

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

- Cash position of €2.5 million as of 30 June 2019, reinforced in July 2019 by the private placement of Convertible Notes for a total amount of € 9.2 million out of which € 5.0 million was paid immediately
- Cash burn of €6.0 million in the first half of 2019 mainly linked to the ongoing gp-ASIT+TM pivotal phase III trial, on track to deliver top-line results in December 2019

Brussels, Belgium, 18 September 2019, 07.00 am (CEST) – ASIT biotech (ASIT - BE0974289218), a clinical stage biopharmaceutical company focused on the research, development and future commercialization of breakthrough allergy immunotherapy products, today announces its 2019 half-year results, and provides an update on its R&D, clinical and commercial developments.

- The Company continues to execute its focused product development strategy.
- As of 30 June 2019, the Company had a cash position of €2.5 million.
- Cash burn of €6.0 million in the first half of 2019 mainly linked to the ongoing gp-ASIT+TM pivotal phase III trial, on track to deliver top-line results in December 2019
- The treatment phase of the pivotal phase III clinical study with gp-ASIT+TM in grass pollen rhinitis was completed for all patients, well in time for the grass pollen season, with no major safety concerns.
- The Company continues to make steady progress towards internalizing manufacturing capabilities.

Significant events after June 30, 2019

- The Company announced on 22 July 2019 that it successfully placed senior, unsecured Convertible Notes, for a total amount of € 9.225 million via private placement.
- On 5 September 2019, the Company announced that following the successful pollen season it remains on track for Phase III top-line results of gp-ASIT+™ in December 2019.

The 2019 half-year financial report can be downloaded on the website of the Company under the section Investors / Documentation / Financial reports.

Michel Baijot, CEO of ASIT biotech, says: "The strategic change initiated at the end of 2018 has led to an increased focus on the commercialization of our lead asset, gp-ASIT+TM, for the treatment of allergic grass pollen rhinitis. We have now treated all 651 patients in our pivotal clinical study for gp-ASIT+TM, with no major safety issues and primary endpoints results are expected by year end 2019. I confirm we are on track. Subject to the outcome of this study, the company is well-poised to initiate market registration activities in Europe. The Company also continues to make great strides to strengthen her commercial capabilities to support a successful market entry."

FINANCIAL RESULTS AS OF 30 JUNE 2019

In thousands of euros - IFRS	30.06.2019	30.06.2018
Revenue	-	-
Other Operating Income	859	385
Research & Development Expenses	-6,885	-4,463

¹ Half year financial statements have been subject to a limited review

General & Administrative Expenses	-1,783	-1,280
Operating profit / loss	-7,809	-5,356
Financial income / expense	-15	-20
Tax	-	1
Net profit / loss	-7,824	-5,374

ASIT biotech recorded no revenue during the first half of 2019, as the Company's product portfolio remains in clinical development. The other operating income of €859 thousand mainly consists of tax credits on R&D activities and grant income.

The operating costs amounted to €8.7 million as of 30 June 2019 versus €5.7 million as of 30 June 2018. Both R&D and G&A expenses increased by 54% and 39% respectively. R&D expenses of €6.9 million increased mainly as a result of clinical trial costs and G&A expenses of €1.8 million were mainly due to an increase in payroll and independent contractors.

The operating loss as of 30 June 2019 amounted to €7.8 million, versus €5.4 million the previous year.

FINANCIAL STRUCTURE

On 30 June 2019 the Company had a cash position of €2.5 million. In addition to 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 announced on 22 July 2019 that it successfully placed senior, unsecured Convertible Notes, for a total amount of €9.225 million via private placement. The Company has also streamlined its previous warrant plans and issued new warrant plans for its directors, management and employees.

UPDATE ON R&D PROGRAMS

The Company intends to do a follow-up study with gp-ASIT+TM to evaluate the long-term benefits of gp-ASIT+TM and build a strategy to achieve a regulatory indication for efficacy beyond a single pollen season. The Company expects the preclinical package of the pnt-ASIT+TM drug candidate for peanut allergy to be ready by year end. The preclinical package of the hdm-ASIT+TM drug candidate for house dust mite allergy is expected shortly thereafter, subject to testing results at the Imperial College of London. The Company intends to be ready to clinically develop, co-develop or partner these assets when and if needed.

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.

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

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Forward-looking statements

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