Shareholders' Meeting

All holders of Shares, warrants, profit-sharing certificates, non-voting Shares, bonds, subscription rights or other securities issued by the Company, as the case may be, and all holders of certificates issued with the cooperation of the Company (if any) can attend the Shareholders' Meetings insofar as the law or the Articles of Association entitles them to do so and, as the case may be, gives them the right to participate in voting.

In order to be able to attend a Shareholders' Meeting, a holder of securities issued by the Company must satisfy two criteria: being registered as holder of securities on the registration date for the meeting, and notify the Company:



- Firstly, the right to attend Shareholders' Meetings applies only to persons who are registered as owning securities on the fourteenth day prior to the Shareholders' Meeting at midnight (Central European Time) via registration, in the applicable register book for the securities concerned (for registered securities) or in the accounts of a certified account holder or relevant settlement institution for the securities concerned (for dematerialised securities or securities in book-entry form).
- Secondly, in order to be admitted to the Shareholders' Meeting, securities holders must notify the Company at the latest on the sixth day prior to the Shareholders' Meeting whether they intend to attend the meeting and indicate the number of Shares in respect of which they intend to do so. For the holders of dematerialised securities or securities in book-entry form, the notice should include a certificate confirming the number of securities that have been registered in their name on the record date. The certificate can be obtained by the holder of the dematerialised securities or securities in book-entry form with the certified account holder or the applicable settlement institution for the securities concerned.

The formalities for the registration of securities holders, and the notification of the Company must be further described in the notice convening the Shareholders' Meeting.

# *▶* Voting by proxy or remote voting

Each Shareholder has, subject to compliance with the requirements set forth above under "—Formalities to attend the Shareholders' Meeting", the right to attend a Shareholders' Meeting and to vote at the Shareholders' Meeting in person or through a proxy holder, who does not need to be a Shareholder. A Shareholder may designate, for a given meeting, only one person as proxy holder, except in circumstances where Belgian law allows the designation of multiple proxy holders. The appointment of a proxy holder may take place in paper form or electronically (in which case the form shall be signed by means of an electronic signature in accordance with applicable Belgian law), through a form which shall be made available by the Company. The signed original paper or electronic form must be received by the Company at the latest on the sixth calendar day preceding the meeting. The appointment of a proxy holder must be made in accordance with the applicable rules of Belgian law, including in relation to conflicts of interest and the keeping of a register.

The notice convening the meeting may allow Shareholders to vote remotely in relation to the Shareholders' Meeting, by sending a paper form or, if specifically allowed in the notice convening the meeting, by sending a form electronically (in which case the form shall be signed by means of an electronic signature in accordance with applicable Belgian law). These forms shall be made available by the Company. The original signed paper form must be received by the Company at the latest on the sixth calendar day preceding the date of the meeting. Voting through the signed electronic form may occur until the last calendar day before the meeting.

The Company may also organise a remote vote in relation to the Shareholders' Meeting through other electronic communication methods, such as, among others, through one or several websites. The Company shall specify the practical terms of any such remote vote in the convening notice.

Holders of securities who wish to be represented by proxy or vote remotely must, in any case comply with the formalities to attend the meeting.

# Quorum and majorities

In general, there is no attendance quorum requirement for a Shareholders' Meeting and decisions are generally passed with a simple majority of the votes of the Shares present or represented. However, capital increases (other than those decided by the Board of Directors pursuant to the authorised capital), decisions with respect to the Company's dissolution, mergers, de-mergers and certain other reorganisations of the Company, amendments to the Articles of Association (other than an amendment of the corporate purpose), and certain other matters referred to in the BCC do not only require the presence or



representation of at least 50% of the share capital of the Company but also a majority of at least 75% of the votes cast. An amendment of the Company's corporate purpose requires the approval of at least 80% of the votes cast at a Shareholders' Meeting, which can only validly pass such resolution if at least 50% of the share capital of the Company and at least 50% of the profit certificates, if any, are present or represented. In the event where the required quorum is not present or represented at the first meeting, a second meeting needs to be convened through a new notice. The second Shareholders' Meeting may validly deliberate and decide regardless of the number of Shares present or represented. The special majority requirements, however, remain applicable.

# > Right to ask questions

Within the limits of article 540 of the BCC, Shareholders have a right to ask questions to the directors in connection with the report of the Board of Directors or the items on the agenda of such Shareholders' Meeting. Shareholders can also ask questions to the statutory auditor in connection with its report. Such questions can be submitted in writing prior to the meeting or can be asked at the meeting. Written questions must be received by the Company no later than the sixth day prior to the meeting. Written and oral questions will be answered during the meeting concerned in accordance with applicable law. In addition, in order for written questions to be considered, the Shareholders who submitted the written questions concerned must comply with the formalities to attend the meeting.

### 14.2.5. DIVIDEND RIGHTS

All Shares, including the Shares offered in the Offering, entitle the holder thereof to an equal right to participate in the Company's profits (if any). Pursuant to the BCC, the Shareholders can in principle decide on the distribution of profits with a simple majority vote at the occasion of the annual Shareholders' Meeting, based on the most recent statutory audited financial statements, prepared in accordance with the generally accepted accounting principles in Belgium and based on a (non-binding) proposal of the Company's Board of Directors. The Company's Articles of Association also authorise the Board of Directors to declare interim dividends without Shareholder approval subject to the terms and conditions of the BCC.

The Company's ability to distribute dividends is subject to availability of sufficient distributable profits as defined under Belgian law on the basis of the Company's statutory financial statements. In particular, dividends can only be distributed if following the declaration and issuance of the dividends the amount of the Company's net assets on the date of the closing of the last financial year as follows from the statutory financial statements (i.e., summarised, the amount of the assets as shown in the balance sheet, decreased with provisions and liabilities, all in accordance with Belgian accounting rules), decreased with the non-amortised costs of incorporation and extension and the non-amortised costs for research and development, does not fall below the amount of the paid-up capital (or, if higher, the issued capital), increased with the amount of non-distributable reserves. In addition, prior to distributing dividends, 5% of the net profits must be allotted to a legal reserve, until the legal reserve amounts to 10% of the Company's share capital.

### 14.3. NOTIFICATION OF SIGNIFICANT SHAREHOLDINGS

Pursuant to the Belgian Law of 2 May 2007 on the disclosure of significant shareholdings in issuers whose securities are admitted to trading on a regulated market and containing various provisions (*Loi relative à la publicité des participations importantes dans des émetteurs dont les actions sont admises à la négotiation sur un marché règlementé et portant dispositions diverses/*) (the *Transparency Law*), implementing in Belgian law Directive 2004/109/EC, a notification to the Company and to the FSMA is required by all natural and legal persons in the following instances:

• an acquisition or disposal of voting securities, voting rights or financial instruments that are treated as voting securities;



# 14 ARTICLES OF ASSOCIATION

- the holding of voting securities upon first admission of them to trading on a regulated market;
- the passive reaching of a threshold;
- the reaching of a threshold by persons acting in concert or a change in the nature of an agreement to act in concert;
- where a previous notification concerning the voting securities is updated;
- the acquisition or disposal of the control of an entity that holds the voting securities; and
- where the Company introduces additional notification thresholds in its Articles of Association, in each case where the percentage of voting rights attached to the securities held by such persons reaches, exceeds or falls below the legal threshold, set at 5% of the total voting rights, and 10%, 15%, 20% and so on at intervals of 5% or, as the case may be, the additional thresholds provided in the Articles of Association.

The notification must be made as soon as possible and at the latest within four trading days following the acquisition or disposal of the voting rights triggering the reaching of the threshold. Where the Company receives a notification of information regarding the reaching of a threshold, it has to publish such information within three trading days following receipt of the notification. No shareholder may cast a greater number of votes at a Shareholders' Meeting of the Company than those attached to the rights or securities it has notified in accordance with the Transparency Law at least 20 days before the date of the Shareholders' Meeting, subject to certain exceptions.

The form on which such notifications must be made, as well as further explanations, can be found on the website of the FSMA (www.fsma.be)





# **ASIT BIOTECH**

Société anonyme

Avenue Ariane 5

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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.

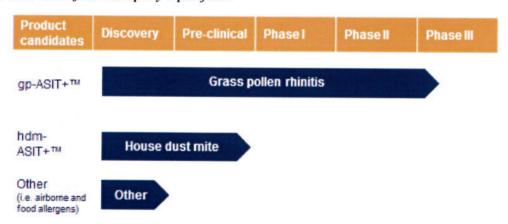
# 1.1. Portfolio

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.

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# 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 thou	sand 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;

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 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 <del></del>	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

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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 Francois Meurgey

(...) 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

 $(\ldots)$ 

"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

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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		120	18	÷	18
Costs of capital increase	15	-		(593)	(593)
As at 31 December 2015	11,625	840	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