PAION AG

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

H1 2020 results

RATING	**BUY**
PRICE TARGET	**€ 4.90**
Return Potential	82.2%
Risk Rating	High

INTERNATIONAL ROLLOUT OF REMIMAZOLAM PROCEEDING APACE

H1/20 results were close to our expectations. Revenue was €3.5m (FBe: €3.5m; H1/19: €7.5m) while EBIT came in at €-6.8m (FBe: €-6.6m; H1/19: €-0.6m). Over the past month remimazolam has been launched in Japan in the indication general anaesthesia and in China in procedural sedation. Remimazolam was approved by the FDA in procedural sedation in July and US marketing partner, Acacia, expects to launch the drug in Q4. EU approval of remimazolam in procedural sedation is expected in 2021. This should be followed by approval in general anaesthesia provided that phase III trial data due later this year are positive. By the end of this year PAION will also take decisions on whether or not to develop remimazolam for the ICU and whether or not to build up its own distribution network in Europe. We expect positive decisions in both cases. PAION estimates the peak sales opportunity for remimazolam at USD500m annually for each of the three indications procedural sedation, general anaesthesia and ICU sedation. 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. We maintain our Buy recommendation and price target of €4.90.

H1/20 revenue based on Asian milestone payments H1/20 revenue was comprised of milestone payments in connection with the market approval of remimazolam in Japan (€1.5m) and the license extension signed with Hana Pharm of South Korea to cover six additional countries in Southeast Asia (€2.0m). H1/19 revenue of €7.5m stemmed solely from the milestone payment in connection with filing for approval in the U.S. for remimazolam in the indication procedural sedation. H1/20 R&D expenses of €6.4m (H1/19: €6.2m) related mainly to the EU Phase III trial in general anaesthesia. (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	-588.5%	-273.1%	-450.3%	-116.6%	6.7%	-27.6%
Net income (€ m)	-20.12	-12.09	-9.94	-7.02	2.37	-5.45
EPS (diluted) (€)	-0.38	-0.20	-0.16	-0.11	0.04	-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	3.53	-13.29
Net gearing	-120.7%	-98.5%	-82.7%	-97.4%	-102.3%	-55.1%
Liquid assets (€ m)	30.11	24.84	17.23	18.79	27.33	19.05

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 with multiple approvals in different regions and in different indications.

MARKET DATA

As of 14 Aug 2020	
Closing Price	€ 2.69
Shares outstanding	66.23m
Market Capitalisation	€ 178.15m
52-week Range	€ 1.41 / 3.46
Avg. Volume (12 Months)	147,179

Multiples	2019	2020E	2021E
P/E	n.a.	74.6	n.a.
EV/Sales	20.5	8.0	7.5
EV/EBIT	n.a.	119.4	n.a.
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW

COMPANY DATA

As of 30 Jun 2020	
Liquid Assets	€ 12.41m
Current Assets	€ 18.84m
Intangible Assets	€ 1.91m
Total Assets	€ 20.82m
Current Liabilities	€ 9.07m
Shareholders' Equity	€ 11.73m

SHAREHOLDERS

Cosmo Pharmaceuticals	8.9%
Free Float	91.1%

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SG&A expenses increased to €3.6m (H1/19: €2.3m) due mainly to pre-commercial activities and the set-up of a supply chain for remimazolam.

Figure 1: H1/20 results vs. our forecasts

in EURm	H1/20A	H1/19E	Delta	H1/19A	Delta
Total revenue	3.52	3.50	0.6%	7.50	-53.1%
R&D expenses	6.40	6.20	3.2%	6.17	3.7%
S,G&A expenses	3.61	3.90	-7.4%	2.32	55.5%
EBIT	-6.79	-6.60	n.a.	-0.58	n.a.
Tax credit	0.74	0.40	85.0%	1.17	-36.5%
Net income	-6.05	-6.30	n.a.	0.59	n.a.
margin	*neg.*	*neg.*	-	*7.8%*	-
EPS (dil., in EUR)	-0.09	-0.09	n.a.	0.01	n.a.

Source: PAION, First Berlin Equity Research estimates

Remimazolam recently launched in Japan and China… In January remimazolam was approved in Japan in the indication general anaesthesia. In early August PAION announced that its commercial partner in Japan, Mundipharma, had made its first commercial sales of remimazolam and listed the drug in multiple university and general hospitals. Remimazolam was approved in China for the indication procedural sedation in July. On 11 August PAION published a press release stating that its Chinese partner, Yichang Humanwell, had launched remimazolam in procedural sedation in China and also started recruitment to a phase III trial of the drug in general anaesthesia.

…US launch to follow in Q4 The FDA approved remimazolam for the indication procedural sedation in July. However, marketing of remimazolam in the US cannot commence until the Drug Enforcement Administration has determined scheduling of the drug under the Controlled Substances Act. PAION anticipate that remimazolam will be assigned to schedule IV - the same category as competitor drug midazolam. PAION's US commercial partner, Acacia, expects to launch remimazolam later this year.

EU approval of remimazolam in procedural sedation/general anaesthesia likely from 2021 PAION submitted a marketing authorisation application 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. Recruitment to the phase III trial of remimazolam with general anaesthesia patients was completed in April and topline data are expected later this year. Provided that remimazolam is granted 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 anaesthesia. The EMA usually processes marketing authorisation extensions more quickly than marketing authorisation applications.

Build-up of own EU marketing infrastructure dependent on acquisition of complementary products In the H1/20 report management repeated its position that the build-up of an own distribution infrastructure in Europe will be dependent on the company's ability to add more products to its commercial portfolio. Given the high priority which management has accorded efforts to identify suitable additional products, we assume they will be successful. We thus also assume that PAION will market remimazolam itself on major European markets but have not included revenue from additional products in our forecasts.

We expect development of remimazolam for the ICU to go ahead The third indication for remimazolam after procedural sedation and general anesthesia is ICU sedation. The completion of clinical development of remimazolam for the ICU is likely to cost €25m. Management are currently assessing the return potential on this investment and have stated that a decision on whether or not to go ahead will be taken by the end of this year. We continue to expect a positive decision because of the drug's superior performance compared with propofol with regard to cardiac stability. This was already demonstrated in the phase II trial of remimazolam for general anaesthesia. In this trial, use of norepinephrine (used to counteract decreases in blood pressure), was 36.7% lower in remimazolam-treated patients compared with the propofol group.

Cash reach to H2/21 – before drawdown of €20m EIB loan PAION had cash and equivalents of €12m at the end of H1/20. This sum, combined with expected operational cashflows and the €15m milestone payment received in connection with the US approval of remimazolam is expected by management to secure cash reach into H2/21. Funding over and above operational cashflow will be required to finance the acquisition of products complementary to remimazolam, the build-up of an own marketing organisation on selected EU markets and the multi-year pediatric development plan. In order to be in a position to make these expenditures, PAION concluded a €20m loan agreement with the European Investment Bank in June 2019. None of these funds have so far been drawn down. The loan can be drawn down in three tranches of which the first is already available. The availability of the other two tranches is dependent on the achievement of operational milestones which have not been specified but which we assume are the approvals of remimazolam in procedural sedation in the US and EU. The loan can be drawn down until mid-2021.

Figure 2: 2020 revenue and profit guidance

in EURm	FY/20 Guidance
Total revenue	ca. €20m
R&D expenses	ca. €10 - €12m
S,G&A expenses	ca. €7 - €9m
Tax credits	ca. €1 - €1.5m
Net result	ca. €0.5m - €4m

Source: Paion

We maintain our Buy recommendation and price target of €4.90 PAION is guiding to revenues of €20m this year, the largest element of which is a €15m milestone payment from Cosmo in connection with the approval of remimazolam in the US. Further milestone income stems from remimazolam's market approval in Japan, the Hana Pharm license extension to cover six additional Southeast Asian countries, and market approval in China. Royalties on sales of remimazolam in Japan, the US and China are expected to account for under €1m. 2020 revenue and expense guidance given in the H1/20 report are unchanged on the 2019 annual report published in March with the exception of the tax and net profit lines. In the H1/20 report the company revised up guidance for net profit to a range of €0.5m to €4m (previously a range of €-1m to €3m). The change reflects a modification of expectations regarding taxation. In past years the company booked significant tax credits in connection with R&D expenses incurred in the UK. In March management was of the opinion that these tax credits would be insignificant in 2020 due to a change in calculation and capping rules. However, the H1/20 results presentation shows expected tax credits of €1m to €1.5m. We have adjusted our 2020 forecast to reflect the higher than originally expected tax credit. Our projections are otherwise unchanged. We maintain our Buy recommendation and price target of €4.90.

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	3 Years
Remimazolam	PS CHN	€17.8M	33,260K	€10	€346.5M	10%	€45.7M	10%	15%	15	-
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		€695.7M									
Costs PV (4)		€427.6M									
NPV		€268.1M									
Milestones PV		€37.3M									
Pro forma net cash		€18.9M									
Fair Value		€324.3M									
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

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	1,250	1,363
Net income / loss	**-20,118**	**-12,093**	**-9,937**	**-7,016**	**2,372**	**-5,452**
Diluted EPS	**-0.38**	**-0.20**	**-0.16**	**-0.11**	**0.04**	**-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.	11.6%	-24.9%
Cash Coverage of Expenses						
Cash / G&A	5.9x	6.5x	5.1x	3.7x	3.4x	3.1x
Cash / R&D	1.3x	1.4x	1.4x	1.4x	2.5x	1.6x
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**	**33,566**	**33,882**
Cash and cash equivalents	30,111	24,839	17,227	18,787	27,327	19,050
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**	**35,720**	**35,969**
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**	**21,727**	**16,240**
Total consolidated equity and debt	**37,984**	**31,885**	**24,323**	**24,912**	**35,720**	**35,969**
Ratios						
Current ratio (x)	2.69	4.41	6.29	2.23	3.74	3.49
Quick ratio (x)	2.69	4.41	6.29	2.23	3.37	2.43
Net gearing	-120.7%	-98.5%	-82.7%	-97.4%	-102.3%	-55.1%
Book value per share (€)	0.45	0.41	0.33	0.23	0.33	0.25
Return on equity (ROE)	-66.5%	-48.2%	-43.2%	-39.5%	13.0%	-28.7%

CASH FLOW STATEMENT

All figures in EUR '000	2016	2017	2018	2019	2020E	2021E
Net result	**-20,118**	**-12,093**	**-9,939**	**-7,016**	**2,372**	**-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**	**3,561**	**-13,218**
CAPEX	-192	-25	-13	-14	-32	-74
Free cash flow	**-11,778**	**-17,745**	**-12,826**	**-2,861**	**3,529**	**-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**	**8,541**	**-8,278**
Cash, start of the year	32,680	30,111	24,839	17,227	18,787	27,327
Cash, end of the year	**30,111**	**24,839**	**17,227**	**18,787**	**27,327**	**19,050**

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	9 July 2020	€2.93	Buy	€4.90
47	Today	€2.69	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/

SUPERVISORY AUTHORITY: Bundesanstalt für Finanzdienstleistungsaufsicht (German Federal Financial Supervisory Authority) [BaFin], Graurheindorferstraße 108, 53117 Bonn and Marie-Curie-Straße 24-28, 60439 Frankfurt am Main

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