PAION AG

Germany / Biotechnology
Frankfurt Prime Standard
Bloomberg: PA8 GR
ISIN: DE000A0B65S3

BYFAVO gains FDA approval

RATING	**BUY**
PRICE TARGET	**€ 4.90**
Return Potential	67.2%
Risk Rating	High

BYFAVO APPROVAL LOWERS OPERATIONAL RISK IN BOTH THE US AND EU

PAION has announced that the FDA has approved remimazolam (US brandname: BYFAVO) in the indication procedural sedation. PAION will receive a milestone payment of EUR15m from its US licensing partner Cosmo Pharmaceuticals (Cosmo) and tiered royalties on net sales in the US ranging from 20% to 25%, which may be adjusted under certain conditions but cannot fall below 15% of net sales. Approval in procedural sedation in the US substantially raises the probability of EU approval of remimazolam in the same indication in 2021. Following EU approval in procedural sedation and providing topline data from the EU trial due by the end of this year are positive, PAION will then be able to submit an extension of the remimazolam EU marketing authorisation application (MAA) for general anesthesia. In general the review period for MAA extensions is shorter than for an MAA. We have raised our price target from €3.60 to €4.90 to reflect the reduction in risk entailed by BYFAVO's approval in the US for both PAION's US and EU operations. We maintain our Buy recommendation.

BYFAVO approval triggers €10m net cash transfer to commercialisation partner Acacia Cosmo sublicensed BYFAVO to Acacia Pharma Group (Acacia) in January this year following a delay in FDA approval of its diagnostic product candidate Methylene Blue MMX. Acacia is a Euronext-listed hospital pharmaceutical company based in Cambridge, UK, and Indianapolis. At the end of February Acacia achieved FDA approval for BARHEMSYS, which is indicated for post-operative nausea and vomiting (PONV). Acacia's management quantifies the US market opportunity for BARHEMSYS at USD460m annually (assumes 15% market share of the PONV "rescue" market plus a 10% share of the combination prophylaxis market). This compares with our peak sales estimate for remimazolam in procedural sedation in the US of €203m. Revenues from both products will be required to justify the ca. 50 person marketing team Acacia is currently building for the US market. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2016	2017	2018	2019	2020E	2021E
Revenue (€ m)	4.26	5.81	2.77	8.00	20.37	21.94
Y-o-y growth	n.a.	36.4%	-52.4%	189.2%	154.6%	7.7%
EBIT (€ m)	-25.08	-15.87	-12.46	-9.33	1.37	-6.06
EBIT margin	n.a.	n.a.	n.a.	n.a.	6.7%	n.a.
Net income (€ m)	-20.12	-12.09	-9.94	-7.02	1.12	-5.45
EPS (diluted) (€)	-0.38	-0.20	-0.16	-0.11	0.02	-0.08
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-11.78	-17.75	-12.83	-2.86	2.28	-13.29
Net gearing	-120.7%	-98.5%	-82.7%	-97.4%	-102.5%	-51.3%
Liquid assets (€ m)	30.11	24.84	17.23	18.79	26.08	17.80

RISKS

Risks to our price target include but are not limited to: drug development, finding development partners on favourable terms, financial, and legal risks.

COMPANY PROFILE

PAION is a specialty pharmaceutical company headquartered in Aachen (Germany) with operations in Cambridge (United Kingdom). PAION's lead substance, remimazolam, is an intravenous ultra-short-acting benzodiazepine anaesthetic that has completed phase III clinical development for procedural sedation.

MARKET DATA

As of 08 Jul 2020

Closing Price	€ 2.93
Shares outstanding	66.23m
Market Capitalisation	€ 194.04m
52-week Range	€ 1.41 / 3.46
Avg. Volume (12 Months)	125,006

Multiples	2019	2020E	2021E
P/E	n.a.	168.9	n.a.
EV/Sales	22.0	8.7	8.0
EV/EBIT	n.a.	128.6	n.a.
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW

COMPANY DATA

As of 31 Mar 2020

Liquid Assets	€ 17.97m
Current Assets	€ 22.23m
Intangible Assets	€ 2.01m
Total Assets	€ 24.34m
Current Liabilities	€ 9.29m
Shareholders' Equity	€ 15.03m

SHAREHOLDERS

Cosmo Pharmaceuticals	8.9%
TIAA-CREF	2.8%
Free Float	88.3%

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The rationale presented by Acacia for licensing in BYFAVO is that both products target the same key physicians and that the value proposition underlying both products lies in mobilising patients more quickly after a procedure.

Figure1: Summarised terms of the Cosmo/Acacia BYFAVO licensing agreement

To be received by Acacia in respect of the BYFAVO license (€m)	
Cosmo upfront strategic equity investment	10
Cosmo loan facility I on approval of BARHEMSYS	10
Cosmo loan facility II on approval of BYFAVO	25
To be received by Cosmo in respect of the BYFAVO license (€m)	
Acacia shares upfront	10
Acacia shares on BYFAVO approval	15
Cash on BYFAVO approval	15
Net cash to Acacia (€m)	30

Source: Acacia Pharma

Figure 1 summarises the terms of the BYFAVO licensing agreement between Cosmo and Acacia and of the equity and debt investments made by Cosmo in Acacia. As figure 1 shows, as a consequence of the FDA approval of both BARHEMSYS and BYFAVO, Acacia will receive net cash of €30m from Cosmo. This sum should be adequate to launch both products on the US market. So far Acacia has hired ca. 20 of the 50 persons it envisages will comprise its marketing team when this reaches its targeted size.

PAION guiding for combined 2020 royalty income from US and Japan of <€1m Acacia has stated that it intends to launch both BARHEMSYS and BYFAVO during the second half of this year but notes that marketing of BYFAVO in the US cannot commence until the Drug Enforcement Administration has determined scheduling of the drug under the Controlled Substances Act. We gather from Acacia's conference call on 6 July that this may take between a few weeks and a few months. The pace at which BYFAVO is launched in the US will also depend on access to decision-makers which has been made more difficult in recent months by the SARS-CoV-2 pandemic. Remimazolam was approved in Japan in the indication general anesthesia in January this year. PAION's Japanese licensee, Mundipharma, has stated that it has recently launched the drug. The prevalence of SARS-CoV-2 is far lower in Japan than in the US but in the 2019 annual report management gave conservative guidance (which we have adopted) of under €1m for combined 2020 royalties from both markets.

EU approval in procedural sedation likely from early 2021… PAION submitted an MAA for procedural sedation to the EMA in November 2019 after having been informed at a February 2019 pre-submission meeting with the Agency that the US Phase III data package would meet its requirements. PAION expects a decision on market approval at the beginning of 2021 at the earliest.

…to be followed by accelerated EU approval process in general anesthesia At the beginning of April, PAION announced the closure of enrolment in the EU phase III trial of remimazolam in general anesthesia. The original plan was to recruit 500 patients. But in view of the difficulty in completing recruitment during the SARS-CoV-2 pandemic, the Data Monitoring Committee agreed that the 424 patients enrolled by the last week of March would be sufficient to conduct the planned statistical analyses. Topline study results are expected in H2 2020. Providing that remimazolam receives the expected EU approval in procedural sedation in 2021, PAION intends to submit an application for an extension to the drug's marketing authorisation to include general anesthesia. The EMA usually processes marketing authorisation extensions more quickly than marketing authorisation applications.

Price target raised from €3.60 to €4.90. Buy recommendation maintained Figure 2 shows changes to our forecasts. Our numbers for 2020 are almost unchanged but we have reduced our 2021 revenue forecast (revenue and royalty income from BYFAVO/remimazolam) to reflect our view that SARS-CoV-2 will continue to delay non-essential surgical procedures into next year. The impact of this on our valuation is however greatly outweighed by the reduction in risk for both PAION's US and EU operations entailed by BYFAVO's approval in the US. We have raised our price target from €3.60 to €4.90 and maintain our Buy recommendation.

Figure 2: Changes to our forecasts

	2020E			2021E		
in EURm	**Old**	**New**	**Δ**	**Old**	**New**	**Δ**
Revenues	0.89	0.87	-2.1%	21.50	18.44	-14.3%
Other operating income	19.50	19.50	0.0%	3.50	3.50	0.0%
Total revenues	20.39	20.37	-0.1%	25.00	21.94	-12.3%
SG&A	-8.00	-8.00	-	-12.86	-12.69	-
% total revenues	-39.2%	-39.3%	-	-51.4%	-57.9%	-
R&D	-11.00	-11.00	-	-12.00	-12.00	-
% total revenues	-53.9%	-54.0%	-	-48.0%	-54.7%	-
EBIT	1.39	1.37	-1.3%	-3.16	-6.06	n.a.
margin	*6.8%*	*6.7%*	-	*-12.6%*	*-27.6%*	-
Net income	1.14	1.12	-1.6%	-3.13	-5.45	n.a.
margin	*5.6%*	*5.5%*	-	*-12.5%*	*-24.9%*	-
EPS (dil., in EUR)	0.02	0.02	-1.6%	-0.05	-0.08	n.a.

Source: First Berlin Equity Research

Figure 3: Pipeline valuation model

Compound	Project (1)	Present Value	Patient Pop	Treatment Cost	Market Size	Market Share	Peak Sales	PACME Margin (2)	Discount Factor	Patent Life (3)	Time to Market
Remimazolam	PS EU	€67.0M	15,144K	€14	€208.6M	25%	€68.1M	30%	15%	12	1 Year
Remimazolam	PS US	€164.2M	20,000K	€20	€400.0M	40%	€202.9M	20%	12%	11	-
Remimazolam	PS CAN	€6.8M	1,056K	€20	€21.1M	50%	€13.4M	18%	15%	10	2 Years
Remimazolam	GA EU	€112.1M	15,144K	€40	€605.8M	20%	€159.9M	30%	15%	11	2 Years
Remimazolam	GA US	€88.7M	23,925K	€40	€957.0M	20%	€242.7M	20%	15%	8	4 Years
Remimazolam	GA JAP	€101.7M	10,000K	€40	€400.0M	25%	€131.9M	18%	12%	13	-
Remimazolam	GA CHN	€17.3M	51,000K	€28	€1,405.0M	10%	€185.4M	10%	15%	15	4 Years
Remimazolam	PS CHN	€14.2M	33,260K	€10	€346.5M	10%	€45.7M	10%	15%	15	1 Year
Remimazolam	GA KOR	€9.4M	3,750K	€28	€103.3M	25%	€34.1M	10%	15%	15	1 Year
Remimazolam	GA CIS/MENA/TUR	€55.1M	55,247K	€28	€1,566.6M	10%	€206.7M	12%	15%	15	2 Years
Remimazolam	ICU US	€17.7M	1,561K	€250	€390.2M	25%	€123.7M	20%	15%	7	5 Years
Remimazolam	ICU EU	€33.3M	2,439K	€167	€406.5M	25%	€136.8M	30%	15%	8	4 Years
Remimazolam	ICU Japan	€4.7M	606K	€167	€101.0M	25%	€33.3M	18%	15%	9	5 Years
PACME PV		€692.1M									
Costs PV (4)		€423.7M									
NPV		€268.4M									
Milestones PV		€37.3M									
Pro forma net cash		€18.9M									
Fair Value		€324.6M									
Pro forma share count		66,226K									
Price Target		€4.90									

1) A project typically refers to a specific indication or, where necessary or relevant, a combination between indication and geographic market
PS EU = Procedural Sedation in the EU
PS US = Procedural Sedation in the US
PS CAN = Procedural Sedation in Canada
GA EU = General Anaesthesia in the EU
GA US = General Anaesthesia in the US
GA JAP = General Anaesthesia in Japan
GA CHN = General Anaesthesia in China
GA KOR = General Anaesthesia in South Korea
GA CIS/MENA/TUR = General Anaesthesia in the Commonwealth of Independent States, Middle East & North Africa, and Turkey
ICU US = General Anaesthesia in Intensive Care Units in the US
ICU EU = General Anaesthesia in Intensive Care Units in the EU
Other projects: GGF2 (HF) and Solulin (HPH)
HF = Heart Failure
HPH = Haemophilia

2) PACME (Profit After Costs and Marketing Expenses) reflects the company's profit share on future revenues.
This share may be derived in the form of royalties (outsourced marketing/manufacturing) or operating EBITDA margin (in-house model), or some mix of both (depending on the specific parameters of partnership agreements)

3) Remaining patent life in years after the point of approval

4) Includes company-level R&D, G&A, Financing Costs, CapEx and working capital; COGS and S&M are factored into the PACME margin for each project

Source: First Berlin Equity Research

Figure 4: Changes to pipeline valuation model

	Old	New	Delta
NPV	**€187.9M**	**€268.4M**	**42.8%**
Milestones PV	€33.5M	€37.3M	11.4%
Pro Forma Net Cash	€16.9M	€18.9M	11.8%
Fair Value	€238.3M	€324.6M	36.2%
Diluted Share Count	66.2M	66.2M	0.0%
Fair Value Per Share	**€3.60**	**€4.90**	**36.2%**

Source: First Berlin Equity Research

INCOME STATEMENT

All figures in EUR '000	2016	2017	2018	2019	2020E	2021E
Net revenues	**0**	**0**	**0**	**0**	**872**	**18,435**
Other op. inc. (including milestones)	**4,262**	**5,811**	**2,766**	**8,000**	**19,500**	**3,500**
Total revenue	**4,262**	**5,811**	**2,766**	**8,000**	**20,372**	**21,935**
Cost of goods sold	0	0	0	0	0	3,305
Gross profit	**4,262**	**5,811**	**2,766**	**8,000**	**20,372**	**18,630**
S,G&A	5,129	3,828	3,408	5,023	8,000	12,695
R&D	23,408	17,854	12,167	13,099	11,000	12,000
Other operating income (expense)	-807	-2	354	796	0	0
Operating income (EBIT)	**-25,082**	**-15,872**	**-12,455**	**-9,326**	**1,372**	**-6,065**
Net financial result	21	20	8	-122	-250	-750
Pre-tax income (EBT)	**-25,061**	**-15,852**	**-12,447**	**-9,448**	**1,122**	**-6,815**
Income taxes	4,944	3,759	2,510	2,432	0	1,363
Net income / loss	**-20,118**	**-12,093**	**-9,937**	**-7,016**	**1,122**	**-5,452**
Diluted EPS	**-0.38**	**-0.20**	**-0.16**	**-0.11**	**0.02**	**-0.08**
EBITDA	**-24,758**	**-15,626**	**-12,265**	**-9,186**	**1,512**	**-5,925**
Ratios						
EBIT margin	n.m.	n.m.	n.m.	n.m.	6.7%	-27.6%
EBITDA margin	n.m.	n.m.	n.m.	n.m.	7.4%	-27.0%
Net margin	n.m.	n.m.	n.m.	n.m.	5.5%	-24.9%
Cash Coverage of Expenses						
Cash / G&A	5.9x	6.5x	5.1x	3.7x	3.3x	2.9x
Cash / R&D	1.3x	1.4x	1.4x	1.4x	2.4x	1.5x
Y-Y Growth						
Total revenue	5851.0%	36.4%	-52.4%	189.2%	154.6%	7.7%
Operating income	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
Net income/ loss	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.

BALANCE SHEET

All figures in EUR '000	2016	2017	2018	2019	2020E	2021E
Assets						
Current assets, total	**35,128**	**29,357**	**22,037**	**22,650**	**32,316**	**32,632**
Cash and cash equivalents	30,111	24,839	17,227	18,787	26,077	17,800
Short-Term Investments	0	0	0	0	0	0
Receivables	0	37	1,500	500	131	1,557
Inventories	0	0	0	0	3,358	10,275
Other current assets	5,017	4,481	3,311	3,363	2,750	3,000
Non-current assets, total	**2,855**	**2,529**	**2,286**	**2,262**	**2,154**	**2,088**
Property, plant & equipment	167	114	74	46	16	26
Right-of-use assets	0	0	0	79	91	105
Goodwill & other intangibles	2,688	2,415	2,212	2,137	2,047	1,957
Other Assets	0	0	0	0	0	0
Total assets	**37,984**	**31,885**	**24,323**	**24,912**	**34,470**	**34,719**
Shareholders' equity & debt						
Current Liabilities, Total	**13,040**	**6,656**	**3,501**	**10,154**	**8,964**	**9,696**
Convertible bond	0	0	0	4,354	0	0
Short-term debt	0	0	0	0	0	0
Accounts payable	6,353	5,921	2,218	4,843	8,000	8,727
Milestone	5,730	0	0	0	0	0
Provisions	555	391	630	270	2	37
Lease liabilities	0	0	0	55	63	72
Other current liabilities	403	344	654	632	900	860
Longterm liabilities, total	**0**	**0**	**0**	**26**	**5,029**	**10,034**
Convertible bond	0	0	0	0	0	0
Long-term debt	0	0	0	0	5,000	10,000
Provisions	0	0	0	0	0	0
Lease liabilities	0	0	0	26	29	34
Deferred revenue	0	0	0	0	0	0
Shareholders' equity	**24,943**	**25,229**	**20,822**	**14,732**	**20,477**	**14,990**
Total consolidated equity and debt	**37,984**	**31,885**	**24,323**	**24,912**	**34,470**	**34,719**
Ratios						
Current ratio (x)	2.69	4.41	6.29	2.23	3.60	3.37
Quick ratio (x)	2.69	4.41	6.29	2.23	3.23	2.31
Net gearing	-120.7%	-98.5%	-82.7%	-97.4%	-102.5%	-51.3%
Book value per share (€)	0.45	0.41	0.33	0.23	0.31	0.23
Return on equity (ROE)	-66.5%	-48.2%	-43.2%	-39.5%	6.4%	-30.7%

CASH FLOW STATEMENT

All figures in EUR '000	2016	2017	2018	2019	2020E	2021E
Net result	**-20,118**	**-12,093**	**-9,939**	**-7,016**	**1,122**	**-5,452**
Depreciation and amortization	759	347	255	118	140	140
Changes in working capital	1,137	-911	-4,647	3,516	1,049	-7,906
Milestone	5,730	-5,730	0	0	0	0
Net taxes received	585	838	1,219	3	0	0
Other items	321	-170	299	532	0	0
Operating cash flow	**-11,586**	**-17,720**	**-12,813**	**-2,847**	**2,311**	**-13,218**
CAPEX	-192	-25	-13	-14	-32	-74
Free cash flow	**-11,778**	**-17,745**	**-12,826**	**-2,861**	**2,279**	**-13,291**
Debt financing, net	**0**	**0**	**0**	**0**	**5,000**	**5,000**
Convertible bond financing, net	**0**	**0**	**0**	**4,472**	**-4,354**	**0**
Lease financing, net	**0**	**0**	**0**	**-52**	**12**	**14**
Equity financing, net	**9,212**	**12,494**	**5,214**	**0**	**4,354**	**0**
Other changes in cash	**-2**	**-22**	**0**	**1**	**0**	**0**
Net cash flows	**-2,568**	**-5,273**	**-7,612**	**1,560**	**7,291**	**-8,278**
Cash, start of the year	32,680	30,111	24,839	17,227	18,787	26,077
Cash, end of the year	**30,111**	**24,839**	**17,227**	**18,787**	**26,077**	**17,800**

Y-Y Growth						
Operating cash flow	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
Free cash flow	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
EBITDA/share	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.

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PRICE TARGET DATES

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ASSET VALUATION SYSTEM

First Berlin's system for asset valuation is divided into an asset recommendation and a risk assessment.

ASSET RECOMMENDATION

The recommendations determined in accordance with the share price trend anticipated by First Berlin in the respectively indicated investment period are as follows:

Category		1	2
Current market capitalisation (in €)		0 - 2 billion	> 2 billion
Strong Buy[1]	An expected favourable price trend of:	> 50%	> 30%
Buy	An expected favourable price trend of:	> 25%	> 15%
Add	An expected favourable price trend of:	0% to 25%	0% to 15%
Reduce	An expected negative price trend of:	0% to -15%	0% to -10%
Sell	An expected negative price trend of:	< -15%	< -10%

[1] The expected price trend is in combination with sizable confidence in the quality and forecast security of management.

Our recommendation system places each company into one of two market capitalisation categories. Category 1 companies have a market capitalisation of €0 – €2 billion, and Category 2 companies have a market capitalisation of > €2 billion. The expected return thresholds underlying our recommendation system are lower for Category 2 companies than for Category 1 companies. This reflects the generally lower level of risk associated with higher market capitalisation companies.

RISK ASSESSMENT

The First Berlin categories for risk assessment are low, average, high and speculative. They are determined by ten factors: Corporate governance, quality of earnings, management strength, balance sheet and financial risk, competitive position, standard of financial disclosure, regulatory and political uncertainty, strength of brandname, market capitalisation and free float. These risk factors are incorporated into the First Berlin valuation models and are thus included in the target prices. First Berlin customers may request the models.

RECOMMENDATION & PRICE TARGET HISTORY

Report No.:	Date of publication	Previous day closing price	Recommendation	Price target
Initial Report	2 April 2012	€0.79	Buy	€2.00
2...38	↓	↓	↓	↓
39	28 March 2019	€2.17	Buy	€4.10
40	21 August 2019	€2.26	Buy	€4.20
41	19 February 2020	€2.22	Buy	€3.80
42	23 April 2020	€1.74	Buy	€3.60
43	Today	€2.93	Buy	€4.90

INVESTMENT HORIZON

Unless otherwise stated in the financial analysis, the ratings refer to an investment period of twelve months.

UPDATES

At the time of publication of this financial analysis it is not certain whether, when and on what occasion an update will be provided. In general First Berlin strives to review the financial analysis for its topicality and, if required, to update it in a very timely manner in connection with the reporting obligations of the analysed company or on the occasion of ad hoc notifications.

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Legally required information regarding

- **key sources of information in the preparation of this research report**
- **valuation methods and principles**
- **sensitivity of valuation parameters**

can be accessed through the following internet link: https://firstberlin.com/disclaimer-english-link/

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