

Regulated information

ASIT biotech 2017 Annual Results: ongoing ASIT+™ products development in respiratory and food allergies

- Cash position at end-2017 of €2.13 million, reinforced by €9.4 million from the recent private placement
- Reduction in operating expenses in line with the Company's expectations
- Clinical and R&D programs on track with multiple development milestones expected in 2018

Brussels, Belgium, 12 February 2018 - 07:00 am CET - ASIT biotech (ASIT - BE0974289218), a Belgian clinical-stage biopharmaceutical company focused on the research, development and future commercialization of breakthrough immunotherapy products for the treatment of allergies, today announces its annual results¹ for the year 2017, prepared in accordance with the IFRS standards adopted by the European Union, as well as its recent clinical developments and 2018 outlook.

Thierry Legon, CEO of ASIT biotech, says: *"2017 was a pivotal year in terms of both clinical and corporate developments. The first Phase III clinical study with gp-ASIT+™ in grass pollen rhinitis has confirmed, for the first time ever, the clinical efficacy in real life of our proprietary allergenic peptides. This clinical study has also allowed a more complete understanding of the mechanism of action of our peptides. This understanding paves the way for the development of other ASIT+™ therapeutic product candidates for house dust mite and food allergies, indications with even higher unmet medical need. The publications of the clinical data of gp-ASIT+™ in renowned scientific peer-reviewed journals such as Allergy and JACI (Journal of Allergy and Clinical Immunology) confirmed the high quality and the real originality of the results that we have obtained with our first product candidate. ASIT biotech is now focusing all its efforts on maximizing the chances of success of the next Phase III clinical trial with gp-ASIT+™. Site selection would start in late 2018 in order to treat all patients prior to the 2019 grass pollen season. In parallel, we continue the optimization of our second product candidate for house dust mite rhinitis, hdm-ASIT+™ with the objective to start human trials at the beginning of 2019. ASIT biotech also received a €6 million non-diluting financing from the Walloon Region for a very promising food allergy drug development program with the objective to select, by the end of this year, at least one product candidate with an optimal immunogenicity. Finally, the approval received in December from our shareholders to proceed with a refinancing round was a strong mark of confidence that allowed us to successfully complete a €9.4 million private placement at the very beginning of this year, with a potential further funding of €23 million. This strengthened financial structure will enable us to continue the development of all our drug candidates aiming to treat millions of people suffering from allergies."*

¹ Audit in progress

Financial results¹ at 31 December 2017

<i>In thousands of euros - IFRS</i>	31.12.2017	31.12.2016
Revenue	-	-
Other operating income	590	1,667
Research & Development expenses	-10,903	-12,123
General & Administrative expenses	-1,663	-1,822
Operating profit / loss	-11,976	-12,278
Financial income / expense	-9	-60
Tax	-2	-1
Net profit / loss	-11,986	-12,339

Operating income, which totaled €590 thousand, consisted mainly of a recoverable advance of €458 thousand from the Walloon government for the food-ASIT+™ program and research tax credit of €112 thousand.

Operating expenses totaled €12.6 million over the year 2017 (versus €13.9 million at 31 December 2016) given the stabilization of the Company's clinical development. R&D spending, which accounted for 87% of the total operating expenses, was entirely devoted to the development of ASIT biotech's R&D programs and was allocated as follows:

- 70% for the most advanced drug candidate, gp-ASIT+™, for the treatment of grass pollen rhinitis;
- 15% for the second drug candidate, hdm-ASIT+™, for the treatment of house dust mite rhinitis;
- 15% for preclinical activities and the discovery of product candidates for other types of allergies (mainly peanut, cow milk and egg white).

The operating loss over the year ending 31 December 2017 was thus €11.9 million, versus a loss of €12.3 million at 31 December 2016.

Financial structure

ASIT biotech had a net cash position of €2.1 million at 31 December 2017, compared with €13.4 million at 31 December 2016. The €11.2 million cash decrease over the last 12 months was in line with budget and notably the result of:

- Operating cash burn up to €12.3 million
- €400 thousand in working capital increase
- €200 thousand in investments
- €1.7 million received from the Walloon government as recoverable advances

The cash position at 31 December 2017 does not include the proceeds of €9.4 million from the first phase of the private placement, as announced on 25 January 2018. A second subscription phase is currently taking place, allowing the Company to raise additional €2 million.

Furthermore, each newly issued share within the framework of this private placement being coupled with two warrants enabling the holder to subscribe two new shares at the price of €3.83 per share, ASIT biotech has the possibility of raising up to a further €23 million over the upcoming two years.

As of the date of this press release, the audit by the Statutory Auditors of the consolidated financial statements as of 31 December 2017 is in progress. The Statutory Auditors have already indicated that their report would include a supplementary statement recalling the conditions and assumptions set by the Board of Directors, which are subject to the assumption of the business continuity in accordance with Article 144 §7 of the Belgian Company Code.

The annual financial report (regulated information) will be available in the Investors / Documentation section of the Company's website from 18 April 2018.

2018 outlook and upcoming milestones

gp-ASIT+™ in grass pollen allergy

- Preparation of a 2nd Phase III in Europe in adults with site selection in Q4 2018 and first-patient first-visit in Q1 2019
- Pre-IND Meeting with FDA in H2 2018 to agree on the clinical development strategy in the US

hdm-ASIT+™ in house dust mite allergy

- Screening of several product candidates to select one with the best immunogenicity profile for further clinical development in house dust mite allergy:
 - *ex vivo* immunogenicity screening on house dust mite allergic patient blood samples
 - preclinical *in vivo* immunogenicity testing
- Regulatory required preclinical development and IMP² GMP³ manufacturing

food-ASIT+™ in food allergy

- Design, development and screening of several product candidates to select the ones with the best immunogenicity profile for further clinical development in food allergies:
 - *ex vivo* immunogenicity screening on food allergic patient blood samples
 - preclinical *in vivo* immunogenicity testing
- Regulatory required preclinical development and IMP GMP manufacturing for one food allergen

About ASIT biotech

ASIT biotech is a Belgian clinical stage biopharmaceutical company focused on the development and future commercialization of a range of breakthrough immunotherapy products for the treatment of allergies. Thanks to its innovative ASIT+™ technology, ASIT biotech is currently the only developer of AIT product candidates consisting of carefully size selected and qualified natural peptides extracted from highly purified original allergen. This innovation results in a short treatment, expected to improve patient compliance and real-life effectiveness. ASIT biotech's product pipeline entails two novel ASIT+™ product candidates targeting respiratory allergy with the highest prevalence (i.e. grass pollen: gp-ASIT+™ and house dust mite: hdm-ASIT+™), that could significantly expand the current immunotherapy market. The Company believes that its innovative ASIT+™ platform is flexible and would be applicable across a range of allergies.

ASIT biotech has a headcount of 22 staff members, at its headquarters in Brussels and a laboratory in Liège, Belgium.

Further information can be found at www.asitbiotech.com.

² IMP: Investigational Medicinal Products

³ GMP: Good Manufacturing Practice

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