

ASIT biotech

FY18 results

All the bases loaded for ASIT011

ASIT's FY18 preliminary results were dominated by the initiation of the second Phase III study of gp-ASIT+ where randomisation is now complete. The company's FY18 operating loss increased slightly to €12.8m compared to FY17. R&D comprised the bulk of operating expense at €10.9m and included €9.9m on the Phase III study. Cash at the end of FY18 and March 19 was €8.5m and €5.9m, respectively, while the previously announced convertible note offering should extend the cash runway from Q319 until Q320.

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
12/19e	0.0	(9.7)	(0.52)	0.0	N/A	N/A
12/20e	0.0	(5.4)	(0.21)	0.0	N/A	N/A

Note: *PBT and EPS are both as reported.

FY18 results include the pivotal Phase III study

The improvements that ASIT and its CRO have implemented to improve the likelihood of success in the larger ASIT011 Phase III study in grass allergy patients have come at a lower R&D spend than we had estimated. The first of 624 patients was dosed at the end of January for the 2019 allergy season and enrolment is now complete. ASIT's FY18 operating loss increased slightly to €12.8m from €12.0m. R&D was the largest operating expense but was flat at €10.9m compared to FY17. Our estimates of FY18 operating loss and R&D spend were higher at €13.8m and €12.0m, respectively. Net loss increased to €14.3m (from €12m in FY17) after €1.6m in expenses associated with the 2018 offerings. Cash at end-FY18 was €8.5m (vs €2.1m at end-FY17). Including its existing equity line, ASIT estimates that its cash runway will last until Q319 before the convertible note issue announced in February, which is required to complete the ASIT011 study. This should extend the cash needs until the end of Q320. By that time, we expect gp-ASIT+ to have been filed and partnerships to have been signed.

Busy time in business development

ASIT has provided more detail on the out-licensing of its pipeline, which includes hdm-ASIT+ and pnt-ASIT+ for house dust mite and peanut allergies, respectively. These earlier two products will enter Phase I in partnership or with co-financing. This means that business development (BD) moves to centre stage, adding to the ongoing BD effort to secure a marketing partner for gp-ASIT+ in the US. While the optimal partnering strategy for shareholders may result in different partners for each product, clinical success in the ASIT011 Phase III study that reports at the end of 2019 will validate the platform and likely assist all ASIT's BD.

Valuation: Virtually unchanged

Our valuation of ASIT is unchanged at €119m, or €6.4 per share. We have made minor changes to our financial model but will update the valuation after the €9–12m convertible note offering has completed and the full FY18 financials published.

Pharma & biotech

3 April 2019

Price €1.58

Market cap €31m

US\$/€0.88

Cash (€m) at end-March 2019 5.9

Shares in issue 19.4m

Free float 57%

Code ASIT

Primary exchange Euronext Brussels

Secondary exchange Euronext Paris

Share price performance



%	1m	3m	12m
Abs	37.1	(1.2)	(57.4)
Rel (local)	33.7	(14.8)	(56.0)

52-week high/low €4.0 €1.1

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

hdm- and pnt-ASIT+ licensing news	Ongoing
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H119 results	August 2019
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gp-ASIT+ Phase III results	December 2019
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Exhibit 1: Financial summary

	€'000s	2017	2018	2019e	2020e	2021e
Year end 31 December		IFRS	IFRS	IFRS	IFRS	IFRS
INCOME STATEMENT						
Revenue		0	0	0	0	0
Cost of Sales		0	0	0	0	0
Gross Profit		0	0	0	0	0
General and Administrative Expenses		(1,676)	(2,481)	(2,456)	(2,432)	(2,407)
Research and Development Expenses		(10,903)	(10,856)	(8,000)	(3,480)	(2,000)
Other Operating Income		604	570	599	628	660
Reported operating profit		(11,975)	(12,767)	(9,858)	(5,283)	(3,747)
Net Interest		(9)	(1,557)	180	(144)	(274)
Profit before tax (as reported)		(11,984)	(14,324)	(9,678)	(5,427)	(4,021)
Reported tax		(2)	3	2	1,628	1,206
Profit after tax (reported)		(11,986)	(14,321)	(9,676)	(3,779)	(2,815)
Minority interests		0	0	0	0	0
Net income (reported)		(11,986)	(14,321)	(9,676)	(3,779)	(2,815)
Basic average number of shares outstanding ('m)		12,806	16,704	18,434	18,434	18,434
EPS - basic, as reported (€)		(0.94)	(0.86)	(0.52)	(0.21)	(0.15)
BALANCE SHEET						
Non-Current Assets		1,837	1,998	2,011	1,935	1,849
Property Plant and equipment, net		691	683	686	620	534
Other intangible assets		0	0	0	0	0
Other Non-Current Assets		1,146	1,315	1,315	1,315	1,315
Current Assets		2,448	8,753	17,097	28,512	25,571
Cash and cash equivalents		2,126	8,500	16,844	28,265	25,318
Accounts receivable		0	0	0	0	0
Inventories		0	0	0	0	0
Other current assets		322	253	253	253	253
Current Liabilities		2,654	4,196	3,340	2,684	2,467
Accounts payable		1,264	2,354	1,498	842	625
Short term debt and borrowings		34	38	38	38	38
Other current liabilities		1,356	1,804	1,804	1,804	1,804
Non-Current Liabilities		432	446	9,446	16,446	16,446
Loans and borrowings		432	446	9,446	16,446	16,446
Other non-current liabilities		0	0	0	0	0
Equity		1,199	6,617	4,140	2,141	(673)
Common stock / Capital		9,989	13,125	13,125	13,125	13,125
Additional paid-in capital / Share premium		21,957	27,449	24,972	22,973	20,159
Other reserves and surplus		(28,645)	(33,957)	(33,957)	(33,957)	(33,957)
Other Equity		(2,102)	0	0	0	0
CASH FLOW						
Cash Flow from Operations						
Net income (loss)		(11,986)	(12,807)	(9,676)	(3,779)	(2,815)
Depreciation and Amortization		205	176	184	181	160
Interest income/expense		9	40	(180)	144	274
Stock-based compensation		54	0	0	0	0
Non-Cash Adjustments		(492)	0	0	0	0
(Increase) decrease in inventories		0	0	0	0	0
(Increase) decrease in trade receivables		74	0	0	0	0
(Increase) decrease in other current assets		(112)	69	0	0	0
Increase (decrease) in trade payables		(586)	2,180	(856)	(656)	(217)
Net cash used in Operating activities		(12,834)	(10,342)	(10,527)	(4,129)	(2,598)
Cash Flow from Investing						
Purchases of fixed assets		(161)	(255)	(197)	(106)	(75)
Other Investing Activities		0	0	0	0	0
Net cash used in Investing activities		(161)	(255)	(197)	(106)	(75)
Cash Flow from Financing						
Change in Debt		0	0	9,000	7,000	0
Change in Capital Stock		0	16,900	7,200	1,800	0
Interest paid		(10)	(42)	(24)	(474)	(824)
Other Financing Activities		1,743	2	204	330	550
Net cash used in Financing activities		1,733	16,860	16,380	8,656	(274)
Net Changes in Cash and Cash Equivalent		(11,262)	6,262	5,655	4,421	(2,947)
Net cash (debt) at the beginning of the period		12,968	1,694	8,054	7,398	11,819
Net cash (debt) at the end of the period		1,694	8,054	7,398	11,819	8,872

Source: ASIT Biotech SA, Edison Investment Management

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