Regulated information

ASIT biotech presents its results for the first half of 2016 and its recent clinical breakthroughs

- Cash position of €19 million at end-June 2016, following the funds raised through its IPO
- Phase 3 clinical trial with gp-ASIT+™, the drug candidate designed to treat grass pollen rhinitis, proceeding in accordance with the roadmap
- Authorization to initiate a phase 2a clinical trial with hdm-ASIT+™, the drug candidate designed to treat house dust mite rhinitis, in Germany
- Launch of regulatory preclinical developments for rag-ASIT+™, the third drug candidate designed to treat ragweed-induced rhinitis

Brussels, Belgium, 23 September 2016 – 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 results for the first half of the year to 30 June 2016[1], prepared in accordance with the IFRS standards adopted by the European Union, as well as its recent clinical developments. The Interim Financial Report (regulated information) is available on the Company's website (Investors / Documentation).

Thierry Legon, CEO of ASIT biotech, comments: "*The Company's first-half results are in line with the execution of the development strategy we presented at the time of our IPO. All of our R&D programs are progressing in accordance with our planned roadmap. Furthermore, we are about to launch preclinical trials on a new drug candidate targeting ragweed-induced rhinitis. With a solid financial structure, highly-committed teams of experts and, henceforth, a portfolio of 3 drug candidates, ASIT biotech has solid assets to enable it to eventually meet the needs of patients who are looking for more efficient allergen immunotherapies that are easier to comply with and whose efficacy in real life is in line with doctors and patients' expectations.*"

Results for the first half of 2016

In thousands of euros - IFRS	30.06.2016	30.06.2015
Revenue	-	3
Other operating income	298	-
Research & Development expenses	(6,757)	(2,573)
General & Administrative expenses	(937)	(621)
Operating profit/loss	**(7,396)**	**(3,190)**
Net profit/loss	**(7,481)**	**(3,187)**

[1] Consolidated first-half accounts have been reviewed by the statutory auditors

ASIT biotech recorded no revenue during the first half of 2016, as the Company is still in the clinical development phase.

R&D spending totaled €6.8 million during the first half of 2016 (versus €2.6 million in the first half of 2015), and accounted for 88% of the Company's operating expenses. This sum was entirely devoted to the development of the Company's R&D programs, and was divided as follows:

- 85% for the most advanced drug candidate, gp-ASIT+™, to treat grass pollen rhinitis;
- 10% for the second drug candidate, hdm-ASIT+™, to treat house dust mite allergies;
- 5% for the discovery of other potential drug candidates for other types of allergies.

Over the six months to 30 June 2016, the Company recorded an operating loss of -€7.4 million, compared with -€3.2 million at 30 June 2015.

Solid financial structure

Over the first 6 months of the year, the Company's financial structure substantially improved thanks to:

- the capital increase resulting from its IPO on the Euronext Brussels and Euronext Paris regulated markets in May 2016;
- the conversion, on 12 May 2016, of €4.1 million of convertibles bonds.

ASIT biotech had a cash position of €19 million at 30 June 2016, versus €4.6 million at 31 December 2015.

The Company also benefited from a repayable advance of a €1.3 million granted in December 2015 by the Walloon Region for the development of the hdm-ASIT+™ drug candidate, of which €940 thousand is still to be gradually received as this program progresses.

Lastly, ASIT biotech should receive €302 thousand in Research Tax Credit booked at 31 December 2015.

Recent clinical and industrial breakthroughs

- gp-ASIT+™: the phase 3 clinical trial is being undertaken in 67 hospitals in 6 European countries (Belgium, the Czech Republic, France, Germany, Italy and Spain); 516 patients received the treatment before the start of the 2016 grass pollen season. These patients were monitored during the summer and no side effects were observed. The final medical visits are currently taking place, and gp-ASIT+™'s efficacy results should be available, as expected, in early 2017.

- hdm-ASIT+™: the Company has received approval from the German health authorities and the Technical University of Dresden's Ethics Committee to launch a phase 2a clinical trial with hdm-ASIT+™. This study aims to evaluate this drug candidate's safety and tolerance profile on some forty patients with an allergy to house dust mites. The study will also assess the impact of hdm-ASIT+™ on the immune system and reactivity to a conjunctival provocation test. The results of this study are expected at the end of 2016.

- New drug candidates: the Company has initiated the preclinical development required by the regulatory authorities of rag-ASIT+™, the third drug candidate from its ASIT+™ technological platform. This new drug candidate targets ragweed-induced rhinitis. Its regulatory preclinical development should be completed by end-2016; production of the first batches in line with Good Manufacturing Practice should begin before the end of this year. The Company is continuing to assess additional drug candidates, notably for food allergies.

- **Grass pollen peptide manufacturing supply chain secured:** as the Company announced in its press release of 21 June 2016, ASIT biotech has completed and secured the industrial process development of the definitive pharmaceutical form of gp-ASIT+™. These products would be suitable for phase 3 clinical trials in the US, as well as for registration purposes in Germany.

Organizational strengthening

In recent months, in order to be ready for the ramping up of its R&D programs, the Company has continued to strengthen its teams with the appointment of two internationally-recognized experts:

- **Dr. Vincent Bille** as Vice President of Manufacturing & Controls;
- **Dr. Mohamed Shamji**, from Imperial College London, as Scientific Advisor for the discovery of new drug candidates and for preclinical activities.

Second-half 2016 prospects and catalysts

ASIT biotech intends to continue the preclinical and clinical development of its drug candidates in accordance with the planned schedule. By the end of this year, the Company should:

- **gp-ASIT+™**:
  - finalize the phase 3 clinical trial currently taking place in Europe with a view to publishing its results during the first quarter of 2017;
  - announce the results of its discussions with the FDA concerning the launch of gp-ASIT+™'s clinical development in the United States;
- **hdm-ASIT+™**: finalize the ongoing phase 2a clinical trial by the end of 2016;
- **rag-ASIT+™**, the new ASIT+^{TM} drug candidate for treating ragweed-induced rhinitis:
  - finalize the preclinical tests required by the regulatory authorities;
  - launch production, in accordance with Good Manufacturing Practice, of the first clinical batches of the active substance and definitive pharmaceutical form.

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About ASIT biotech

ASIT biotech is a Belgian clinical stage biopharmaceutical company focused on the development and future commercialisation of a range of breakthrough immunotherapy products for the treatment of allergies. Thanks to its innovative ASIT+^{TM} technology platform, ASIT biotech is currently the only developer of 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 entails two novel ASIT+™ product candidates targeting respiratory allergy with the highest prevalence (i.e. grass pollen: gp-ASIT+^{TM} and house dust mite: hdm-ASIT+^{TM}), 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.

Contacts

Company
Thierry Legon, CEO
ASIT biotech
Tel. +32 2 264 03 90
investors@asitbiotech.com

Media and Investor Relations - France
NewCap
Dusan Oresansky / Pierre Laurent
Tel.: +33 1 44 71 94 92
asitbiotech@newcap.eu

Media Relations - Belgium
Laure-Eve Monfort
Tel.: +32 2 290 90 93
monfort@comfi.be

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