EDISON

Acacia Pharma

FY18 results

Ready for BARHEMSYS launch in H119

Pharma & biotech

Acacia Pharma has now established its initial US sales and marketing infrastructure, ahead of the potential launch of lead asset BARHEMSYS. This is the first step in its strategy to bring antiemetic drugs to the hospital setting for unmet needs in PONV and CINV. The FDA has accepted Acacia's revised New Drug Application (NDA) for BARHEMSYS and has now set a Prescription Drug User Fee Act (PDUFA) date of 5 May. We continue to expect launch of BARHEMSYS in H119. We value Acacia at €635m (or €11.9/share) vs €602m (or €11.3/share) previously.

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
12/17	0.0	(6.5)	(2.32)	0.00	N/A	N/A
12/18	0.0	(16.2)	(0.35)	0.00	N/A	N/A
12/19e	1.1	(46.0)	(0.83)	0.00	N/A	N/A
12/20e	13.5	(41.7)	(0.76)	0.00	N/A	N/A

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

CRL deficiencies addressed and PDUFA date set

Following the submission of the original NDA for BARHEMSYS, the FDA issued a complete response letter (CRL) that related to issues at the contract manufacturer responsible for producing the active pharmaceutical ingredient (API). Acacia and the API manufacturer prepared a corrective and preventative action plan to address the outstanding deficiencies at the manufacturing facility. This plan was submitted to the FDA by the contract manufacturer alongside a resubmission of the NDA by Acacia. Importantly, the FDA did not request additional clinical data. We do not anticipate any additional problems and expect BARHEMSYS to be approved on or before its PDUFA date. However, sensitivities remain until approval is achieved.

US commercial infrastructure in place

Acacia has hired 35 staff in the US (in sales, regulatory, marketing and operational roles) in preparation for a launch of BARHEMSYS in H119. By mid-2019 Acacia expects this to rise to 40 staff as the drug nears approval and to 100 once direct field staff have been employed. Reps will focus on anaesthetists at ~1,600 US hospitals that account for ~80% of relevant surgical procedures. We estimate that successful commercialisation could enable Acacia to achieve break-even in 2023.

FY18 results: Building US operations

Net loss rose to £15.5m in FY18 vs £6.2m in FY17, predominately as a result of increased SG&A (FY18: £11.3m vs FY17: £1.5m) expenses as Acacia prepares for the US launch of BARHEMSYS. We forecast this trend to continue with a net loss of £44.4m in FY19 driven by significant investment in sales and marketing. Near-term funding will be required to grow the US operations (see our initiation report).

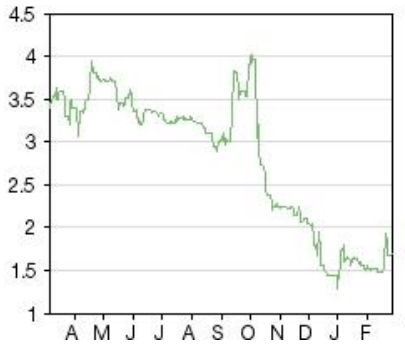
Valuation: €635m or €11.9/share

Our valuation has increased to €635m or €11.9/share vs €602m or €11.3/share previously. This is a result of updating for net cash, FX rates and rolling forward our model. Our valuation is predominantly based on a risk-adjusted NPV model of BARHEMSYS for PONV, in addition to the CINV opportunity for the US market only.

27 February 2019

Price	**€1.69**
Market cap	**€90m**
	$1.32/£, $1.14/€, €1.16/£
Net cash (£m) at 31 December 2018	22.1
Shares in issue	53.3m
Free float	100%
Code	ACPH
Primary exchange	Euronext
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	8.5	(18.6)	N/A
Rel (local)	5.2	(21.5)	N/A
52-week high/low		€4.0	€1.2

Business description

Acacia Pharma is a hospital pharmaceutical company focused on the development and commercialisation of new nausea and vomiting treatments for surgical and cancer patients. Its main product, BARHEMSYS, is for the treatment of PONV and is forecast to launch in 2019.

Next events

BARHEMSYS US FDA PDUFA review goal	5 May 2019
BARHEMSYS US launch	H119

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Edison profile page

R&D activities strengthen company

Acacia continues to advance its R&D operations, as noted in recent publications and announcements on BARHEMSYS. In November 2018, Acacia published its data from the positive Phase III clinical trial of BARHEMSYS as rescue treatment for established PONV (post-operative nausea and vomiting) in the journal Anesthesiology. In January 2019, the company announced positive cardiac data (DP10022 study) for BARHEMSYS, which demonstrated that there was no significant risk of heart rhythm disturbances (arrhythmias) at the highest proposed dose of BARHEMSYS, given alone or in combination with intravenous ondansetron, a widely used PONV therapy with a known effect on the heart.

As a result of its strong clinical data package to date, the company is seeking the following label from the FDA:

1. treatment of PONV in patients who have received antiemetic prophylaxis with an agent of a different class or who have not received prophylaxis (at a dose of 10mg); and
2. prevention of PONV, either alone or in combination with an antiemetic of a different class (at a dose of 5mg).

In addition to BARHEMSYS, Acacia is developing APD403 (repurposed amisulpride, the active ingredient in BARHEMSYS, in both an intravenous form for use alongside chemotherapy and an oral version for use at home in the subsequent days) for management of chemotherapy-induced nausea and vomiting (CINV) as a follow-on indication. In December 2018, the company announced its positive Phase II clinical trial data of APD403 in CINV had been published in the journal Supportive Care in Cancer.

FY18 results: Cost base rises as it readies for launch

Acacia continues to ramp up its US commercial operations in preparation for launch of BARHEMSYS (amisulpride injection). As result, SG&A increased in FY18 to £11.3m vs £1.5m in FY17. The increase was predominately driven by sales and marketing costs of £6.9m (vs FY17: £0.0) from hiring a new commercial team and the subsequent pre-launch marketing, education, training, distribution and regulatory activities. G&A costs rose to £4.3m in FY18 (vs FY17: £1.5m) as a result of the costs of the Euronext IPO and ongoing costs of being a public company. R&D rose to £3.8m (vs FY17: £1.5m) as a result of the NDA submission, product development and the DP10022 study.

Financial income rose to £0.9m (vs FY17: £0.002m) due to the increased cash balance from the IPO, while financial expenses dropped to £2.1m (vs FY17: £3.5m) because of the conversion of both the preferred shares and the convertible loan. Tax credits rose slightly to £0.7m (vs FY17: £0.3m).

Net loss rose in FY18 to £15.5m (vs FY17: £6.2m). The year-end cash balance of £29.4m was aided by the £33.9m net raise from the IPO in March and the drawdown of $10m from the $30m credit facility with Hercules Technology Growth Capital (Hercules). In FY18, the company repaid the existing £5.2m Silicon Valley Bank loan. To fund ongoing operations, we forecast that an additional c £70m (in addition to the remaining $20m from Hercules) will need to be raised in 2019 and 2020. We note that, for simplicity, in our model we currently illustrate this as a debt raise. However, Acacia management has stated that it plans to finance the company by a combination of equity and debt.

We forecast revenue in FY19 of £1.1m, growing to £13.5m in FY20. In the short term, revenues remain wholly dependent on the success of BARHEMSYS. We project R&D costs of £7.6m in

FY19, growing to £9.9m in FY20, driven by the clinical trial programme for APD403. We anticipate that SG&A costs will increase to £37.1m in FY19, growing to £42.0m in FY20. We forecast a net loss of £44.4m in FY19 and £40.4m in FY20, and that Acacia will reach break-even in 2023.

Valuation: €635m or €11.9/share

Our valuation of Acacia Pharma, at €635m or €11.9/share vs €602m or €11.3/share previously, is mainly based on a risk-adjusted NPV model of BARHEMSYS for rescue treatment and prophylaxis of PONV, in addition to the CINV opportunity for the US market only. We do not include any contribution from Europe or ROW opportunities as these will be dependent on out-licensing agreements with various future partners, on which we have no visibility. We include end-December 2018 net cash of €25.6m (£22.1m) in our valuation and use a 12.5% discount rate.

Exhibit 1: Valuation

Product	Indication	Launch	Peak sales ($)	Value (€)	Probability	rNPV (€m)	rNPV/share (€)
BARHEMSYS US only	PONV	2019	404.7	661.5	90%	595.4	11.2
APD403 US only	CINV	2024	107.9	77.9	30%	14.0	0.3
Net cash at 31 Dec 2018				25.6	100%	25.6	0.5
Valuation				765.0		634.9	11.9

Source: Edison Investment Research

For a full overview of our valuation please see our previously published initiation report.

Exhibit 2: Financial summary

Accounts: IFRS, year-end: December, £m	2015	2016	2017	2018	2019e	2020e
PROFIT & LOSS						
Revenue	0.0	0.0	0.0	0.0	1.1	13.5
Operating revenues	0.0	0.0	0.0	0.0	1.1	13.5
Cost of sales	0.0	0.0	0.0	0.0	(0.1)	(0.8)
Gross profit	0.0	0.0	0.0	0.0	1.0	12.6
Gross margin %	N/A	N/A	N/A	N/A	*0.9*	*0.9*
SG&A (expenses)	(2.4)	(0.8)	(1.5)	(11.3)	(37.1)	(42.0)
R&D costs	(10.1)	(13.6)	(1.5)	(3.8)	(7.6)	(9.9)
Other income/(expense)	0.0	0.0	0.0	0.0	0.0	0.0
EBITDA (reported)	(12.5)	(14.4)	(3.0)	(15.0)	(43.7)	(39.2)
Depreciation and amortisation	0.0	0.0	0.0	0.0	0.0	0.0
Reported Operating Income	(12.5)	(14.4)	(3.0)	(15.0)	(43.7)	(39.2)
Operating Margin %	N/A	N/A	N/A	N/A	*n/a*	*n/a*
Finance income/(expense)	(2.6)	(1.8)	(3.5)	(1.1)	(2.3)	(2.5)
Exceptionals and adjustments	0.0	0.0	0.0	0.0	0.0	0.0
Reported PBT	(15.1)	(16.3)	(6.5)	(16.2)	(46.0)	(41.7)
Income tax expense (includes exceptionals)	2.2	2.8	0.3	0.7	1.6	1.3
Reported net income	(12.9)	(13.5)	(6.2)	(15.5)	(44.4)	(40.4)
Basic average number of shares, m	2.7	2.7	2.7	44.1	53.3	53.3
Year-end number of shares, m	2.7	2.7	2.7	53.3	53.3	53.3
Basic EPS (p)	(4.83)	(5.06)	(2.32)	(0.35)	(0.83)	(0.76)
Adjusted EPS (p)	(4.83)	(5.06)	(2.32)	(0.35)	(0.83)	(0.76)
Dividend per share (p)	0.00	0.00	0.00	0.00	0.00	0.00
BALANCE SHEET						
Property, plant and equipment	0.0	0.0	0.0	0.0	1.2	14.1
Goodwill	0.0	0.0	0.0	0.0	0.0	0.0
Intangible assets	0.0	0.0	0.0	0.0	0.0	0.0
Other non-current assets	0.0	0.0	0.0	0.0	0.0	0.0
Total non-current assets	0.0	0.0	0.0	0.0	1.2	14.1
Cash and equivalents	5.5	6.9	3.1	29.4	35.0	20.1
Inventories	0.0	0.0	0.0	0.0	0.0	0.1
Trade and other receivables	0.3	0.5	0.2	0.3	0.2	2.2
Other current assets	2.1	2.8	0.3	0.7	0.7	0.7
Total current assets	7.9	10.2	3.6	30.4	35.9	23.1
Non-current loans and borrowings	0.0	5.0	0.0	7.0	57.0	97.0
Other non-current liabilities	0.0	0.0	0.0	0.0	0.0	0.0
Total non-current liabilities	0.0	5.0	0.0	7.0	57.0	97.0
Trade and other payables	2.9	5.1	1.0	3.7	5.1	5.7
Current loans and borrowings	0.0	2.7	5.2	0.3	0.0	0.0
Other current liabilities	7.8	9.1	15.2	0.0	0.0	0.0
Total current liabilities	10.8	17.0	21.4	4.1	5.1	5.7
Equity attributable to company	(2.8)	(11.7)	(17.8)	19.3	(25.0)	(65.4)
CASH FLOW STATEMENT						
Operating Profit	(15.1)	(16.3)	(6.5)	(16.2)	(46.0)	(41.7)
Depreciation and amortisation	0.0	0.0	0.0	0.0	0.0	0.0
Share based payments	0.0	0.0	0.0	0.0	0.0	0.0
Other adjustments	2.7	1.9	3.7	1.6	2.3	2.5
Movements in working capital	1.6	2.0	(3.8)	2.6	1.5	(1.5)
Interest paid / received	0.0	0.0	0.0	0.2	(2.3)	(2.5)
Income taxes paid	1.1	2.2	2.8	0.3	1.6	1.3
Cash from operations (CFO)	(9.7)	(10.2)	(3.7)	(11.6)	(43.3)	(40.9)
Capex	0.0	0.0	0.0	0.0	(1.2)	(14.1)
Acquisitions & disposals net	0.0	0.0	0.0	0.0	0.0	0.0
Other investing activities	0.0	0.0	0.0	0.2	0.3	0.2
Cash used in investing activities (CFIA)	0.0	0.0	0.0	0.2	(0.8)	(13.9)
Net proceeds from issue of shares	12.5	4.5	3.4	34.2	0.0	0.0
Movements in debt	0.0	7.1	(3.4)	1.5	49.7	40.0
Other financing activities	0.0	0.0	0.0	0.0	0.0	0.0
Cash from financing activities (CFF)	12.5	11.7	0.0	35.7	49.7	40.0
Cash and equivalents at beginning of period	2.6	5.5	6.9	3.1	29.4	35.0
Increase/(decrease) in cash and equivalents	2.8	1.4	(3.8)	26.3	5.6	(14.9)
Cash and equivalents at end of period	5.5	6.9	3.1	29.4	35.0	20.1

Source: Acacia Pharma accounts, Edison Investment Research

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