

Allergy immunotherapy as simple ASIT can be...



## INTERIM FINANCIAL REPORT

AS OF 30 JUNE 2017

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***ASIT biotech SA***

*A limited liability company (société anonyme) incorporated under Belgian law,  
with its registered office at avenue Ariane 5, 1200 Brussels (enterprise number 460.798.795)*

# **INTERIM FINANCIAL REPORT AS OF 30 JUNE 2017**

This report is prepared in accordance with article 13 of the Royal Decree of 14 November 2007

ASIT biotech SA (hereinafter “**ASIT biotech**” or the “**Company**”) has prepared its interim financial report in French and in English. In case of discrepancies between both versions, the English version shall prevail

# I. INTERIM MANAGEMENT REPORT

# I. Interim management report

## 1. CORPORATE INFORMATION

ASIT biotech is a clinical stage biopharmaceutical company focused on the development and future commercialization of a range of breakthrough immunotherapy products for the treatment of allergies, based on its ASIT+™ technology platform.

The Company aims at becoming a key global player in allergy immunotherapy. Its product pipeline currently consists of 2 novel ASIT+™ product candidates at clinical stage targeting the respiratory allergies with the highest prevalence as well as 3 product candidates targeting food allergies in preclinical development.

ASIT biotech is a limited liability company with registered office located at 1200 Brussels, 5 avenue Ariane. The Company has an office in Liège that hosts the R&D team in charge of the product development, the preclinical development and the quality control.

ASIT biotech launched its initial public offering on Euronext Brussels and Euronext Paris on 11 May 2016.

## 2. IMPORTANT EVENTS THAT OCCURRED DURING THE FIRST 6 MONTHS OF THE FINANCIAL PERIOD

### a. R&D and Tax-Credit

Over the first six months of the year 2017 the Company has invested in R&D for an amount of 6,336 K€, entitling ASIT to a Tax-Credit of 290 K€. This amount has been accrued for in the interim statements as of 30 June 2017.

### b. Recoverable Cash Advances (RCA) from the Walloon Region

On 17 February 2017, the RCA agreement executed between the Company and the Walloon Region relating to the house-dust mite treatment – support of the Walloon Region of up to 1,254 K€ - has been amended. The research phase which initially covered a period from 1 January 2015 until 31 December 2016 has been extended until 31 May 2017.

In addition, on 12 January 2017 the Company was granted with a RCA of about 6,000 K€ from the Walloon Region to finance 55% of the food allergies drug development program. The conditions of this grant are in substance like the ones applicable to the house-dust mite program, except that the percentage of the royalties to be paid during the exploitation phase amounts to 0,11% of the future sales of the Company. The total amount repayable to the Walloon Region is capped to twice the initial refundable advance amount. Under this agreement, if the Company decides to exploit the result of its research after 2019, the minimum amount of 30% refund will be triggered and payable during the next 10 years. Royalty payments will only occur if the Company is able to sell successfully the designed product. Since the discovery phase only began in early 2017, the Company has no view yet on whether or not the outcome of the research will be fruitful and whether it will decide to continue the exploitation of its findings after 2019, or if sales will be generated.

### c. Share Capital decrease

On 8 June 2017, the amount of the share capital of the Company was decreased by 7,517K € through the incorporation of losses carried forward to bring it from K€17,506 to K€ 9,989.

### d. Patent Situation

Since the IPO:

- the patent “Allergen Purification” (BTT04) has been granted in Japan, India and accepted for grant in Europe. Procedure is ongoing in USA, Brazil, China for the divisional application.
- the patent “Production of Hydrolyzed Allergen” (BTT07) has been granted in Australia and accepted for grant in Europe. Procedure is ongoing in USA, Japan, China, Brazil, India and Canada.

**e. ASIT+™ lead product: gp-ASIT+™ for grass pollen rhinitis**

### Registration and Clinical development in Europe

After examination of the first Phase III study (BTT009), the Paul-Ehrlich-Institut (PEI) acknowledged that the results of the primary endpoint reached statistical significance ( $p < 0.05$ ). However, these results cannot be regarded as a confirmatory (pivotal) study because they missed the predefined 20% difference of CSMS between placebo and treated group (i.e. an absolute score difference versus placebo of -0.31) for a registration based on one compelling Phase III study.

All the data (primary, secondary endpoints and post-hoc analyses) point to symptom improvement in patients after a 3-week treatment with gp-ASIT+™. Furthermore, the immunological study results showed a clear effect of gp-ASIT+™ on the immune system which supports the clinical efficacy.

PEI considered BTT009 study as supportive and stated that an additional compelling pivotal study is needed before considering a Marketing Authorization Application (MAA) submission for Germany, and for a future expansion of this MAA to other European countries based on international guidelines.

### Phase III Study - BTT-009

This study was a randomised, double-blind, placebo-controlled, international and multicentric confirmatory phase III study in patients with grass pollen allergic rhinoconjunctivitis. The study was conducted in 6 countries in Europe (Belgium, Czech Republic, Germany, France, Italy and Spain) in 57 centers. The primary objective of this study was to demonstrate the clinical efficacy of a cumulative dose of 170 µg gp-ASIT+™ over the peak pollen season, using a combined CSMS. Secondary efficacy objectives included the evaluation of individual symptom and medication scores over the peak and entire pollen season, change in CPT score, and assessment of Quality of Life using standardized questionnaires. Safety and local tolerability were assessed in all patients and the immunogenicity of gp-ASIT+™ and its mechanism of action was investigated in the subgroup of patients recruited at one site in Belgium.

#### *Demography*

Overall, 889 patients were screened over a period of 3.5 months. From these, 554 (62.32%) were randomized: 182 patients were allocated to the placebo group and 372 to the gp-ASIT+™ group. 178 (97.80%) patients of the placebo group and 367 (98.65%) patients of the gp-ASIT+™ group were included in the population used for safety assessment. The targeted number of randomized patients was not reached, due to a higher than expected screening failure rate induced by stringent inclusion criteria. Unfortunately, it was not possible to extend the screening period as the treatment phase had to be performed before the beginning of the grass pollen season. The two groups were well balanced with respect to demographics.

#### *Clinical efficacy*

The objective of this first phase III clinical study was to demonstrate the clinical efficacy of gp-ASIT+™ during one grass pollen season when administered subcutaneously prior to the season to patients suffering from hay fever. The primary endpoint was the reduction (in the treated group compared with the placebo

group) of the Combined Symptom and Medication Score (CSMS) which is the sum of the daily Rhinoconjunctivitis Total Symptom Score (RTSS) and the daily Rescue Medication Score (RMS) over the peak of the grass pollen season subsequent to treatment.

More precisely, clinical efficacy was analyzed over the peak period (period of 2 consecutive weeks with the highest pollen count in the air) and over the entire pollen season, in the intention-to-treat population (ITT) and in the per protocol (PP) population.

Due to the limited number of patients with a complete set of daily symptom scores and drug consumption in their diaries, an imputation rule was defined before the unblinding of the database. For the patients with a limited number of missing data, no data for oral corticosteroid intake were replaced by no oral corticosteroid intake, 50% or less missing data for daily symptoms score were replaced by the mean of the available daily symptom scores on the concerned period. There were 310 observed cases for the peak and 159 observed cases for the entire pollen season while with imputation, the number of patients increased to 400 patients for the peak and 296 for the entire season. The acceptability of the imputation rule was confirmed after unblinding and statistical analysis as it does not significantly impact the magnitude of the primary and secondary outcomes but improve their statistical significance.

Before the unblinding of the database, it was observed that the distribution of the CSMS data was non-Gaussian. Therefore, a non-parametric statistical analysis model was also used to analyze the data. Complementary to this analysis, a parametric analysis (ANOVA) was also applied on the data. Overall, whatever the statistical method used, gp-ASIT+™ induced a significant decrease (non-parametric tests) or a trend (ANOVA) toward superiority suggesting an improvement in CSMS score both during the peak pollen period and the entire pollen season.

Following implementation of the imputation rule defined above, the mean CSMS during the pollen peak was 1.475 (SD = 1.049) in the placebo group and 1.247 (SD = 0.972) in the gp-ASIT+™ group. This represents a CSMS reduction of 15.5% reduction for patients treated with gp-ASIT+™ compared to placebo ( $p=0.041$ , non-parametric testing). The reduction of CSMS during the entire pollen season was in line with the primary endpoint (17.9%,  $p=0.03$ ).

The effect of gp-ASIT+™ was found to be associated with a reduction in values of all clinical secondary endpoints, i.e. RTSS, RMS, ESS, and NSS (observed cases). Symptom scores were systematically reduced in the gp-ASIT+™ group when compared to placebo, supportive of a clinical benefit of gp-ASIT+™ treatment in terms of rhinoconjunctivitis symptoms and rescue medication intake. The relative difference was -18.5% in both RTSS and NSS, -20.3% in ESS and -14.9% in RMS. The non-parametric statistical analysis led to a statistically significant treatment effect for all scores but RMS over the peak pollen period ( $p < 0.05$ ) but not over the entire pollen period. In parallel an increase in the number of well-days was observed, also attaining significance over the peak pollen period ( $p < 0.05$ ).

Conjunctival provocation testing (CPT) is widely considered by the medical community as an appropriate surrogate endpoint for clinical benefit during the pollen season. All enrolled patients showed reactivity to CPT at screening, in accordance with the eligibility criteria. A responder was defined as a patient for whom the reactivity to CPT decreased by at least 1 point (corresponding to 1 log concentration in test solution) after treatment compared to screening. Accordingly, in the placebo and gp-ASIT+™ groups respectively 56 (37.58%) and 177 (60.00%) patients responded to the treatment in terms of CPT reactivity. The difference between the 2 groups is highly significant ( $p < 0.0001$ ). The observed responses to CPT thus further support the clinical efficacy findings. Moreover, in the subgroup of the most allergic patients characterized by the highest CPT reactivity at baseline (CPT reactivity score 3 and 4), representing more than half of all the Phase III patients, the symptom improvement compared to placebo reached 20% during the peak pollen period ( $p=0.05$ ) and 24% over the entire season ( $p=0.05$ ).



The clinical benefit experienced by patients in BTT009 is also reflected by the increased percentage of well-days (23% during the peak pollen season) and the improvement of quality of life scores. Quality of life was assessed by RQLQ, measuring rhinoconjunctivitis related quality of life, and NRQLQ, measuring nighttime impact of these symptoms, before the pollen season but after treatment (V6), during the pollen season (V7) and after the pollen season (V8). Scores were significantly lower in the gp-ASIT+™ group compared to placebo for both RQLQ and NRQLQ during the pollen season, which is further supportive of a clinical benefit for grass-pollen allergic patients treated with gp-ASIT+™.

Overall, even though the 20% CSMS reduction threshold objective that was mentioned in the Offering prospectus was not reached, this phase III study is positive considering the statistically significant CSMS reduction, the very good consistency between the different symptoms score, the immunogenicity results and an atypical pollen season (only one – usually very short - peak early in the season, large discrepancy in pollen counts between centers).

Finally, the clinical efficacy results of gp-ASIT+™ are in the range of the results obtained with the sublingual tablets Grazax and Oralair (Stallergènes) which require at least six months of daily drug intake for 3 years. The 18.5% RTSS reduction over the pollen peak after gp-ASIT+™ treatment is close to the 20% weighted mean RTSS reduction reported for Grazax (calculated on the results of the clinical studies supporting FDA registration). Similarly, the 15.6% RTSS reduction over the entire pollen season after gp-ASIT+™ treatment is in the range of the 6.1% to 31% RTSS reduction reported for Grazax and the 11% to 38% reduction reported for Oralair in the clinical studies supporting FDA registrations of these two products.

#### *Immunological outcomes*

Furthermore, the immunological study results showed a clear effect of gp-ASIT+™ on the immune system which supports CSMS improvement. As planned prior to the start of the Phase III study, all the patients enrolled at the University Hospital in Ghent (n=21 gp-ASIT+™; n=11 placebo) provided blood samples to allow the study of the mechanism of action of gp-ASIT+™ by Dr. Mohamed Shamji, Scientific Advisor of ASIT Biotech and Associate Professor at Imperial College London.

Short-course treatment with gp-ASIT+™ was found to inhibit significantly 2 mechanisms leading to allergic reactions: (1) the increase of grass pollen specific IgE antibodies, and (2) grass pollen-induced basophil activation. Additionally, a short-course treatment with gp-ASIT+™ induced protective allergen blocking antibodies produced by regulatory B cells which were associated with an impressive clinical effect during the pollen season.

The relevance of these immunological results is supported by the clinical results in this subgroup of patients in which a substantial reduction was observed in both the CSMS (-35.1% during the peak period and -53.7% during the entire pollen season) and the RTSS (-27.4% during the peak period and -56.9% during the entire pollen season) during a high pollen count season in Belgium.

The discovery of the mechanism of action of gp-ASIT+™ is a major milestone for the company that strongly confirms - for the first time ever - the biological relevance of allergen peptide immunotherapy. The knowledge of this mechanism of action constitutes the basis for rational drug design of future ASIT+™ products. It reduces the risk of further developments of gp-ASIT+™ as well as the rest of our product portfolio with a strong emphasis on our food allergy program.

#### *Safety*

Overall, the safety profile of gpASIT+™ in this pivotal phase III trial is satisfactory, confirms previous observations made during Phase I and II clinical trials and is in-line with commercially available AIT products.



Given the nature of the product, local reaction at the injection site, as well as to systemic allergic reactions were followed-up. As expected, many patients experienced wheal and/or redness at the injection site, but most of local reactions were mild in intensity and resolved within a few days. Systemic allergic reactions, recorded as per WAO classification, were experienced by approximately one patient in five, most of them being of WAO Grade 1 and of mild to moderate intensity. Of note, in 5% of placebo recipients a systemic reaction was reported as well.

Out of the 367 subjects treated with gp-ASIT+™, only a limited number of systemic allergic reactions required medical follow-up, and all were resolved with adequate medical care, as recommended with the use of these class of products. Incidences of such reactions did not exceed what is reported for other investigational and marketed immunotherapy products administered by injection (Calderon et al., 2007).

### *Conclusion*

In summary, gp-ASIT+™ has shown the ability to confer significant clinical benefit over the pollen season when considering the observed improvement in a range of typical allergy clinical symptoms, impacting the patient quality of life. Also, the 3-week administration schedule followed may encourage patients' acceptance and compliance, and hence their relief from a condition which, while not life-threatening, is however of public health concern. gp-ASIT+™ yielded an overall positive benefit/risk balance. In terms of safety and tolerance, the prevention and/or occurrence of systemic allergic reactions is manageable given that gp-ASIT+™ is intended for prescription by allergists, who are well trained for the management of such reactions.

### *PEI feedback on BTT009*

The PEI granted a scientific advice session to ASIT biotech to review the results of BTT009 and agreed on further clinical and regulatory developments. At that session, the PEI acknowledged that the results of the primary endpoint analyzed in the patient group reached statistical significance ( $p < 0.05$ ). However, these results cannot be regarded as a confirmatory (pivotal) study due to the fact that they missed the predefined 20% difference of CSMS between placebo and treated group (i.e. an absolute score difference versus placebo of -0.31) for a registration based on one compelling Phase III study.

The PEI acknowledged that all the data (primary, secondary endpoints and post-hoc analyses) point to symptom improvement in patients after a short course treatment with gp-ASIT+™.

In conclusion, the PEI considers BTT009 study as supportive and states that an additional, compelling pivotal study is needed before considering a Marketing Authorization Application (MAA) submission for Germany, and for a future expansion of this MA to other European countries based on international guidelines.

### **Phase III Study - ABT-011**

Out of the feasibility study performed to date, the next Phase III with gpASIT+™ (ABT011) should be a randomised, double-blind, placebo-controlled, international multi-centric confirmatory phase III study aiming to randomize about 600 patients with grass pollen-related allergic rhinoconjunctivitis. Eligible patients should be randomised according to a 1:1 ratio to placebo or gpASIT+™ treatment. Study treatment should be administered before the beginning of the pollen season from January to mid-March. The treatment schedule should be administered during 4 visits over 3 consecutive weeks. After the treatment period ending mid-April, 3 follow-up visits should be planned before during and after the pollen season.

As mentioned hereabove, the following improvements compared to study BTT009 needs to be implemented to ensure optimal outcomes and significantly reduce the risk of the next Phase III study with gpASIT+™:

- One sole CRO vendor responsible for ABT011: the entire study will be organized and coordinated by SyntheractHCR, a CRO (Contract Research Organization) acknowledged for its expertise in running clinical trials in the field of respiratory disorders. SyntheractHCR and ASIT biotech have

reached an agreement that foresees the preparation and execution of the next clinical trials, from the choice and auditing of sites to the analysis of clinical data. ASIT biotech is therefore ready to initiate the next clinical trials in Europe and in the United States.

- Higher number of clinical centers: compared to BTT009 that was conducted in 57 centers spread over 6 countries in Europe (Belgium, Czech Republic, Germany, France, Italy and Spain), ABT011 should be conducted in about 100 centers spread over 7 countries (Belgium, Czech Republic, Germany, Hungary, Poland, Austria and Spain). This high number of sites is meant to ensure the planned number of patients are included and treated in relatively short period of time prior to the grass pollen season. About 130 centers have already been screened to participate in ABT011, about 90 centers have already been selected at the end of the feasibility study. An additional factor should be that each center will be limited to a maximum number of patients, to ensure that the overall study is not unduly dependent of the local pollen concentration affecting a small number of over-recruiting centers. This is also a major factor reducing the risk.

Inclusion criteria to randomize the most allergic patients: in order to randomize the most allergic patients, the following inclusion criteria should be based on the historical medical dossier of the patients. Moreover, the feasibility of the use of alternative inclusion criteria based on the CPT reactivity score is still ongoing for CMC, regulatory and marketing aspects.

- Use of electronic diary: patients will be provided with an electronic diary (eDiary) during the treatment phase and grass pollen season; during the treatment phase, the eDiary will be used to capture rescue medication use and injection site reactions; during the pollen season, the eDiary will be used to capture daily rescue medication use and symptoms; the use of eDiary should limit the number of missing data.

To reduce the operational risks of the next Phase III clinical trial with gp-ASIT+™ and to maximize the chances of success, the screening period of the next Phase III clinical trial would start by Q4 2018 in order to treat the patients prior the 2019 grass pollen season. Moreover, starting this Phase III in Q4 2018 should also allow finetuning of the gpASIT+™ clinical development in accordance to the feedback of the FDA which is expected Q4 2017.

### **Registration and Clinical development in the United States**

In order to address the specificities of North American clinical developments, ASIT biotech has set up a Committee of experts notably including Dr. Linda Cox, Past President of the American Academy of Allergy, Asthma & Immunology (AAAAI) and of the immunotherapy and allergy diagnostics committees of both the AAAAI and the ACAAI (American College of Allergy, Asthma & Immunology), and Dr. Peter Creticos, former Director of the Division of Allergy and Clinical Immunology of the Johns Hopkins University School of Medicine, and now clinical Director of research for his own entity and who has worked with governmental agencies and industry to design, develop, and conduct clinical research on the therapeutic efficacy of new drugs or underlying mechanisms of allergen immunotherapy. These recognized leaders in the field of allergy and immunology will contribute their extensive expertise to the preparation and monitoring of the clinical trials undertaken by ASIT biotech in the United States.

ASIT biotech has received in November 2016 the FDA's initial comments regarding the gp-ASIT+™ Master File including very useful recommendations regarding the product's quality and the launch of a first clinical trial in the United States. ASIT biotech has filed in July 2017 answers to the FDA's initial comments as well as a Master file updated with the results of the Phase III. FDA feedback is expected Q4 2017. Depending on the FDA feedback, a pre-IND meeting will be requested to discuss remaining clinical issues to be solved before the possible launch of a first clinical trial in the US. Depending on the outcomes of the pre-IND meeting, the Company would submit an approval application for a first clinical trial whose phase will depend on the conclusion of the Company's interaction with the FDA.

## Conclusion

The clinical efficacy of gp-ASIT+™ has been demonstrated in the framework of BTT009 Phase III study. This demonstration validates the relevance of the ASIT+™ technology platform. Moreover, the discovery of mechanism of action paves the route of the development of other ASIT+™ products candidates for house dust mite and food allergies. The knowledge of this mechanism has already been translated in collaboration with Imperial College of London and King's College Hospital in a rational drug design programme for the screening of the other ASIT+™ products. This programme should reduce the risk and increase the speed of further developments of all the ASIT+™ products.

### f. HDM ASIT+™ product candidates for house dust mite allergies

The second product candidate for respiratory allergy is hdm-ASIT+™ for the treatment of house dust mite allergy which consists in a mixture of natural allergen fragments obtained from a purified specific proteinic extract from house dust mite (*dermatophagoides pteronyssinus*). In contrast to synthetic peptides, natural peptides (70% of the fragments ranging from 1,000<MW<10,000) include a wide range of epitopes that stimulate the immune system with optimal complexity.

hdm-ASIT+™ has already reached the stage of clinical development. The first in man Phase I/IIa double-blind placebo-controlled clinical trial in house dust mite rhinitis<sup>1</sup> was completed in Q1 2017. It was carried out at the Carl Gustav Carus University Hospital in Dresden, Germany. Of the 36 randomized patients, 27 were treated with hdm-ASIT+™ whilst the other 9 received the placebo.

The trial's primary endpoint was achieved, insofar as hdm-ASIT+™ showed, at this stage, a good safety and tolerability profile for the product candidate. No serious or unexpected adverse treatment-related event was observed during the trial, even at the highest allergen dose of 200 µg, which was 200 times greater than the first dose administered. The two groups were comparable at baseline for all the tested parameters, except house dust mite allergen-specific IgE antibodies, which were substantially lower in the treated group than the placebo group.

Assessing hdm-ASIT+™'s impact on the immune system and on the reduction in reactivity to a conjunctival provocation test (CPT)<sup>2</sup> were amongst the secondary objectives. An effect was observed on the immune system in a limited number of patients. However, there was no difference overall between the treated group and the placebo group regarding immunogenicity parameters. Lastly, the trial showed a somewhat stronger reduction in CPT reactivity between baseline and post-treatment visits in the treated group compared to the placebo group. In any case, the study was not powered to show statistical significance for these two outcomes. In any way, the absence of a larger reduction can be explained by a substantial response to placebo (55%), the limited number of patients, the short observation period in this perennial disease and/or the nature of the product.

The Company is following a two-pronged strategy for further development of hdm-ASIT+™. The first strategy is to perform a follow-up study to assess the impact of a prolonged (six months) natural exposure to the house dust mite on the immunogenicity parameters and the reactivity to the conjunctival provocation test. Indeed, hdm-ASIT+™ could adequately prime the immune system but may require a prolonged exposure to the house dust mite allergen to uniformly induce allergen specific antibodies among the treated patients and positively impact the reactivity the conjunctival provocation test. Such a need for a prolonged exposure to the house dust mite allergen was observed in animal models.

<sup>1</sup> This research program is partly funded by the Walloon region in the form of recoverable advances, in accordance with the agreement signed at the beginning of 2016.

<sup>2</sup> A test enabling both the diagnosis of a patient's allergy and the determination of their level of hypersensitivity at various times during the desensitization process.

The Company has received the approval of the regulatory authorities and ethical committee to start a short follow-up study with the patients treated during the Phase IIa clinical trial with its hdm-ASIT+™ product candidate for house dust mite rhinitis.

This follow-up study is carried out at the Carl Gustav Carus University Hospital in Dresden, Germany. A subset of the 36 initially randomized patients (27 treated with hdm-ASIT+™ - 9 placebo) will undergo complementary medical visits to assess their reactivity score to a conjunctival provocation test and their titers of house dust mite allergen specific antibodies (IgG, IgG4, IgE and blocking antibodies). The results of this follow-up should be available by the end of 2017.

The second strategy is to design and to test a set of hdm-ASIT+™ products prototypes *ex vivo* on the blood cells of allergic patients in the framework of a rational drug design program run in close collaboration with Dr M. Shamji from the Imperial College of London. Complementary *in vivo* preclinical development will also be performed to fine tune immunogenicity of the product. A improved hdm-ASIT+™ product candidate with an optimal immunological profile should be available. in Q1 2018.

#### **g. RAG ASIT+™ product candidates for ragweed allergies**

The third product candidate for respiratory allergy is rag-ASIT+™ for the treatment of ragweed rhinitis which consists in a mixture of natural allergen fragments obtained from a purified specific proteinic extract from ragweed (ambrosia). In contrast to synthetic peptides, natural peptides (70% of the fragments ranging from 1,000<MW<10,000) include a wide range of epitopes that stimulate the immune system with optimal complexity.

The characterisation and quality control tests of the manufacturing process have been developed and were qualified by the CMO by the end of Q3 2016 at an industrial scale. The manufacturing process was transferred to the CMO, which has released a GMP clinical batch during Q4 2016. No further scaling-up is anticipated at this stage of development.

Preclinical studies include assessment of the immunogenicity and toxicity of the investigational product manufactured under the same procedures and meeting the same specifications as products intended for use in human studies (*ex vivo* study and planned clinical trial). The first phase of preclinical development of rag-ASIT+™ was completed by the end of 2016.

However, starting clinical development with rag-ASIT+™ is postponed.

#### **h. ASIT+™ product candidates for FOOD allergies**

The product candidates for food allergies consists in mixtures of natural allergen fragments obtained from a purified specific proteinic extract from peanut, cow's milk and egg white. In contrast to synthetic peptides, natural peptides (70% of the fragments ranging from 1,000<MW<10,000) include a wide range of epitopes that stimulate the immune system with optimal complexity.

Food allergies are among the most dangerous allergies causing life-threatening systemic reactions such as anaphylaxis, which can potentially be fatal. The prevalence of food allergies is 1-2% of the total population in Western countries and is increasing worldwide together with the number of hospitalisations for anaphylaxis. Among food allergens, peanut, cow's milk and egg white are the three most frequent. There is currently no treatment recommended for routine clinical use. The standard management of food allergic patients is strict avoidance of the culprit allergen and use of rescue medication such as antihistamines or epinephrine auto-injector in case of accidental exposure. Considering the high burden and anxiety generated by a constant food surveillance and the challenge of strict avoidance, a treatment inducing tolerance in case of a contact with the allergen is of great interest.

Previous clinical trials of immunotherapy for food allergens showed a high risk of systemic reactions potentially leading to anaphylactic life-threatening reactions. Therefore, new developments are based on long administration schedules with a slow increase over time of the allergen. These treatments rely on full-size allergens administered via different routes. Clinical research in specialised hospitals in collaboration with universities and public health administrations generally favour the oral route (oral immunotherapy – OIT). Pharmaceutical companies have also considered other modes of administration such as the subcutaneous and the epicutaneous routes.

To minimize allergenicity and systemic reactions while maximizing antigenic properties of the active ingredients, the Company is, to our knowledge, the only one to develop natural allergen-fragment based products. These products should be used in shorter periods of treatment compared to other active ingredients currently in development.

Another important factor for the development of immunotherapy for food allergens is the transient protective effect of current in-development treatments. Several studies have shown that constant OIT does not generate a long-lasting tolerance for peanut allergy. Patients treated for 2 to 5 years by OIT and who stopped their treatment were no longer able to demonstrate a sustained unresponsiveness to the allergen within 1 to 3 months. These observations suggest that sustained responsiveness to peanut exposure following peanut OIT is likely to be dose-dependent and duration-dependent. As a consequence, the company intends to perform a close follow-up of treated patients and investigate the use of a periodic boost in order to prevent a potential relapse.

### **Product description**

The product candidate consists of a mixture of natural peptides (ranging from 1,000 to 10,000 kDa) obtained from the purified specific allergen extracted from:

- peanut
- cow's milk
- egg white.

### **Competitor products in food immunotherapy**

The two main competitors in the development of food immunotherapy products are Aimmune Therapeutics and DBV technologies. Both companies are still at the development stage with no product on the market yet. The most advanced product of DBV technology is Viaskin Peanut® (ongoing phase III) for peanut allergy which relies on the administration of whole peanut allergens through the skin via an epithelial device. Aimmune Therapeutics product relies on the OIT route for its food allergy program. The most advanced product is AR101 for the treatment of peanut allergy with an ongoing phase III.

### **Target product profile**

Based on the similarities with the gp-ASIT<sup>TM</sup> product issued from the same ASIT<sup>TM</sup> platform, the target product profile of food-ASIT<sup>TM</sup> product should consist of:

- a ready-to-use natural allergen-fragment based product;
- an adjuvant-free product;
- a good safety profile;
- a short treatment regimen completed by boosts at regular intervals of time;
- a rapid onset of action, both on symptomatic and immunological parameters.



All these characteristics need to be confirmed during the preclinical and clinical development of the three product candidates.

### Development program

The Company has recently launched in close collaboration with Dr M. Shamji (Senior Lecturer in Immunology and Allergy at Imperial College of London) and Dr S. Thill consultant Allergist at Guy's & St Thomas' Hospitals and Reader at King's College London. He is one of the few specialist doctors accredited in Adult Allergy by the General Medical Council a rational drug design program to develop new ASIT+™ drugs for the main food allergies (peanut, cow's milk and egg white). This program includes *ex vivo* studies on allergic patient blood cells up to the end of the first in man clinical study. For this project, the Company has received a recoverable cash advance of about EUR 6 million from the Walloon Region to co-finance on a 55% basis the food allergy drug development program.

Considering the higher risk of systemic reaction during immunotherapy with food allergens, special attention will be paid to the safety and immunogenicity profile of food-ASIT+™ product candidates. The objective of this collaboration is to test the allergenicity and immunogenicity of food-ASIT+™ product candidates on human *ex vivo* food allergy models and optimize the safety/efficacy ratio of its new product candidates. The *ex vivo* tests would be performed in Q4 2017 and Q2 2018 on blood cells from patients suffering from food allergy.

The peanut-ASIT+™ product candidate with best safety/efficacy ratio will be selected to test its immunogenicity and toxicity in animal models as required by regulatory authorities prior to start in man clinical study. In parallel to the preclinical development, the production process and quality control procedure will be transferred to an appropriate CMO to produce GMP clinical batches of drug substance and drug product. These activities will take place in 2018.

Afterwards, upon approval by regulatory authorities, one selected product candidate for peanut allergy will be tested in a first in man clinical trial that will be performed in the framework of the collaboration with Dr Stephen Till. The objective of this collaboration is to assess the safety and clinical impact of the product candidates on a food allergen provocation test. This first in man clinical trial with peanut ASIT+™ is expected to be conducted during the second half of 2018 and until the end of 2019.

### 3. FINANCIAL HIGHLIGHTS

#### Interim condensed Statement of Comprehensive Income (in EUR' 000')

	30/06/2017	30/06/2016
Revenue .....	-	-
Other operating income / (expense) .....	300	298
Cost of goods sold.....	-	-
Research and development expenses .....	(6,337)	(6,757)
General and administrative expenses .....	(785)	(937)
<b>Operating loss for the period</b>	<b>(6,816)</b>	<b>(7,396)</b>

As the Company is mostly engaged in R&D activities, over 93 % of the IFRS operating loss for the period is related to R&D costs of 6,337 K€, the remainder relating to General and administrative expenses.

The R&D costs are mainly outsourced and therefore easy to control. As a policy, the Company only firmly commits to new contracts in R&D if it has the capability to fund them. Therefore, the execution of the business plan and clinical development plan described in the preceding pages, in size as well as in timing, will be subject to Company's further ability to raise funds.

At the date of this report, the Company has no investment commitments outstanding or other firm contractual obligations that could not be covered by the cash available.

As of 30 June 2017, the Company's cash amounted to 8,266 K€ (13,387 K€ as of December 2016).

#### **4. PRINCIPAL RISKS AND UNCERTAINTIES**

The Board of Directors considers that the key risk factors summarized in section 2 of the prospectus relating to the Offering, as well as in section 1 of the 2016 annual report remain relevant and up to date, which is deemed to be reproduced here. The prospectus of the Offering as well as the annual report are available on the website of the Company on [www.asitbiotech.com](http://www.asitbiotech.com).

#### **5. RELATED PARTY TRANSACTIONS**

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

By decision of the Board of Directors dated 22 June 2017, the fixed amount of the remuneration of the CEO, M. Thierry Legon, was increased up to EUR 245,000 per year, coming into effect on 1<sup>st</sup> July 2017.

Other than the transaction listed in this section of the interim report, 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.



## **II. INTERIM CONDENSED FINANCIAL STATEMENTS FOR THE PERIOD ENDED 30 JUNE 2017**

## II. Interim condensed IFRS financial statements for the period ended 30 June 2017

### 1. MAIN FIGURES

#### Interim Condensed Statement of financial position for the period ending on June 30, 2017

EUR '000'

	<u>30/06/2017</u>	<u>31/12/2016</u>
<b>ASSETS</b>		
<b>Non-current assets</b>		
Intangible assets .....	-	-
Property, plant and equipment .....	734	736
Other long term receivables .....	1,340	1,034
	<u>2,074</u>	<u>1,770</u>
<b>Current assets</b>		
Trade receivables .....	-	3
Other receivables .....	103	323
Other current assets.....	49	72
Cash and cash equivalents.....	8,266	13,387
	<u>8,418</u>	<u>13,785</u>
<b>Total assets</b>	<u>10,492</u>	<u>15,555</u>

	<u>30/06/2017</u>	<u>31/12/2016</u>
<b>EQUITY AND LIABILITIES</b>		
<b>Capital and reserves</b>		
Capital.....	9,989	17,506
Share premium.....	21,957	21,957
Cost of capital increase.....	(2,102)	(2,102)
Share based payment reserve.....	221	216
Accumulated deficit.....	<u>(23,751)</u>	<u>(24,445)</u>
<b>Total equity attributable to shareholders</b>	<b><u>6,314</u></b>	<b><u>13,132</u></b>
<b>LIABILITIES</b>		
<b>Non-current liabilities</b>		
Financial debt.....	437	419
	<b><u>437</u></b>	<b><u>419</u></b>
<b>Current liabilities</b>		
Financial debt	12	12
Trade payables.....	2,056	1,707
Other payables.....	1,674	285
	<b><u>3,742</u></b>	<b><u>2,004</u></b>
<b>Total liabilities</b>	<b><u>4,178</u></b>	<b><u>2,423</u></b>
<b>Total equity and liabilities</b>	<b><u>10,492</u></b>	<b><u>15,555</u></b>

**Interim condensed Statement of Comprehensive Income for the six-month period ending on June 30**

EUR '000'

	<b>30/06/2017</b>	<b>30/06/2016</b>
Revenue .....	-	-
Other operating income / (expense).....	300	298
Cost of goods sold.....	-	-
Research and development expenses.....	(6,337)	(6,757)
General and administrative expenses.....	(785)	(937)
<b>Operating loss for the period</b>	<b>(6,816)</b>	<b>(7,396)</b>
Financial income .....	17	13
Financial expense.....	(23)	(98)
<b>Loss for the period before taxes</b>	<b>(6,821)</b>	<b>(7,481)</b>
Taxes.....	(1)	
<b>Loss for the period</b>	<b>(6,822)</b>	<b>(7,481)</b>
Other comprehensive income.....		
<b>Comprehensive loss for the period</b>	<b>(6,822)</b>	<b>(7,481)</b>
<b>Loss for the year</b>		
Attributable to shareholders .....	(6,822)	(7,481)
<b>Earnings per share</b>		
(in EUR per share)		
- basic and diluted .....	(0,53)	(0,77)

**Interim Condensed Statement of changes in equity as at June 30, 2017**

EUR '000'

	<u>Capital</u>	<u>Share premium</u>	<u>Share-based Payment reserve</u>	<u>Cost of capital increase</u>	<u>Accumulated deficit</u>	<u>Total equity attributable to the owners of the Company</u>
<b>As at 1<sup>st</sup> January 2016</b> .....	<b>11,625</b>	-	<b>591</b>	<b>(593)</b>	<b>(12,481)</b>	<b>(858)</b>
Loss of the period.....	-	-	-	-	(7,481)	(7,481)
Share-based payment .....	-	-	21	-	-	21
Capital increase (IPO).....	4,579	18,871	-	(1,509)	-	21,941
Capital increase (Conversion of bonds) .....	1,234	2,896	-	-	-	4,130
<b>As at 30 June 2016</b> .....	<b>17,439</b>	<b>21,767</b>	<b>612</b>	<b>(2,102)</b>	<b>(19,962)</b>	<b>17,754</b>
<b>As at 1<sup>st</sup> January 2017</b> .....	<b>17,506</b>	<b>21,957</b>	<b>216</b>	<b>(2,102)</b>	<b>(24,445)</b>	<b>13,132</b>
Capital decrease.....	(7,517)				7,517	-
Loss of the period.....					(6,822)	(6,822)
Share-based payment.....			4			4
<b>As at 30 June 2017</b> .....	<b>9,989</b>	<b>21,957</b>	<b>220</b>	<b>(2,102)</b>	<b>(23,750)</b>	<b>6,314</b>

Note :

On 28th December 2016, thanks to the exercise of warrants, capital was increased by 67 K and share premium by 190 K€

**Interim Condensed Statement of cash flows for the six-month period ending on 30 June**

EUR '000'

	<b>30/06/2017</b>	<b>30/06/2016</b>
<b>Loss of the period</b>	<b>(6,822)</b>	<b>(7,481)</b>
Adjustments .....		
Tax credit on R&D activities.....	(306)	(302)
Depreciation on property, plant and equipment.....	99	60
Share-based payments expense.....	4	21
Financial (income) / expense .....	5	85
<b>Changes in working capital</b>		
Trade receivables, other receivables and other current assets .....	246	(444)
Other non-current liabilities, trade payables and other payables.....	239	763
<b>Cash flow from operating activities</b>	<b>(6,535)</b>	<b>(7,298)</b>
<b>Investing activities</b>		
Purchase of property, plant and equipment .....	(97)	(62)
(Increase) /Decrease of long-term receivables .....	-	(16)
<b>Cash flow from investing activities</b>	<b>(97)</b>	<b>(78)</b>
<b>Financing activities</b>		
Capital increase.....	-	21,941
Recoverable cash advance received .....	1,499	-
Interests received .....	17	13
Interests paid.....	(5)	(198)
<b>Cash flow from financing activities</b>	<b>1,511</b>	<b>21,756</b>
<b>Net increase / (decrease) in cash and cash equivalents</b>	<b>(5,121)</b>	<b>14,380</b>
<b>Cash and cash equivalents at the beginning of the period</b>	<b>8,266</b>	<b>4,621</b>
<b>Cash and cash equivalents at the end of the period</b>	<b>13,387</b>	<b>19,001</b>

### 2. GENERAL INFORMATION

The Company is a clinical-stage biopharmaceutical company focused on the development and future commercialisation of a range of immunotherapy products for the treatment of allergies. The lead product candidate gp-ASIT<sup>TM</sup> is designed for treatment of grass pollen allergy.

Beside this lead investigational product, the Company's product pipeline includes two other products against respiratory allergies, hdm-ASIT<sup>TM</sup>, intended for treatment of house dust mite allergy and Rag-ASIT<sup>TM</sup>, intended for treatment of ragweed allergy.

Overmore, since beginning of 2017 and thanks to the support of the Walloon Region, the Company has started a development program in the 3 major food allergies indications (peanut, egg white and cow milk).

These product candidates are being developed using the Company's innovative technology, ASIT<sup>TM</sup>, 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.

The Company has so far been funded by a combination of private and public funds (from regional and national authorities). The Company completed its initial public offering on Euronext Brussels and Euronext Paris in May 2016, new shares were issued in that respect. Furthermore, several grants have been awarded to the Company to support its R&D activities.

The condensed financial statements, together with the interim report, have been authorized for issue on 13 September 2017 by the Board of Directors of the Company.

### 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

All-important accounting policies used for preparing the interim condensed consolidated financials are detailed hereafter.

#### a. **Basis of preparation**

The interim condensed financial statements have been prepared in accordance with the International Financial Reporting Standards (IFRS) as adopted for use in the European Union, and with IAS 34 "Interim Reporting".

These financial statements should be read in conjunction with the annual financial statements for the year ended 31 December 2016, which have also been prepared in accordance with IFRS.

The preparation of the Company's financial statements required management to make judgments, estimates and assumptions that affected the reported amounts of revenues, expenses, assets and liabilities at the end of the reporting period. Uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of the asset or liability affected in future periods. However, the principal risks relating to the interim reporting period have not materially changed from those mentioned in the 2016 Financial Statements and detailed in the 2016 annual report.

#### b. **Significant accounting policies**

The accounting policies and methods used by the Company in 2017 are consistent with those applied in the 31 December 2016 financial statements.

There is no new IFRS standard or amendment adopted by the EU for which the application date relates to accounting periods starting on or after 1 January 2017.



**c. Significant estimates**

**(A) Recoverable Cash Advances (RCA) from the Walloon Region**

**House dust mite allergy (hdm-ASIT+™)**

In December 2015, the Walloon Region granted a subsidy consisting in a refundable advance amounting to 1,254 K€ for the development of the house dust mite treatment. 314 K€ were received by the Company in December 2015 and 815 K€ were received in 2016. The balance of 125 K€ will be wired upon finalization of the file.

The RCA covers a maximum of 55% of eligible expenses incurred by the Company during a research phase of two years (from January 1, 2015 until 31 May 2017 according to last appendix signed on 17/01/2017) for the development of the house dust mite treatment. This cash advance is not bearing any interest. If the Company decides (between 2017 and 2026) to further proceed with the developments and seek commercialization of the product resulting from the subsidised R&D program, it will have to proceed to the repayment of 30% of the advance granted (376 K€). In addition, the Walloon Region is entitled to the payment of a fee equivalent to 0,12 % of the sales amount during the first 120 months of commercial exploitation. The total amount repayable to the Walloon Region is capped to twice the initial refundable advance amount or 2,508 K€ taking into account the first repayment of 30%.

When determining the amount to be reimbursed in the future to the Walloon Region under this agreement – and which is recognized among financial debts for a total of 449 K€ as at June 30, 2017 - the Company has considered different scenario with respect of the possible outcomes of the program currently benefiting from the support of the Walloon Region.

Based on the scenarios, management has considered that:

- 1) The probability to have to proceed to the 30% repayment between 2017 and 2026 is close to 100%. Company has therefore accounted for the NPV (at 8% discount rate) of this debt, amounting to 250 K€ as of 31 December 2016.
- 2) The probability to reimburse the variable part (royalty of 0,12% calculated on future sales) has been estimated to 15%. This probability rate corresponds to the rate of success generally accepted by the market for product in early clinical development. Taking into account this probability of success and discounting the royalty future flows at a discount rate of 8 %, leads to estimate the NPV of the variable part of the grant to be reimburse as of 31 December 2016 at 181 K€.

As a consequence, it is possible but unlikely that the Company will generate in the future sales from products currently benefiting from the Walloon Region support to an extent that the Company may have to reimburse the Walloon Region an amount in exceeding the amount of the financial debt currently booked.

The determination of the amount to be eventually paid to the Walloon Region under the signed agreement is subject to a high degree of uncertainty as it depends on the amount of the future sales that the Company will generate (or not) in the future. Should the Company review the probability to have to reimburse the variable part by an additional 10% (25% probability instead of 15 %) the amount to be paid to the Walloon Region would then need to be increased by 121 K€.

As of 30 June 2017, management has decided to keep the same position and liability towards the region except regarding the impact of the un-discounting of the related financial liabilities considering a discount rate of 8% (impact of 17 K€).

### Food allergies

The Company was granted on 12 January 2017 with a RCA of about 6,000 K€ from the Walloon Region to finance 55% of its food allergy drug development program. The conditions of this grant are in substance similar to the ones received for the house-dust mite program describe above at the difference that the percentage of the royalties to be paid during the exploitation phase is 0,11% of the future sales of the Company. The total amount repayable to the Walloon Region is capped to twice the initial refundable advance amount. If the company decides to exploit the results of its research in 2019 and beyond, the minimum amount of 30% refund will be triggered and payable during the next 10 years. Royalties' payments will only occur if the Company is able to sell successfully the product designed. As the discovery phase has only begun early 2017, the Company has no view at this stage whether the outcome of the research will be fruitful or not and, whether it will decide to continue to exploit its results, neither if sales will be generated.

On 15 May 2017, the Company received the first working capital advance for 1,499 K€.

Considering that as of 30 June 2017 the first activity report and the related expenses incurred have not been validated yet by the Walloon Region, the Company has recognised the full amount of the advance as short term financial liability.

#### *(B) Grant relating to the acquisition of assets*

During the course of the first semester 2017, the Company signed with the Walloon Region an agreement by which the Walloon Region will partly finance the acquisition of laboratory equipments. The support of the Walloon Region amounts to 142 K€ and is subject to employment conditions, which at the time being are not yet met. Consequently, no amount has been booked in the interim financial statements in that respect.

#### *(C) Reduction of withholding tax*

As a research company, ASIT is entitled to request a reduction of withholding tax for its employees implicated in R&D programs. In June 2017, Company was submitted to a tax control on the deduction applied during the years 2015 and 2016. Further to this Control the Company was informed by the inspector that he was considering to reject the deduction for the controlled years as, even if ASIT had a regular correspondence with BELSPO filing required forms in due time, one aspect of ASIT inscriptions with BELSPO was not properly validated. Company has regularized its inscription with BELSPO in July 2017 and obtained the confirmation that everything was in order as of 1<sup>st</sup> July 2017. The Company has now requested from BELSPO to extend this authorization retroactively to January 2015 but has not received any confirmation to date. Although the amount challenged by the tax authorities could amount to up to 608 K€, the Company has not paid such amount at the date of this report as, according to its lawyers, the spirit of the law was perfectly respected and no official rectification advise has been received to date.

### 4. OPERATING SEGMENT INFORMATION

The Company does not make the distinction between different operating segments.

### 5. 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.

***Fair value hierarchy***

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

- Level 1: quoted (unadjusted) market prices in active markets for identical assets or liabilities;
- Level 2: technical assessments for which the lowest level input that is significant to the fair value measurement is directly or indirectly observable; and
- Level 3: technical assessments for which the lowest level input that is significant to the fair value measurement is unobservable.

<i>(in EUR 000)</i>	<b>Carrying amount</b>		<b>Fair value</b>	
	<b>30/06/2017</b>	<b>31/12/2016</b>	<b>30/06/2017</b>	<b>31/12/2016</b>
<b>Financial Assets</b>				
Other long-term receivables	1,340	1,034	1,340	1,034
Trade and other receivables.	103	326	103	326
Other current assets.....	49	72	49	72
Cash and cash equivalents...	8,266	13,387	8,266	13,387
<b>Financial liabilities</b>				
Financial liabilities measured at amortised cost.....	449	431	449	431
Trade and other payables.....	3,730	1,992	3,730	1,992

**6. GOING CONCERN**

As the Board of Directors and Management have the possibility to drastically reduce the scope of the R&D activities as well as G&A for the next 12 months, the financial statements have been prepared on a going concern basis.

However, in order to be able to continue its full development program as describe above, in accordance with what was announced in the offering prospectus and in the latest annual report , the Company should organise a new financing round before December 2017.

At the date of this report, the Company has no investment commitments outstanding or other firm contractual obligations that could not be covered by the cash available.

### **III. DETAILS OF THE INTERIM CONDENSED FINANCIAL STATEMENTS**

**1. FINANCIAL RESULTS OF THE PERIOD**

The loss for the six-month period ending 30 June 2017 amounts to 6.822 K€.

This result mainly relates to the 6.337 K€ amount of the R&D expenses for the period under review. The major R&D programs of the Company contributed as follows:

- 61 % Grass Pollen
- 13 % House Dust Mite
- 9 % Ragweed
- 17 % Food

Most of the expenses of the Grass Pollen product candidate (over 1 million euros) still related to the finalisation of the first clinical phase III study (BTT009).

The other income of 300 K€ mainly relates to the recognition of a research Tax-Credit triggered by R&D expenditures incurred in the first half 2017.

**2. R&D AND GENERAL & ADMINISTRATIVE EXPENSES**

The following table provides a breakdown of R&D and of General & Administrative expenses by nature:

	<b>30/06/2017</b>	<b>30/06/2016</b>
Payroll.....	921	608
Share-Based Payment .....	4	17
Studies .....	4,519	5,571
Laboratory .....	244	244
Licenses.....	111	76
Rent.....	50	58
Facilities.....	130	85
External services.....	184	2
ICT.....	21	8
Depreciation.....	79	48
Other.....	73	38
<b>Total Research &amp; Development Expenses</b>	<b>(6,337)</b>	<b>(6,757)</b>
Payroll.....	278	216
Share-Based Payment .....	-	4
Studies .....	-	-
Laboratory .....	-	5
Licenses.....	-	-
Rent.....	8	12
Facilities.....	27	22
External services.....	371	568
ICT.....	4	2
Depreciation.....	20	12
Other.....	76	94
<b>Total General &amp; Administrative ExpG &amp;A Expenses</b>	<b>(785)</b>	<b>(937)</b>

### 3. FINANCIAL POSITION

#### *Assets*

The assets of the Company primarily include property, plant and equipment (734 K€) representing mainly laboratory equipment. Other long-term receivables (1.340 K€) represent mainly the tax-credit relating to the R&D activities. Other receivables (103 K€) represents mainly VAT to be recovered and cash and cash equivalents (8,266 K€).

Total assets as at 30 June 2017 amount to 10,492 K€ to be compared with total assets of 15,555 K€ as at 31 December 2016. The decrease is mainly explained by the cash consumed through the R&D activities; partly compensated by the receipt of a recoverable cash advance for 1,499 K€

#### *Equity and liabilities*

Shareholders' equity amounts to 6,314 K€ as at 30 June 2017 whereas as at 31 December 2016 it represented 13,132 K€. The decrease is mainly explained by the loss of the six-month period amounting to 6,822 K€.

During the period, a capital decrease of 7,517 K€ took place with a corresponding decrease of the accumulated loss. As the number of shares remained unchanged (12,806,100) the par value (*pair comptable*) decrease from 1,367 € to 0,78 €.

On 28 June 2017, an extraordinary shareholders' meeting took place by which 1,000,000 warrants were issued. Such warrants have not been granted yet, and accordingly no share-based payment expense was accounted for in the interim financial statements for the period ending on 30 June 2017.

As for the liabilities, the Company accounted 2,056 K€ of Trade Payables and 1,674 K€ of Other Payables including 1,499 K€ from the advance in working capital received from the Walloon Region.

### 4. CASH FLOW

The net cash-outflow for the period amounts to 5,121 K€.

It mainly relates to an operating cash outflow of 6,535 K€ due to the continuation of the R&D activities and a financing cash inflow of 1,511 K€ (the first down payment on the recoverable cash advance for the "FOOD" research program was received from the Walloon Region for an amount of 1,499 K€).

During the period, acquisition of property, plant & equipment took place for an amount of 97 K€.

### 5. EVENTS AFTER 30 JUNE 2017

There is no material subsequent event to report.

## IV. RESPONSIBILITY STATEMENT



**RESPONSIBILITY STATEMENT**

The Board of Directors of ASIT biotech, represented by all its members, declares that, to the best of its knowledge:

- the condensed financial statements for the six-months period ended 30 June 2017, which have been prepared in accordance with IAS 34 “Interim Financial reporting” as adopted by the European Union, give a true and fair view of the assets, the financial position and the results of ASIT biotech;
- the interim management report contains a fair description of the important events and main transactions between related parties, which occurred during the first 6 months of the financial period and on their incidence on the condensed financial statements, as well as a description of the main risks and uncertainties for the remaining months of the financial period.

**V. REPORT OF THE STATUTORY AUDITORS ON  
THE LIMITED REVIEW OF THE CONDENSED  
FINANCIAL STATEMENTS**



**Company number: BE 0460.798.795**

**STATUTORY AUDITOR'S REPORT ON THE REVIEW OF THE CONDENSED INTERIM FINANCIAL  
INFORMATION OF ASIT BIOTECH SA  
FOR THE PERIOD ENDED 30 JUNE 2017**

*Introduction*

We have reviewed the *condensed interim financial information* of ASIT BIOTECH SA as of June 30, 2017, and for the period of six months ended on that date, which comprises the condensed interim statement of profit or loss and other comprehensive income, the condensed interim statement of financial position, the condensed interim statement of cash flows, the condensed interim statement of changes in equity, the accounting policies, and a selection of explanatory notes.

The board of directors is responsible for the preparation and fair presentation of this condensed interim financial information in accordance with the international standard IAS 34 - *Interim Financial Reporting* as adopted by the European Union. Our responsibility is to express a conclusion on this condensed interim financial information based on our review.

*Scope of Review*

We conducted our review in accordance with the international standard ISRE (*International Standard on Review Engagements*) 2410 "Review of Interim Financial Information Performed by the Independent Auditor of the Entity". A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

*Conclusion*

Based on our review, nothing has come to our attention that causes us to believe that the preceding condensed interim financial information is not prepared, in all material respects, in accordance with the international standard IAS 34 - *Interim Financial Reporting* as adopted by the European Union.

*Emphasis of Matter*

Without modifying the above conclusion, we draw attention to Note 6 Going concern in the financial statements which describes the uncertainty with regard to the Company's ability to attract additional funding to further develop its operations in the long run and the ability of the Company's management to reassess its development plan.

Brussels, September 13, 2017

Mazars Réviseurs d'Entreprises SCRL  
Statutory Auditor  
Represented by

RSM Réviseurs d'Entreprises SCRL  
Statutory Auditor  
represented by

Xavier DOYEN

Luis LAPERAL

