

# Acacia Pharma

Corporate update

## FDA issues CRL for BARHEMSYS

Pharma & biotech

10 October 2018

**Price** €3.20

**Market cap** €170m

\$1.29/£, \$1.16/€, €1.11/£

Net cash (£m) at 30 June 2018 29.0

Shares in issue 53.1m

Free float 100%

Code ACPH

Primary exchange Euronext

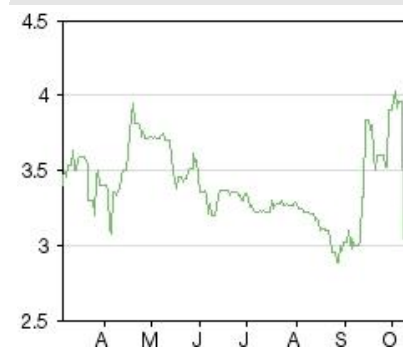
Secondary exchange N/A

Acacia Pharma has received a Complete Response Letter (CRL) from the FDA for lead asset BARHEMSYS (repurposed amisulpride) for the management of post-operative nausea and vomiting (PONV). The CRL comes as a surprise as it relates to deficiencies at the contract manufacturers responsible for producing the API. Importantly, we note that the FDA has not requested additional clinical data or trials for BARHEMSYS's potential approval. We expect Acacia to work with its contract manufacturer and the FDA to discuss the exact requirements to resolve the agency's concerns. At this point, Acacia expects a quick resolution and maintains a potential launch of BARHEMSYS for PONV rescue in H119. Our valuation is unchanged at €10.9/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	(20.3)	(0.36)	0.0	N/A	N/A
12/19e	2.7	(45.6)	(0.82)	0.0	N/A	N/A

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

### Share price performance



% 1m 3m 12m

Abs 6.7 (0.9) N/A

Rel (local) 6.3 3.0 NA

52-week high/low €4.0 €2.9

### 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 launch as PONV 'rescue treatment' H119

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## CRL issued on 5 October PDUFA date

While the CRL issued by the FDA for BARHEMSYS was unexpected, the issues raised do not relate to the safety and efficacy of BARHEMSYS in PONV, but rather to deficiencies that the FDA had identified during a recent pre-approval inspection of the amisulpride API contract manufacturer. This means no further clinical trials or clinical data are required, which is positive. Furthermore, Acacia notes that no inadequacies were noted regarding the purity or stability of the API or the quality of the finished product. While the exact issues are unknown, we expect a resolution and potential approval post-resubmission of the application once the concerns of the agencies have been addressed. If it is deemed a Class 1 resubmission, it implies up to a two-month review period.

## BARHEMSYS US launch in H119 still possible

While the delay to BARHEMSYS approval on its original 5 October PDUFA date is unexpected, we believe the CRL manufacturing issues should be resolvable, with the timing to an approval the main unknown. Acacia needs to build up its commercial operations including the sizeable salesforce of 60-100 reps required for the PONV indication in the US. Acacia had been targeting a H119 launch, which is still a possibility if the issues are solved quickly with the FDA. Funding in the near term will be required to build the required US organisation (see [initiation report](#)).

## Valuation: €579m or €10.9per share

Our valuation of Acacia Pharma remains unchanged at €579m or €10.9/share. While we anticipate that the manufacturing deficiencies will be resolved and an H119 launch is still possible, we note the risk that the timelines for BARHEMSYS approval and subsequent launch could slip from our H119 assumption. 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.

**Exhibit 1: Financial summary**

Accounts: IFRS, Year-end: December, £m	2015	2016	2017	2018e	2019e	2020e
<b>PROFIT &amp; LOSS</b>						
Revenue	0.0	0.0	0.0	0.0	2.7	13.7
Operating revenues	0.0	0.0	0.0	0.0	2.7	13.7
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	12.9
Gross margin %	N/A	N/A	N/A	N/A	0.9	0.9
SG&A (expenses)	(2.4)	(0.8)	(1.5)	(16.7)	(37.8)	(42.7)
R&D costs	(10.1)	(13.6)	(1.5)	(2.9)	(7.7)	(10.1)
Other income/(expense)	0.0	0.0	0.0	0.0	0.0	0.0
EBITDA (reported)	(12.5)	(14.4)	(3.0)	(19.6)	(43.0)	(39.9)
Depreciation and amortisation	0.0	0.0	0.0	0.0	0.0	0.0
Reported Operating Income	(12.5)	(14.4)	(3.0)	(19.6)	(43.0)	(39.9)
Operating Margin %	N/A	N/A	N/A	N/A	N/A	N/A
Finance income/(expense)	(2.6)	(1.8)	(3.5)	(0.7)	(2.5)	(2.6)
Exceptionals and adjustments	0.0	0.0	0.0	0.0	0.0	0.0
Reported PBT	(15.1)	(16.3)	(6.5)	(20.3)	(45.6)	(42.4)
Income tax expense (includes exceptionals)	2.2	2.8	0.3	1.0	2.0	1.6
Reported net income	(12.9)	(13.5)	(6.2)	(19.3)	(43.6)	(40.8)
Basic average number of shares, m	2.7	2.7	2.7	53.1	53.1	53.1
Basic EPS (£)	(4.83)	(5.06)	(2.32)	(0.36)	(0.82)	(0.77)
Adjusted EPS (£)	(4.83)	(5.06)	(2.32)	(0.36)	(0.82)	(0.77)
Dividend per share (£)	0.00	0.00	0.00	0.00	0.00	0.00
<b>BALANCE SHEET</b>						
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	12.7	14.0	11.1
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	2.3
Other current assets	2.1	2.8	0.3	0.3	0.3	0.3
Total current assets	7.9	10.2	3.6	13.0	15.0	14.2
Non-current loans and borrowings	0.0	5.0	0.0	6.7	56.7	96.7
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	6.7	56.7	96.7
Trade and other payables	2.9	5.1	1.0	9.1	5.2	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	9.5	5.2	5.8
Equity attributable to company	(2.8)	(11.7)	(17.8)	(3.2)	(46.8)	(87.6)
<b>CASH FLOW STATEMENT</b>						
Operating Profit	(15.1)	(16.3)	(6.5)	(20.3)	(45.6)	(42.4)
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	0.7	2.5	2.6
Movements in working capital	1.6	2.0	(3.8)	(6.9)	(4.5)	(1.5)
Interest paid / received	0.0	0.0	0.0	(0.7)	(2.5)	(2.6)
Income taxes paid	1.1	2.2	2.8	1.0	2.0	1.6
Cash from operations (CFO)	(9.7)	(10.2)	(3.7)	(26.3)	(48.2)	(42.4)
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	0.1	0.1	0.1
Cash used in investing activities (CFIA)	0.0	0.0	0.0	0.1	0.0	(0.6)
Net proceeds from issue of shares	12.5	4.5	3.4	33.9	0.0	0.0
Movements in debt	0.0	7.1	(3.4)	1.9	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	35.8	49.6	40.0
Cash and equivalents at beginning of period	2.6	5.5	6.9	3.1	12.7	14.0
Increase/(decrease) in cash and equivalents	2.8	1.4	(3.8)	9.6	1.4	(3.0)
Cash and equivalents at end of period	5.5	6.9	3.1	12.7	14.0	11.1

Source: Company accounts, Edison Investment Research

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