EDISON

ASIT biotech

Initiation of coverage

New generation of allergy immunotherapy

Pharma & biotech

ASIT biotech is an allergy immunotherapy (AIT) discovery and development company leveraging its proprietary ASIT+ platform. The lead product, gp-ASIT+ for grass pollen allergy, has already been tested in a Phase III trial. Although the study missed the predefined percentage difference in primary efficacy endpoint between placebo and the treatment group, a statistically significant reduction in allergy severity was demonstrated in the study. Having learnt the lessons and been encouraged by the opinion of the German regulatory authority, ASIT is now recharging for a confirmatory Phase III trial. Our valuation is €119.6m or €7.3/share.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/17	0.0	(12.0)	(0.9)	0.0	N/A	N/A
12/18e	0.0	(11.8)	(0.8)	0.0	N/A	N/A
12/19e	0.0	(12.3)	(0.8)	0.0	N/A	N/A
12/20e	10.4	(5.3)	(0.2)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles and exceptional items.

Preparing confirmatory Phase III with gp-ASIT+

In February 2017, ASIT presented the results of BTT009, its most advanced multi-centre Phase III clinical study (n=554) evaluating the clinical efficacy of gp-ASIT+. Depending on the analyses used, the improvement in defined clinical score reached statistical significance with 15% (at peak allergy season) to 21% (over entire pollen season) reduction compared to placebo. However, the study missed the predefined average 20% difference in the scores between placebo and the treatment group over the peak season (primary endpoint) due to several confounding factors, including a weak pollen season. ASIT received scientific advice from the German regulator, the Paul-Ehrlich Institute, and is now preparing for the redesigned confirmatory Phase III study, planned to start in late 2018.

Allergy immunotherapy: Unique and large market

ASIT biotech has several other assets developed using its proprietary ASIT+ platform with second lead product hdm-ASIT+ for house dust mite and several other preclinical projects for food allergies. The global allergic rhinitis immunotherapy market can be uniquely characterised by a vast patient population and a substantial unmet need due to cumbersome existing AITs, which cause very low compliance rates. ASIT believes its core technology will shorten the AIT from several years of monthly to daily dosing to just four visits over a three-week treatment course ahead of the allergy season. Potential upside can come from developing AIT for food allergies, where there are no other options other than avoiding the allergen.

Valuation: rNPV of €119.6m or €7.3/share

We value ASIT biotech at €119.6m or €7.3share using a risk-adjusted NPV model. We base this on the two lead assets (gp-ASIT+ and hdm-ASIT+) and also include the potential peanut allergy product. Our model projects cash reach into 2019. The company expects to deliver the confirmatory Phase III gp-ASIT+ data readout in late 2019, which should provide a significant share price catalyst.

29 May 2018

Price	**€3.42**
Market cap	**€56m**
Net cash (€m) at end-Q417 + share issue of €13.9m	15.6
Shares in issue	16.5m
Free float	53%
Code	ASIT
Primary exchange	Euronext Brussels
Secondary exchange	Euronext Paris

Share price performance

%	1m	3m	12m
Abs	(4.4)	(21.2)	(45.4)
Rel (local)	(2.4)	(17.9)	(44.5)
52-week high/low		€6.5	€3.2

Business description

ASIT biotech is a clinical-stage company focused on the development of therapies for allergies. The company's products are based on the proprietary ASIT+ technology platform, which allows the development of products containing highly purified allergen fragments in an adjuvant-free formulation, selected to be safe while maintaining the capacity to stimulate the immune system. The lead product is gp-ASIT+ for allergic rhinitis.

Next events

Start of confirmatory Phase III with gp-ASIT+	Q418
hdm-ASIT+ and food-ASIT+ product preclinical update	2018

Analysts

Andy Smith +44 (0)20 3077 5700
Jonas Peciulis +44 (0)20 3077 5728
Alice Nettleton +44 (0)20 3681 2527

healthcare@edisongroup.com
Edison profile page

Investment summary

Company description: Immunotherapies for allergy

ASIT biotech (formerly Biotech Tools) was founded in 1997 and is based in Liège, Belgium. It completed its listing on Euronext Brussels and Euronext Paris in May 2016, raising €23.5m in gross proceeds. Its pipeline is based on the proprietary ASIT+ technology platform, which allows the development of products containing highly purified allergen fragments in an adjuvant-free formulation, selected to be safe while maintaining the capacity to stimulate the immune system. Its products aim to overcome the current limitations of AIT, ie the long and cumbersome treatment that results in low compliance rates. Its products have the potential to significantly reduce the number of doctor visits, improving the patient's quality of life and providing better efficiency for healthcare systems. ASIT's lead products are gp-ASIT+ for moderate-to-severe allergic rhinitis, hdm-ASIT+ for house dust mite allergy and food-ASIT+, a preclinical-stage project for various food allergies.

Exhibit 1: Pipeline overview

Product	Indication	Phase	Comments
gp-ASIT+	Grass pollen rhinitis	Phase III	Completed first Phase III trial. To start an EU Phase III trial in Q418.
hdm-ASIT+	Dust mite allergy	Phase I/II	Selection of new ASIT+ active components. Start Phase IIb in Q119.
food-ASIT+	Peanut, egg white, cow's milk	Preclinical	Selection of ASIT+ active components. Start Phase I/II trial in Q119.

Source: Edison Investment Research, ASIT biotech

Valuation: rNPV of €119.6m or €7.3/share

Our ASIT valuation is €119.6m or €7.3/share using an rNPV, which also includes net cash of €15.6m at end-Q417 (with recent fund-raise). Our model includes three of ASIT's projects: gp-ASIT+ for allergic rhinitis caused by grass pollen, hdm-ASIT+ for allergic rhinitis caused by house dust mite and food-ASIT+ for peanut allergy. We have used conservative assumptions on the addressable patient populations, potential market shares for ASIT's products, comparable pricing, clinical costs ultimately adjusting the calculated cash flow for historical clinical trial success rates. We assume ASIT will market itself in Europe, while finding partners for the US and China markets.

Financials: Phase III trial with gp-ASIT+ funded

ASIT reported an operating loss of €12.0m for FY17 (€12.3m, FY16), mainly due to the previous Phase III study. R&D expenses were €10.9m vs €12.1m a year ago. 2017 G&A costs were €1.7m vs €1.8m in FY16. Our total operating expense estimates are €11.9m in 2018 and €12.3m in 2019, with R&D costs staying at a similar level to 2017. ASIT recently completed a two-part fund-raising in February 2018 of €13.9m including €2.4m from a warrant exercise, and excluding a potential further €20.6m from possible future warrant exercise. We expect a cash positon of €4.7m by end-2018 and our model implies a €7.6m cash requirement in 2019. ASIT expects to deliver the Phase III gp-ASIT+ data readout in late 2019, which should provide a significant catalyst for the share price.

Sensitivities: R&D risk dominates in near term

ASIT is an innovative product developer. Value creation depends on successful R&D, clinical progress and any potential partnering activities. R&D risk is balanced across the ASIT+ platform: gp-ASIT+, hdm-ASIT+ assets and other indications in preclinical stage, such as peanut allergy. Although data from the first Phase III trial fell short of being sufficient for gp-ASIT+ registration, we see signs of potential efficacy and take into account ASIT's insights on how to improve chances of successful outcome in the upcoming study. The severity of the next pollen season is a key factor and has confounded the registration effects of others, as implied by a meta-analysis of 50 SLIT clinical studies where 22 failed to report or prevented calculation of the relative clinical impact. On the other hand, there are no seasonal effects known with other indications that would benefit from the ASIT+ platform, and their R&D risk may be lower.

Allergy 101 and high public burden

Allergy can be defined as excessive sensitivity of the immune system to certain substances, and the presentation can vary significantly from minor local reactions to systemic anaphylaxis that can be lethal. This and high global prevalence make allergy one of the top public health issues. From the pathophysiological perspective the mechanism of an allergic reaction is similar for different allergens. This process typically requires previous exposure to the allergen, which triggers the production of anti-allergen IgE antibodies. After repeated exposure the IgE-mediated allergic reaction involves bridging of at least two IgE molecules on the surface of granulocytes (mast cells or basophils). This results in the degranulation of the cells and release of inflammatory chemicals such as histamine, which is responsible for the symptoms of an allergic reaction (Exhibit 3A).

Exhibit 2: Allergy basics

What is allergy?	Allergy results when the immune system, designed to fight and protect against disease, mistakenly recognises a harmless substance (an allergen) as a threat, triggering an immune response. On exposure to an allergen, an allergic patient's immune system will overreact to attack the allergen. This immune response leads to the allergic reaction, which can range from sneezing and itchy eyes (for example from hayfever) through to life-threatening anaphylaxis often associated with certain food allergies.
What are the most common allergies?	Common allergens are pollens, house dust mites, pets, fungal or mould spores, food (particularly milk, eggs, wheat, soya, seafood, fruit and nuts), bee's stings, some medicines and household chemicals. More than one-third of allergic patients are sensitive to several allergens. Peanut allergy is one of the most severe food allergies causing serious and sometimes fatal reactions.
How is allergy treated?	Respiratory allergy sufferers can treat the symptoms with antihistamines, nasal sprays and corticosteroids. However, food allergies sufferers have no pharmaceutical treatment options. Instead, patients must avoid the allergen and in severe cases are advised to carry an adrenaline pen (EpiPen) in case of accidental exposure.
What is allergy immunotherapy?	Allergy immunotherapy can be used to treat moderate to severe cases and aims to treat the underlying condition by desensitising the immune system via repeated exposure to small, controlled concentrations of the allergen. Allergy immunotherapy is available as injections (SCIT, subcutaneous immunotherapy), drops under the tongue (SLIT, sublingual immunotherapy) and as tablets.

Source: Edison Investment Research

Current treatments for allergy are largely symptomatic, offering temporary relief of symptoms; for instance, antihistamines that block the action of histamine responsible for the hypersensitivity reactions like sneezing and itching. Symptomatic therapies also include non-specific immunosuppressants like steroids, leukotriene modifiers that have anti-inflammatory action and anti-IgE antibodies, such as Xolair (omalizumab, Roche), which neutralise the action of IgE antibodies. Symptomatic treatment effects are usually short-lived and the drugs have to be used continuously during the exposure to the allergen. This often results in development of side effects, deterioration of compliance and quality of life.

Targeting the root cause of disease with AIT

AIT is the only treatment that addresses the root cause of the disease and can provide long-term relief. Often called desensitisation therapy, the treatment involves administration of the allergen to build the immune system's tolerance to it. Immunotherapy treatment usually begins with the administration of a low allergen dose to avoid allergic reaction. The dose is then escalated until an effective maintenance dose is reached and then given around every month for a long period of time (2-5 years). AIT is considered an effective therapy, but the cost-effectiveness can vary significantly between countries[1] with no way of prospectively predicting the outcome. The established AIT technology is either subcutaneous immunotherapy (SCIT) or sublingual immunotherapy (SLIT) (drops or tablets):

- SCIT requires repeated injections over a long period of time: typically, an initial course of two injections twice a week for up to six months (escalation phase) and then monthly injections for up to three to five years.
- SLIT involves even more doses and is less effective than SCIT. The typical treatment regime is daily dosing for at least six months to three to five years.

1 https://www.eaaci.org/documents/EAACI-ICON-AIT.pdf

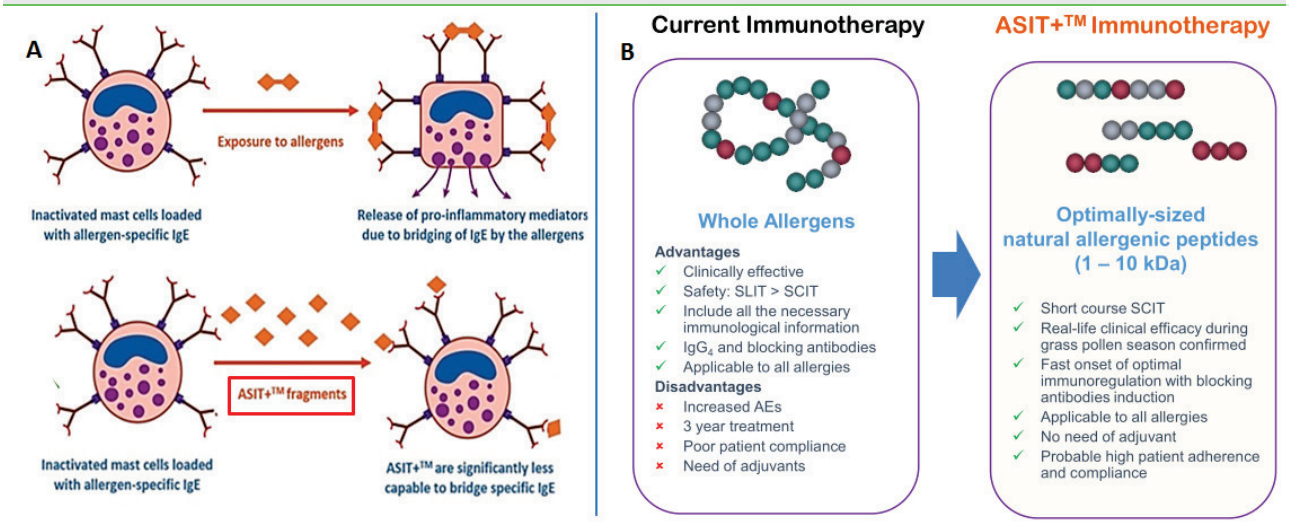
Because of the risk of systemic allergic reactions, the AIT dose of whole natural allergens is low, therefore the treatment period is long with repeated dosing and commuting to the allergy centre (in the case of SCIT). This results in low compliance for both options. A recent study by Musa et al found a 59% compliance rate among patients on SCIT and 12% among those on SLIT after three years of treatment. Consequently, according to ASIT, only about half of eligible patients are willing to endure such a lengthy treatment.

Differentiated ASIT+ platform for multiple applications

The company's ASIT+ technology platform allows the development, characterisation, manufacturing and quality control of highly purified natural allergen peptide fragments to be used as active pharmaceutical ingredients. The adjuvant-free formulation of the final product is intended to improve the safety profile, while maintaining the capacity to stimulate immune tolerance to the allergen to which the patient is hypersensitive.

An allergic reaction is triggered when allergens bridge the granulocyte-bound IgE antibodies, which leads to cell degranulation. Current AIT uses whole allergens extracted from various sources (pollens, foods, dusts, etc) or obtained via recombinant techniques, therefore the AIT needs to start at a very low dose during the escalation phase to avoid triggering allergic reaction. ASIT's technology revolves around purified natural allergens that have been broken down into optimal size fragments to lower the capacity to bridge IgE on mast cells (Exhibit 3). Based on existing data for its lead product gp-ASIT+, the company believes that its technology platform can be used to design novel AIT products for a variety of allergies, including for food allergies.

Exhibit 3: ASIT+ technology platform and advantages over conventional AIT



Source: ASIT biotech

ASIT's lead product candidates target widespread respiratory allergies (grass pollen and house dust mite), while preclinical-stage projects include potential products targeting food allergies. The most advanced product candidate, gp-ASIT+, is for grass pollen. Based on the existing data, ASIT's technology potentially has multiple advantages over conventional AIT:

- The treatment duration is expected to be short. Only four treatment visits over a three-week course before the start of pollen season are expected to be sufficient for gp-ASIT+.
- Given the small size of peptides, the risk of worsening the allergy is reduced, therefore improving the safety profile.

- ASIT's product will likely not include any adjuvants, further increasing safety and compliance. Conventional AITs use adjuvants such as aluminium to reduce the number of injections.
- The treatment effect is expected to last for at least one allergy season.

gp-ASIT+: Gearing for second European Phase III trial

gp-ASIT+ consists of a mixture of natural small allergen fragments from purified protein extract from *Lolium perenne* pollen. Allergic rhinitis is a common inflammatory condition affecting the upper airways with conjunctivitis also often present. The condition is widespread, affecting around 400 million people globally. The most frequent allergens in European allergic rhinitis patients are grass pollen (c 60%), house dust mite (c 50%), tree pollen (c 40%), weed pollen (c 30%), animal dander (c 30%) and mould spores (10%). In the US the most frequent allergens are grass pollen (c 55%), ragweed (c 50%), house dust mite (45%) and tree pollen (c 20%). A patient can be sensitive to several allergens.

In February 2017, ASIT presented the results of BTT009, its most advanced multi-centre Phase III clinical study evaluating the clinical efficacy of gp-ASIT+. The study randomised 554 patients with grass pollen-induced rhinoconjunctivitis with or without controlled asthma (ratio of 1:2) to receive once-weekly injections of placebo or increasing doses of gp-ASIT+, reaching the cumulative dose of 170µg in three weeks. The **primary endpoint** was a statistically significant reduction (predefined at 20%) in the combined clinical symptoms and medication score (CSMS) over placebo over the peak of pollen season after treatment. The CSMS consists of six individual scores for nasal and conjunctival symptoms and three scores for concomitant medication, as recommended by the task force of the EAACI Immunotherapy Interest Group. The symptoms and the use of medicines were documented in a diary. The symptom score can be 0, none; 1, mild; 2, moderate; and 3, severe.

Depending on analyses used, the improvement in CSMS reached statistical significance with 15% (at peak) to 21% (over the entire pollen season) reduction compared to placebo. However, the study missed the predefined absolute average 20% difference in CSMS between placebo and the treatment group over the peak season.

Exhibit 4: Analysis of the primary endpoint

Period	Population	Results
Peak period	With imputation* (n=400)	**15.5% reduction. (p<0.05)** with non-parametric test; trend but not significant with parametric test.
	Observed cases** (n=310)	15.7% reduction; not significant with neither test.
Entire pollen season	With imputation* (n=296)	**17.9% reduction. (p<0.05)** with non-parametric test; not significant with parametric test.
	Observed cases** (n=159)	21.1% reduction; not significant with neither test.

Source: Edison Investment Research, ASIT biotech. Note: *With imputation includes observed cases and patients, which had a limited number of data missing. This allows the statistical analysis to be run on a larger sample of patients when data are missing. Epub: Allergy. 2018 Mar 7. **Observed cases = patients who have provided data for all the days of the considered period.

These data compare with Allergy Therapeutics' 1,028-patient G301 study with Pollinex Quattro Grass, which showed 13.6% improvement in CSMS (p=0.0038) on an intention to treat (ITT) basis (n=514 active, 514 placebo) and 24.3% improvement (p=0.0031) in the subgroup with a complete dataset (n=177 active, 166 placebo).

The **secondary endpoint** was reduction in reactivity to the conjunctival provocation test (CPT). CPT decreased significantly in 60.0% of patients treated with gp-ASIT+ compared with 35.6% in the placebo group (p<0.0001, Chi-square test). In a patient subgroup with the highest CPT reactivity at baseline (reactivity scores 3 and 4), which represented more than half of all Phase III patients, the symptomatic improvement compared to placebo reached 20% during the peak pollen period (p=0.05) and 24% over the entire season (p=0.05); CPT reactivity observed at baseline was predictive of later clinical response.

In terms of **safety**, systemic allergic reactions (SARs) were assessed according to the World Allergy Organization grading system. Each grade is based on organ system involvement and severity, from 1 to 5. There were 16.6% grade 1 in the active arm (vs 4.5% in placebo), 5.2% grade 2 SAR (0.6% placebo), 0.3% grade 3 and 4 (0% placebo). There were no grade 5 SARs in either arm.

We view the data as encouraging and believe there is a potential treatment effect. However, the magnitude of this effect will have to be proven in the confirmatory Phase III trial. One explanation put forward by ASIT is that the trial was conducted during an atypical, mild pollen season, which contributed to the mixed results (one very short peak pollen season and discrepancies in pollen counts between centres). This variability in the natural seasonal challenge to allergic patients is part of the risk of conducting clinical trials in allergy and, for example, influenza. In the past, even effective influenza vaccines have failed in clinical studies because a mild influenza season resulted in so few cases of confirmed influenza that the active and placebo arms could not be statistically separated.

Next steps: Confirmatory Phase III study

ASIT received scientific advice from the German regulator, the Paul-Ehrlich Institute, which considered the results supportive and requested an additional pivotal study for registration in Germany. ASIT is currently preparing to start a second Phase III trial in Q418 aimed at registration in Germany, then subsequently in other EU countries. If successful, Germany could act as reference member state for a marketing authorisation application (MAA) registration in other EU countries.

ASIT has taken a number of steps to ensure the confirmatory Phase III study is designed to maximise the probability of success:

- For example, when recruitment was lagging the expected target in the previous Phase III study, a very large number of patients were recruited in a single study site in Germany in the hope that the grass pollen season there would pick up. Unfortunately, it did not. To prevent this happening again in the next Phase III, each study site will be restricted in the number of patients that can be enrolled.
- A higher number of clinical centres will be opened. The BTT009 trial was conducted in 57 centres in six countries, while the confirmatory Phase III trial will be carried out in 80 centres in seven countries. The trial sites will be selected in regions with a good history of high pollen rates.
- The study will seek to enrol the most allergic patients. Various measures will be put in place to engage with the patients, such as electronic diary.
- The entire study will be subcontracted to a single contract research organisation (CRO) experienced in allergy studies.

The trial (BTT011) will start screening patients in Q418 to start dosing before the pollen season from January to mid-March 2019. Presuming positive data, the company expects to file an MAA in Germany in H120.

Exhibit 5: Confirmatory BTT011 Phase III trial

Main aspects	Comments
Study design	Randomised, double-blind, placebo controlled, international multi-centric.
Number of patients	600
Treatment schedule	Four visits over three consecutive weeks. After the treatment period, three follow-up visits should be planned before, during and after the pollen season.
Changes since first study	▪ More selective inclusion criteria with more allergic patients and more homogeneous population. The highly reactive patient group improved its CSMS score by up to 24% in the BTT009 trial.
	▪ More centres: 80 centres in seven countries (vs 57 centres in six countries before); maximum number of patients per centre limited to avoid overrepresentation of few centres and local pollen conditions. Faster recruitment.
	▪ Use of one CRO vendor specialised in clinical trials in respiratory disorders.
	▪ Use of an electronic diary (eDiary) to limit the number of missing data.

Source: ASIT biotech

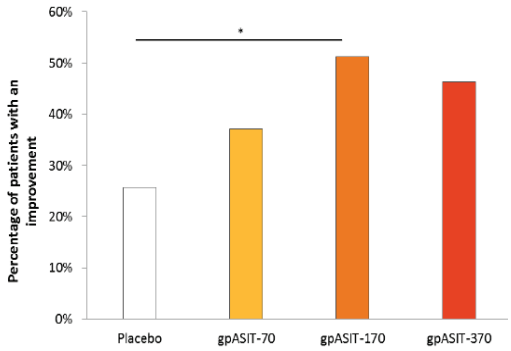
Phase II data showed potential for gp-ASIT+

ASIT biotech ran the BTT008 Phase IIb clinical trial with the objective of establishing the dose with the best safety/efficacy ratio for Phase III testing. This was a double-blind, placebo-controlled, dose-finding study in 21 centres in Germany. The primary objective was to assess the clinical effect as measured by the change in CPT reactivity of treated patients in comparison to placebo and three different cumulative doses of subcutaneous gp-ASIT+ in adult patients with grass pollen-induced allergic rhinoconjunctivitis. The secondary objectives were to assess the impact of gp-ASIT+ on the immunological status of the patients in comparison with placebo, as well as to assess the safety and clinical tolerability of gp-ASIT+. The study randomised 198 grass pollen-allergic adults to receive placebo or cumulative doses of 70µg, 170µg or 370µg of gp-ASIT+.

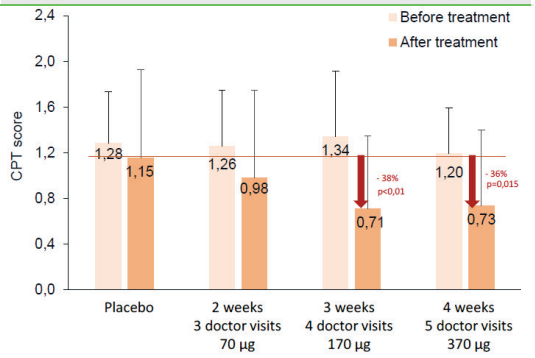
After completion of five visits, 51.2% (170µg: p=0.023), 46.3% (370µg, non-statistically significant), and 38.6% (70µg, non-statistically significant) of patients receiving gp-ASIT+ vs 25.6% of patients receiving placebo had an improvement of CPT. This was a modified per-protocol set of patients (mPPS); the overall ITT data have not been disclosed. CPT was used as the primary endpoint in Allergy Therapeutics' recent dose-finding study.

Exhibit 6: Phase IIb main results

Percentage of patients with an improvement to CPT after five treatment visits vs baseline (mPPS)



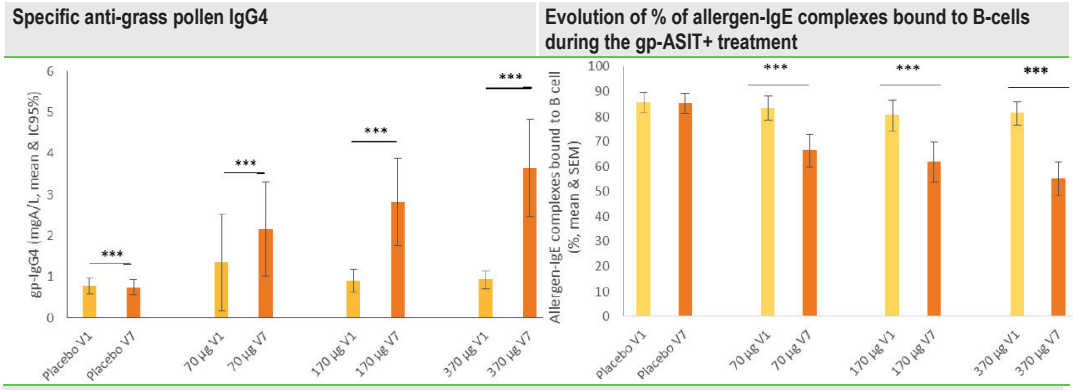
Evolution of CPT score (mPP)



Source: ASIT biotech. Published in Allergy. 2018 Apr; 73(4):896-904

In another Phase IIa trial, gp-ASIT+ demonstrated it was able to induce tolerance by generating grass pollen-specific IgG_4 antibodies in a dose-dependent manner. In particular, specific IgG_4 increased 1.6x, 3.1x and 3.9x in the patients who received 70µg, 170µg and 370µg of gp-ASIT+, respectively ($p<0.001$, Wilcoxon test). The percentage of B-cells binding IgE/allergen complexes is considered a marker of a good desensitisation process and its decline indicates a more subdued allergic reaction. In the Phase IIa trial, it decreased by 17% after a two-week treatment, by 19% after a three-week treatment and by 26% after a four-week treatment, all statistically significant ($p<0.001$) as shown in Exhibit 7.

Exhibit 7: Phase IIa results



Source: ASIT biotech. Note: *** p<0.001. Published in Allergy 2018; 1–9.

While gp-ASIT+ has shown a dose response in terms of immunology, statistically significant clinical protection seems to require the 170µg dose with some interference in dose response at 370µg. The achieved doses seemed to be safe.

Leveraging the platform for other allergies

As mentioned, ASIT's platform can be used to develop AIT for various allergies. Besides grass pollen the company is also focusing on house dust mite (second lead asset, Phase IIb ready) and food allergies (preclinical). There is also no theoretical reason why an effective component of a SCIT cannot be used in a SLIT product.

hdm-ASIT+ for house dust mite allergy

hdm-ASIT+ consists in a mixture of optimally sized natural peptides obtained from the purified allergen extracted from the house dust mite (*Dermatophagoides pteronyssinus).* This product is expected to have similar properties to gp-ASIT+, hence it is advantageous over conventional HDM AITs which, as for grass pollen, are based on whole allergens. ASIT completed an exploratory Phase I/IIa study that randomised 36 patients (27 to hdm-ASIT+ and nine to placebo) in 2016/17. It showed a good safety and tolerability profile of hdm-ASIT+ and no serious or unexpected, adverse treatment-related events, even at the highest allergen dose of 200µg. Therefore the primary endpoint of the study was reached. However, there was no difference in the secondary endpoint of laboratory investigations, particularly in immunogenicity parameters between the treated group and the placebo group. The study was of limited size and therefore not powered to show statistical significance. In addition, a substantial placebo response has been observed. ASIT is now selecting a more potent prototype from the ongoing preclinical studies and plans to restart a Phase I/II development in Q119.

food-ASIT+: Peanut allergy likely first choice

While still at an early preclinical stage, peanut allergy is an indication with a high unmet need and commercial potential given that in some cases it can be a life-threatening condition. Other food sensitivities on top of the company's list are cow's milk and egg white allergies. There are no approved immunotherapy treatments for food allergies and the only available option is food allergen avoidance. This situation developed partly due to high risk of serious systemic reactions observed in previous attempts to develop AIT for food allergies. Given that ASIT's platform is built on fragmented allergens to reduce the risk of the AIT worsening the allergy, the rationale for food allergies is potentially very attractive. Over the next six to 12 months ASIT plans to select potential

product candidates for peanut, cow's milk and egg white allergies, likely prioritising peanut with a first-in-man trial in H119.

Peanut allergy is one of the most severe food allergies causing serious and sometimes fatal reactions. It is estimated that it affects around 1.4% of children in the US, up from 1.2% in 2002 and from 0.6% in 1997.[2] There are around 30,000 emergency room visits for food allergy per year in the US, with around 200 deaths. Research suggests that around 74% of children and 44% of adults in the US seek treatment for their peanut allergy.[3]

Unique AIT market: Seeking paradigm shift

According to multiple sources (EvaluatePharma, GlobalData, key players in the field and ASIT's own commissioned market research), around 4.7 million people globally are estimated to be receiving AIT treatment, while around 50 million people are eligible. Global AIT sales in 2017 were projected to be $1.2bn. The European AIT market was valued at c $884m with 1.4 million patients receiving treatment; Germany and France comprise two-thirds of the European market. SCIT formulations account for the majority of the sales (55%) globally, with SLIT drops (40%) and SLIT tablets (6%) following.

Slow change in regulatory landscape

The global market is dominated by SCIT formulations marketed under named patient product (NPP) status, which represents the majority (90%) of the global sales. From a regulatory perspective SCIT treatments are rather unique among other therapies. NPPs are typically allergen extracts for which formal efficacy studies have never been performed. The decision to prescribe NPPs as a treatment, rather than any other therapy is made by the allergists in consultation with the patients. The EU Medicinal Products Directive was expected to result in regulatory change since it defined AIT treatments as classical medicinal products requiring marketing authorisation and supported by a fully documented safety and efficacy file. However, technically the directive is not applicable to medicinal products prepared in a pharmacy on a named product basis and many member states still allow AITs to be marketed as NPPs without the need for an MAA, which would require exhaustive data packages.

A historically less-structured pharmacovigilance environment with AITs has resulted in scepticism in some countries about safety and efficacy, and lack of reimbursement, for example in the UK. Germany, on the other hand, is one of the most advanced countries in terms of the acceptance of reimbursement and use of AITs. It has made progressive regulatory efforts and increasingly requires fully documented application for AIT products, although some of the products are still being sold as NPPs. Germany constitutes the larger market share of AIT globally (c 40%) with France (c 30%), Spain (10%) and Italy (10%) following. Other European countries are also moving away from AIT treatments marketed as NPPs, for example by limiting reimbursement. This potentially could result in lower availability of NPP AITs and ASIT believes it could present an opportunity for AIT products with marketing authorisation supported by full safety/efficacy data. Such AITs should also be preferred by payers and other stakeholders like patients and physicians due to documented safety and efficacy. So far only SLIT tablets have been granted marketing authorisations. First introduced in 2006, SLIT tablets (Grazax for grass pollen, ALK-Abello) were once envisioned as a paradigm-changing formulation due to perceived convenience. However, still long treatment times

[2] US prevalence of self-reported peanut, tree nut, and sesame allergy: 11-year follow-up. Sicherer SH, Muñoz-Furlong A, Godbold JH, Sampson HA. J Allergy Clin Immunol. 2010 Jun;125(6):1322-6.

[3] Prevalence of peanut and tree nut allergy in the United States determined by means of a random digit dial telephone survey: a five-year follow-up study. Sicherer SH, Muñoz-Furlong A, Sampson HA. J Allergy Clin Immunol. 2003 Dec;112(6):1203-7.

and diminished efficacy hindered more widespread use and SCIT formulations remain the most popular AIT.

The US market mainly consists of NPP SCIT therapies compounded by allergists in their office-based practices using allergens purchased from suppliers at relatively low prices ('homebrew'), rather than FDA-approved drugs. These treatments represent an economic incentive for office-based physicians, with payments for both the drug compounding and the administration over many doses. In addition, the compounded therapies tend to include more than one allergen if the patient has multiple allergies. Such polysensitisation is somewhat unique to the US market and further hindered the acceptance of single allergen formulations such as SLIT drops/tablets. As a result, US AIT product sales (excluding allergist services) are estimated at just c $194m, with three million people receiving treatment. The FDA has also approved four SLIT tablets: two grass pollen allergy tablets, Oralair (Stallergenes Greer) and Grastek (ALK-Abello); a short ragweed allergy tablet, Ragwitek; and Odactra for dust mite allergies (both from ALK-Abello). Sales have not been strong because of a preference for subcutaneous homebrew treatments. When an FDA-approved SCIT product becomes available in the US, the value of the market would be expected to increase as the US moves from a market valued on the purchase of homebrew allergen components to one based on regulated pharmaceutical pricing.

We believe a new and efficacious therapy approved by the FDA (via a biologics licence application) could compete with the established compounded competition, not the least because reimbursement becomes more difficult for compounded drugs with an FDA-approved alternative. If approved and marketed, gp-ASIT+ may have higher patient compliance given the familiarity of SCIT treatments, particularly in the US, and the much greater convenience of the shorter four-dose course. Given the unique aspects of the US market (homebrew formulations and polysensitisation), ASIT plans to position its products not as a substitute to classical SCIT therapy, but rather as a complement to it, primarily targeting those patients who refuse to commit to years of therapy (around 50% of all patients who are offered the treatment according to ASIT) or those who drop out (also around 50% of those who start it).

The main players in the global AIT market are ALK-Abello (FY17 AIT sales of DKK2.45bn; 35% share) and Stallergenes Greer (FY17 AIT sales of €250m; c 30% market share). ALK-Abello's sales of SCIT and SLIT drops were DKK1.9bn and sales of SLIT tablets were DKK0.53bn in 2017. Overall, 76% of sales came from Europe, 21% from North America and 3% from other international markets. Stallergenes Greer markets SLIT Actair tablets for house dust mite allergy and Oralair for grass pollen allergy, with combined FY17 sales of €30.5m. SLIT Staloral drops for allergic rhinitis and allergic asthma reported FY17 sales of €125.5m. Sales of SCIT products were €70.4m in 2017. Most sales come from Europe (58.7%), followed by the US (33.8%) and international markets (7.5%). The most advanced competitor is Allergy Therapeutics' Pollinex Quattro Grass, an allergy vaccine marketed in Europe as an NPP. It has been tested in the recently announced Phase II G205 clinical trial, which provided an optimal dose for the pivotal Phase III programme for registration in the US and Europe.

Sensitivities

ASIT biotech is an innovative product developer. For the foreseeable future value creation will therefore depend on successful R&D, clinical progress and any potential partnering activities. The near-term R&D sensitivities are balanced across the ASIT+ platform: gp-ASIT+, hdm-ASIT+ and other indication in preclinical stage, such as peanut allergy. Although the data from the first Phase III trial fell short of being sufficient for the registration of gp-ASIT+, we see signs of potential efficacy and take into account the company's insights on how to improve the chances of successful outcome in the upcoming study. Admittedly, the severity of the next pollen season is still one of the key factors. In our valuation model, we have assumed risk-adjusted clinical trial success, self-

marketing of gp-ASIT+ in Europe and licensing in other countries. The type and terms of ASIT's licensing deals are discussed in our valuation section, but there is currently low visibility of what terms could actually be achieved. We have assumed further funding rounds before ASIT reaches break-even. Our valuation is based on our estimates for price and penetration, which we believe are reasonable. Unknown future pricing dynamics could lead to a lower price than we currently assume.

Valuation

We value ASIT Biotech based on a risk-adjusted NPV using a 12.5% discount rate, including €15.6m net cash estimated at end-Q118. This results in a value of €119.6 or €7.3/share. We value three of ASIT's projects (see Exhibits 9 and 10 for assumptions and valuation):

- gp-ASIT+ for allergic rhinitis caused by grass pollen;
- hdm-ASIT+ for allergic rhinitis caused by house dust mite; and
- food-ASIT+ for peanut allergy.

ASIT's **strategy** is to develop all three products internally, and to market them in Europe with a focus on Germany. The company plans to license the commercialisation rights for US and Chinese markets. We forecast sales for Europe (EU5), US and China for gp-ASIT+ and hdm-ASIT+, with licensing deals for US and China. For food-ASIT+ (peanut) we forecast Europe (EU5) and US, with a licensing deal for US.

Competitors in the AIT field have also licensed rights for markets outside Europe (ALK-Abello, Allergy Therapeutics and Stallergenes Greer). For example ALK has entered into many agreements to market its AIT SLIT-tablets worldwide, including with Schering-Plough in 2007 (now Merck) for US rights to grass (Grastek), ragweed and house dust mite SLIT tablets, Torii in Japan for house dust mite and Japanese cedar SLIT tablets, Eddingpharm in China, Abbott in selected emerging markets, Menarini in selected European countries and CSL in Australia and New Zealand. Allergy Therapeutics, another competitor in AIT, has also entered into several development, commercialisation and distribution agreements for its Pollinex Quattro product range. Partners include Paladin Labs, Nycomed, Ergomed and AllerPharma. Stallergenes Greer also licensed Japanese and Taiwanese rights for its Actair product to Shionogi, and Canadian rights to Paladin Labs.

Deal terms are based on two comparable AIT deals (sourced from EvaluatePharma) shown in Exhibit 8. A comparable corticosteroid deal is included for context. We use the two AIT deals when considering our deal terms, so take $35m upfront and $155 for sales milestones (average of $120m and $190m) and assumed a conservative 10% flat royalty rate. This is used for each individual product deal in the US, and for China deal for hdm-ASIT+. According to our model, gp-ASIT+ in China has low peak sales ($10m). Therefore any China deal is likely to be of a relatively low value so for valuation purposes we include the China deal as part of the US deal. No peanut allergy deals with financials disclosed were found, so this deal was also used for a US licensing deal in the peanut indication. We have modelled individual deals for valuation purposes but in reality a deal could include more than one product and/or geography. We have assumed a conservative probability of a late-stage licensing deal (60%).

We assume a prevalence of allergic rhinitis (hay fever) in the US population caused by grass pollen allergy c 26m in US 2018 (c 45m or 14% have allergic rhinitis,[4] of which c 56% have grass pollen allergy). The prevalence of allergic rhinitis in Europe is slightly higher than US at 18% of

[4] http://www.worldallergy.org/UserFiles/file/WhiteBook2-2013-v8.pdf

population,[5] of which c 60% have grass pollen allergy.[6] The prevalence of allergic rhinitis in China is c 11%, but the prevalence of grass pollen allergy in China is thought to be very low at c 1% of the total population which is much lower than US and Europe. House dust mite allergy has similar prevalence rates to grass pollen in US and Europe: 45% of allergic rhinitis cases in US and 52.5% in Europe. Again there is a lack of literature for China so we take the midpoint between US and Europe % of allergic rhinitis patients (58.75%).

For both grass pollen and house dust mite allergy, AIT is recommended for patients who have failed first and second line treatments (ie antihistamines or corticosteroids), which leaves c 10% (estimates range from 10% to 25%) of patients that are eligible for AIT treatment. Currently, the AIT market is only reaching a small proportion of the eligible population. We assume this is 30% (although estimates range from 30% to 40%) of the eligible patients in the US and 20% in Europe (where estimates range from 20% to 30%), but to be conservative we assume a 10% penetration (15% in Europe) to the current market rather than the addressable market. In the US we assume the product is sold via a licensee and in Europe that it will be by direct sales). Note that if a less frequently dosed AIT were available, the addressable market could expand and penetration into this larger market would be lower. We have used a more conservative view of the AIT market due to the fact that the sales of AIT treatments have been flat. However, in using the most conservative estimates of the eligible population and market shares in the first instance, we recognise that significant upsides could exist. While we have assumed a 10% eligible patient population, the range of estimates is from 10% (ours) to 24% of patients seeking treatment then failing or not being well-controlled by earlier lines of therapy. Furthermore, our market estimates of 769,000 patients in the US and 691,000 in the EU may be higher if a shorter-course, more effective approved drug was available. In that latter case, a higher proportion of the patients who have a positive grass pollen skin prick test could comprise a larger addressable population.

If successful, a four-dose course of an approved treatment (ASIT's and others) would capture both existing patients and expand the current market. This is the most obvious and perhaps the easiest challenge to our conservative assumptions of market size and share. China is not currently a major market for AIT and has lower access to healthcare, so we assume a lower current market than US and EU (assume only 5% of eligible patients are currently treated with AIT). We also assume peak penetration into the current market of 30% (via a licensee).

Current pricing for gp-ASIT+ and hdm-ASIT+ is assumed to be around $2,000 per patient per year in US, €750 in EU and much lower in China (we assume €250). This is more in line with the available SLIT treatments, rather than the SCIT treatments which are priced lower. This is because we believe that the short course treatments such as ASIT's products may be able to command a higher price per patient per year than existing SCIT treatments. Our pricing assumptions for gp-ASIT+ and hdm-ASIT+ are not aggressive, partly because of the variability in reimbursement and the inclination of national (European, and US commercial) payers to shift the burden of a non-fatal indication onto the self-pay market. We assume a higher price for peanut of $4,500 per patient per year in US, and €3,150 in EU (70% of US price). This is because peanut allergy, unlike grass pollen allergy in almost all cases, can be a life-threatening condition.

For peanut allergy, two age groups are considered: <15 years and 15-55 years. Aimmune's PALISADE trial only includes patients up to the age of 55. Prevalence of peanut allergy in US and Europe in <15 years is c 1.2% and in 15-55 is c 0.5%.[7] In 2018 this results in c 740k and one million patients respectively in both US and Europe, or a total of 1.7 million patients. We assume

[5] http://www.worldallergy.org/UserFiles/file/WhiteBook2-2013-v8.pdf; https://www.ncbi.nlm.nih.gov/pubmed/15516669

[6] Bauchau V & Durham SR. Prevalence and rate of diagnosis of allergic rhinitis in Europe. Eur Respir J. 2004 Nov 24 (5):758-64

[7] https://www.jacionline.org/article/S0091-6749(10)00575-0/abstract

the addressable market is the patient group carrying an EpiPen, since these patients are at risk of an anaphylactic reaction and so more severe and likely eligible for AIT (c 50% of patients). We assume a conservative 15% peak penetration into the addressable population for US and Europe due to more clinically advanced competitors DBV Technologies and Aimmune. We currently only include the US and Europe in our model, because ASIT has not detailed a China strategy for peanut.

We assume an SG&A cost of 30% of sales and a COGS of 10% of sales. This COGS is lower than competitors; ALK-Abello reported a 43.57% COGS in 2017, and Allergy Therapeutics reported a 26.2% COGS in 2017 (source: Bloomberg).

Exhibit 8: Comparable AIT deals

Date	Licensor	Licensee	Product(s) and indication(s)	Pharmacological class	Upfront ($m)	Regulatory and commercial milestones ($m)	Rights
31/10/2013	Stallergenes	Greer	Oralair for the treatment of Grass pollen allergy (5 grasses)	Sublingual immunotherapy tablet	Undisclosed	120	Exclusive commercialisation in US (product under review by FDA)
28/01/2008	Nycomed	Sepracor	OMNARIS AQ Nasal Spray for the treatment of allergic rhinitis ALVESCO HFA Inhalation Aerosol for the treatment of asthma	Corticosteroid	150 (includes both products)	280 (includes both products)	Exclusive commercialisation in US (product approved)
03/01/2007	ALK-Abello	Schering-Plough	Tablet based immunotherapy (SLIT) tablets against grass pollen allergy (GRAZAX), house dust mite allergy and ragweed allergy	Sublingual immunotherapy tablet	35	255 (65 clinical and regulatory/190 sales)	Development and commercialisation in US, Canada and Mexico (product in clinical stages)

Source: Edison Investment Research, EvaluatePharma, company press releases

Exhibit 9: Sum-of-the-parts ASIT biotech valuation

Product	Launch	Peak sales ($m)	Unrisked NPV (€m)	Unrisked NPV/share (€)	Probability (%)	Licensing transaction probability (%)	rNPV (€m)	rNPV/ share (€)
gp-ASIT+ – allergic rhinitis caused by grass pollen EU	2022	139	155.8	9.5	50	100	74.3	4.5
gp-ASIT+ – allergic rhinitis caused by grass pollen ex-EU	2024	264	88.6	5.4	50	60	17.3	1.1
hdm-ASIT+ – house dust mite allergy	2026	373	142.1	8.6	10	60	5.7	0.3
food-ASIT+ – peanut allergy	2027	1,448	376.2	22.8	5	60	6.7	0.4
Estimated net cash at end-Q118 +fund-raise of €13.9m			15.6	0.9	100		15.6	0.9
Valuation			**778.2**	**47.2**			**119.6**	**7.3**

Source: Edison Investment Research. Note: WACC = 12.5% for product valuations

Exhibit 10: Assumptions for R&D projects

Product/stage/indication	Comments
gp-ASIT+ Phase III Allergic rhinitis caused by grass pollen	Treated population US: Prevalence of AR (grass pollen) in the US c 26m in US 2018 (14% prevalence of allergic rhinitis,[8] of which c 56% grass pollen allergy), growth rate of US population. c 10% eligible for AIT treatment, or 5m patients. Current market addressing 30% (769k patients), which is at the top of addressable market estimated, but with a low 10% penetration into current market (via licensee), six years to peak sales. Treated population Europe (EU5): Prevalence of AR in Europe 18% of population,[9] of which c 60% have grass pollen allergy[10] = c 58m in 2018, growth rate of EU5 population. 10% eligible for AIT = c 3.5m patients, of which 20% (which is at the low end of estimates) are currently treated with AIT (691k). We temper this with a low (15%) peak penetration into the current market (market directly), six years to peak sales. Treated population China Prevalence of AR caused by grass pollen allergy in China c 1% = c 14m AR patients in 2018, growth rate of China population. 10% eligible for AIT = 1.4m patients. Assume 5% currently treated with AIT, or 70k patients. Peak penetration into current market 30% (via licensee) six years to reach peak sales. Pricing: $2,000 per patient per year in US, €750 in EU and much lower in China (we assume €250). Assumed 2.5% annual price increase. R&D cost: Phase III costs $13m (split across three years), and assume $2m for regulatory submission costs.[11] Rights: last patent expires in 2032,[12] but 12 years' data exclusivity due to biologic in US and 11 in Europe. Launch dates: Europe in 2022, US and China 2024. Licensing deals: US deals on approval (includes China), $35m upfront, $155 in sales milestones, 10% flat royalty rate. Probability 60% Ex-EU, (100% EU since self-marketing)
hdm-ASIT+ Phase I House dust mite allergy	Treated population US: US prevalence of AR x 45% house dust mite allergy x 10% eligible for AIT x 10% current market = 206k patients in 2018 (although estimates range up to 30% or 618k), growth rate of US population. 30% peak penetration (higher prevalence rates are associated with a 10% peak penetration) into the current market (via licensee), six years to peak sales. Treated population Europe (EU5): Europe prevalence of AR x 52.5% house dust mite allergy[13] x 10% eligible for AIT x 10% (although estimates range up to 20%) current market = 300k (or 600k at higher estimates) patients 2018, growth rate of EU5 population. 30% (or 15% at higher prevalence rates) peak penetration into current market (market directly), six years to peak sales. Treated population China: China prevalence of AR 11%[14] x proportion of house dust mite allergy (midpoint of US and Europe 58.75%) x 10% eligible for AIT x 5% current market. 30% peak penetration into current market (via licensee), six years to peak sales. Pricing: $2,000 per patient per year in US, €750 in EU and €250 in China with 2.5% annual price increase R&D cost: $1.1m for new Phase I split across 2 years (assume same number of patients as for previous Phase I = 36 * $30k per patient); $10m for Phase II split across 2 years and $13m for Phase III split across 3 years (same as gp-ASIT+). Rights: last patent expires in 2032,[15] but 12 years data exclusivity due to biologic in US and 11 in Europe. Launch dates: Europe and US in 2026, China in 2029. Licensing deals: US and China deals on approval, $35m upfront, $155 in sales milestones, 10% flat royalty rate. Probability 30% (estimates could be up to 60% ex-EU).
food-ASIT+ (peanut) Soon to start Phase I (currently in product candidate selection) Peanut allergy	Treated population US: Prevalence of peanut allergy in <15 years is c 1.2% and in 15-55 is c 0.5%.[16] In 2018 this results in a total of 1.7m patients, growth rate of US population. c50% (880k) patients with an EpiPen. 15% peak penetration (via licensee), six years to peak sales. Treated population Europe (EU5): Same prevalence as US. In 2018 this results in c 740k and 1m patients respectively, or a total of 1.7m, growth rate of EU5 population. C 50% (880k) patients carry an EpiPen. 15% peak penetration (market directly), six years to peak sales. Pricing: $4,500 per patient per year in US, €3,150 in EU (70% of US price) with 2.5% annual price increase. R&D cost: Assume same costs as hdm-ASIT+ Rights: last patent expires in 2032,[17] but 12 years data exclusivity due to biologic in US and 11 in Europe. Launch dates: Europe and US 2027. Licensing deals: US deal, $35m upfront, $155 in sales milestones, 10% flat royalty rate. Deal occurs on approval. Probability 60%

Source: Edison Investment Research. Notes: AR = allergic rhinitis

[8] http://www.worldallergy.org/UserFiles/file/WhiteBook2-2013-v8.pdf

[9] http://www.worldallergy.org/UserFiles/file/WhiteBook2-2013-v8.pdf; https://www.ncbi.nlm.nih.gov/pubmed/15516669

[10] Bauchau V & Durham SR. Prevalence and rate of diagnosis of allergic rhinitis in Europe. Eur Respir J. 2004 Nov 24 (5):758-64

[11] PhRMA report 2015

[12] ASIT biotech Annual report 2017 p81 "protection until at least 2027 (for both gp- and hdm-ASIT+'s most relevant patents, that are BTT04 (expiration date 2027) and BTT07 (expiration date 2032)"

[13] Bauchau V & Durham SR. Prevalence and rate of diagnosis of allergic rhinitis in Europe. Eur Respir J. 2004 Nov 24 (5):758-64

[14] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5721020/pdf/jtd-09-11-4607.pdf

[15] ASIT biotech Annual report 2017 p81 "protection until at least 2027 (for both gp- and hdm-ASIT+'s most relevant patents, that are BTT04 (expiration date 2027) and BTT07 (expiration date 2032)"

[16] https://www.jacionline.org/article/S0091-6749(10)00575-0/abstract

[17] ASIT biotech Annual report 2017 p81 "protection until at least 2027 (for both gp- and hdm-ASIT+'s most relevant patents, that are BTT04 (expiration date 2027) and BTT07 (expiration date 2032)"

Financials

ASIT reported an operating loss of €12.0m for FY17 (€12.3m in FY16), mainly due to the previous Phase III study and regulatory interactions. Consequently, R&D expenses were €10.9m vs €12.1m in the previous year. G&A costs were €1.7m vs €1.8m in FY16. Our total operating expense estimates are €11.9m for 2018 and €12.3m for 2019, with R&D costs remaining at a similar level as in 2017.

As an early-stage biotech company, ASIT biotech has reported losses since inception. The company recently completed a two-part fund-raising in February 2018 of €13.9m including €2.4m from warrant exercise, and excluding a potential further €20.6m from possible future warrant exercise. At end December 2017, ASIT reported a cash balance of €2.1m, which has now been bolstered by the recent raises. We expect a cash positon of €4.7m by end-2018 and our model implies €7.6m cash requirement in 2019. The company expects to deliver the Phase III gp-ASIT+ data readout in late 2019, which should provide a significant catalyst for the share price.

ASIT reported total gross debt of €466k at the end of 2017. This is a refundable subsidy payable to the Walloon Region of Belgium, which funded the house dust mite and food allergy programmes, and is repayable under certain circumstances. These are expected to be the registration and first sales of the company's hdm-ASIT+ and peanut allergy products.

Exhibit 11: Financial summary

€'000s	2015	2016	2017	2018e	2019e	2020e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
INCOME STATEMENT						
Revenue	4	0	0	0	0	10,351
Cost of Sales	(3)	0	0	0	0	0
Gross Profit	1	0	0	0	0	10,351
General and Administrative Expenses	(947)	(1,822)	(1,676)	(1,659)	(1,643)	(1,626)
Research and Development Expenses	(6,691)	(12,123)	(10,903)	(10,903)	(11,361)	(14,293)
Other Operating Income	(3)	1,667	604	634	666	699
Reported operating profit	(7,640)	(12,278)	(11,975)	(11,928)	(12,337)	(4,869)
Net Interest	(75)	(60)	(9)	104	10	(416)
Profit before tax (reported)	(7,715)	(12,338)	(11,984)	(11,824)	(12,327)	(5,285)
Reported tax	0	(1)	(2)	(2)	2	1,586
Profit after tax (reported)	(7,715)	(12,339)	(11,986)	(11,826)	(12,325)	(3,700)
Minority interests	0	0	0	0	0	0
Net income (reported)	(7,715)	(12,339)	(11,986)	(11,826)	(12,325)	(3,700)
Basic average number of shares outstanding	8,504	11,219	12,806	15,526	16,432	16,432
EPS - basic reported (€)	(0.91)	(1.10)	(0.94)	(0.76)	(0.75)	(0.23)
Dividend (€)	0.00	0.00	0.00	0.00	0.00	0.00
BALANCE SHEET						
Non-current Assets	506	1,770	1,837	1,886	1,931	1,825
Property Plant and equipment, net	494	736	691	740	785	679
Other intangible assets	0	0	0	0	0	0
Other non-current Assets	12	1,034	1,146	1,146	1,146	1,146
Current Assets	4,968	13,785	2,448	5,037	322	(2,851)
Cash and cash equivalents	4,621	13,387	2,126	4,715	0	(3,173)
Accounts receivable	2	3	0	0	0	0
Inventories	11	0	0	0	0	0
Other current assets	334	395	322	322	322	322
Current Liabilities	6,332	2,004	2,654	3,218	3,282	3,703
Accounts payable	1,611	1,707	1,264	1,828	1,892	2,313
Short term debt and borrowings	4,232	12	34	34	34	34
Other current liabilities	489	285	1,356	1,356	1,356	1,356
Non-current Liabilities	0	419	432	432	8,023	8,023
Loans and borrowings	0	419	432	432	8,023	8,023
Other non-current liabilities	0	0	0	0	0	0
Equity	(858)	13,132	1,199	3,273	(9,052)	(12,751)
Common stock / Capital	11,625	17,506	9,989	13,615	13,615	13,615
Additional paid-in capital / Share premium	0	21,957	21,957	20,405	8,080	4,380
Other reserves and surplus	(12,483)	(24,229)	(28,645)	(28,645)	(28,645)	(28,645)
Other Equity	0	(2,102)	(2,102)	(2,102)	(2,102)	(2,102)
CASH FLOW						
Cash Flow from Operations						
Net income (loss)	(7,715)	(12,339)	(11,986)	(11,826)	(12,325)	(3,700)
Depreciation and Amortization	80	141	205	189	202	203
Interest income/expense	75	60	9	(104)	(10)	416
Stock-based compensation	18	0	54	0	0	0
Non Cash Adjustments	0	11	(492)	0	0	0
(Increase) decrease in inventories	3	0	0	0	0	0
(Increase) decrease in trade receivables	(819)	(62)	74	0	0	0
(Increase) decrease in other current assets	0	(1,016)	(112)	0	0	0
Increase (decrease) in trade payables	751	(492)	(586)	564	64	421
Net cash used in Operating activities	(7,606)	(13,697)	(12,834)	(11,177)	(12,069)	(2,659)
Cash Flow from Investing						
Purchases of fixed assets	(372)	(383)	(161)	(239)	(247)	(97)
Other Investing Activities	1	(6)	0	0	0	0
Net cash used in Investing activities	(371)	(389)	(161)	(239)	(247)	(97)
Cash Flow from Financing						
Change in Debt	4,130	0	0	0	7,591	0
Change in Capital Stock	0	22,199	0	13,900	0	0
Interest paid	(6)	(204)	(10)	(23)	(23)	(403)
Other Financing Activities	33	857	1,743	128	34	(14)
Net cash used in Financing activities	4,157	22,852	1,733	14,004	7,601	(416)
Net Changes in Cash and Cash Equivalent	(3,820)	8,766	(11,262)	2,589	(4,715)	(3,173)
Cash and Cash Equivalents - Beginning	8,441	4,621	13,387	2,125	4,714	(1)
Cash and Cash Equivalents - End	4,621	13,387	2,125	4,714	(1)	(3,174)

Source: Company accounts, Edison Investment Research

Contact details	Revenue by geography
Avenue Ariane 5 1200 Woluwe-Saint-Lambert Belgium www.asitbiotech.com	N/A

Management team

CEO: Thierry Legon	CFO: Everard van der Straten
Before founding ASIT, Thierry Legon was in charge of managing the intellectual property and technology transfer of the University of Brussels (ULB) for 10 years. Previously he was a board member at Euroscreen (a drug discovery company) for eight years. Mr Legon founded ASIT biotech, which was a spin-off from the ULB, in May 1997. He took the role of the CEO in 2000 and has since led the company from an early-stage AIT developer through to Phase III trial.	Before joining ASIT, Everard van der Straten worked as an auditor at Arthur Anderson. Previously he was MD of Metallo-Chimique Group and a board member of the Metallum Group until end 2008. Mr van der Straten holds a Master's degree from the Solvay Brussels School of Economics and Management.

Marketing & commercialisation: Philippe Ghem

A commercial engineer from the Solvay Brussels School of Economics and Management and holder of a special licence in business and marketing from HEC Saint-Louis (now ICHEC, Brussels), Philippe brings more than 20 years' commercial expertise in the pharmaceutical industry (retail, hospital, vaccines, devices) gained in sales and marketing positions for big pharma (Abbott, GlaxoSmithKline and Novartis) and speciality companies (Coloplast and Grünenthal). In recent positions (eg VP of global brands lifecycle management at Grünenthal) he was also regularly involved in market access and business development activities. Philippe joined ASIT biotech in April 2018 as chief commercial officer to improve the company's communication to investors and stakeholders, interact with potential licensing partners, and improve commercial processes and launch preparedness for ASIT's lead products.

Principal shareholders	(%)
Rodolphe de Spoelberch	10
Société Financière Publique d'Investissements	8
EPIMEDE	6
Meusinvest	6
Société Régionale Wallonne d'investissements	6
Société Régionale Bruxelloise d'investissements	5
ASIT Biotech management	4

Companies named in this report

ALK-Abello, Allergy Therapeutics, Stallergenes Greer

Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
295 Madison Avenue, 18th Floor
10017, New York
US

Sydney +61 (0)2 8249 8342
Level 4, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia