EDISON

ASIT biotech

Phase III starts

The 82-centre gp-ASIT+ Phase III study launches

Pharma & biotech

In a well-received announcement, ASIT has launched the confirmatory Phase III study on gp-ASIT+ for grass pollen allergy with study centres in six European countries. The results of the study are expected in December 2019. ASIT has learned from the previous Phase III study by making a number of improvements to the protocol to enhance the chances of success. In addition, ASIT has made announcements on its other products illustrating its pipeline in allergy extends beyond gp-ASIT+.

Year end	Revenue (€m)	PBT* (€m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/17	0.0	(12.0)	(0.9)	0.0	N/A	N/A
12/18e	0.0	(13.3)	(0.9)	0.0	N/A	N/A
12/19e	0.0	(16.1)	(0.9)	0.0	N/A	N/A
12/20e	0.0	(6.2)	(0.3)	0.0	N/A	N/A

Note: *PBT and EPS are both as reported.

(Protocol) change is good

The primary endpoint of the Phase III study of gp-ASIT+ for grass pollen allergy remains the same as in the first Phase III study that reported in 2017: a 20% reduction in the combined clinical symptom and medication score in the treatment arm compared to the placebo patients. However, a number of potentially confounding variables have been addressed in the planned conduct of this second confirmatory study. The choice of ICON as the single clinical research organisation for the study brings ICON's deep experience in running allergy clinical trials. Of the eight other improvements in the Phase III protocol, the restriction in the maximum number of patients that can be recruited at any one of the centres and the increase in the number of patients to 624 (from 554 in the first Phase III study) are the most important. An earlier launch date in the pollen season, the recruitment of more severe patients than in the first Phase III study and the selection of centres with regular historical pollen levels are also important variables to re-define.

pnt-ASIT+ accelerates

ASIT recently announced the finalisation of the manufacturing process for its short-course peptide vaccination (pnt-ASIT+) to treat peanut allergies that will be used in the Phase I/II studies expected to start in H219. Like ASIT's other products, the peptides comprising pnt-ASIT+ were selected and tested by interdisciplinary teams at Imperial Collage London to have significantly less anaphylactic potential than the native antigen but retain the potential to down-regulate the immune response. There are revenue-smoothing advantages to ASIT's portfolio because grass pollen allergies result in a large number of seasonal symptomatic patients, with little mortality, whereas peanut allergies result in a smaller number of year-round, but potentially fatal food allergies.

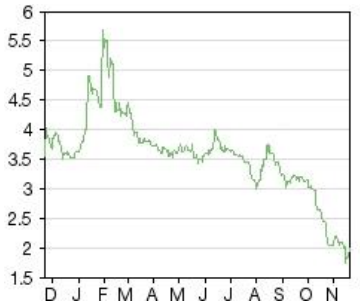
Valuation: Unchanged

We have not changed our valuation, which remains €118m or €6.7 per share. We will be keeping a close eye on the catalyst of the severity of the 2019 allergy season and note that commercialisation will require further funding in 2020.

20 November 2018

Price	**€1.99**
Market cap	**€36m**
	US$/€0.86
Cash (€m) at 30 June 2018 plus €12m convertible bond issued in July 2018 converting over 20 months	13.5
Shares in issue	18.1m
Free float	72.6%
Code	ASIT
Primary exchange	Euronext Brussels
Secondary exchange	Euronext Paris

Share price performance



%	1m	3m	12m
Abs	(18.4)	(44.9)	(46.8)
Rel (local)	(18.0)	(40.7)	(39.9)
52-week high/low		€5.7	€1.8

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

Additional hdm-ASIT+ and pnt-ASIT+ progress	2019
FY18 results	April 2019
pnt-ASIT+ Phase I/II start	H2 2019
gp-ASIT+ Phase III results	December 2019

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Edison profile page

Exhibit 1: 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	0
Cost of Sales	(3)	0	0	0	0	0
Gross Profit	1	0	0	0	0	0
General and Administrative Expenses	(947)	(1,822)	(1,676)	(2,547)	(2,522)	(2,497)
Research and Development Expenses	(6,691)	(12,123)	(10,903)	(11,500)	(14,480)	(4,520)
Other Operating Income	(3)	1,667	604	789	829	870
Reported operating profit	(7,640)	(12,278)	(11,975)	(13,258)	(16,173)	(6,146)
Net Interest	(75)	(60)	(9)	(40)	113	(49)
Profit before tax (as reported)	(7,715)	(12,338)	(11,984)	(13,298)	(16,060)	(6,196)
Reported tax	0	(1)	(2)	(1)	3	1,859
Profit after tax (reported)	(7,715)	(12,339)	(11,986)	(13,298)	(16,057)	(4,337)
Minority interests	0	0	0	0	0	0
Net income (reported)	(7,715)	(12,339)	(11,986)	(13,298)	(16,057)	(4,337)
Basic average number of shares outstanding (m)	8,504	11,219	12,806	15,694	17,507	17,507
EPS - basic, as reported (€)	(0.91)	(1.10)	(0.94)	(0.85)	(0.92)	(0.25)
BALANCE SHEET						
Non-Current Assets	506	1,770	1,837	2,008	2,136	2,044
Property Plant and equipment, net	494	736	691	693	821	729
Other intangible assets	0	0	0	0	0	0
Other Non Current Assets	12	1,034	1,146	1,315	1,315	1,315
Current Assets	4,968	13,785	2,448	9,851	(126)	9,987
Cash and cash equivalents	4,621	13,387	2,126	9,598	(379)	9,734
Accounts receivable	2	3	0	0	0	0
Inventories	11	0	0	0	0	0
Other current assets	334	395	322	253	253	253
Current Liabilities	6,332	2,004	2,654	5,286	4,294	2,853
Accounts payable	1,611	1,707	1,264	3,444	2,452	1,011
Short term debt and borrowings	4,232	12	34	38	38	38
Other current liabilities	489	285	1,356	1,804	1,804	1,804
Non-Current Liabilities	0	419	432	446	446	7,446
Loans and borrowings	0	419	432	446	446	7,446
Other non-current liabilities	0	0	0	0	0	0
Equity	(858)	13,132	1,199	6,126	(2,731)	(5,268)
Common stock / Capital	11,625	17,506	9,989	13,125	13,125	13,125
Additional paid-in capital / Share premium	0	21,957	21,957	26,958	18,101	15,564
Other reserves and surplus	(12,483)	(24,229)	(28,645)	(33,957)	(33,957)	(33,957)
Other Equity	0	(2,102)	(2,102)	0	0	0
CASH FLOW						
Cash Flow from Operations						
Net income (loss)	(7,715)	(12,339)	(11,986)	(13,298)	(16,057)	(4,337)
Depreciation and Amortization	80	141	205	176	196	214
Interest income/expense	75	60	9	40	(113)	49
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)	69	0	0
Increase (decrease) in trade payables	751	(492)	(586)	2,180	(992)	(1,441)
Net cash used in Operating activities	(7,606)	(13,697)	(12,834)	(10,833)	(16,966)	(5,515)
Cash Flow from Investing						
Purchases of fixed assets	(372)	(383)	(161)	(265)	(323)	(123)
Other Investing Activities	1	(6)	0	0	0	0
Net cash used in Investing activities	(371)	(389)	(161)	(265)	(323)	(123)
Cash Flow from Financing						
Change in Debt	4,130	0	0	0	0	7,000
Change in Capital Stock	0	22,199	0	16,900	7,200	1,800
Interest paid	(6)	(204)	(10)	(42)	(24)	(24)
Other Financing Activities	33	857	1,743	2	137	(25)
Net cash used in Financing activities	4,157	22,852	1,733	16,860	7,313	8,751
Net Changes in Cash and Cash Equivalent	(3,820)	8,766	(11,262)	5,761	(9,976)	3,113
Net cash (debt) at the beginning of the period	8,441	4,621	12,968	1,694	9,152	(825)
Net cash (debt) at the end of the period	4,621	12,968	1,694	9,152	(825)	2,288

Source: Company accounts, Edison Investment Research

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