

# ASIT biotech

Phase III failure

## Statistically significant clinical insignificance

Reported gp-ASIT+ Phase III allergy data unfortunately confirmed the outcome of the first Phase III: a statistically proven, inadequate clinical response, in this case a 0.15 reduction in the peak allergy score; 0.3 was the endpoint. Given the current cash position of €3.8m and the €9.23m debt from July now unlikely to convert, it is hard to see how ASIT can fund and progress its remaining preclinical allergy projects or run any revised gp-ASIT+ programme. Our forecasts and valuation are withdrawn till the strategy for the business and the overall financial position become clearer.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/17	0.0	(12.0)	(0.94)	0.0	N/A	N/A
12/18	0.0	(14.3)	(0.86)	0.0	N/A	N/A

Note: \*PBT and EPS are both as reported.

## Not the crescendo we expected

The second gp-ASIT+ Phase III study showed a clinical allergy score reduction of 0.15 against a 0.3 reduction set, by the German regulator, as the primary endpoint for clinical significance; the drop was statistically valid,  $P=0.05$ . The study also confirms the first Phase III result – deemed to have failed due to a poor pollen season. Why the product has shown such a disappointing efficacy remains unclear although analysis of the full data set may offer some insight. The product was safe but, a strong, durable immune tolerance response was clearly not generated. Perhaps a longer dose regimen might have succeeded – but how ASIT might fund the trials needed to test this is not clear. Longer treatment periods were not considered at Phase II which used fast readout surrogate endpoints and not the Phase III scoring system.

## Limited cash and financial options

After a major Phase III failure, biotech company recovery depends on strong cash and a viable earlier-stage portfolio. In ASIT's case, cash on 22 November was €3.8m and the other allergy products are preclinical. The H1 operating loss was €7.8m so ASIT will, on our estimates, have cash into Q120. We assume that the second convertible note tranche of €4.2m, previously expected in December 2019, will not be available. The first loan tranche of €5.03m is now unlikely to convert and is repayable by 31 December 2020 with a 3% interest rate. The Equity Line convertible notes of July 2018 can, on average, provide €600k a month to February 2020 but only if the share price is over €1.1368. At the time of writing, the shares were suspended. The last report of 30 June 2019 showed €5.8m remaining of the equity line but some of this has been drawn down over H219.

## Valuation: suspended

A valuation of ASIT is not currently possible. Edison's valuation and financial forecasts are withdrawn until there is a clear statement about the direction of ASIT from the board.

Pharma & biotech

26 November 2019

Price **€0.46**

Market cap **€10m**

US\$/€0.89

Cash (€m) at 22 November 2019 3.8

Shares in issue (at 7 November 2019) 21.44m

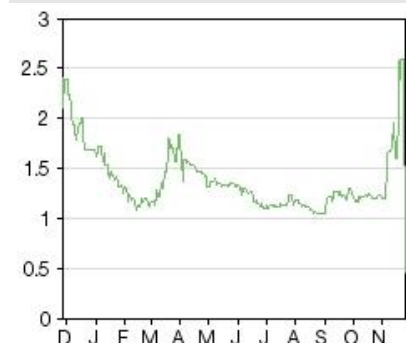
Free float 72%

Code ASIT

Primary exchange Euronext Brussels

Secondary exchange Euronext Paris

### Share price performance



% 1m 3m 12m

Abs (61.7) (56.5) (76.8)

Rel (local) (63.2) (61.2) (79.5)

52-week high/low €2.60 €0.46

### Business description

ASIT biotech is a clinical-stage company focused on the development of short-course therapies for allergies. ASIT's products are based on the proprietary ASIT+ technology platform, allowing the development of products containing highly purified allergen fragments in an adjuvant-free formulation, selected to be safe while maintaining the capacity to stimulate immune tolerance.

### Next events

FY19 results March 2020

### Analyst

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**ASIT biotech is a research client of Edison Investment Research Limited**

**Exhibit 1: Financial summary**

	€'000s	2017	2018
Year end 31 December		IFRS	IFRS
<b>INCOME STATEMENT</b>			
Revenue		0	0
Cost of Sales		0	0
Gross Profit		0	0
General and Administrative Expenses		(1,676)	(2,468)
Research and Development Expenses		(10,903)	(10,856)
Other Operating Income		604	557
Reported operating profit		(11,975)	(12,767)
Net Interest		(9)	(1,557)
Profit before tax (as reported)		(11,984)	(14,324)
Reported tax		(2)	3
Profit after tax (reported)		(11,986)	(14,321)
Minority interests		0	0
Net income (reported)		(11,986)	(14,321)
Basic average number of shares outstanding (m)		12.8	16.7
EPS - basic, as reported (€)		(0.94)	(0.86)
<b>BALANCE SHEET</b>			
Non Current Assets		1,837	2,398
Property Plant and equipment, net		691	810
Other intangible assets		0	0
Other Non Current Assets		1,146	1,588
Current Assets		2,448	9,156
Cash and cash equivalents		2,126	8,458
Accounts receivable		0	0
Inventories		0	0
Other current assets		322	698
Current Liabilities		2,654	4,621
Accounts payable		1,264	2,980
Short term debt and borrowings		34	25
Other current liabilities		1,356	1,616
Non Current Liabilities		432	465
Loans and borrowings		432	465
Other non-current liabilities		0	0
Equity		1,199	6,468
Common stock / Capital		9,989	14,350
Additional paid-in capital / Share premium		21,957	37,034
Other reserves and surplus		(28,645)	(42,889)
Other Equity		(2,102)	(2,027)
<b>CASH FLOW</b>			
Cash Flow from Operations			
Net income (loss)		(11,986)	(14,321)
Depreciation and Amortization		205	253
Interest income/expense		9	1,557
Stock-based compensation		54	73
Non Cash Adjustments		(492)	(564)
(Increase) decrease in inventories		0	0
(Increase) decrease in trade receivables		74	(376)
(Increase) decrease in other current assets		(112)	360
Increase (decrease) in trade payables		(586)	0
Net cash used in Operating activities		(12,834)	(13,018)
Cash Flow from Investing			
Purchases of fixed assets		(161)	(371)
Other Investing Activities		0	0
Net cash used in Investing activities		(161)	(371)
Cash Flow from Financing			
Change in Debt		0	0
Change in Capital Stock		0	19,591
Interest paid		(10)	(2)
Other Financing Activities		1,743	134
Net cash used in Financing activities		1,733	19,723
Net Changes in Cash and Cash Equivalent		(11,262)	6,334
Net cash/(debt) at the beginning of the period		12,956	1,660
Net cash/(debt) at the end of the period		1,660	7,968

Source: ASIT biotech accounts

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