Regulated information
Privileged information

ASIT biotech presents its 2018 half-year results and provides an update on its clinical programs until end-2019

- Cash position at 30 June 2018 of €13.5 million, reinforced by a €12 million convertible bond issued in July
- Reduction in operating expenses leading to the decrease in operating loss (€5.4 million at 30 June 2018 versus 6.8 million at 30 June 2017)
- Clinical and R&D programs on track with multiple development milestones by end-2019:
  - Clinical center selection for the confirmatory phase III trial of gp-ASIT+™ in progress and patients screening expected to start early 2019 in order to complete their treatment prior to the start of the 2019 grass pollen season
  - Preparation of a pre-IND meeting with the FDA to define the U.S. clinical development strategy for gp-ASIT+™
  - First-in-man clinical studies of hdm-ASIT+™ for house dust mite rhinitis and of pnt-ASIT+™ for peanut allergy planned in H2 2019

Brussels, Belgium, 19 September 2018 - 07:00 am CEST - 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 2018 half-year results[1], prepared in accordance with the IFRS standards adopted by the European Union, and provides an update on its R&D and clinical developments.

The 2018 half-year financial report can be downloaded on the website of the Company under the section Investors / Documentation / Financial reports.

Thierry Legon, CEO of ASIT biotech, says: *"The first half of 2018 was notably marked by the reinforcement of our financial structure to support our ambitious development plan in allergy immunotherapy. In the first semester of this year, we have successfully completed a private placement of over €16 million and an additional amount of €4 million could still be raised before December 2019 in the case of execution of warrants issued within the frame of this fundraising approved by the shareholders' meeting of 7 December 2017. In July 2018, the Company issued convertible bonds within the framework of a private placement that had a great success among investors who committed to subscribe for up to €12 million over the next 20 months.*
This flexible financial structure enables us to continue our developments with a priority given to the execution of the confirmatory phase III study of gp-ASIT™, our lead product candidate for patients suffering from grass pollen induced allergic rhinitis. Preparation of this clinical study is almost finished

[1] Half-year financial statements have been the subject of a limited review.

and we expect to start patient screening in Q1 2019 in order to treat all of them before the start of the 2019 pollen season. Thanks to the identification of the original mechanism of action of gp-ASIT™ in our first phase III study, we were able to adapt the selection method of active substances and optimize the profile of our other drug candidates, hdm-ASIT+™ and pnt-ASIT+™, that should enter their first-in-man clinical studies in H2 2019 respectively for house dust mite and peanut allergies."

FINANCIAL RESULTS[1] AT 30 JUNE 2018

In thousands of euros - IFRS	30.06.2018	30.06.2017
Revenue	-	-
Other operating income	**385**	**300**
Research & Development expenses	-4,461	-6,337
General & Administrative expenses	-1,280	-785
Operating profit / loss	**-5,356**	**-6,816**
Financial income / expense	-20	-6
Tax	1	-1
Net profit / loss	**-5,374**	**-6,822**

ASIT biotech recorded no revenue during the first half of 2018, as the Company's product portfolio is still in clinical development. The other operating income of €385 thousand mainly consists of a research tax credit and the balance of the Walloon Region subsidy for the development of the house dust mite treatment.

The operating costs totaled €5.7 million at 30 June 2018 versus €7.1 million at 30 June 2017. Research & Development expenses of €4.5 million accounted for 78% of the total operating cost and were fully devoted to the development of ASIT biotech's R&D programs over the half year.

The operating loss at 30 June 2018 amounted to €5.4 million, versus €6.8 million the previous year.

FINANCIAL STRUCTURE

ASIT biotech's cash position increased to €13.5 million at 30 June 2018, compared with €2.1 million at 31 December 2017. This reinforcement of the cash position results from the capital increases, related to the private placement approved by the Shareholders' Meeting on 7 December 2017, completed over the 1st half of 2018, for a total gross amount of €15.4 million.

Furthermore, in July, the Company raised €12 million in committed capital in the form of a convertible-bond private placement that will be paid in 20 equal tranches over the next 20 months.

UPDATE ON THE R&D PROGRAMS AND OUTLOOK

gp-ASIT+™ product candidate for grass pollen induced allergic rhinitis

- Preparation of the European confirmatory Phase III study in adults (ABT-011) is underway with the screening of patients expected to start early 2019 and the first-patient first-visit planned in Q1 2019.
- Discussions with the U.S. Food and Drug Administration (FDA) are ongoing to define the clinical development of gp-ASIT+™ in the U.S. that should most probably start after the completion of the ABT-011 study.

hdm-ASIT+™ product candidate for house dust mite allergy

- Following the screening of several product candidates, ASIT biotech has selected, in June 2018, a new hdm-ASIT+™ product candidate with an improved immunological profile.
- This new product candidate has been transferred for toxicity study and clinical GMP batches will be manufactured to prepare a phase I/II clinical study to be carried out in H2 2019.

Development in food allergies

- Early June 2018, ASIT biotech selected pnt-ASIT+™, its first product candidate in the domain of food allergies, specifically targeting peanut allergy.
- Regulatory required preclinical development and GMP manufacturing for pnt-ASIT+™ should be performed between H1 2018 and H2 2019.
- A first-in-man clinical study of pnt-ASIT+™ is planned in H2 2019.
- Preclinical development and design of product candidates for allergies on cow milk and egg white will take place in parallel in the Company's Liege Laboratories.

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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 platform, ASIT biotech is currently the only developer of allergy immunotherapy (AIT) product candidates consisting of a unique mixture of highly purified natural allergen fragments in an optimal size selection. This innovation results in a short treatment, expected to improve patient compliance and real-life effectiveness. ASIT biotech's product pipeline contains three novel ASIT+™ product candidates targeting respiratory allergies with the highest prevalence (i.e. grass pollen: gp-ASIT+™ and house dust mite: hdm-ASIT+™), and food allergies (peanut allergy: pnt-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 26 staff members, at its headquarters in Brussels and a laboratory in Liège, Belgium.

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

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