

Regulated information

Privileged information

ASIT biotech provides clinical update and publishes its 2018 full-year results

- Randomization in the phase III trial of its lead compound, gp-ASIT+™, successfully completed with the anticipated number of patients
- Last patient last treatment visit expected by end of April, on track to deliver primary study results by end-2019
- Planned private placement of convertible notes providing cash runway until Q3 2020, allowing the launch of a follow-up study subsequent to the ongoing phase III study

Brussels, Belgium, April 2, 2019 - 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 2018, prepared in accordance with the IFRS standards adopted by the European Union, and provides business update.

Michel Baijot, CEO of ASIT biotech, says: *“The previous year resulted in fructuous changes and strategic improvements within ASIT biotech. We have decided to focus our resources on our most advanced product candidate in grass pollen rhinitis, gp-ASIT+™, while our two other product candidates for peanut and house dust mite allergies are packaged for partnering. As for the clinical development, we have successfully completed the randomization of the planned number of patients in the confirmatory phase III study with gp-ASIT+™. The study is on track to deliver primary results by end-2019. The planned private placement of convertible notes of €9 to 12 million will reinforce our financial structure and extend our financial visibility until Q3 2020. It will cover our financial needs for both the conduction of our phase III trial and the launch of a follow-up study aiming to enhance the future market position of gp-ASIT+™ in the increasingly attractive field of allergy immunotherapy.”*

Recent developments and 2019 outlook

Recent developments confirm the Company’s new strategy disclosed on February 25, 2019:

Clinical development of gp-ASIT+™ in grass pollen allergy is on track

- The phase III study conducted in Europe in adults is ongoing, with top line results expected by end 2019. The target of randomized patients (first injection of gp-ASIT+ or placebo) was reached before the start of the grass pollen season. Last patient last treatment visit is expected by end of April.
- Following the recent recommendations of Scientific Advisory Boards organized by ASIT biotech, the Company intends to initiate a follow-up study with gp-ASIT+™ in Q2 2019. This study should

¹ Audit in progress

include the patients currently randomized in the phase III trial and contribute to evaluate the long-term benefits of ASIT biotech's subcutaneous immunotherapy in patients suffering from grass-pollen rhinitis.

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

- Preclinical packages of both drug candidates will be completed by mid-2019, allowing the filing of a request for Phase I/II as soon as the Company identifies a partner for co-development and commercialization in major developed markets (United-States & Europe) as well as in important emerging markets such as China, marked by a high prevalence of house dust mite rhinitis.

Financial results¹ at December 31, 2018

<i>In thousands of euros – IFRS</i>	31.12.2018	31.12.2017
Revenue	-	-
Other operating income / expense	570	590
Research & Development expenses	-10,856	-10,903
General & Administrative expenses	-2,481	-1,663
Operating profit / loss	-12,767	-11,976
Financial income / expense	-1,557	-9
Tax	3	-2
Net profit / loss	-14,321	-11,986

Operating income, which totaled €570 thousand, consisted mainly of a recoverable advance of €125 thousand from the Walloon government for the hdm-ASIT+™ program and research tax credit of €443 thousand.

Operating expenses totaled €13.3 million over the year 2018 (versus €12.6 million over 2017) given the stabilization of the Company's clinical development. R&D spending, which accounted for 81% of the total operating expenses, was entirely devoted to the development of ASIT biotech's R&D programs and was allocated as follows:

- 86% for the most advanced drug candidate, gp-ASIT+™, for the treatment of grass pollen rhinitis;
- 5% for the second drug candidate, hdm-ASIT+™, for the treatment of house dust mite rhinitis;
- 9% for preclinical activities and the discovery of product candidates for other types of allergies (mainly peanut).

The operating loss over the year ending December 31, 2018 reached €12.8 million, compared to a loss of €12.0 million the year before.

Financial structure

End of 2018, ASIT biotech presented a cash position of €8.5 million compared with €2.1 million a year before, reflecting:

- a cash consumption of €13.7 million over 2018, including €9.9 million spent on the preparation and launch of the confirmatory phase III study with gp-ASIT+™.
- €4.2 million in gross proceeds from the drawdowns on the equity line including the conversion of warrants attached.
- €16.1 million in gross proceeds from the capital increases over the first quarter of 2018 and the exercise of some of the related warrants.

Taking into account the proceeds of €1.1 million from the existing convertible warrants exercised over the first quarter of 2019 and operating expenses over the period, the cash position as of end of March amounts to € 5.9 million, in line with expectations.

Upon conditional drawdown of the remaining €6.7 million on the equity line, the Board of Directors confirmed that the activities of ASIT biotech are covered until end of Q3 2019. Furthermore, the planned private placement of new convertible notes for a total amount of €9 to 12 million, as disclosed in February, will cover the cash needs until end of Q3 2020.

As of the date of this press release, the audit by the Statutory Auditors of the financial statements as of December 31, 2018 is in progress. The Statutory Auditors have already indicated that their report shall include a separate section under the Heading "Material uncertainty related to the going concern". The annual financial report (regulated information) will be available in the Investors / Documentation section of the Company's website from April 26, 2019.

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+™ - in ongoing phase III - 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 its facilities in Liège, Belgium.

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

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