EDISON

Acacia Pharma

Full-year results

BARHEMSYS and BYFAVO launched in the US

Pharma & biotech

The year 2020 was transformational for Acacia Pharma, with the US approval of its two lead assets, BARHEMSYS (amisulpride injection) for the treatment and prevention of post-operative nausea and vomiting (PONV) and BYFAVO (remimazolam), an IV sedative for use during invasive medical procedures. Both assets have now been launched, BARHEMSYS in August 2020 and BYFAVO in January 2021. By marketing two products through a small but experienced salesforce, Acacia should realise significant operational synergies. Launches are in the early phase, with the focus on gaining wide formulary access in FY21; this should translate to significant revenue generation from FY22 onwards and maiden operating profit from FY23. Our updated valuation of Acacia Pharma is €1,278m.

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS ($)	P/E (x)	Yield (%)
12/19	0.0	(21.1)	(0.38)	0.00	N/A	N/A
12/20	0.2	(28.5)	(0.38)	0.00	N/A	N/A
12/21e	8.0	(39.9)	(0.40)	0.00	N/A	N/A
12/22e	39.7	(34.1)	(0.33)	0.00	N/A	N/A

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

BARHEMSYS early formulary wins are a good start

During 2021, we expect early BARHEMSYS sales to trickle through as Acacia focuses on formulary wins against a tough COVID-19 background; formulary access is key for initial sales in the hospital setting. Since Acacia's commercial team started customer engagement in mid-October 2020, the company has secured 120 accounts on formulary, representing >85% win rate. A backlog of surgical procedures could additionally aid early sales adoption; BARHEMSYS use results in shorter times in post-anaesthesia care units, which enables increased surgical throughput. Ex US, Acacia is evaluating out-licensing deals for BARHEMSYS in PONV.

BYFAVO launched January 2021

BYFAVO is the first new sedative launched to be in the US in 20 years. Importantly, the broad label granted by FDA covers all adult invasive medical procedures of less than 30-minute duration (extends its utility beyond bronchoscopy and gastroscopy procedures to ophthalmology, interventional radiology and plastic surgery). Acacia estimates the total addressable market in procedural sedation to be >$1.5bn/year. The pandemic has led to the inclusion of competitor procedural anaesthetics (midazolam and propofol) on the FDA drug shortage list, thus a timely launch of BYFAVO is key to benefit from increased pent-up demand of these drug classes.

Valuation: €1,278m or €12.8/share

Our revised valuation is €1,278m or €12.8/share versus €1,170m or €13.4/share previously. Our sales forecasts are unchanged, we have reduced R&D costs, we roll our model forward, update FX and reflect a net cash position of $10.0m at 31 December 2020. Acacia is funded into 2022, additional funding will be needed in H222 for further commercial expansions. Given Acacia's operational focus on the US and the opportunities for BARHEMSYS and BYFAVO in this key market, we believe a Nasdaq listing would be appropriate to further widen the investor base.

1 April 2021

Price	**€2.37**
Market cap	**€236m**
	US$1.18:€
Net cash ($m) at 31 December 2020	10.0
Shares in issue	99.7m
Free float	80%
Code	ACPH
Primary exchange	Euronext
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(13.3)	(10.4)	4.4
Rel (local)	(16.4)	(16.8)	(22.3)
52-week high/low		€3.48	€1.85

Business description

Acacia Pharma is a commercial-stage biopharmaceutical company focused on commercialising novel products to improve the care of patients undergoing serious medical treatments such as surgery, invasive procedures or chemotherapy. It has two assets, BARHEMSYS (launched for the treatment of PONV in the US) and in-licensed asset BYFAVO (launched for procedural sedation in the US).

Next events

BARHEMSYS and BYFAVO formulary wins	2021
Initiation of pivotal CINV trial (APD403)	2022

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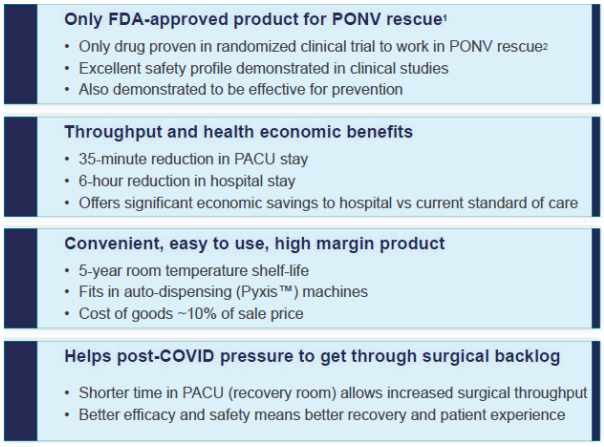
Edison profile page

Focus on BARHEMSYS and BYFAVO sales execution

During the last eight months, Acacia Pharma has successfully launched BARHEMSYS, its first internally developed asset to reach the market, and in-licensed BYFAVO in the key US market (Exhibit 1 and 2). The rationale for in-licensing BYFAVO was to enable operational leverage and accompanying sales and marketing synergies as Acacia builds and expands its US commercial operations. Ahead of potential approvals, Acacia's core US commercial infrastructure was established with c 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. In October Acacia added an additional 30 sales representatives (five in each of the six regions).

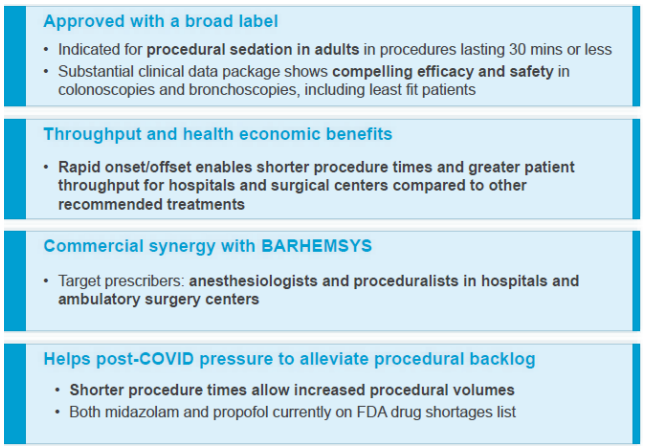
Our sales forecasts are unchanged. We forecast peak BARHEMSYS sales of $405.3m and peak BYFAVO sales of $125.6m. To successfully commercialise BARHEMSYS and BYFAVO, Acacia must ensure the products are accepted on each hospital's formulary (a list of drugs that healthcare providers in the hospital can prescribe). This often requires the hospital's pharmacy and therapeutics (P&T) committee to be convinced of the clinical and economic benefits of the drug before approving it, which takes nine to 12 months on average. Once the drug is on a hospital formulary, treatment by both assets would be provided under diagnosis-related group codes where the treatment costs would be included in the total cost of surgery. Although inclusion takes time, it leads to a steady annuity-like revenue stream driven by procedure volumes and automated use rather than relying on individual prescriber decisions. Acacia has hired a highly experienced commercial team with direct experience in successfully launching other products such as OFIRMEV (acetaminophen injection) into the same customer base.

Exhibit 1: BARHEMSYS clinical and commercial proposition



Source: Acacia Pharma corporate presentation

Exhibit 2: BYFAVO clinical and commercial proposition



Source: Acacia Pharma corporate presentation

BARHEMSYS broad label includes 'rescue' differentiation

The US label of BARHEMSYS for PONV (approved 26 February 2020) is broad. It 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 (such as ondansetron). Initial detailing will focus on rescue treatment (BARHEMSYS is the only antiemetic with this indication). Acacia estimates the total addressable US population to be c 34 million patients, a sizable opportunity. It also estimates the annual PONV 'rescue' market to be $2.7bn. In October 2020, Acacia's highly experienced commercial team started driving formulary

adoption by initially targeting ~900 hospitals. BARHEMSYS has now been added to formulary at 120 hospitals, representing a P&T committee review success rate of 85%.

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. Management has indicated that a single Phase III clinical trial would be required for submission for CINV and we expect the company to initiate this trial in 2022, once BARHEMSYS and BYFAVO launches are well underway and there is further visibility on cash runway. 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. We maintain our forecast peak sales potential of $107.9m in 2031 for CINV.

BYFAVO first new sedative launched in the US in 20 years

Acacia's product portfolio offering was expanded by the BYFAVO in-licence deal with Cosmo Pharmaceuticals (January 2020), done to enable significant leverage of its US commercial infrastructure. Furthermore, under the deal terms, Acacia has access to the short-term funding required to expand its US footprint. BYFAVO (remimazolam) is an ultra-short-acting and reversible intravenous benzodiazepine sedative/anaesthetic approved (July 2020) for use during procedural sedation. BYFAVO has been designated a Schedule IV (low potential for abuse and low risk of dependence) medicine by the US Drug Enforcement Agency; importantly, this is in line with its benzodiazepine peers. Initial discussions with hospital P&T committees are underway and have netted seven accounts on formulary within eight weeks of launch. Acacia believes BYFAVO's inclusion on formulary has been more rapid than that of BARHEMSYS as the company is able to leverage its existing relationships established through BARHEMSYS inclusions. Acacia is targeting the 40m annual short-duration surgical procedures a year, this includes 25m gastrointestinal endoscopic procedures, but additional opportunities exist for ophthalmology procedures, plastic surgery and in interventional radiology.

Financials

Acacia reported maiden revenues of $0.2m in FY20, related to initial sales of BARHEMSYS. During the year Acacia continued to build on its US commercial operations in preparation for the launch of BARHEMSYS and BYFAVO. As a result, net loss rose in FY20 to $33.5m (vs FY19: $22.8m). SG&A expenses increased in FY20 to $31.0m versus $18.5m in FY19, reflecting the increased activity leading up to the product launches and the amortisation of intangibles (which represent the amounts paid to Cosmo for the BYFAVO licence) that is included in this figure. R&D expenses declined to $0.1m (vs FY19: $3.9m) reflecting completion of BARHEMSYS clinical programme and a credit of $1.4m related to reversal of inventory provisions on the drugs approval.

We forecast revenues in FY21 of $8.0m, growing to $39.7m in FY22. 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 the CINV indication and further product in-licensing. We forecast a net loss of $47.3m in FY21 and $41.4m in FY22 and that Acacia will reach break-even in 2023. We anticipate that SG&A costs will increase to $50.6m in FY21, growing to $68.9m in FY22 – this investment is necessary to support product commercialisation.

In June 2018, Acacia drew down $10m from the loan facility with Hercules Technology Growth Capital. The deal with Cosmo provides an additional €25m loan facility, interest-rate only until January 2023 and repayable over the following 24 months. Until the Hercules debt is fully repaid, the Cosmo loan interest is 11%, after which it decreases to 9%. Acacia reported cash and cash equivalents of $46.7m at 31 December 2020 (vs $17.0m in 2019). In August 2020, Acacia raised

€25m gross through the placing of 12.5m shares. Thus, including Cosmo's equity investments (€20m), Acacia gained access to €70m additional capital in the form of debt and equity in FY20. Post period, Acacia raised €27m gross through a 10m share placing (11.1% of prior share capital). To fund further expansions in US operations, we forecast that an additional c $35m will need to be raised in 2022. We note that, for simplicity, in our model we illustrate this as long-term debt funding. A US listing could make sense in the future depending on market conditions and, importantly, Acacia's status quo post launch of BARHEMSYS and BYFAVO in terms of sales.

Valuation

Our revised valuation is €1,278m or €12.8/share versus €1,170m or €13.4/share previously. Our sales forecasts are unchanged, we roll our model forward, update FX and reflect a net cash position of $10.0m at 31 December 2020.

Exhibit 3: Valuation

Product	Indication	Launch	Peak sales ($m)	Value ($m)	Probability	rNPV ($m)	rNPV (€m)	rNPV/share (€)
BARHEMSYS US only	PONV	2020	405.3	1,153.0	100%	1,153.0	977.8	9.8
APD403 US only	CINV	2025	107.9	70.3	30%	18.4	15.6	0.2
BYFAVO US only	Procedural sedation	2020	125.6	325.8	100%	325.8	276.2	2.8
Net cash at 31 December 2020				10.0	100%	10.0	8.5	0.1
Valuation				**1,559.1**		**1,507.2**	**1,278.1**	**12.8**

Source: Edison Investment Research

Exhibit 4: Financial summary

Year end 31 December (US$m)	2018	2019	2020	2021e	2022e
PROFIT & LOSS					
Operating revenues	0.0	0.0	0.2	8.0	39.7
Cost of sales	0.0	0.0	(0.0)	(0.5)	(3.1)
Gross profit	0.0	0.0	0.2	7.5	36.6
Gross margin %	N/A	N/A	86%	94%	92%
SG&A (expenses)	(15.0)	(18.5)	(31.0)	(50.6)	(68.9)
R&D costs	(5.0)	(3.9)	(0.1)	(1.0)	(7.0)
Other income/(expense)	0.0	0.0	0.0	0.0	0.0
EBITDA	(20.0)	(22.3)	(27.8)	(36.0)	(31.2)
Reported operating Income	(20.0)	(22.4)	(30.9)	(44.1)	(39.3)
Operating Margin %	N/A	N/A	N/A	N/A	N/A
Finance income/(expense)	(1.5)	(1.1)	(3.2)	(3.9)	(2.8)
Exceptionals and adjustments	0.0	0.0	0.0	0.0	0.0
Reported profit before tax	(21.6)	(23.5)	(34.1)	(48.0)	(42.1)
Normalised profit before tax	(20.9)	(21.1)	(28.5)	(39.9)	(34.1)
Income tax expense (includes exceptionals)	0.9	0.7	0.6	0.7	0.7
Reported net income	(20.7)	(22.8)	(33.5)	(47.3)	(41.4)
Basic average number of shares, m	44.1	53.7	73.6	98.1	99.7
Year-end number of shares, m	53.3	54.9	89.6	99.7	99.7
Basic EPS ($)	(0.47)	(0.43)	(0.45)	(0.48)	(0.42)
Adjusted EPS ($)	(0.45)	(0.38)	(0.38)	(0.40)	(0.33)
Dividend per share ($)	0.00	0.00	0.00	0.00	0.00
BALANCE SHEET					
Property, plant and equipment	0.0	0.0	0.0	0.3	2.2
Intangible assets	0.0	0.0	52.2	44.1	36.1
Other non-current assets	0.0	0.4	0.3	0.3	0.3
Total non-current assets	0.0	0.4	52.4	44.8	38.6
Cash and equivalents	37.4	17.0	46.7	35.0	31.0
Inventories	0.0	0.0	2.7	1.0	4.3
Trade and other receivables	0.4	0.6	0.5	1.4	4.3
Other current assets	0.9	0.7	0.6	0.6	0.6
Total current assets	38.7	18.3	50.4	38.0	40.2
Non-current loans and borrowings	8.9	4.7	31.3	31.3	66.3
Other non-current liabilities	0.0	0.0	0.0	0.0	0.0
Total non-current liabilities	8.9	4.7	31.3	31.3	66.3
Trade and other payables	4.7	4.2	5.7	6.9	9.4
Current loans and borrowings	0.5	5.5	5.4	0.0	0.0
Other current liabilities	0.0	0.0	0.0	0.0	0.0
Total current liabilities	5.2	9.6	11.1	6.9	9.4
Equity attributable to company	24.7	4.3	60.5	44.5	3.1
CASH FLOW STATEMENT					
Profit before tax	(21.6)	(23.5)	(34.0)	(48.0)	(42.1)
Depreciation and amortisation	0.0	0.1	3.1	8.1	8.1
Share based payments	0.6	2.4	2.6	0.0	0.0
Other adjustments	1.5	1.1	3.2	3.9	2.8
Movements in working capital	(3.9)	(0.8)	(1.0)	2.0	(3.7)
Interest paid	0.0	0.0	0.0	(3.9)	(2.8)
Income taxes paid	0.4	0.8	0.7	0.7	0.7
Cash from operations (CFO)	(15.4)	(19.8)	(25.4)	(37.3)	(37.1)
Capex	0.0	0.0	0.0	(0.4)	(1.9)
Acquisitions & disposals net	0.0	0.0	0.0	0.0	0.0
Other investing activities	0.2	0.4	0.0	0.0	0.0
Cash used in investing activities (CFIA)	0.2	0.4	0.0	(0.3)	(1.9)
Net proceeds from issue of shares	47.1	0.2	48.4	31.4	0.0
Movements in debt	1.8	(1.0)	7.7	(5.4)	35.0
Other financing activities	0.0	(0.1)	(0.1)	0.0	0.0
Cash from financing activities (CFF)	48.9	(0.9)	56.0	25.9	35.0
Cash and equivalents at beginning of period	4.1	37.4	17.0	46.7	35.0
Increase/(decrease) in cash and equivalents	33.7	(20.3)	30.7	(11.7)	(3.9)
Effect of FX on cash and equivalents	(0.4)	(0.1)	(1.0)	0.0	0.0
Cash and equivalents at end of period	37.4	17.0	46.7	35.0	31.0
Net (debt)/cash	28.1	6.9	10.0	3.7	(35.3)

Source: Acacia Pharma, Edison Investment Research

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