

Allergy immunotherapy as simple ASIT can be...



## INTERIM FINANCIAL REPORT

AS OF 30 JUNE 2018

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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 2018**

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 allergy immunotherapy products, 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, 1 at phase III clinical stage targeting the grass pollen rhinitis and 1 at preclinical stage targeting the house dust mite rhinitis. These 2 respiratory allergies have the highest prevalence. ASIT biotech is also developing 3 product candidates targeting food allergies that are at preclinical development stage.

ASIT biotech is a limited liability company with registered office located at 1200 Brussels, 5 avenue Ariane. The Company has offices and laboratories in Liège that host the R&D team in charge of the product development, technology transfer and the quality control as well as the preclinical and clinical developments.

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 2018 the Company has invested in R&D an amount of 4,350 K€, entitling ASIT to a Tax-Credit of 174 K€. This amount has been accrued for in the interim statements as of 30 June 2018.

### 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 development of a house-dust mite allergy immunotherapy product – 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. On 13 February 2018 the Company has cashed in the remaining balance of the RCA HDM for an amount of 125 K€. This amount has been registered as “other operating income”.

No changes have occurred on the RCA food allergy immunotherapy products (peanut, egg white and cow’s milk) since the closing of the 2017 accounts. As the pace of development of the program has been slowed down, an agreement has been reached with the Walloon Region to extend the time devoted to the research programme.

### c. Share Capital Increase

On first November 2017 the Board of Directors resolved to propose to the Shareholders’ meeting to be held on 7 December 2017 to issue a total of 3 million new shares (the “**Initial New Shares**”) and to delegate to the Board of Directors the mission to organize the subscription of such Initial New Shares with some existing shareholders and with third parties investors and to acknowledge such subscription, in one or several time, before the Notary Public. This proposal has been chosen by the Board of Directors after having examined

and considered several financing structures (such as rights issue, private placement through accelerated book building, etc.).

To encourage the subscription of the Initial New Shares, the Board of Directors proposed to issue a total of 6 million subscription rights (the “**Warrants**”) allowing the holder of each Warrant to subscribe to one new share of the Company. Each person subscribing to one Initial New Share received, for free, two Warrants: the Warrant n°1 can be exercised at any time until 30 June 2018 and the Warrant n°2 can be exercised at any time, provided that the Warrant n°1 has been prior exercised, until 31 December 2019.

The subscription of the Initial New Shares has been organized by the Board of Directors and no accelerated book building procedure took place. This subscription occurred after the decision taken by the Shareholders’ Meeting to cancel the preferential subscription rights of the existing Shareholders. In this subscription process it has been decided that each subscriber shall subscribe to Initial New Shares for a minimum amount of EUR 100,000. The identity of the subscribers have been freely determined by the Board of Directors among the existing shareholders and third parties investors.

The subscription price of each Initial New Shares was EUR 3.83 per share. The exercise price of each Warrant was also EUR 3.83 per Warrant.

A total of 3 million Initial New Shares, 3 million Warrants 1 and 3 million Warrants 2 have been subscribed on 25 January and 23 February 2018.

Until 30 June 2018, a total of 1,020,923 Warrants have been exercised and 1,020,923 new shares have been issued. On July 4 a remaining amount of 182,769 of warrants have been exercised creating same amount of new shares.

On 11 July 2018, via a private placement organised by Bryan, Garnier & Co. who acted as Sole Bookrunner, the Company raised a total of €12 million committed capital in the form of Convertible Bonds (CB) that will be paid in 20 equal tranches over the next 20 months.

During the last 12 months company has secured over 25 M€ financing and, at the date of this report, 1,091,498 Warrants 2 are still outstanding (representing an additional financing of 4,180,437.34 EUR at the price of 3,83 €/share if fully exercised) entitling their holders to participate to subsequent share capital increases for the same amount.

#### **d. Patent Situation**

Since the issuance of the 2017 annual report, 2 patent applications have been filed on new topics:

- The development of a new methodology for the detection of blocking antibodies in animal and in human serum (submitted in February 2018);
- A new method for the evaluation of hydrolyzed allergen preparations (based on the test performed in ex vivo studies) (submitted in April 2018)

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

### **Registration and Clinical development in Europe**

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

Out of the feasibility study performed to date, the next Phase III with gpASIT+™ (ABT011) will be a randomized, 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 will be randomized according to a 1:1 ratio placebo:gpASIT+™ treated patients. Study treatment will be administered before the beginning of the 2019 pollen season. The treatment will be administered during 4 visits over 3 consecutive weeks. After the treatment period, 3 follow-up visits are planned before, during and after the pollen season.

The following improvements compared to study BTT009 should be implemented to ensure optimal outcomes by significantly reducing the risk of this Phase III study with gpASIT+™:

- One sole CRO vendor responsible for ABT011: the entire study will be sub contracted to ICON, an international CRO (Contract Research Organization) acknowledged for its expertise in running clinical trials in the field of respiratory disorders.
- 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 80 centers spread over 6 countries (Belgium, Czech Republic, Germany, Hungary, Poland, and France). This higher 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. To ensure that the overall study is not unduly dependent of the local pollen concentration affecting a small number of over-recruiting centers, a maximum number of patients per center and per country has been defined.
- Pollen history: if there is no pollen circulating, we will not be able to measure the product efficacy against placebo as there will be no/few allergic reactions. Therefore, we have engaged with a European network of pollen counting, based in Vienna, to help us selecting the clinical sites in regions with a history of high pollen rates and high-quality pollen counts
- Inclusion criteria to randomize the most allergic patients: in order to randomize the most allergic patients, the inclusion criteria should be based on the historical medical dossier of the patients and the drug intake during the 2 previous grass pollen seasons.
- 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 and integrated alerts should optimize data collection and limit the number of missing data.

Upon finalization of the preparation phase by August 2018, the screening of the patients will start by Q4 2018 in order to treat the patients prior the 2019 grass pollen season (first patient in expected in Jan 2019).

### Registration and Clinical development in the United States

Exchanges with the FDA occurred in 2016 and 2017 and are still ongoing. ASIT biotech continues its interactions with the FDA to reach an agreement on the clinical development plan in the USA. The nature and the timing of the starts of US clinical studies will depend of the outcome of the discussions. The start of the clinical development in the United States will most probably occur after the completion ABT-011 Phase III study and it's funding will be addressed at that time.

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

### ➤ **Product description**

The product candidate, hdm-ASIT+™ consists in a mixture of natural peptides (ranging from 1kDa to 10kDa) obtained by hydrolysis of purified allergen extracted from *Dermatophagoïdes pteronyssinus*.

### ➤ **First in man study (Phase IIa - hdmASIT001)**

Following the completion of regulatory required preclinical studies in Q4 2015, the Company has filed Q2 2016 in Germany the clinical trial documentation for a first in man clinical study with a first hdm-ASIT+™ product candidate. The Company received the approval of the Paul Ehrlich Institute (German Regulatory Authority) for this clinical study in September 2016. Its primary objective was the determination of the maximum tolerated dose of hdm-ASIT+™ in adult patients with a clinical history of house dust mite allergy. The following endpoints were assessed as secondary endpoints:

- safety and clinical tolerability of the product;
- impact of the treatment on immunological parameters;
- impact of the treatment on the reactivity to an allergen provocation test.

The patients received increasing doses of hdm-ASIT+™ under close medical supervision. 40 patients were screened on the basis of a positive house dust mite allergen skin prick test, house dust mite-specific IgE above the relevant threshold and positive allergen provocation test at baseline. Out of them, 36 patients have been randomized and 33 patients finished the study mid January 2017.

The Company announced on 4 April 2017 that the primary endpoint was achieved, insofar as the first hdm-ASIT+™ product candidate showed, during the trial, a good safety and tolerability profile. 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.

Regarding the secondary endpoints, the first hdm-ASIT+™ product candidate had no significant impact on the immune system or on the reduction of the reactivity to a conjunctival provocation test (CPT).

### ➤ **Further clinical development**

The clinical results previously obtained with gp-ASIT+™, the lead product candidate of the company for grass pollen rhinitis, and the understanding of its mechanism of action constitute a powerful and reliable assessment tool for new product candidates to reach the required potential immunological and clinical changes for the immunotherapy of the other targeted allergies.

As this assessment tool was not available at the time of the development of the first hdm-ASIT+™ product candidate, it has been decided to compare in collaboration with Dr M. Shamji's team from the Imperial College of London, the first hdm-ASIT+™ product candidate with 4 other hdm-ASIT+™ product prototypes for their immunological profile on allergic patient's blood cells

The results of the ex vivo study had showed the low immunological profile of the first hdm-ASIT+™ and allowed the selection of a second hdm-ASIT+™ product candidate with an improved immunological profile. In June 2018 the selected improved hdm-ASIT+™ product candidate has been transferred for toxicity study and clinical GMP batches will be manufactured to prepare for a second clinical study to be performed in H2 2019.

### ➤ **ASIT+™ product candidates for FOOD allergies Product description**

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

- peanut

- cow's milk
- egg white.

➤ **Development programme**

The food-ASIT+™ product candidates will be designed in collaboration with Dr M. H. Shamji (Senior Lecturer in Immunology and Allergy) who has established the Immunomodulation and Tolerance Group established by within Allergy and Clinical Immunology Department at Imperial College of London. The objective of this collaboration is to test the allergenicity and antigenicity of food-ASIT+™ product candidates on human ex-vivo food allergy model and optimize the safety/efficacy ratio of its new product candidates.

When the food-ASIT+™ product candidates with optimal safety/efficacy ratio will be selected, their immunogenicity and toxicity will be tested in animal model as required by regulatory authorities to be allowed to start in man clinical study. In parallel to the preclinical development, the production process and quality control procedure will be transferred for GMP productions clinical batches of drug substances and drug products.

Afterwards, the selected product candidates will be tested in the frame of clinical trials that will be performed in the framework of a collaboration with Dr Stephen Till who is one of few specialist doctors accredited in Adult Allergy by the General Medical Council (UK). His current research interests include immunotherapy (desensitisation) and food allergy. The objective of this collaboration is to assess the safety, the immunogenicity and the clinical impact on a food allergen provocation test of the product candidates

Based on the preliminary testings performed and taking into consideration the unmet medical needs, the Company has decided to concentrate first its effort on the developpement of the peanut (pnt-ASIT+™) product candidate.

The contemplated timing for the next developpement steps of pnt-ASIT+™ product candidates is the following:

- Design, development and screening of several peanut product candidates has been performed and a first pnt-ASIT+™ has been selected in June 2018.
- regulatory required preclinical development and GMP manufacturing for ASIT+™ product for peanut allergy will be performed in H2 2018 - H1 2019
- After achieving successfully the previous steps, a first in man clinical study for Pnt ASIT+™ is planned H2 2019.

Preclinical development and design of product candidates for Cow's milk and Egg white will take place in parallel in the Company's Liege Laboratories.

**3. FINANCIAL HIGHLIGHTS**

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

	<b>30/06/2018</b>	<b>30/06/2017</b>
Revenue .....	-	-
Other operating income / (expense) .....	385	300
Cost of goods sold.....	-	-
Research and development expenses .....	(4,461)	(6,337)
General and administrative expenses .....	(1,280)	(785)
<b>Operating loss for the period</b>	<b>(5,356)</b>	<b>(6,816)</b>

As the Company is mostly engaged in R&D activities, over 83% of the IFRS operating loss for the period is related to R&D costs of 4,461 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 Company's Board has the possibility to adapt the execution of the business plan and clinical development plan described in the preceding pages, in size as well as in timing, in function of Company's ability to raise funds and to secure grants or subsidies.

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.

Thanks to the various capital increases that occurred in H1 2018, as of 30 June 2018, the Company's cash amounted to 13,506 K€ (8,266 K€ as of June 2017 and 2,126 K€ as of December 2017).

In addition, on 11 July 2018, via a private placement organised by Bryan, Garnier & Co. who acted as Sole Bookrunner, the Company raised a total of €12 million committed capital in the form of Convertible Bonds (CB) that will be paid in 20 equal tranches over the next 20 months

#### **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 IPO, as well as in section 1 of the 2017 annual report remain relevant and up to date, which is deemed to be reproduced here. The prospectus of the IPO 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.

The fixed amount of the remuneration of the CEO, M. Thierry Legon, was increased contractually by 2% as from April 2018.

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 IFRS  
FINANCIAL STATEMENTS FOR THE  
PERIOD ENDED 30 JUNE 2018**

## II. Interim condensed IFRS financial statements for the period ended 30 June 2018

### 1. MAIN FIGURES

#### Interim Condensed Statement of financial position for the period ending on 30 June 2018

EUR '000'

	<u>30/06/2018</u>	<u>31/12/2017</u>
<b>ASSETS</b>		
<b>Non-current assets</b>		
Intangible assets .....		-
Property, plant and equipment .....	618	691
Other long term receivables .....	1,315	1,146
	<u>1,933</u>	<u>1,837</u>
<b>Current assets</b>		
Trade receivables .....	-	
Other receivables .....	201	244
Other current assets .....	52	78
Cash and cash equivalents .....	13,506	2,126
	<u>13,759</u>	<u>2,448</u>
<b>Total assets</b>	<u>15,692</u>	<u>4,285</u>

	<u>30/06/2018</u>	<u>31/12/2017</u>
<b>EQUITY AND LIABILITIES</b>		
<b>Capital and reserves</b>		
Capital.....	13,125	9,989
Share premium.....	34,221	21,957
Cost of capital increase.....	(2,340)	(2,102)
Share based payment reserve .....	333	270
Accumulated deficit .....	<u>(34,290)</u>	<u>(28,915)</u>
<b>Total equity attributable to shareholders</b>	<b><u>11,050</u></b>	<b><u>1,199</u></b>
<b>LIABILITIES</b>		
<b>Non-current liabilities</b>		
Financial debt.....	446	432
	<b><u>446</u></b>	<b><u>432</u></b>
<b>Current liabilities</b>		
Financial debt	38	34
Trade payables .....	2,354	1,264
Other payables .....	1,804	1,356
	<b><u>4,196</u></b>	<b><u>2,654</u></b>
<b>Total liabilities</b>	<b><u>4,642</u></b>	<b><u>3,086</u></b>
<b>Total equity and liabilities</b>	<b><u>15,692</u></b>	<b><u>4,285</u></b>

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

EUR '000'

	<b>30/06/2018</b>	<b>30/06/2017</b>
Revenue	-	-
Other operating income / (expense)	385	300
Cost of goods sold	-	-
Research and development expenses	(4,461)	(6,337)
General and administrative expenses	(1,280)	(785)
<b>Operating loss for the period</b>	<b>(5,356)</b>	<b>(6,816)</b>
Financial income	2	17
Financial expense	(22)	(23)
<b>Loss for the period before taxes</b>	<b>(5,375)</b>	<b>(6,821)</b>
Taxes	1	(1)
<b>Loss for the period</b>	<b>(5,374)</b>	<b>(6,822)</b>
Other comprehensive income		
<b>Comprehensive loss for the period</b>	<b>(5,374)</b>	<b>(6,822)</b>
<b>Loss for the year</b>		
Attributable to shareholders	(5,374)	(6,822)
<b>Earnings per share</b> (in EUR per share)		
- basic and diluted	(0,34)	(0,53)

**Interim Condensed Statement of changes in equity as at June 30, 2018**

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>
As at 1 <sup>st</sup> January 2017 .....	17,506	21,957	216	(2,102)	(24,445)	13,132
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>
Loss of the period.....					(5,166)	(5,166)
Share-based payment.....			50			50
<b>As at 31 December 2017.....</b>	<b>9,989</b>	<b>21,957</b>	<b>270</b>	<b>(2,102)</b>	<b>(28,916)</b>	<b>1,199</b>
As at 1 <sup>st</sup> January 2018 .....	9,989	21,957	270	(2,102)	(28,916)	1,199
Capital increases.....	3,136	12,264		(238)		15,162
Loss of the period.....					(5,374)	(5,374)
Share-based payment.....			63			63
<b>As at 30 June 2018.....</b>	<b>13,125</b>	<b>34,221</b>	<b>333</b>	<b>(2,340)</b>	<b>(34,290)</b>	<b>11,050</b>

**Interim Condensed Statement of cash flows for the six-month period ending on 30 June 2018**

EUR '000'

	<b>30/06/2018</b>	<b>30/06/2017</b>
<b>Loss of the period</b>	<b>(5,374)</b>	<b>(6,822)</b>
Adjustments .....		
Tax credit on R&D activities .....	(174)	(306)
Depreciation on property, plant and equipment .....	116	99
Loss on disposal of property, plant and equipment .....	4	
Share-based payments expense .....	63	4
Financial (income) / expense .....	19	5
<b>Changes in working capital</b>		
Trade receivables, other receivables and other current assets .....	68	246
Other non-current liabilities, trade payables and other payables .....	912	239
<b>Cash flow from operating activities</b>	<b>(4,365)</b>	<b>(6,535)</b>
<b>Investing activities</b>		
Purchase of property, plant and equipment .....	(43)	(97)
(Increase) /Decrease of long-term receivables .....	-	-
<b>Cash flow from investing activities</b>	<b>(43)</b>	<b>(97)</b>
<b>Financing activities</b>		
Capital increases .....	15,400	-
Costs of capital increase .....	(238)	
Cash received with respect to capital increase of July, 2018 .....	500	
Recoverable cash advance received .....	125	1,499
Interests received .....	2	17
Interests paid .....	(3)	(5)
<b>Cash flow from financing activities</b>	<b>15,787</b>	<b>1,511</b>
<b>Net increase / (decrease) in cash and cash equivalents</b>	<b>11,379</b>	<b>(5,121)</b>
<b>Cash and cash equivalents at the beginning of the period</b>	<b>2,126</b>	<b>8,266</b>
<b>Cash and cash equivalents at the end of the period</b>	<b>13,506</b>	<b>13,387</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>+</sup>™ is currently in Phase III and is designed for the treatment of grass pollen allergy.

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

These product candidates are being developed using the Company's innovative technology, ASIT<sup>+</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. Subsequent capital increases took place since then. 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 17 September 2018 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 2017, 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 2017 Financial Statements and detailed in the 2017 annual report.

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

The accounting policies and methods used by the Company in 2018 are consistent with those applied in the 31 December 2017 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 2018 that have an impact on the preparation of the interim condensed financial statements of the Company.

**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€ has been received in 2018 and recognized in other operating income.

The RCA covers a maximum of 55% of eligible expenses incurred by the Company during a research phase of two years (from 1 January 2015 until 31 May 2017 according to last appendix signed on 17 January 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 subsidized 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 485 K€ as at 30 June 2018 - 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 2018, 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 34 K€ as of December 2017 plus 19 K€ as of June 2018).

**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€ and in November 2017 an additional provisional amount of 151 K€ was received to cover the expenses incurred in H1 2017. The 1,650 K€ received were accounted for 1,192 K€ as other payable and 458 K€ as result in 2017.

Consequently, as no new final acceptances of related cost have occurred since December 2017 and as the timing of the program is still in discussion with the Walloon Region, accounting of the above RCA will be maintained as per our closing 2017.

### *(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 finances partly the acquisition of laboratory equipment. The support of the Walloon Region amounts to 142 K€ and is subject to employment conditions, therefore the related amount is booked as reduction of the underlying asset.

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

As a research Company, ASIT Biotech is entitled to benefit from a reduction of withholding taxes for certain employees active in Research & Development activities if certain conditions are fulfilled. In June 2017, the Company was submitted to a tax audit that aimed at verifying the correct fulfilment of the conditions attached to the reduction for years 2015 and 2016. Further to this control the Company was informed by the inspector that one aspect of ASIT Biotech inscriptions with BELSPO was not properly made and that consequently the tax authorities were contemplating a rejection of the reductions obtained by the Company for the years under control, and this even if ASIT Biotech had regular correspondence with BELSPO and did file the required forms in due time. The exposure that the Company was facing in this matter could amount up to EUR 608,000.

In July 2017 ASIT Biotech regularized its inscription with BELSPO and has been notified by BELSPO that everything was in order as at 1 July 2017. ASIT Biotech has requested and obtained from BELSPO a retroactive advice with effect as from 1 January 2015 confirming that since that date the Company met all credential to qualify for the withholding reduction.

On 9 July 2018, the Company received via it's lawyer confirmation from the tax authorities that they agreed with the position of BELSPO and that all claims were abandoned.

## **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>30/06/2018</b>	<b>31/12/2017</b>	<b>30/06/2018</b>	<b>31/12/2017</b>
<b>Financial Assets</b>				
Other long-term receivables	1,315	1,146	1,315	1,146
Trade and other receivables.	201	244	201	244
Other current assets .....	52	78	52	78
Cash and cash equivalents...	13,506	2,126	13,506	2,126
<b>Financial liabilities</b>				
Financial liabilities measured at amortised cost.....	484	466	484	466
Trade and other payables.....	4,158	2,621	4,158	2,621

## **6. GOING CONCERN**

Since the Company (i) is currently able to satisfy all financial liabilities, (ii) is able to fulfil all payments and (iii) is able to reduce the costs related to its development plan (by reducing the scope and the speed of the researches), the Board of Directors is of the opinion that the continuity of the Company is not threatened for the next twelve months at the date of this report. Consequently, 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, taking into consideration that the 12 M convertible bond issued early July shall be liberated in 20 monthly instalments the Company should organise a new financing round before end of H1 2019.

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 IFRS FINANCIAL STATEMENTS**

## III. Details of the interim condensed IFRS financial statements

### 1. FINANCIAL RESULTS OF THE PERIOD

The loss for the six-month period ending 30 June 2018 amounts to 5,374 K€.

This result mainly relates to the 4,461 K€ amount of the R&D expenses for the period under review. The major R&D programs of the Company contributed as follows:

- 86 %      Grass Pollen
- 5 %        House Dust Mite
- 9 %        Food

Most of the expenses of the Grass Pollen product candidate (over 1 million euros) relate to the preparation of the clinical phase III study ABT 011.

The “other income” of 396 K€ mainly relates to the recognition of a research Tax-Credit triggered by R&D expenditures incurred in the first half 2018 (174 K€) and to a grant-income of 125 K€ for the House Dust Mite program.

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

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

EUR ‘000’

	<b>30/06/2018</b>	<b>30/06/2017</b>
Payroll.....	961	921
Share-Based Payment .....	50	4
Studies .....	2,718	4,519
Laboratory .....	271	244
Licenses .....	97	111
Rent .....	49	50
Facilities .....	77	130
External services.....	42	184
ICT .....	25	21
Depreciation.....	93	79
Other.....	78	73
<b>Total Research &amp; Development Expenses</b>	<b>(4,461)</b>	<b>(6,337)</b>
Payroll.....	462	278
Share-Based Payment .....	13	-
Rent .....	17	8
Facilities.....	48	27
External services.....	612	371
ICT.....	9	4
Depreciation.....	23	20
Other.....	96	76
<b>Total General &amp; Administrative Exp</b>	<b>(1,280)</b>	<b>(785)</b>

The increase in non-research related payroll expenses as well as the G&A expenses as a whole is not only due to the relative higher increase in the number of experienced administrative staff (ei : hiring a HR manager) compared to R&D staff that increased direct payroll costs but also to induced modification of the splitting ratio between G&A and administrative costs .

#### FINANCIAL POSITIONS

##### *Assets*

The assets of the Company primarily include property, plant and equipment (618 K€) representing mainly laboratory equipment. Other long-term receivables (1,315 K€) represent mainly the tax-credit relating to the R&D activities. Other receivables (201 K€) represent mainly VAT to be recovered and cash and cash equivalents (13,506 K€).

Total assets as at 30 June 2018 amount to 15,692 K€ to be compared with total assets of 4,285 K€ as at 31 December 2017. The increase is mainly explained by the different capital increases that took places during the first half of 2018.

##### *Equity and liabilities*

Shareholders' equity amounts to 11,050 K€ as at 30 June 2018 whereas as at 31 December 2017 it represented 1,199 K€. The increase is mainly explained by the loss of the six-month period amounting to 5,374 K€ as well as the capital increases costs of 238 K€ who were more than compensated by the various capital increases who positively influenced equity for 15,400 K€.

These various capital increases were accounted for a total amount of 3,136 K€ booked as capital as well as 12,264 K€ booked as share premium. As of 30 June 2018, the Company's share capital of 13,125,077.94€ was represented by 16,827,023 shares and the par value (*pair comptable*) remained unchanged at 0.78 €.

On 15 June 2018, 1,250,000 warrants were issued through the authorised capital. Simultaneously, 1,000,000 warrants issued in June 2017 – of witch none were granted – have been cancelled.

In the first half 2018, 62,500 warrants have been granted under the 2014 plan and 345.000 were granted under the 2018 plan (and accepted in July 2018). The related share-based payment expenses were accounted for in the interim financial statements for the period ending on 30 June 2018.

As for the liabilities, the Company accounted 2,354 K€ of Trade Payables (including invoices to be received for 1,551 K€) and 1,804 K€ of Other Payables including 500 K€ with respect to the capital increase that was realised on 4 July 2018; the remaining being mainly composed of grant received (1,192 K€) and deferred (112 K€).

#### 3. CASH-FLOW

The net cash-inflow for the period amounts to 11,379 K€.

It mainly relates to a financing cash inflow of 15,787 K€ due to the capital increases that took place during the first semester for 15,400 K€ , the receipt of a recoverable cash advance for the "HDM" research program for 125 K€ ,and an advance payment of 500 K€ done by 2 shareholders already in June in relation to a capital increase that took place early July , whereas as the R&D activities are negatively affecting the operating cash-flow with an outflow of 4,365 K€

During the period analysed, acquisition of property, plant & equipment took place for an amount of 43 K€.

#### 4. EVENTS AFTER 30 JUNE 2018

On 11 July 2018, via a private placement organised by Bryan, Garnier & Co. who acted as Sole Bookrunner, the Company raised a total of €12 million committed capital in the form of Convertible Bonds (CB) that will be paid in 20 equal tranches over the next 20 months.

The CBs are in registered form, denominated €2,500 each. The CBs will not bear any coupon and have a maturity date of twelve months from issuance. The CBs are convertible to ordinary shares at CB holders' convenience before maturity or are automatically converted on the maturity date at the Conversion Price. The Conversion Price of the CBs will be equal to 92% of the volume-weighted average price over the trading day preceding the CB holder's request of conversion or maturity date. However, the price may not be lower than €1.1368, which is higher than the par value of the company's shares (€0.78). Upon conversion of the CBs, the new shares issued shall immediately bear the same right of all other existing shares and may be traded on the Euronext stock exchanges in Brussels and Paris. The company has the right to redeem the CBs at a price of €2,600 instead of issuing new shares.

Each CB is accompanied by 19 bond warrants (the "Bond Warrants") in registered form with a warrant term of 19 months from the initial issue date. Each Bond Warrant entitles the holder to subscribe to one CB and can be exercised at an exercise price of €2,500 per CB, at the request of the warrant holder at any time during the warrant term. The company may, however, oblige the warrant holders to exercise at least 1 of the 19 Bond Warrants every 30 calendar days.

The net proceeds of the offering will be allocated to the clinical development of Company's product candidates according to the following order of priority:

- **gp-ASIT+™ in grass pollen rhinitis:** financing of the second phase III study in Europe, which should begin in late 2018, prior to the 2019 pollen season;
- **hdm-ASIT+™ in house dust mite rhinitis:** further development of the new drug candidate recently selected on the ASIT+™ platform;
- **pnt-ASIT+™ in peanut allergy:** further development of the first drug candidate for the treatment of food allergies selected in June.
- Part of the funds raised through the offering may also be allocated to researching new product candidates on the ASIT+™ platform.

## IV. RESPONSIBILITY STATEMENT

## IV. Responsibility statement

### 1. 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 2018, 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 IFRS CONDENSED FINANCIAL  
STATEMENT**

# V. Report of the statutory auditors on the limited review of the IFRS condensed financial statement



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 2018

### Introduction

We have reviewed the *condensed interim financial information* of ASIT BIOTECH SA as of June 30, 2018, 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 need to attract additional funding, before the end of the first semester of 2019, to finance its scientific development plan but also the ability of the Company's management to reassess its development plan, if necessary.

Brussels, September 17, 2018

Mazars Réviseurs d'Entreprises SCRL  
Statutory Auditor  
Represented by

Xavier DOYEN

RSM Réviseurs d'Entreprises SCRL  
Statutory Auditor  
represented by

Luis LAPERAL