

Allergy immunotherapy as simple ASIT can be...



## INTERIM FINANCIAL REPORT

AS OF JUNE 30, 2019

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**ASIT biotech SA**

*A limited liability company which makes appeal on or has made an appeal on public savings (société anonyme faisant ou ayant fait appel public à l'épargne) incorporated under Belgian law, with its registered office at 7, rue des Chasseurs Ardennais – 4031 Angleur (enterprise number 460.798.795)*

# **INTERIM FINANCIAL REPORT AS OF JUNE 30, 2019**

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 whose mission is to lead an evolution in allergy therapeutics by creating a new generation of highly effective and efficient immunotherapy treatments for environmental and food allergies. Leveraging our proprietary ASIT+ platform, we intend to deliver a pipeline of best-in-class short course therapies that overcome the risks and limitations of current allergy immunotherapy treatments. Our breakthrough product candidates are intended to deliver recognizable improvement in the quality of life for patients, within weeks rather than months or years following treatment initiation.

ASIT biotech is a limited liability company which makes appeal on or has made an appeal on public savings with a registered office located at 4031 Angleur (Liège), 7 rue des Chasseurs Ardennais since May 2019. Previously, the registered office was located at 1200 Brussel, 5 avenue Ariane. The Company offices and laboratories are based in Liège since 2015. The Company employs a current staff of 23 people.

## 2. BUSINESS UPDATE

At the end of 2018 the Company changed its strategy. Instead of developing several product candidates at the same time, the Company decided to focus on the clinical proof of concept in one indication before leveraging the full potential of its proprietary ASIT+ platform in other indications.

As a result of this strategic change, the Company's main activity is now based on its lead asset gp-ASIT+™, a product candidate in clinical trial for the treatment of allergic rhinitis caused by grass pollen. In this ongoing pivotal phase III study (ABT-gpASIT011) all patients have already been treated with no major safety issues and top line results are expected by year end 2019. Subject to the outcome of this trial, the Company anticipates to file the dossier with the relevant regulatory authority in Germany, the Paul Ehrlich Institute ("PEI"), in 2020 and is preparing the roadmap for market registration in other European countries and in the US. At the same time the Company is actively investigating the opportunity to find a partner for this lead asset once approved and will scale up production to be ready for commercial launch.

Pre-clinical efforts in the pnt-ASIT+™ product candidate for the treatment of peanut allergy and in the hdm-ASIT+™ product candidate for the treatment of allergic rhinitis caused by house dust mites are ongoing with the intention of being ready to clinically develop, co-develop or partner these assets when and if needed.

## 2.a. Product pipeline update

Product	Pre-Clinical	Phase I	Phase II	Phase III	Registration
gp-ASIT+™					
pnt-ASIT+™					
hdm-ASIT+™					
ASIT+ platform					

### Our lead asset gp-ASIT+™

#### Top-line data of the pivotal Phase III trial expected by year end 2019

The treatment phase of the pivotal phase III clinical study with gp-ASIT+™ in grass pollen rhinitis was completed for all patients, well in time before the grass pollen season, with no major safety concerns.

A total of 651 patients with moderate to severe allergic rhinitis have been treated, above the initial target of 624 patients. This high number of patients has been reached earlier than planned which reflects the strong interest for the short-course immunotherapy developed by ASIT biotech and provides a solid sample for statistical analysis.

During the treatment period, the safety data has been monitored on a weekly basis by an independent Data Safety Monitoring Board (DSMB). Based on its analysis, the DSMB recommended to continue the study without modification.

Patient monitoring and data collection is ongoing in the 70 participating European centers, using modern electronic diaries. The whole process during the entire pollen season is under the tight control of the ASIT biotech clinical team and the dedicated CRO, ICON Plc. The Company is on track to obtain primary efficacy results by the end of 2019 as expected.

#### Preparation of the Follow-up study (a second year of injection)

Following the recommendations of the Scientific Advisory Board organized by ASIT biotech in March 2019, the Company is initiating a follow-up study with gp-ASIT+™. This study should include the current patients in the pivotal phase III trial in patients suffering from grass-pollen rhinitis. This follow-up study is a critical step to evaluate the potential long-term benefits of gp-ASIT+™ and build a strategy to achieve a regulatory indication for efficacy beyond a single pollen season.

## **Finalisation of preclinical packages for pnt-ASIT+™ in peanut allergy and hdm-ASIT+™ in house dust mite allergy underway**

The preclinical package of the pnt-ASIT+™ drug candidate is expected to be ready by year end 2019 and the package of the hdm-ASIT+™ drug candidate is expected shortly thereafter, subject to testing results at the Imperial College of London.

### **2.b. Internalization of ASIT biotech's production capabilities**

The Company has designed, built and qualified its internal production capability. An inspection of its production facility by AFMPS has taken place at the end of Q2 2019. The outcome of this inspection is expected in Q4 2019.

If GMP certification is achieved at this in-house facility, the Company will use this capacity to produce active ingredients for clinical application. For the commercial use of gp-ASIT+™, the Company will need to demonstrate the equivalence of these production batches with the active ingredient currently used in our phase III trials and produced by our CMO. These studies will be conducted in the first half of 2020.

### **2.c. Patent situation**

ASIT biotech has a very strong intellectual property portfolio in the allergy immunotherapy space based on the ASIT+ proprietary platform. Currently, the portfolio includes 11 active patent families, granted or under prosecution, covering a broad range of compositions of matter (i.e., a variety of allergens), methods of preparing the compositions, formulations, dosage regimens and uses. Our patent portfolio and all IP-related matters are managed by an external patent counsel working in close collaboration with the Company.

Based on the current IP portfolio, our expectation is that gp-ASIT+™, hdm-ASIT+™ and pnt-ASIT+™ should have patent protection until at least 2027 with some patents already extending to 2032. There may be additional possibilities to extend patent protection (e.g. a supplementary protection certificate) or to receive additional data exclusivity in Europe and the US for biologics; at the appropriate time, the Company will explore such possibilities to maximize IP protection. We regularly monitor all our research efforts in view of possible novel inventions and patent applications.

## **3. FINANCIAL UPDATE**

On June 30, 2019, The Company had a cash position of € 2.5 million. Besides the existing Equity Line, the Company has taken important measures, approved by the Extraordinary General Meeting, to secure the future financing of the Company. The Company has also streamlined its previous warrant plans and has issued new warrant plans for its directors, management and employees.

## Convertible Notes 2018 (Equity Line)

On July 10, 2018, the Company raised € 12 million through a private placement of convertible notes. The net proceeds of this offering were aimed at supporting the clinical development of the product candidates of the Company and especially the second Phase III study in Europe for gp-ASIT+TM.

In this context, the Company issued 240 Convertible Notes 2018 (the CN or CNs) at an issuance price of € 2,500 each and 4,560 subscription rights on convertible notes (the Warrants). The CNs do not bear any coupon and have a maturity date of twelve months from issuance. The CNs are convertible to ordinary shares at CN holders' convenience before maturity or are automatically converted on the maturity date at the Conversion Price. The Conversion Price of the CNs is equal to 92% of the volume-weighted average price over the trading day preceding the CN holder's request of conversion or maturity date, providing that such price may not be lower than € 1.1368, which is higher than the par value of the company's shares, being € 0.78. Upon conversion of the CNs, the new shares issued shall immediately bear the same rights than any other existing shares and may be traded on the Euronext stock exchanges in Brussels and Paris. The Company has the right to redeem the CNs at a price of € 2,600 instead of issuing new shares.

The subscription of one CN gives the right to any subscriber to receive, for free, nineteen Warrants. Each Note can be converted into new shares of the Company. Each Warrant gives the right to subscribe to one new CN at any time during a period of 19 months after their issuance, at an exercise price of € 2,500 per CN. The Company may, however, oblige the holders of Warrants to exercise at least 1 of the 19 Warrants every 30 calendar days. This Company right is however suspended if, and for the duration of, the stock price falls under € 1.1368.

A total of € 12 million has been committed during the offering that took place; payable to the company in 20 equal tranches over a period of 20 months. A total of 240 CNs have been subscribed and a total of 4,560 Warrants have been allocated.

During the first six months of 2019, 812 Warrants were exercised for a total amount of € 2,030,000 and 1,065 CNs were converted resulting in 2,084,663 new shares.

	<u>Equity Line</u> <u>Potential (in €)</u>	<u>Warrants</u> <u>exercised (in €)</u>	<u>Notes</u> <u>converted (in €)</u>	<u>Outstanding</u> <u>CN (in €)</u>	<u>New shares</u> <u>created</u>
<b>At 31/12/18 :</b>	<b>7,800,000</b>	<b>4,200,000</b>	<b>3,337,500</b>	<b>862,500</b>	<b>1,387,056</b>
10 January 2019	7,575,000	225,000	370,000	717,500	243,687
7 February 2019	6,965,000	610,000	895,000	432,500	720,522
7 March 2019	6,910,000	55,000	55,000	432,500	48,380
4 April 2019	6,425,000	485,000	812,500	105,000	654,322
2 May 2019	6,065,000	360,000	167,500	297,500	125,131
6 June 2019	5,770,000	295,000	362,500	230,000	292,621
<b>At 30/06/2019</b>	<b>5,770,000</b>	<b>6,230,000</b>	<b>6,000,000</b>	<b>230,000</b>	<b>3,471,719</b>

On June 30, 2019, there is still an outstanding potential of € 5.8 million. The Equity Line will end in February 2020.

## Warrants 2

The Extraordinary General Meeting of June 28, 2019 decided, with immediate effect, to extend until June 30, 2020 the term of the « warrants 2 » issued by the Company on December 7, 2017 and the period during which they may be exercised, as well as to make them freely transferable.

At the date of this report, 1,091,498 Warrants 2 are still outstanding (representing a total exercise price of € 4,180,437.34 at the price of 3.83 €/share if fully exercised) entitling their holders to participate to subsequent share capital increases for the same amount.

## Convertible Notes 2019

The Extraordinary General Meeting of June 28, 2019 decided to proceed with the issuance of a maximum of 159 nominative Convertible Notes, giving the right to subscribe, under certain conditions, to new shares of the Company, and to set the terms and conditions of the said convertible notes, as described and in accordance with what is provided for in the third report of the board of directors, established in accordance with articles 583 and 596 of the Company Code, and in particular the maturity date of these bonds, i.e. 31 December 2020, and to approve in particular, in accordance with article 556 of the Company Code, the early conversion clause in the event of a change of control of the Company or in the event of a public takeover bid on the Company's shares. We refer to the section Events after June 30, 2019 for more details of the transaction.

## Warrants Plans

The Board of Directors Meeting of June 5, 2019 decided:

- the extension of the exercise period of Warrants, issued by the Company on October 15, 2014 and granted in 2014 and subject to the "2014 Incentive Plan" as well as those granted in 2015 and subject to of the "2015 incentive plan" until June 30, 2020;
- with immediate effect, to cancel 579,999 existing unallocated subscription rights, issued by the Company on June 15, 2018, of which 289,999 were for persons other than members of the Company's staff and 290,000 were for members of the Company's staff;
- the issuance of 641,900 subscription rights giving the right to subscribe, under certain conditions, to new shares of the Company, determination of the terms and conditions of the subscription rights, approval of the related warrants plan (the « Warrants Plan 2019 »).

The Extraordinary General Meeting of June 28, 2019 decided:

- with immediate effect, to cancel 2,549 existing unallocated subscription rights, issued by the Company on October 15, 2014, of which 625 were for persons other than members of the Company's staff and 1,924 were for members of the Company's staff;
- the issuance of 434,240 subscription rights giving the right to subscribe, under certain conditions, to new shares of the Company, determination of the terms and conditions of the subscription rights, approval of the related warrants plan (the « Warrants Plan 2019 »);

- in accordance with article 554, paragraph 7 of the Company Code, to approve the proposal to grant subscription rights to the non-executive directors of the Company to the extent and in accordance with the principles and modalities provided for in the special report of the board of directors and in the Warrants Plan 2019.

## **Interim condensed Statement of financial position under IFRS**

### **Assets**

Total assets as of June 30, 2019 amounted to € 5.9 million to be compared with total assets of € 11.6 million as of December 31, 2018. The decrease is mainly explained by use of cash during the first half of 2019 to support the R&D activities of the Company.

The cash position on June 30, 2019 was € 2.5 million compared to € 8.5 million on December 31, 2018.

The non-current assets of the Company primarily include Property, plant and equipment for € 0.7 million (mainly laboratory equipment), Other long-term receivables for € 1.9 million (mainly the tax-credit relating to the R&D activities) and the Right to use an asset for € 0.1 million.

The other current assets, besides cash and cash equivalents, include Other receivables for € 0.2 million (mainly VAT to be recovered) and Other current assets for € 0.5 million (relating to prepaid expenses).

### **Equity and liabilities**

Shareholders' equity amounted to € 1.6 million as of June 30, 2019 whereas on December 31, 2018 it represented € 6.5 million. The decrease is mainly explained by the loss of the six-month period amounting to € 7.8 million and partially offset by the net proceeds from the Equity Line.

The various capital transactions of the Equity Line were accounted for a total amount of € 2.6 million. As of June 30, 2019, the Company's share capital of € 15,975,578.58 was represented by 20,481,511 shares and the par value (*pair comptable*) remained unchanged at € 0.78.

As for the liabilities, the Company accounted € 2.0 million of Trade Payables (including accrued expenses for € 0.9 million), € 0.8 million of Other Payables (including € 0.7 million with respect to grant received and deferred) and €0.5 million of Financial debt (i.e. the recoverable cash advances from the Walloon Region). There is also a provision of € 0.1 million relating to the ending of the collaboration with the former CEO.

## Interim condensed Statement of Comprehensive Income under IFRS

The Loss for the period was € 7.8 million on June 30, 2019 compared to € 5.4 million on June 30, 2018, an increase of 44%

Both R&D and G&A expenses increased respectively with 54% and 39%. R&D expenses of € 6.9 million increased mainly as a result of an increase in study expenses and G&A expenses of € 1.8 million were mainly due to an increase in payroll and independent contractors.

The major R&D programs of the Company contributed as follows:

- 90 % of expenses were related to gp-ASIT+™, our lead product in grass pollen;
- 6 % of expenses were related to pnt-ASIT+™, and
- 4% of the expenses were related to hdm-ASIT+™.

Most of the expenses of gp-ASIT+™ were related to the ongoing pivotal phase III study ABT-gpASIT011.

The expenses in the first half of 2019 were partially offset by other operating income of € 0.9 million mainly related to the recognition of a research Tax-Credit triggered by R&D expenditures incurred in the first half 2019 (€ 0.3 million) and to a grant-income of (€ 0.5 million for the Food Allergies program).

## Interim condensed Statement of Cash Flows under IFRS

Cash used in operating activities increased from € 4.4 million during the first half of 2018 to € 7.9 million during the first half of 2019, mainly due to the increase in R&D and G&A expenses (see previously).

Cash used in investing activities was limited and reached € 0.1 million during the first half of 2019.

Cash provided by financing activities was € 1.9 million in the first half of 2019 and was mainly related to the net proceeds from the Equity Line.

## 4. PRINCIPAL RISKS AND UNCERTAINTIES

For a detailed description of the risks associated to the activities of the Company, we refer to the Registration Document of July 2019 available on the Company's website.

## **5. OUTLOOK FOR THE SECOND HALF OF 2019**

The Company has important milestones to materialize in the second half of 2019:

- the outcome of the GMP inspection of our in-house production facility is expected in Q4 2019;
- the phase III results of the pivotal study ABT-gpASIT011 of our lead product gp-ASIT+™ in Grass Pollen is expected by end 2019;
- the preclinical package of pnt-ASIT+™ in Peanuts, the first formulation in the food allergy field, is expected by end 2019;
- the acceptance of the protocol of the study on a second-year treatment of the patients (“the follow-up study”) who finished ABT-gpASIT011, which should begin prior to the 2020 pollen season, is expected as well in the second half of 2019;

Besides the above, it is important to highlight that the Company placed the Convertible Notes 2019 for a total amount of € 9.2 million on July 22, 2019. See “Events after June 30, 2019” in Section II.9. for more details.

**II. INTERIM CONDENSED IFRS  
FINANCIAL STATEMENTS FOR THE  
PERIOD ENDED JUNE 30, 2019**

## II. Interim condensed IFRS financial statements for the period ended June 30, 2019

### 1. MAIN FIGURES

#### Interim Condensed Statement of financial position for the period ending on June 30, 2019

EUR '000'

	<u>30/06/2019</u>	<u>31/12/2018</u>
<b>ASSETS</b>		
<b>Non-current assets</b>		
Property, plant and equipment.....	748	810
Right to use an asset.....	98	-
Other long term receivables.....	1,743	1,588
	<u>2,589</u>	<u>2,398</u>
<b>Current assets</b>		
Trade receivables.....	53	-
Other receivables.....	217	280
Other current assets.....	578	418
Cash and cash equivalents.....	2,465	8,458
	<u>3,313</u>	<u>9,156</u>
<b>Total assets</b>	<u>5,902</u>	<u>11,554</u>

	<u>30/06/2019</u>	<u>31/12/2018</u>
<b>EQUITY AND LIABILITIES</b>		
<b>Capital and reserves</b>		
Capital.....	15,976	14,350
Share premium.....	38,070	37,034
Cost of capital increase.....	(2,365)	(2,317)
Share based payment reserve .....	429	344
Specific reserve – convertible notes.....	522	290
Accumulated deficit .....	(51,057)	(43,233)
<b>Total equity attributable to shareholders</b>	<b><u>1,575</u></b>	<b><u>6,468</u></b>
<b>LIABILITIES</b>		
<b>Non-current liabilities</b>		
Financial debt .....	446	465
Leasing debt.....	62	-
Provision .....	132	-
	<b><u>640</u></b>	<b><u>465</u></b>
<b>Current liabilities</b>		
Financial debt .....	38	25
Convertible notes.....	752	1,616
Leasing debt.....	37	-
Trade payables .....	2,032	1,669
Other payables.....	828	1,311
	<b><u>3,687</u></b>	<b><u>4,621</u></b>
<b>Total liabilities</b>	<b><u>4,327</u></b>	<b><u>5,086</u></b>
<b>Total equity and liabilities</b>	<b><u>5,902</u></b>	<b><u>11,554</u></b>

## Interim condensed Statement of Comprehensive Income for the six-month period ending on June 30, 2019

EUR '000'

	<b>30/06/2019</b>	<b>30/06/2018</b>
Revenue .....	-	-
Other operating income / (expense) .....	859	385
Cost of goods sold .....	-	-
Research and development expenses.....	(6,885)	(4,463)
General and administrative expenses .....	(1,783)	(1,280)
<b>Operating loss for the period</b>	<b>(7,809)</b>	<b>(5,356)</b>
Financial income.....	8	2
Financial expense.....	(23)	(22)
<b>Loss for the period before taxes</b>	<b>(7,824)</b>	<b>(5,375)</b>
Taxes.....	-	1
<b>Loss for the period</b>	<b>(7,824)</b>	<b>(5,374)</b>
Other comprehensive income .....	-	-
<b>Comprehensive loss for the period</b>	<b>(7,824)</b>	<b>(5,374)</b>
<b>Loss for the year</b>		
Attributable to shareholders .....	(7,824)	(5,374)
<b>Earnings per share</b>		
(in EUR per share)		
- basic and diluted.....	(0,40)	(0,34)

## Interim Condensed Statement of changes in equity as at June 30, 2019

EUR '000'

	Capital	Share premium	Share-based Payment reserve	Cost of capital increase	Convertible notes reserve	Accumulated deficit	Total equity attributable to the owners of the Company
<b>As at January 1, 2018</b>	<b>9,989</b>	<b>21,957</b>	<b>270</b>	<b>(2,102)</b>	-	<b>(28,915)</b>	<b>1,199</b>
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 June 30, 2018</b>	<b>13,125</b>	<b>34,221</b>	<b>333</b>	<b>(2,340)</b>	-	<b>(34,289)</b>	<b>11,054</b>
<b>As at January 1, 2019</b>	<b>14,350</b>	<b>37,034</b>	<b>344</b>	<b>(2,317)</b>	<b>290</b>	<b>(43,233)</b>	<b>6,468</b>
Conversion of notes	1,626	1,036		(48)	232		2,846
Loss of the period						(7,824)	(7,824)
Share-based payment			85				85
<b>As at June 30, 2019</b>	<b>15,976</b>	<b>38,070</b>	<b>429</b>	<b>(2,365)</b>	<b>522</b>	<b>(51,057)</b>	<b>1,575</b>

## Interim Condensed Statement of cash flows for the six-month period ending on June 30, 2019

EUR '000'

	30/06/2019	30/06/2018
<b>Loss of the period</b>	<b>(7,824)</b>	<b>(5,374)</b>
Adjustments .....		
Tax credit on R&D activities .....	(272)	(174)
Other income - Grant recognised in accordance with IAS 20.....	(460)	
Depreciation on property, plant and equipment & Amortization Right to use an asset.....	167	116
Provisions for risks & charges .....	132	
Loss on disposal of property, plant and equipment .....	-	4
Share-based payments expense.....	85	63
Financial (income) / expense.....	15	19
<b>Changes in working capital</b>		
Trade receivables, other receivables and other current assets.....	(32)	68
Other non-current liabilities, trade payables and other payables.....	339	912
<b>Cash flow from operating activities</b>	<b>(7,851)</b>	<b>(4,365)</b>
<b>Investing activities</b>		
Purchase of property, plant and equipment .....	(86)	(43)
Revenue from current assets.....	4	
(Increase) /Decrease of long-term receivables.....	1	-
<b>Cash flow from investing activities</b>	<b>(81)</b>	<b>(43)</b>
<b>Financing activities</b>		
Capital increase.....		15,400
Costs of capital increase.....	(48)	(238)
Proceeds from issuance of convertible notes (net of transaction costs) .....	2,030	
Cash received with respect to capital increase of July 2018.....		500
Recoverable cash advance received.....		125
Reimbursement of recoverable cash advances.....	(25)	
Reimbursement of leasing debt .....	(21)	
Interests received .....	4	2
Interests paid .....	(1)	(3)
<b>Cash flow from financing activities</b>	<b>1,939</b>	<b>15,787</b>
<b>Net increase / (decrease) in cash and cash equivalents</b>	<b>(5,993)</b>	<b>11,379</b>
<b>Cash and cash equivalents at the beginning of the period</b>	<b>8,458</b>	<b>2,126</b>
<b>Cash and cash equivalents at the end of the period</b>	<b>2,465</b>	<b>13,506</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 investors, by funds from regional and national authorities, by funds collected as a result of the IPO that took place in May 2016, and in 2018 through the issuance of convertible notes. In addition, several grants and recoverable cash advances 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 September 17, 2019 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 December 31, 2018, 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 2018 Financial Statements and detailed in the 2018 annual report.

## **b. Significant accounting policies**

The accounting policies and methods used by the Company in 2019 are consistent with those applied in the December 31, 2018 financial statements.

At the exception of the first-time adoption of IFRS 16 "Leases", 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 January 1, 2019 that have an impact on the preparation of the interim condensed financial statements of the Company.

Application of IFRS 16 *Lease Contracts* is mandatory for the Company as from January 1, 2019. When applying IFRS 16 for the first time, the Company applied the simplified retrospective approach i.e. as if the lease contracts were entered into as at January 1, 2019. As a consequence; no restatement of the comparative figures has been carried out and there is no impact on the opening equity as at January 1, 2019.

The Company does not apply IFRS 16 to lease contracts with a lease term shorter than one year (renewal options considered) and to lease contracts of assets having an insignificant value.

## **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 cash advance (RCA) amounting to € 1.254 million for the development of the house dust mite treatment. K€ 314 were received by the Company in December 2015 and K€ 815 were received in 2016. The balance of K€ 125 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 January 1, 2015 until May 31, 2017 according to last appendix signed on January 17, 2017) for the development of the house dust mite treatment. This cash advance is not bearing any interest. The Company decided in 2017 to further proceed with the development and seek commercialization of the product resulting from the subsidized R&D program. As a result, it has to reimburse 30% of the advance granted (K€ 376 between 2018 and 2027). 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 million 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 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 K€ 250 as of December 31, 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 December 31, 2016 at K€ 181.

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. As at Today, the Company has only to reimburse the fixed part.

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 K€ 121.

As of June 30, 2019, 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% and a re-imbursement of K€ 25 during the first half of 2019 (fixed part).

### **Food allergies cash advance**

The Company was granted on January 12, 2017 a refundable cash advance of about € 6 million from the Walloon Region to finance 55% of its food allergy drug development program. The conditions attached to this grant are in substance similar to the ones for the house-dust mite program as described above, except the fact that the percentage of the royalties to be paid during the exploitation phase is set to 0,11% of the future sales of the related product. The total amount to be paid by the Company to the Walloon Region is capped to twice the amount that the Company will enjoy from the Walloon Region. If the Company decides to exploit the results of the research program currently undertaken, in 2019 and beyond, this would trigger the obligation for the Company to reimburse 30% of the cash advance (and this over a ten-years period). Royalties' payments will only occur if the Company is able to bring the product designed up to commercialization.

With respect to this agreement, it has been considered that no debt had to be recognised as the Company has at this stage no view whether the outcome of the research phase will be fruitful or

not, and whether it will decide to pursue with the exploitation of the results of the research phase or not.

Accordingly, the amount of this cash advance is accounting-wise treated as a government grant in accordance with IAS 20. An amount of K€ 460 has been recognised among other operating income during the first half of 2019.

### **(B) Convertible notes 2018**

In July 2018, the Company raised € 12 million of commitments in a convertible note private placement. The net proceeds of this offering are aimed at supporting the clinical development of the product candidates of the Company and especially the second phase III study in Europe of the product candidate for the treatment of grass pollen rhinitis.

As per this plan, the Convertible Notes (or "CNs") are (or will be) in registered form, denominated € 2,500 each and do not bear any coupon and have a maturity date of twelve months from issuance. The CNs are convertible to ordinary shares at CN holders' convenience before maturity or are automatically converted on the maturity date at the Conversion Price. The Conversion Price of the CNs is equal to 92% of the volume-weighted average price over the trading day preceding the CN 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; being € 0,78. Upon conversion of the CNs, the new shares issued shall immediately bear the same rights than any other existing shares and may be traded on the Euronext stock exchanges in Brussels and Paris. The Company has the right to redeem the CNs at a price of € 2,600 instead of issuing new shares.

Each CN is accompanied by 19 warrants in registered form with a warrant term of 19 months from the initial issue date. Each Warrant entitles the holder to subscribe to one CN and can be exercised at an exercise price of € 2,500 per CN, 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 Warrants every 30 calendar days. A total of € 12 million has been committed during the offering that took place; payable to the company in 20 equal tranches over a period of 20 months.

Considering the fact that the notes will be converted into a variable number of shares, in accordance with IFRS such notes are considered as debt instruments. The different conversion (or non-conversion) features are treated as derivatives and fair valued considering the different variables:

- The estimation of the number of notes that will be ultimately issued considering the fact that if the stock price of the share of the Company is lower than € 1.1368 the note holders are not obliged to subscribe;
- The conversion price of the conversion note, which is equal to 92% of the volume-weighted average price over the trading day preceding the CN holder's request of conversion or maturity date;
- It has been determined adequate to recognize the total fair value of the conversion feature immediately; thus inducing a "Day 1 loss" as the conversion feature of the convertible notes plan allows the note holder to exercise its right to subscribe to notes and to convert them into shares at any moment; but not later than twelve months after issuance of the notes.

The possibility for the Company to redeem the CNs at a price of € 2,600 instead of issuing new shares has no value considering the current business model of the Company as the cash collected through the issuance of the notes is necessary to support the activities of the Company and it is considered that the Company will not make use of this possibility.

As part of this plan, in 2018 the Company supported € 481,480 of transaction costs which have been expensed immediately as financial expense.

When notes are converted into shares; the related portion of the fair value of the conversion features is accounted for in a specific reserve within equity.

In the first half of 2019, 2,492 CNs have been subscribed for a total of € 6.23 million. 2,400 CNs have been converted into ordinary shares of the Company and 92 CNs were still outstanding at June 30, 2019.

#### **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 measurement is 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.

(in EUR 000)

	Carrying amount		Fair value	
	30/06/2019	31/12/2018	30/06/2019	31/12/2018
<b>Financial Assets</b>				
Other long-term receivables	1,861	1,588	1,861	1,588
Trade and other receivables	270	280	270	280
Other current assets	460	418	460	418
Cash and cash equivalents	2,465	8,458	2,465	8,458
<b>Financial liabilities</b>				
Recoverable cash advance	484	490	484	490
Convertible notes	752	1,616	752	1,616
Leasing debt	99	-	99	-
Trade and other payables	2,992	2,980	2,992	2,980

## 6. GOING CONCERN

On June 30, 2019, the Company had a cash position of € 2.5 million.

On July 22, 2019, the Company announced that it successfully placed senior, unsecured Convertible Notes, for a total amount of € 9.2 million, before expenses, from which € 5.0 million has been paid immediately. The remainder of € 4.2 million will be paid upon certain conditions (see Note "Convertible Notes 2019" in Section II.9). Further, the Company has the capacity, under certain conditions, to raise an additional € 5.8 million from the ongoing convertible notes issuance plan (see Note "Convertible Notes 2018 (Equity Line)" in Section I.3.). Lastly, an additional € 4.2 million could be raised if Warrants 2 were exercised (see Note "Warrants 2" in Section I.3.).

In case none of the above financing instruments materialize, the financing gap amounts to € 7.1 million by June 30, 2020. This indicates a material uncertainty that may cast significant doubt on the Company's ability to continue as a going concern and the fact that it may be unable to realize its assets and discharge its liabilities in the normal course of business.

Although there is the possible financing gap of € 7.1 million on June 30, 2020 the Board of Directors is of the opinion that the continuity of the Company is an appropriate assumption, given the current assessment of likely outcome of the ongoing Phase III study in Grass Pollen.

The results of the Phase III study in Grass Pollen with gp-ASIT+™ are expected end of Q4 2019. Positive results will trigger the remaining € 4.2 million to be paid and should provide the opportunity to raise additional capital. Besides this first indication in the respiratory field, the preclinical package of Peanuts with pnt-ASIT+™ (the first formulation in the food allergy field) should also be ready by Q4 2019.

The stock price of the Company at the issuance date of this Interim Financial Report is € 1.27.

This is above the € 1.1368, the minimum conversion price at which the Company can force the Warrant holders to exercise at least 1 of the 19 Warrants every 30 calendar days.

Article 633 of the Belgian Company Code ("BCC") is applicable given the fact that the capital/equity ratio dropped below 50%. In accordance with this code, the Board of directors will take all required measures, including but not limited to, issuing a special report where it will explain why it believes that the going concern is justified, and call a General Shareholders Meeting.

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

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

EUR '000'

	30/06/2019	30/06/2018
Payroll .....	1,297	961
Share-Based Payment .....	69	50
Studies .....	4,712	2,718
Laboratory .....	226	271
Licenses .....	82	97
Rent.....	106	49
Facilities.....	71	77
External services.....	82	42
ICT.....	26	25
Depreciation & amortization .....	132	93
Other .....	82	80
<b>Total Research &amp; Development Expenses</b>	<b>(6,885)</b>	<b>(4,463)</b>
Payroll .....	669	462
Share-Based Payment .....	15	13
Rent.....	36	17
Facilities.....	58	48
External services.....	737	612
ICT.....	9	9
Depreciation & amortization.....	34	23
Provision for risks & charges.....	132	-
Other .....	91	96
<b>Total General &amp; Administrative Expenses</b>	<b>(1,783)</b>	<b>(1,280)</b>

The increase of € 2 million in study costs is mainly explained by the costs of the ongoing Phase III clinical study (over € 3.9 million during the first six months of 2019).

During its meeting of March 22, 2019, the Board of Directors validated an exit indemnity in line with market practice and a valid contract for the former management that will be provisioned in the 2019 financial statements. The total compensation approved by the Board of Directors is K€ 209, of which K€ 77 was already paid in January 2019. In April 2019, Mr. Thierry Legon initiated a

legal procedure against the Company in order to obtain from the latter the payment of a termination indemnity corresponding to two years of remuneration calculated on the basis of the fixed and variable remuneration paid by the Company to Mr. Legon for the last two years before the termination. The Company considers that the amount of such indemnity should be capped at an amount of K€ 209.

## **8. RELATED PARTY TRANSACTIONS**

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

The Company has entered into the following service agreements with companies related to the directors:

- A service agreement executed with YD Advisory & Services SPRL, a company linked to Yves Désiront, relating to services of ad-interim Chief Financial Officer of the Company since January 15, 2019: the consideration for these services is a daily fee of € 1,250;
- A service agreement executed with Cagam Innovative Healthcare Consulting SPRL, a company linked to Michel Baijot, relating to services of Chief Executive Officer of the Company since January 1<sup>st</sup>, 2019: the consideration for these services is an annually fee of € 300,000;

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.

## **9. EVENTS AFTER JUNE 30, 2019**

### **Convertible Notes 2019**

Following the resolution of the Shareholder's meeting of June 28, 2019; the Company announced on July 22, 2019 that it successfully placed senior, unsecured Convertible Notes, for a total amount of € 9.225 million via a private placement.

The Notes are divided into two parts:

- The first part (€ 5.025 million) is paid-up at issuance to cover the cash needs to the end of 2019, corresponding to the outcome and first results of the Phase III study with **gp-ASIT+™**. The conversion will take place upon publication of all satisfactory primary endpoints from this ongoing Phase III study (ABT-gpASIT011) with a conversion premium of 15%, and at a conversion price of € 1.2680 per share (corresponding to the VWAP over the 30 trading days preceding the February 22, 2019 Board of Directors meeting to which a discount has been added);

- The second part (€ 4.2 million) shall be paid-up upon publication of all satisfactory primary endpoints from this ongoing Phase III study. Conversion will take place with a conversion premium of 25%, and at a conversion price equivalent to the issue price of the new ordinary shares of the Company issued in the context of a capital raising to be closed in 2020;
- The maturity date of the convertible notes is December 31, 2020 and the notes bear an interest rate of 3% per annum;
- The new shares will have a lock-up period of 6 months.

## Convertible Notes 2018 (Equity Line)

### *Exercise of Warrants and conversion of CNs*

In the period between June 30, 2019 and the issuance date of this Interim Financial Report, 34 Warrants were exercised for a total amount of € 85,000 and 101 CNs were converted resulting in 221,938 new shares.

	<u>Equity Line</u> <u>Potential (in €)</u>	<u>Warrants</u> <u>exercised (in €)</u>	<u>Notes</u> <u>converted (in €)</u>	<u>Outstanding</u> <u>CN (in €)</u>	<u>New shares</u> <u>created</u>
<b>At 30/06/2019 :</b>	<b>5,770,000</b>	<b>6,230,000</b>	<b>6,000,000</b>	<b>230,000</b>	<b>3,471,719</b>
4 July 2019	5,770,000	0	67,500	162,500	59,202
1 August 2019	5,685,000	85,000	185,000	62,500	162,736
5 September 2019	5,685,000	0	0	62,500	0
<b>At the date of this report</b>	<b>5,685,000</b>	<b>6,315,000</b>	<b>6,252,500</b>	<b>62,500</b>	<b>3,530,921</b>

### **III. RESPONSIBILITY STATEMENT**

## III. 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 June 30, 2019, 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.

**IV. REPORT OF THE STATUTORY  
AUDITORS ON THE LIMITED REVIEW OF  
THE IFRS CONDENSED FINANCIAL  
STATEMENT**

## IV. 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 2019

#### *Introduction*

We have reviewed the *condensed interim financial information* of ASIT BIOTECH SA as of June 30, 2019, 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*

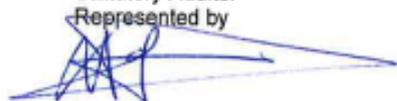
Based on our review, nothing has come to our attention that causes us to believe that the preceding condensed interim financial information is not prepared, in all material respects, in accordance with the international standard IAS 34 - *Interim Financial Reporting* as adopted by the European Union.

#### *Emphasis of matter*

Without modifying the above conclusion, we draw attention to Note 6 Going Concern in the financial statements which describes the conditions of additional fundraising to ensure a sufficient level of cash for a period of at least 12 months from 30 June 2019. This situation indicates the existence of material uncertainty that could cast significant doubt on the Company's ability to continue as a going concern.

Brussels, September 17, 2019

Mazars Réviseurs d'Entreprises SCRL  
Statutory Auditor  
Represented by



Xavier DOYEN

RSM Réviseurs d'Entreprises SCRL  
Statutory Auditor  
represented by



Luis LAPERAL