EDISON

Acacia Pharma

Corporate update

H119 launch remains on track for BARHEMSYS

Pharma & biotech

Acacia Pharma has announced that the FDA has accepted its revised New Drug Application (NDA) for BARHEMSYS and classified it as a Class 2 resubmission. In the revised NDA, Acacia, along with its manufacturing partner, has addressed the deficiencies identified in the 5 October Complete Response Letter (CRL). As this is a Class 2 resubmission (with a six-month total review time), the FDA has now set a Prescription Drug User Fee Act (PDUFA) goal of reviewing and acting on it, of no later than 5 May 2019. Acacia continues to expect to launch BARHEMSYS in H119. We retain our valuation of 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.

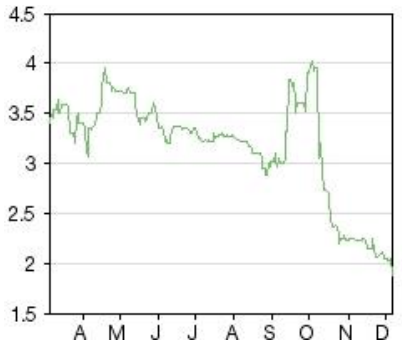
While the original CRL received on 5 October was unexpected, the issues were related to deficiencies at the contract manufacturers responsible for producing the active pharmaceutical ingredient (API) rather than to any other part of the application or the API itself. We do not expect any additional problems with the resubmission and expect BARHEMSYS to be approved on or before the 5 May 2019 PDUFA date, but note that sensitivities remain until approval is achieved.

With the launch of BARHEMSYS expected in H119, Acacia needs to build up its commercial operations, including the sizeable salesforce of 60–100 reps required for the post-operative nausea and vomiting (PONV) indication in the US. Acacia will focus on anaesthetists at ~1,600 US hospitals that account for ~80% of relevant surgical procedures. Inadequately treated PONV leads to prolonged stay in post-anaesthesia care unit (PACU) recovery rooms. BARHEMSYS use could reduce patient hospitalisation time and the associated costs. We estimate that successful commercialisation could enable break-even in 2023 and long-term operating margins of more than 60%. Further funding in the near term will be required to build the required US organisation (see our initiation report for more details).

7 December 2018

Price	**€1.87**
Market cap	**€100m**
	$1.31/£, $1.14/€, €1.15/£
Net cash (£m) at 30 September 2018	27.1
Shares in issue	53.3
Free float	21.7%
Code	ACPH
Primary exchange	Euronext
Secondary exchange	N/A

Share price performance



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.

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