EDISON

Acacia Pharma

Results update

Preparing for US BARHEMSYS launch

Pharma & biotech

Acacia Pharma has reported FY19 results in line with our expectations and the loss after tax increased to $22.8m (FY18 $20.7m) as lower R&D costs offset increased sales and marketing expenses. We anticipate continued investment in SG&A in 2020/21 as Acacia continues to build its US operations ahead of the anticipated launches of BARHEMSYS and ByFavo. BARHEMSYS (reformulated amisulpride) for the management of post-operative nausea and vomiting (PONV) was recently approved by the FDA (26 February). Acacia's product portfolio offering has been expanded by the ByFavo in-licence deal with Cosmo Pharmaceuticals (January 2020), which will enable significant leverage of its US commercial infrastructure, notably under the deal terms, Acacia has access to the short-term funding required to expand its US footprint. We value Acacia at €15.1 per share.

Year end	Revenue ($m)	PBT* ($m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/18	0.0	(21.6)	(0.47)	0.00	N/A	N/A
12/19	0.0	(23.5)	(0.43)	0.00	N/A	N/A
12/20e	2.1	(34.4)	(0.48)	0.00	N/A	N/A
12/21e	28.8	(40.1)	(0.57)	0.00	N/A	N/A

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

BARHEMSYS and potential ByFavo launches ahead

Recently, the FDA granted a broad label for BARHEMSYS for 'rescue treatment' (patients who are uncontrolled following prophylactic treatment with standard-of care antiemetics) and prophylaxis of PONV as monotherapy and in combination with standard-of-care antiemetics. We forecast $386.7m peak sales for BARHEMSYS in PONV with launch in H220. In January, Acacia in-licensed ByFavo (remimazolam), an ultra-short-acting and reversible intravenous benzodiazepine sedative/anaesthetic for use during procedural sedation (NDA under review, PDUFA date 5 April) and launch, if approved, is expected late 2020. We forecast ByFavo peak sales of $126m based on H220 launch.

Investing for growth in 2020

With two de novo product launches expected this year, the focus for Acacia's management is on expanding its marketing capabilities and obtaining access to US hospital pharmacy formulary lists to support successful sales execution. Acacia has near-term funding in place, through the equity investment and first €10m tranche of the loan facility under the Cosmo deal to expand its commercial team by ~30 new hires by June 2020 to support launch of both assets. Further funding (equity or debt) will be needed in 2020 for further infrastructure expansion.

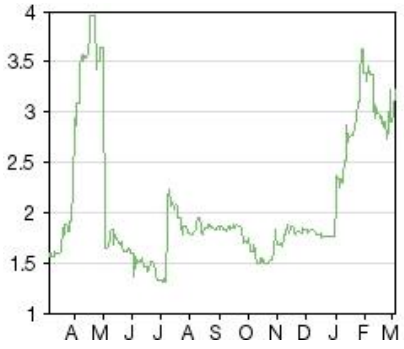
Valuation: €963.2m or €15.1/share

Our revised valuation is €963.2m or €15.1/share (vs €970.5m or €15.2/share previously). Our sales forecasts are unchanged, but we have adjusted our SG&A assumptions and rolled our model forward. Following the 2019 results, we have moved to US dollar-denominated figures for 2018, 2019 and our forecasts.

4 March 2020

Price	**€3.22**
Market cap	**€206m**
	$1.11/€
Net cash ($m) at 31 December 2019	7
Shares in issue	63.9m
Free float	28%
Code	ACPH
Primary exchange	Euronext
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(2.4)	79.3	98.7
Rel (local)	7.2	92.6	102.6
52-week high/low		€4.0	€1.3

Business description

Acacia Pharma is a hospital pharmaceutical company focused on the development and commercialisation of new products for surgical and cancer patients. It has two assets: BARHEMSYS (approved for the treatment of PONV in the US) and in-licensed asset ByFavo (sedative/ anaesthetic).

Next events

ByFavo US FDA PDUFA date	5 April 2020
BARHEMSYS US launch as PONV 'rescue treatment'	H220
ByFavo US launch	H220

Analyst

Dr Susie Jana +44 (0)20 3077 5700

healthcare@edisongroup.com

Edison profile page

Acacia Pharma is a research client of Edison Investment Research Limited

Focus now on BARHEMSYS sales execution

Acacia Pharma is at a major inflection point. Its lead drug, BARHEMSYS, will be its first internally developed asset to reach the market. The US approval of BARHEMSYS for PONV (26 February) comes after the receipt of two complete response letters issued in 2018 and 2019, indicating deficiencies reported at the third-party contract manufacturer. We highlight that no further studies or data analyses were required by the FDA, which has now granted a broad label for the drug. BARHEMSYS (10mg) is indicated for treatment of patients with PONV to include 'rescue treatment' (patients who are uncontrolled following prophylactic treatment with standard-of-care antiemetics) and prophylaxis of PONV as monotherapy and in combination with standard-of-care antiemetics including a 5-HT_3 antagonist. Initial detailing will focus on rescue treatment and we note the total addressable US population is c 34 million patients, a sizable opportunity.

Ahead of potential approval, in 2019 Acacia Pharma's core US commercial infrastructure was established, with 30 personnel focusing on six regions (medical science liaisons, national account directors and regional business directors) and the back-office support staff in the US. To support BARHEMSYS's launch, Acacia has identified key sales representatives hires (target is for 30 field managers) to be put in place in the upcoming months.

To successfully commercialise BARHEMSYS, Acacia must ensure the product is accepted on each hospital's formulary (a list of drugs that healthcare providers in the hospital can prescribe). This often requires the hospital's Pharmacy & Therapeutics committee to be convinced of the clinical and economic benefits of the drug before approving it. Once it is on a hospital formulary, treatment with BARHEMSYS would be provided under Diagnosis-Related Group (DRG) codes, where the treatment costs would be included in the total cost of surgery. Under the DRG system, hospitals will charge third-party payors a standard price for a procedure. As such, the hospitals are incentivised to reduce costs. Acacia will need to show BARHEMSYS can provide a pharmacoeconomic benefit at its specified price point (as shown by the reduction in post-anaesthesia care unit and hospitalisation stay overall (clinical trials DP10017 and DP10019).

We estimate that through an aggregate investment in SG&A of $100–130m over 2020 to 2022, Acacia could build up its commercial operations including the sizeable salesforce of 60–80 reps it needs to focus on the ~1,600 hospitals that account for ~80% of US surgical procedures. Acacia estimates ~65m surgical procedures are conducted in the US per year that could be eligible for an antiemetic drug to treat or prevent PONV. The modest need for R&D expense (to support the Phase III clinical trial of amisulpride in CINV) coupled with high gross margins leads to our forecast that financial break-even in 2023 is feasible on BARHEMYSYS and ByFavo combined sales of c $92.9m. We note that significant risk remains around commercial execution, particularly as financial investment in the short to medium term will be high and Acacia will need to raise further funds in 2020 to expand the sales force to the critical mass it requires.

CINV to add further indications

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 managing chemotherapy-induced nausea and vomiting (CINV) as a follow-on indication. One proof-of-concept trial and one Phase II dose ranging study in patients with highly emetogenic chemotherapy. In December 2018, the company announced its positive Phase II clinical trial data on APD403 in CINV had been published in the journal Supportive Care in Cancer. Management has indicated that a single Phase III clinical trial would be required for submission for CINV. We believe management will refocus on this programme once BARHEMSYS and ByFavo (potential) launches are underway and there is further

visibility on cash runway post launch. In 2017, the global CINV market was valued at $1.7bn (source: MarketInsights reports) and the rising prevalence of cancer has led to increased rates of chemotherapy use. The most highly prescribed drugs in CINV are the 5-HT_3 receptor antagonist and Neurokinin-1 receptor antagonists. Based on the encouraging Phase II data presented so far, we forecast peak sales potential of $108m in 2031.

Financials: Investing in US operations

During FY19 Acacia continued to build on its US commercial operations in preparation for the potential launch of BARHEMSYS (amisulpride injection). As result, net loss rose in FY19 to $22.8m (vs FY18: $20.7m). SG&A increased in FY19 to $14.0m vs $9.3m in FY18, R&D declined to $3.9m (vs FY18: $5.0m) reflecting the ending of the BARHEMSYS PONV clinical programme and NDA filing costs. Financial income declined to $0.4m (vs FY18: £1.2m) due to the lower cash balances held and a foreign exchange loss for the year of $0.1m vs gain reported in 2018 of $0.9m.

The year-end cash and equivalents was $17m. Acacia has a drawn a $10m credit facility with Hercules Technology Growth Capital (Hercules) in place. The deal with Cosmo provides an additional €35m loan facility (contingent on approvals), interest-rate only until January 2023 and repayable over the following 24 months from then. Until the Hercules debt is repaid, the Cosmo loan interest is 11% then reverts to 9%.

The cash injection from Cosmo (€10m equity stake and up to €35m in loan facilities) related to the ByFavo licence deal is vital to enable expansion of the US commercial team to support the launch and early detailing for BARHEMSYS (and ByFavo). The Cosmo loan facility is repayable over 24 months starting in January 2023. To fund further expansions in US operations, we forecast that, in addition to the loan facility from Cosmo Pharma, an additional c £100m will need to be raised in 2020–22 ($20m in 2020, $40m in 2021 and $40m in 2022). We note that, for simplicity, in our model we illustrate this as a debt raise.

We forecast revenues in FY20 of $2.1m, growing to $28.8m in FY21. In the short term, revenues remain dependent on the successful sales execution of BARHEMSYS in PONV and ByFavo in procedural sedation. Future BARHEMSYS sales could derive from CINV indication and further product in-licensing. We forecast a net loss of $33.7m in FY20 and $39.5m in FY21 and that Acacia will reach break-even in 2023. We anticipate that SG&A costs will increase to $31.5m in FY20, growing to $54.6m in FY21 – this investment is necessary to support product commercialisation.

As Julian Gilbert (former CEO) and Christine Soden (CFO) both stepped down in the last 12 months, new management is more US centric with the appointment of Mike Bolinder (CEO) and Gary Gemignani (CFO). A US listing could make sense in the future depending on market conditions and, importantly, Acacia's status quo (post approval of BARHEMSYS and ByFavo with sales.

Valuation: €963.2m or €15.1/share

Our valuation of Acacia Pharma, at €963.2m or €15.1/share vs €970.5m or €15.2/share previously, is based on a risk-adjusted NPV model. Our sales forecasts are unchanged but we have adjusted our SG&A assumptions and rolled our model forward. Following the FY results we have moved to US-dollar denominated figures for 2018, 2019 and our forecasts. Our sales forecasts for BARHEMSYS for rescue treatment and prophylaxis of PONV and the CINV opportunity for the US market remain unchanged (Exhibit 1). We include end December 2019 net cash of $7m in our valuation ($17m cash and $10m Hercules debt) and use a 12.5% discount rate.

Exhibit 1: Valuation

Product	Indication	Launch	Peak sales ($m)	Value ($m)	Probability	rNPV ($m)	rNPV (€m)	rNPV/ share (€)
BARHEMSYS US only	PONV	2020	386.7	854.9	100%	854.9	769.4	12.0
APD403 US only	CINV	2024	107.9	73.1	30%	12.9	11.6	0.2
ByFavo US only	Procedural sedation	2020	125.6	222.1	90%	195.5	175.9	2.8
Net cash at 31 December 2019 (US$)				7.0	100%	7.0	6.3	0.1
Valuation				1,157.1		1,070.3	963.2	15.1

Source: Edison Investment Research

Exhibit 2: Financial summary

Year-end 31 December	US$m	2018	2019	2020e	2021e
PROFIT & LOSS					
Revenue		0.0	0.0	2.1	28.8
Operating revenues		0.0	0.0	2.1	28.8
Cost of sales		0.0	0.0	(0.2)	(2.4)
Gross profit		0.0	0.0	1.9	26.4
Gross margin %		n/a	n/a	0.9	0.9
SG&A (expenses)		(15.0)	(18.5)	(31.5)	(54.6)
R&D costs		(5.0)	(3.9)	(2.8)	(10.0)
Other income/(expense)		0.0	0.0	0.0	0.0
EBITDA (reported)		(20.0)	(22.4)	(32.4)	(38.3)
Depreciation and amortisation		0.0	0.0	0.0	0.0
Reported Operating Income		(20.0)	(22.4)	(32.4)	(38.3)
Operating Margin %		n/a	n/a	n/a	n/a
Finance income/(expense)		(1.5)	(1.1)	(2.0)	(1.9)
Exceptionals and adjustments		0.0	0.0	0.0	0.0
Reported PBT		(21.6)	(23.5)	(34.4)	(40.1)
Income tax expense (includes exceptionals)		0.9	0.7	0.7	0.7
Reported net income		(20.7)	(22.8)	(33.7)	(39.5)
Basic average number of shares, m		44.1	53.7	69.7	69.7
Year-end number of shares, m		53.3	53.3	69.7	69.7
Basic EPS ($)		(0.47)	(0.43)	(0.48)	(0.57)
Adjusted EPS ($)		(0.45)	(0.38)	(0.48)	(0.57)
Dividend per share ($)		0.00	0.00	0.00	0.00
BALANCE SHEET					
Property, plant and equipment		0.0	0.0	2.1	3.2
Goodwill		0.0	0.0	0.0	0.0
Intangible assets		0.0	0.0	0.0	0.0
Other non-current assets		0.0	0.4	38.8	38.8
Total non-current assets		0.0	0.4	40.9	42.0
Cash and equivalents		37.4	17.0	24.7	22.5
Inventories		0.0	0.0	0.0	0.4
Trade and other receivables		0.4	0.6	0.3	4.7
Other current assets		0.9	0.7	0.7	0.7
Total current assets		38.7	18.3	25.7	28.4
Non-current loans and borrowings		8.9	4.7	57.5	97.5
Other non-current liabilities		0.0	0.0	0.0	0.0
Total non-current liabilities		8.9	4.7	57.5	97.5
Trade and other payables		4.7	4.2	4.3	7.5
Current loans and borrowings		0.5	5.5	0.0	0.0
Other current liabilities		0.0	0.0	0.0	0.0
Total current liabilities		5.2	9.6	4.3	7.5
Equity attributable to company		24.7	4.3	4.8	(34.7)
CASH FLOW STATEMENT					
Operating Profit		(21.6)	(23.5)	(34.4)	(40.1)
Depreciation and amortisation		0.0	0.0	0.0	0.0
Share based payments		0.0	0.0	0.0	0.0
Other adjustments		1.6	1.1	2.0	1.9
Movements in working capital		(3.9)	(0.8)	0.4	(1.6)
Interest paid / received		0.2	0.4	(2.0)	(1.9)
Income taxes paid		0.4	0.8	0.7	0.7
Cash from operations (CFO)		(15.4)	(19.8)	(33.9)	(41.3)
Capex		0.0	0.0	(2.2)	(1.4)
Acquisitions & disposals net		0.0	0.0	0.0	0.0
Other investing activities		0.2	0.4	0.6	0.6
Cash used in investing activities (CFIA)		0.2	0.4	(14.4)	(0.8)
Net proceeds from issue of shares		47.1	0.2	8.5	0.0
Movements in debt		1.8	(1.0)	47.4	40.0
Other financing activities		0.0	(0.1)	0.0	0.0
Cash from financing activities (CFF)		48.9	(0.9)	55.9	40.0
Cash and equivalents at beginning of period		4.1	37.4	17.0	24.7
Increase/(decrease) in cash and equivalents		33.3	(20.4)	7.6	(2.1)
Cash and equivalents at end of period		37.4	17.0	24.7	22.5
Net (debt)/cash		28.1	6.9	(32.9)	(75.0)

Source: Acacia Pharma, Edison Investment Research

General disclaimer and copyright

This report has been commissioned by Acacia Pharma and prepared and issued by Edison, in consideration of a fee payable by Acacia Pharma. Edison Investment Research standard fees are £49,500 pa for the production and broad dissemination of a detailed note (Outlook) following by regular (typically quarterly) update notes. Fees are paid upfront in cash without recourse. Edison may seek additional fees for the provision of roadshows and related IR services for the client but does not get remunerated for any investment banking services. We never take payment in stock, options or warrants for any of our services.

Accuracy of content: All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report and have not sought for this information to be independently verified. Opinions contained in this report represent those of the research department of Edison at the time of publication. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations.

Exclusion of Liability: To the fullest extent allowed by law, Edison shall not be liable for any direct, indirect or consequential losses, loss of profits, damages, costs or expenses incurred or suffered by you arising out or in connection with the access to, use of or reliance on any information contained on this note.

No personalised advice: The information that we provide should not be construed in any manner whatsoever as, personalised advice. Also, the information provided by us should not be construed by any subscriber or prospective subscriber as Edison's solicitation to effect, or attempt to effect, any transaction in a security. The securities described in the report may not be eligible for sale in all jurisdictions or to certain categories of investors.

Investment in securities mentioned: Edison has a restrictive policy relating to personal dealing and conflicts of interest. Edison Group does not conduct any investment business and, accordingly, does not itself hold any positions in the securities mentioned in this report. However, the respective directors, officers, employees and contractors of Edison may have a position in any or related securities mentioned in this report, subject to Edison's policies on personal dealing and conflicts of interest.

Australia

Edison Investment Research Pty Ltd (Edison AU) is the Australian subsidiary of Edison. Edison AU is a Corporate Authorised Representative (1252501) of Crown Wealth Group Pty Ltd who holds an Australian Financial Services Licence (Number: 494274). This research is issued in Australia by Edison AU and any access to it, is intended only for "wholesale clients" within the meaning of the Corporations Act 2001 of Australia. Any advice given by Edison AU is general advice only and does not take into account your personal circumstances, needs or objectives. You should, before acting on this advice, consider the appropriateness of the advice, having regard to your objectives, financial situation and needs. If our advice relates to the acquisition, or possible acquisition, of a particular financial product you should read any relevant Product Disclosure Statement or like instrument.

New Zealand

The research in this document is intended for New Zealand resident professional financial advisers or brokers (for use in their roles as financial advisers or brokers) and habitual investors who are "wholesale clients" for the purpose of the Financial Advisers Act 2008 (FAA) (as described in sections 5(c) (1)(a), (b) and (c) of the FAA). This is not a solicitation or inducement to buy, sell, subscribe, or underwrite any securities mentioned or in the topic of this document. For the purpose of the FAA, the content of this report is of a general nature, is intended as a source of general information only and is not intended to constitute a recommendation or opinion in relation to acquiring or disposing (including refraining from acquiring or disposing) of securities. The distribution of this document is not a "personalised service" and, to the extent that it contains any financial advice, is intended only as a "class service" provided by Edison within the meaning of the FAA (i.e. without taking into account the particular financial situation or goals of any person). As such, it should not be relied upon in making an investment decision.

United Kingdom

This document is prepared and provided by Edison for information purposes only and should not be construed as an offer or solicitation for investment in any securities mentioned or in the topic of this document. A marketing communication under FCA Rules, this document has not been prepared in accordance with the legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of investment research.

This Communication is being distributed in the United Kingdom and is directed only at (i) persons having professional experience in matters relating to investments, i.e. investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "FPO") (ii) high net-worth companies, unincorporated associations or other bodies within the meaning of Article 49 of the FPO and (iii) persons to whom it is otherwise lawful to distribute it. The investment or investment activity to which this document relates is available only to such persons. It is not intended that this document be distributed or passed on, directly or indirectly, to any other class of persons and in any event and under no circumstances should persons of any other description rely on or act upon the contents of this document.

This Communication is being supplied to you solely for your information and may not be reproduced by, further distributed to or published in whole or in part by, any other person.

United States

Edison relies upon the "publishers' exclusion" from the definition of investment adviser under Section 202(a)(11) of the Investment Advisers Act of 1940 and corresponding state securities laws. This report is a bona fide publication of general and regular circulation offering impersonal investment-related advice, not tailored to a specific investment portfolio or the needs of current and/or prospective subscribers. As such, Edison does not offer or provide personal advice and the research provided is for informational purposes only. No mention of a particular security in this report constitutes a recommendation to buy, sell or hold that or any security, or that any particular security, portfolio of securities, transaction or investment strategy is suitable for any specific person.

Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
1,185 Avenue of the Americas
3rd Floor, New York, NY 10036
United States of America

Sydney +61 (0)2 8249 8342
Level 4, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia