

PAION AG

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

H1 results

RATING PRICE TARGET

BUY € 4.20

Return Potential 85.8% Risk Rating High

US/JAPAN APPROVALS IN 2019/20; EIB LOAN REDUCES FUTURE DILUTION

PAION filed for U.S. market approval of remimazolam in the indication procedural sedation in April - four months after having filed for market approval of remimazolam in the indication general anaesthesia in Japan. First revenues from remimazolam in the U.S. and Japan are likely in 2020. The €7.5m milestone payment in connection with the U.S. filing accounted for all of H1/19 revenue. Management has not changed full year guidance. Following discussions with the European Medicines Agency (EMA), PAION plans to submit a Marketing Authorization Application for remimazolam in procedural sedation later this year based on the existing data package from the U.S. phase III clinical development program. Meanwhile, patient recruitment for the EU phase III clinical trial with remimazolam in general anaesthesia is now expected in Q1 2020. PAION's main priority over the next few years is to gain regulatory approval for remimazolam in as many countries for as many indications as possible. PAION estimates the peak sales opportunity for remimazolam at over USD500m annually for each of the three indications: procedural sedation, general anaesthesia and intensive care unit sedation. In late June PAION announced that it had signed a €20m financing agreement with the European Investment Bank. This suggests that dilution through future equity raises will be lower than we had previously modelled and so we raise our price target from €4.10 to €4.20. We maintain our Buy recommendation.

Remimazolam's competitive advantages The two main incumbent products in the above-mentioned indications are midazolam which is used mainly in conscious sedation, and propofol which is used mainly in deep sedation. Remimazolam's advantage over midazolam is shorter onset/offset times and over propofol clinically meaningful lower cardiodepressive and respiratory depressant effects. The most valuable single indication/geography for remimazolam is procedural sedation in the U.S. where colonoscopies account for nearly half of the annual 43 million medical procedures in which sedation is used. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2016	2017	2018	2019E	2020E	2021E
Revenue (€m)	4.26	5.81	2.77	8.00	37.45	47.11
Y-o-y growth	n.a.	36.4%	-52.4%	189.2%	368.2%	25.8%
EBIT (€m)	-25.08	-15.87	-12.46	-10.50	17.20	17.93
EBIT margin	2.0%	3.0%	4.0%	5.0%	6.0%	7.0%
Net income (€m)	-20.12	-12.09	-9.94	-8.48	19.23	16.14
EPS (diluted) (€)	-0.38	-0.20	-0.16	-0.13	0.30	0.25
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-11.78	-17.75	-12.83	-2.05	14.07	7.09
Net gearing	-120.7%	-98.5%	-82.7%	-117.0%	-90.9%	-75.3%
Liquid assets (€m)	30.11	24.84	17.23	20.18	39.25	66.34

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 20 Aug 2019
Closing Price	€ 2.26
Shares outstanding	63.86m
Market Capitalisation	€ 144.32m
52-week Range	€ 2.04 / 2.60
Avg. Volume (12 Months)	61,590

Multiples	2018	2019E	2020E
P/E	n.a.	n.a.	7.5
EV/Sales	45.2	15.6	3.3
EV/EBIT	n.a.	n.a.	7.3
Div Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA	As of 30 Jun 2019
Liquid Assets	€ 28.73m
Current Assets	€ 35.13m
Intangible Assets	€ 2.65m
Total Assets	€ 37.58m
Current Liabilities	€ 10.21m
Shareholders' Equity	€ 27.37m

SHAREHOLDERS

Cosmo Pharmaceuticals	9.1%
TIAA-CREF	3.0%
Free Float	87 9%

In the U.S., colonoscopies are typically carried out in large outpatient clinics. PAION's management believes that the efficiencies stemming from remimazolam's shorter onset/offset times relative to midazolam amount to several USD100s per patient. Faster time to full recovery also equates to a better experience not only for patients but also for persons (typically friends or relatives) accompanying the patients to and from the procedure.

H1/19 results close to our expectations H1/19 results were close to our forecasts and management has left full year guidance unchanged (see figures 1 and 2 below). H1/19 revenue of €7.5m stemmed solely from the milestone payment from licensing partner Cosmo in connection with filing for approval in the U.S. for remimazolam in the indication procedural sedation. The €0.5m in revenue expected for H2/19 corresponds to revenue from the Russian remimazolam licensee, R-Pharm, in connection with the transfer of the Japanese filing dossier translated into English or transfer of the U.S. filing dossier. H1/18 revenue resulted mainly from the license agreement with Japanese partner Mundipharma. H1/19 R&D expenses of €6.2m related mainly to the ongoing EU Phase III trial in general anaesthesia. S,G&A expenses rose mainly because of the set-up of the supply chain for remimazolam. The income tax credit of €1.2m corresponds to claims for reimbursement of R&D expenses from the British tax authorities.

Figure 1: FY/18 results vs. our forecasts

in EURm	H1/19A	H1/19E	Delta	H1/18A	Delta
Total revenue*	7.50	7.50	0.0%	0.52	1350.7%
R&D expenses	6.17	7.00	-11.8%	6.54	-5.7%
S,G&A expenses	2.32	2.50	-7.2%	1.76	31.9%
EBT	-0.58	-1.50	n.a.	-7.73	92.5%
Tax credit	1.17	1.00	16.6%	1.49	-21.6%
Net income	0.59	-0.50	n.a.	-6.24	n.a.
margin	7.8%	neg.	-	neg.	-
EPS (dil., in EUR)	0.01	-0.01	n.a.	-0.10	n.a.

^{*} including other operating income such as milestone payments

Source: PAION, First Berlin Equity Research estimates

Figure 2: Management 2019 guidance

in EURm	FY/19 Guidance
Total revenue*	ca. €8m
R&D expenses	ca. €13-€15m
S,G&A expenses	ca. €4-€5m
Tax credits	ca. €2m
Net result	ca. €-7 to €-10m

^{*} including other op. income such as milestone payments

Source: PAION

FDA targets completion of market approval application review by 5 April 2020 The FDA informed Cosmo that it had accepted the filing for market approval in procedural sedation and set a PDUFA (Prescription Drug User Fee Act) date of 5 April 2020. This is the target date for completion of the FDA review.

EU filing for approval in procedural sedation likely without further trials PAION's management discussed data from the U.S. phase III clinical development programme of remimazolam for procedural sedation at a pre-submission meeting with the EMA in February. Based on this meeting, PAION now expects to be able to file for approval of remimazolam in procedural sedation in the EU later this year without carrying out any further trials. The filing will be subject to EMA approval of the Pediatric Investigation Plan (PIP).

Accelerated approval of remimazolam for general anaesthesia in EU likely Approval in procedural sedation in the EU and availability of the data from the ongoing EU Phase III clinical trial in general anesthesia would allow accelerated processing of the market approval filing in the latter indication. Management now expects completion of patient recruitment for the phase III trial in general anaesthesia in Q1/20. In the Q1/19 report released in May, completion of recruitment was scheduled for the end of 2019. Over 200 out of a planned 500 patients have been treated so far and PAION has initiated the opening of additional study sites in order to accelerate recruitment. Although recruitment for the general anaesthesia trial is behind the original schedule, we continue to expect first EU revenues in this indication in 2021 due to the strong likelihood of an accelerated approval process outlined above.

Filing for approval of remimazolam in multiple countries PAION's licensing partners filed for approval of remimazolam for procedural sedation in China and for general anaesthesia in Japan in November and December 2018 respectively. In both countries, decisions by the local authorities on market approval are expected by the end of 2019 at the earliest.

PAION's Canadian licensing partner, Pharmascience, is expected to use the U.S. market approval dossier as the basis for filing for market approval in Canada while R-Pharm (remimazolam licensee for Turkey, the Middle East and North Africa) plans to file for market approval in Turkey based on the U.S. or Japanese dossier. In Russia, R-Pharm completed a phase III trial in general anaesthesia in November 2018 and plans to file for approval later this year.

In South Korea recruitment for a phase III trial of remimazolam in general anaesthesia was completed in October 2018. Local partner Hana Pharm expects to file for market approval by the end of 2019.

€20m financing agreement signed with the European Investment Bank In late June PAION signed a financing agreement with the European Investment Bank (EIB) for a loan of up to €20m. The loan is unsecured and can be drawn down over the next two years in three tranches based on certain conditions such as the achievement of operational milestones. PAION plans to draw down the first tranche of up to €5m before the end of this year. Each tranche has a term of five years and the interest rate corresponds to the market conditions for venture debt.

Buy recommendation maintained, price target raised to €4.20 (previously: €4.10) PAION had cash and cash equivalents of €19.2m at the end of H1/19 (FY/18: €17.2m). Management stated in the H1/19 report that the company's cash reach extends into the second half of 2020. The assumptions underlying this statement do not include milestone payments or any funds from the EIB. Potential future milestone payments from Cosmo and Mundipharma amount to €59m, an unspecified part of which relates to the marketing approvals which we expect in both the U.S. and Japan during the course of the next ten months. PAION's management has stated that a further €10m will be required until filing for approval for general anaesthesia in the EU and that this could be partially or completely covered by the EIB loan. PAION also points out that additional funds will be required in coming years for planned own commercialisation in selected European markets as well as for planned development of remimazolam for the indication ICU sedation. We expect that future revenues and milestones will cover most of these costs, but assume the issue of a €10m convertible in 2021. We have removed two €5m equity issues, previously respectively modelled in 2019 and 2020, from our projections. The resulting reduction in dilution causes us to raise our price target from €4.10 to €4.20. We maintain our Buy recommendation.

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	€111.5M	15,144K	€14	€208.6M	25%	€69.9M	60%	15%	15	2 Years
Remimazolam	PS US	€150.6M	20,000K	€20	€400.0M	50%	€257.5M	2)%	15%	13	1 Year
Remimazolam	PS CAN	€7.0M	1,056K	€20	€21.1M	50%	€13.6M	18%	15%	13	1 Year
Remimazolam	GA EU	€181.6M	15,144K	€40	€605.8M	20%	€162.3M	6%	15%	15	3 Years
Remimazolam	GA US	€71.8M	23,925K	€40	€957.0M	20%	€246.5M	2%	15%	13	4 Years
Remimazolam	GA JAP	€80.6M	10,000K	€40	€400.0M	25%	€134.0M	8%	15%	15	1 Year
Remimazolam	GA CHN	€15.8M	51,000K	€28	€1,405.0M	10%	€188. 2 M	10%	15%	15	4 Years
Remimazolam	PS CHN	€15.1M	33,260K	€10	€346.5M	10%	€46.4M	1%	15%	15	1 Year
Remimazolam	GA KOR	€7.6M	3,750K	€28	€103.3M	25%	€34.6M	10%	5%	15	2 Years
Remimazolam	GA CIS/MENA/TUR	€66.2M	55,247K	€28	€1,566.6M	10%	€209.9M	12%	15%	15	1 Year
Remimazolam	ICU US	€16.1M	1,561K	€250	€390.2M	25%	€125.6M	2)%	15%	13	5 Years
Remimazolam	ICU EU	€66.5M	2,439K	€167	€406.5M	25%	€136.8M	6%	15%	15	4 Years
Remimazolam	ICU Japan	€4.3M	606K	€167	€101.0M	25%	€33.8M	18%	15%	15	5 Years
PACME PV	·	€794.5M									
Costs PV (4)		€584.0M									
NPV		€210.5M									
Milestones PV		€41.0M									
Pro forma net ca	sh	€22.8M									
Fair Value		€274.3M									
Pro forma share	count	65,047K									
Price Target		€4.20									

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

Source: First Berlin Equity Research

Figure 4: Changes to pipeline valuation model

NPV	Old €209.5M		
Milestones PV	€41.0M	€41.0M	0.0%
Pro Forma Net Cash	€26.2M	€22.8M	-13.1%
Fair Value	€282.7M	€274.3M	-3.0%
Diluted Share Count	68.2M	65.0M	-4.6%
Fair Value Per Share	€4.10	€4.20	2.4%

Source: First Berlin Equity Research

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 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



INCOME STATEMENT

All figures in EUR '000	2016	2017	2018	2019E	2020E	2021E
Net revenues	0	0	0	0	12,902	42,560
Other op. inc. (including milestones)	4,262	5,811	2,766	8,000	24,550	4,550
Total revenue	4,262	5,811	2,766	8,000	37,452	47,110
Cost of goods sold	0	0	0	0	0	4,407
Gross profit	4,262	5,811	2,766	8,000	37,452	42,703
S,G&A	5,129	3,828	3,408	4,500	5,250	9,776
R&D	23,408	17,854	12,167	14,000	15,000	15,000
Other operating income (expense)	-807	-2	354	0	0	0
Operating income (EBIT)	-25,082	-15,872	-12,455	-10,500	17,202	17,927
Net financial result	21	20	8	19	-374	-757
Pre-tax income (EBT)	-25,061	-15,852	-12,447	-10,481	16,828	17,171
Income taxes	4,944	3,759	2,510	2,000	2,400	-1,034
Net income / loss	-20,118	-12,093	-9,937	-8,481	19,228	16,137
Diluted EPS	-0.38	-0.20	-0.16	-0.13	0.30	0.25
EBITDA	-24,758	-15,626	-12,265	-10,360	17,342	18,067
Ratios						
EBIT margin	n.m.	n.m.	n.m.	n.m.	45.9%	38.1%
EBITDA margin	n.m.	n.m.	n.m.	n.m.	46.3%	38.4%
Net margin	n.m.	n.m.	n.m.	n.m.	51.3%	34.3%
Cash Coverage of Expenses						
Cash / G&A	5.9x	6.5x	5.1x	4.5x	7.5x	10.6x
Cash / R&D	1.3x	1.4x	1.4x	1.4x	2.6x	4.4x
Y-Y Growth						
Total revenue	5851.0%	36.4%	-52.4%	189.2%	368.2%	25.8%
Operating income	n.m.	n.m.	n.m.	n.m.	n.m.	4.2%
Net income/ loss	n.m.	n.m.	n.m.	n.m.	n.m.	-16.1%



BALANCE SHEET

All figures in EUR '000	2016	2017	2018	2019E	2020E	2021E
Assets						
Current assets, total	35,128	29,357	22,037	23,679	49,053	85,319
Cash and cash equivalents	30,111	24,839	17,227	20,179	39,249	66,335
Short-Term Investments	0	0	0	0	0	0
Receivables	0	37	1,500	0	1,935	4,731
Inventories	0	0	0	0	4,119	10,502
Other current assets	5,017	4,481	3,311	3,500	3,750	3,750
Non-current assets, total	2,855	2,529	2,286	2,166	2,046	1,966
Property, plant & equipment	167	114	74	44	14	24
Goodwill & other intangibles	2,688	2,415	2,212	2,122	2,032	1,942
Other Assets	0	0	0	0	0	0
Total assets	37,984	31,885	24,323	25,845	51,099	87,285
Shareholders' equity & debt						
Current Liabilities, Total	13,040	6,656	3,501	7,875	8,926	9,035
Convertible bond	0	0	0	0	0	0
Short-term debt	0	0	0	0	0	0
Accounts payable	6,353	5,921	2,218	7,000	8,000	8,000
Milestone	5,730	0	0	0	0	0
Provisions	555	391	630	0	26	85
Other current liabilities	403	344	654	875	900	950
Longterm liabilities, total	0	0	0	5,000	10,000	30,000
Convertible bond	0	0	0	0	0	10,000
Long-term debt	0	0	0	5,000	10,000	20,000
Provisions	0	0	0	0	0	0
Deferred revenue	0	0	0	0	0	0
Shareholders' equity	24,943	25,229	20,822	12,970	32,173	48,250
Total consolidated equity and debt	37,984	31,885	24,323	25,845	51,099	87,285
Ratios						
Current ratio (x)	2.69	4.41	6.29	3.01	5.50	9.44
Quick ratio (x)	2.69	4.41	6.29	3.01	5.03	8.28
Net gearing	-120.7%	-98.5%	-82.7%	-117.0%	-90.9%	-75.3%
Book value per share (€)	0.45	0.41	0.33	0.20	0.50	0.76
Return on equity (ROE)	-66.5%	-48.2%	-43.2%	-50.2%	85.2%	40.1%



CASH FLOW STATEMENT

All figures in EUR '000	2016	2017	2018	2019E	2020E	2021E
Net result	-20,118	-12,093	-9,939	-8,481	19,228	16,137
Depreciation and amortization	759	347	255	140	140	140
Changes in working capital	1,137	-911	-4,647	6,314	-5,279	-9,130
Milestone	5,730	-5,730	0	0	0	0
Net taxes received	585	838	0	0	0	0
Other items	321	-170	1,518	0	0	0
Operating cash flow	-11,586	-17,720	-12,813	-2,027	14,089	7,147
CAPEX	-192	-25	-13	-20	-20	-60
Free cash flow	-11,778	-17,745	-12,826	-2,047	14,069	7,087
Debt financing, net	0	0	0	5,000	5,000	20,000
Convertible bond financing, net	0	0	0	0	0	0
Equity financing, net	9,212	12,494	5,214	0	0	0
Other changes in cash	-2	-22	0	0	0	0
Net cash flows	-2,568	-5,273	-7,612	2,953	19,069	27,087
Cash, start of the year	32,680	30,111	24,839	17,227	20,179	39,249
Cash, end of the year	30,111	24,839	17,227	20,179	39,249	66,335
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.



FIRST BERLIN 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
236	\downarrow	1	\downarrow	1
37	10 April 2018	€2.23	Buy	€4.30
38	20 November 2018	€2.40	Buy	€4.30
39	28 March 2019	€2.17	Buy	€4.10
40	Today	€2.26	Buy	€4.20

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First Berlin Equity Research GmbH (hereinafter referred to as: "First Berlin") prepares financial analyses while taking the relevant regulatory provisions, in particular the German Securities Trading Act [VVpHG], Regulation (EU) No 596/2014 of the European Parliament and of the Council of April 16, 2014, on market abuse (market abuse regulation) and the German Ordinance on the Analysis of Financial Instruments [FinAnV] into consideration. In the following First Berlin provides investors with information about the statutory provisions that are to be observed in the preparation of financial analyses.

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PRICE TARGET DATES

Unless otherwise indicated, current prices refer to the closing prices of the previous trading day.

AGREEMENT WITH THE ANALYSED COMPANY AND MAINTENANCE OF OBJECTIVITY

The present financial analysis is based on the author's own knowledge and research. The author prepared this study without any direct or indirect influence exerted on the part of the analysed company. Parts of the financial analysis were possibly provided to the analysed company prior to publication in order to avoid inaccuracies in the representation of facts. However, no substantial changes were made at the request of the analysed company following any such provision.

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 $\le 0 - \le 2$ billion, and Category 2 companies have a market capitalisation of $> \le 2$ 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.

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