

Acacia Pharma

Q3 results

BARHEMSYS NDA resubmitted to FDA

Acacia Pharma has resubmitted a New Drug Application (NDA) to the FDA for its lead asset BARHEMSYS (repurposed amisulpride) for the management of post-operative nausea and vomiting (PONV). While the original complete response letter (CRL) received was unexpected, the issues related to deficiencies at the contract manufacturers responsible for producing the active pharmaceutical ingredient (API) and not to any other part of the application or the API itself. Within 30 days of this resubmission, the FDA will determine whether the application constitutes a Class 1 (up to two months) or Class 2 (up to six months) review. Acacia maintains that a potential launch of BARHEMSYS for PONV rescue is possible in H119. It has reported a 9M18 net loss of £10.0m, driven by preparation activities for the commercial launch of BARHEMSYS. We value Acacia at €602m or €11.3/share.

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
12/16	0.0	(16.3)	(5.06)	0.0	N/A	N/A
12/17	0.0	(6.5)	(2.32)	0.0	N/A	N/A
12/18e	0.0	(18.4)	(0.33)	0.0	N/A	N/A
12/19e	2.6	(45.1)	(0.81)	0.0	N/A	N/A

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

BARHEMSYS launch still on track for H119

Since the CRL was received in October, Acacia and the API manufacturer have worked quickly to prepare a corrective and preventative action (CAPA) plan to address the outstanding deficiencies at the manufacturing facility. This plan has now been submitted to the FDA by the contract manufacturer alongside the NDA by Acacia. The time required by the FDA to review the NDA will depend on whether it is deemed a Class 1 or Class 2 resubmission. A launch under either scenario is still possible in H119. For launch, Acacia needs to build up its commercial operations, including the sizeable salesforce of 60-100 reps required for the PONV indication in the US. Funding in the near term will be required to build the required US organisation (see our [initiation report](#)).

Q3 results: Operations ramp-up ready for launch

Net loss in 9M18 rose to £10.0m vs £4.1m in the same period in 2017 (9M17). This was driven by increased expenses across the business as Acacia prepares for the launch of BARHEMSYS. R&D expenses increased in 9M18 to £2.2m (9M17: £1.0m), S&M rose to £3.3m (9M17: £0.6m) and G&A rose to £3.4m (9M17: £0.5m). We have lowered our FY18 S&GA forecasts to £13.8m (from £16.7m), resulting in a reduced FY18 net loss of £17.5m. Gross cash as of 30 September was £33.8m.

Valuation: €602m or €11.3 per share

Our valuation of Acacia Pharma has increased to €602m or €11.3/share (vs €579m or €10.9/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.

Pharma & biotech

7 November 2018

Price €2.25

Market cap €120m

\$1.31/£, \$1.14/€, €1.15/£

Net cash (£m) at 30 Sept 2018 27.1

Shares in issue 53.3m

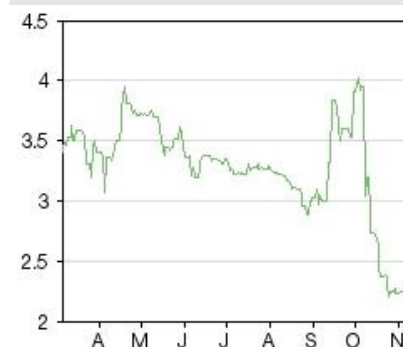
Free float 21.7%

Code ACPH

Primary exchange Euronext

Secondary exchange N/A

Share price performance



%	1m	3m	12m
Abs	(43.1)	(30.5)	N/A
Rel (local)	(40.2)	(23.3)	N/A
52-week high/low		€4.0	€2.2

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

FDA notification on Class 1 or 2 BARHEMSYS review	Q418
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BARHEMSYS US launch as PONV 'rescue treatment'	H119
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Acacia Pharma is a research client of Edison Investment Research Limited

Exhibit 1: Financial summary

Accounts: IFRS, Year-end: December, £m	2015	2016	2017	2018e	2019e	2020e
PROFIT & LOSS						
Revenue	0.0	0.0	0.0	0.0	2.6	13.6
Operating revenues	0.0	0.0	0.0	0.0	2.6	13.6
Cost of sales	0.0	0.0	0.0	0.0	(0.2)	(0.9)
Gross profit	0.0	0.0	0.0	0.0	2.5	12.8
Gross margin %	N/A	N/A	N/A	N/A	0.9	0.9
SG&A (expenses)	(2.4)	(0.8)	(1.5)	(13.8)	(37.5)	(42.4)
R&D costs	(10.1)	(13.6)	(1.5)	(2.9)	(7.7)	(10.0)
Other income/(expense)	0.0	0.0	0.0	0.0	0.0	0.0
EBITDA (reported)	(12.5)	(14.4)	(3.0)	(16.7)	(42.7)	(39.6)
Depreciation and amortisation	0.0	0.0	0.0	0.0	0.0	0.0
Reported Operating Income	(12.5)	(14.4)	(3.0)	(16.7)	(42.7)	(39.6)
Operating Margin %	N/A	N/A	N/A	N/A	N/A	N/A
Finance income/(expense)	(2.6)	(1.8)	(3.5)	(1.7)	(2.4)	(2.4)
Exceptionals and adjustments	0.0	0.0	0.0	0.0	0.0	0.0
Reported PBT	(15.1)	(16.3)	(6.5)	(18.4)	(45.1)	(42.0)
Income tax expense (includes exceptionals)	2.2	2.8	0.3	0.9	2.0	1.6
Reported net income	(12.9)	(13.5)	(6.2)	(17.5)	(43.2)	(40.4)
Basic average number of shares, m	2.7	2.7	2.7	44.2	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)	(0.33)	(0.81)	(0.76)
Adjusted EPS (P)	(4.83)	(5.06)	(2.32)	(0.33)	(0.81)	(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	0.1	0.8
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	0.1	0.8
Cash and equivalents	5.5	6.9	3.1	23.2	32.2	29.6
Inventories	0.0	0.0	0.0	0.0	0.1	0.5
Trade and other receivables	0.3	0.5	0.2	0.0	0.5	2.2
Other current assets	2.1	2.8	0.3	0.3	0.3	0.3
Total current assets	7.9	10.2	3.6	23.6	33.1	32.7
Non-current loans and borrowings	0.0	5.0	0.0	7.3	57.3	97.3
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	7.3	57.3	97.3
Trade and other payables	2.9	5.1	1.0	1.9	5.1	5.8
Current loans and borrowings	0.0	2.7	5.2	0.4	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	2.3	5.1	5.8
Equity attributable to company	(2.8)	(11.7)	(17.8)	14.0	(29.1)	(69.6)
CASH FLOW STATEMENT						
Operating Profit	(15.1)	(16.3)	(6.5)	(18.4)	(45.1)	(42.0)
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	1.7	2.4	2.4
Movements in working capital	1.6	2.0	(3.8)	1.0	2.7	(1.5)
Interest paid / received	0.0	0.0	0.0	(1.7)	(2.4)	(2.4)
Income taxes paid	1.1	2.2	2.8	0.9	2.0	1.6
Cash from operations (CFO)	(9.7)	(10.2)	(3.7)	(16.7)	(40.8)	(42.2)
Capex	0.0	0.0	0.0	0.0	(0.1)	(0.7)
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	0.3
Cash used in investing activities (CFIA)	0.0	0.0	0.0	0.2	0.2	(0.4)
Net proceeds from issue of shares	12.5	4.5	3.4	34.1	0.0	0.0
Movements in debt	0.0	7.1	(3.4)	2.5	49.6	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	36.6	49.6	40.0
Cash and equivalents at beginning of period	2.6	5.5	6.9	3.1	23.2	32.2
Increase/(decrease) in cash and equivalents	2.8	1.4	(3.8)	20.2	9.0	(2.6)
Cash and equivalents at end of period	5.5	6.9	3.1	23.2	32.2	29.6

Source: Company accounts, Edison Investment Research

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