

PAION AG

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

Update

RATING PRICE TARGET

BUY € 4.90

Return Potential 100.0% Risk Rating High

U.S. LAUNCH OF REMIMAZOLAM UNDERWAY

PAION has reported positive topline data from its European phase III trial of remimazolam in the indication general anesthesia. The trial met both its primary endpoint and its key secondary endpoint. Following receipt of a schedule IV designation from the Drug Enforcement Administration, PAION's U.S. licensing partner plans to launch remimazolam in the indication procedural sedation by the end of this year. In Europe we expect the launch of the drug in procedural sedation in H2 2021 and in general anesthesia in 2022. Management indicated recently that the decision on whether or not to develop remimazolam for the ICU in the U.S. will be taken over the next few months in consultation with U.S. partner, Acacia. We expect the value proposition represented by remimazolam's superior performance compared with propofol with regard to cardiac stability and the likelihood of a three-year extension of remimazolam's US patent term to 2034 to prompt a positive decision. If the decision is taken to proceed, we anticipate that Acacia will bear part of the cost of the phase III trial. Meanwhile, PAION is still looking hard for additional products to complement its commercial portfolio. The outcome of these efforts will determine whether the company builds up its own distribution network in Europe. We have reduced our 2021 revenue forecast by €11m mainly to reflect the likely impact of the intensification of the pandemic on remimazolam's U.S. launch. We also now expect the EU launch of remimazolam in procedural sedation in September next year (previously: June). Forecasts for subsequent years are unchanged. The negative impact of the forecast reduction on our valuation is cancelled out by the derisking effect of the positive result of the EU phase III trial of remimazolam in general anesthesia. We retain our Buy recommendation and price target of **€4.90**.

Positive results of EU phase III trial in general anesthesia The European phase III trial of remimazolam in the indication general anesthesia met both its primary and key secondary endpoints. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2016	2017	2018	2019	2020E	2021E
Revenue (€m)	4.26	5.81	2.77	8.00	20.94	10.54
Y-o-y growth	n.a.	36.4%	-52.4%	189.2%	161.7%	-49.7%
EBIT (€m)	-25.08	-15.87	-12.46	-9.33	1.94	-21.05
EBIT margin	-588.5%	-273.1%	-450.3%	-116.6%	9.3%	-199.8%
Net income (€m)	-20.12	-12.09	-9.94	-7.02	2.94	-17.44
EPS (diluted) (€)	-0.38	-0.20	-0.16	-0.11	0.04	-0.27
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-11.78	-17.75	-12.83	-2.86	5.43	-25.07
Net gearing	-120.7%	-98.5%	-82.7%	-97.4%	-108.3%	19.4%
Liquid assets (€m)	30.11	24.84	17.23	18.79	24.23	19.17

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 08 Dec 2020
Closing Price	€ 2.45
Shares outstanding	66.23m
Market Capitalisation	€ 162.25m
52-week Range	€ 1.41 / 3.46
Ava. Volume (12 Months)	167.401

Multiples	2019	2020E	2021E
P/E	n.a.	54.9	n.a.
EV/Sales	17.2	6.6	13.1
EV/EBIT	n.a.	71.1	n.a.
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA	As of 30 Sep 2020
Liquid Assets	€ 24.51m
Current Assets	€ 18.84m
Intangible Assets	€ 1.86m
Total Assets	€ 32.61m
Current Liabilities	€ 7.87m
Shareholders' Equity	€ 24.73m

SHAREHOLDERS

Cosmo Pharmaceuticals 8.8% Free Float 91.2%

The primary endpoint was non-inferiority against propofol during elective surgery and the key secondary endpoint the demonstration of superior hemodynamic stability compared to propofol. PAION submitted a marketing authorisation application (MAA) for procedural sedation to the EMA in November 2019. Management expects a CHMP opinion (Committee for Medicinal Products for Human Use) by the end of January 2021, and, providing that this is positive, a decision on market approval by the end of H1 2021. If remimazolam is granted the expected EU approval in procedural sedation, PAION intends to submit an application for an extension to the drug's MAA to include general anaesthesia. The EMA usually processes marketing authorisation extensions more quickly than MAAs and so we expect the European launch of remimazolam in general anesthesia in 2022.

Acacia plans to launch remimazolam in the U.S. towards the end of this year The U.S. Drug Enforcement Administration designated remimazolam as a Schedule IV medicine in early October. Schedule IV is the designation for drugs with low potential for abuse. The designation cleared the way for remimazolam's commercial launch towards the end of this year. However, PAION does not expect any royalty income from the drug in 2020. Remimazolam was approved in Japan in the indication general anesthesia in January this year. PAION's Japanese licensing partner, Mundipharma, launched remimazolam at midyear. 250-300 hospitals are expected to have the drug listed by year-end. In China remimazolam was approved in the indication general anesthesia in July and the commercial launch followed later in the third quarter.

Build-up of own EU marketing infrastructure dependent on acquisition of complementary products In the 9M 2020 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 value proposition, likely patent extension to prompt 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 recently indicated that a decision on whether or not to go ahead will be taken in consultation with Acacia over the next few months. We expect a positive decision for two reasons. First, remimazolam has demonstrated superior performance compared with propofol with regard to cardiac stability. Second, it is likely that remimazolam's U.S. patent term will by extended by three years to 2034. In the phase II trial of remimazolam for general anaesthesia the use of norepinephrine (used to counteract decreases in blood pressure), was 36.7% lower in remimazolam-treated patients than in the propofol group. Remimazolam's U.S. patent currently expires in 2031. Under the Patent Term Restoration Act of 1984 ("Hatch-Waxman"), there is scope to extend patent life to 14 years after a drug's regulatory approval. In the case of remimazolam this would be until 2034. Acacia has stated that it intends to request this extension from the U.S. Patent and Trademark Office. In the event of a decision to proceed with development of remimazolam for the ICU, we anticipate that Acacia will bear part of the cost of the phase III trial.

U.S. approval milestone accounted for over 75% of 9M/2020 revenue Revenue for the first nine months of 2020 was €19.3m (9M/19: €7.5m) while EBIT came in at €5.0m (9M/19: €-5.4m). 9M/20 revenue was comprised mainly of milestone payments in connection with the market approval of remimazolam in the U.S. (€15.0m), Japan (€1.0m), China (€1.0m) and the license extension signed with Hana Pharm of South Korea to cover six additional countries in Southeast Asia (€2.0m). 9M/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. 9M/20 R&D expenses of €8.5m (9M/19: €9.7m) related mainly to the EU Phase III trial in general anaesthesia. SG&A expenses increased to €5.5m (9M/19: €3.6m) due mainly to pre-commercial activities and the set-up of a supply chain for remimazolam.

Figure 1: 9M 2020 results

in EURm	9M/20A	9M/19A	Delta
Total revenue	19.27	7.50	156.9%
R&D expenses	8.49	9.69	-12.4%
S,G&A expenses	5.54	3.63	52.6%
EBIT	5.01	-5.35	n.a.
Net financial result	-0.13	-0.02	n.a.
Tax credit	0.80	2.00	-59.8%
Net income	5.69	-3.38	n.a.
margin	29.5%	neg.	-
EPS (dil., in EUR)	0.09	-0.05	n.a.

Source: PAION, First Berlin Equity Research estimates

Cash reach to H2 2021 – before drawdown of €20m EIB loan PAION had cash and equivalents of €24.5m at the end of 9M 2020. This sum, combined with expected operational cashflows, 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 but are available 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 2020 revenue and expense guidance given in the 9M/20 report are unchanged on the H1/20 report published in August. A further milestone of €1m is expected before the end of 2020 from the approval of remimazolam for general anesthesia in South Korea. Royalties on sales of remimazolam in Japan and China are expected to account for under €1m.

We have reduced our 2021 revenue forecast by €11m mainly to reflect the likely impact of the intensification of the pandemic on remimazolam's U.S. launch. We also now expect the EU launch of remimazolam in procedural sedation in September next year (previously: June). In addition, we have raised our 2021 SG&A expense forecast to reflect a more conservative view of the cost of building up own commercialisation infrastructure in Europe. The reduction in our R&D expense forecast reflects the end of the EU phase III trial of remimazolam in general anesthesia. Forecasts for subsequent years are unchanged. The negative impact of these forecast changes on our valuation is cancelled out by the derisking effect of the positive result of the EU phase III general anesthesia trial. We retain our Buy recommendation and price target of €4.90.

Figure 3: Changes to our forecasts

		2020E			2021E	
in EURm	Old	New	Δ	Old	New	Δ
Revenues	0.87	0.94	7.7%	18.44	7.54	-59.1%
Other operating income	19.50	20.00	2.6%	3.50	3.00	-14.3%
Total revenues	20.37	20.94	2.8%	21.94	10.54	-52.0%
SG&A	-8.00	-8.00	-	-12.70	-20.28	-
% total revenues	-39.3%	-38.2%	-	-57.9%	-192.5%	-
R&D	-11.00	-11.00	-	-12.00	-8.00	-
% total revenues	-54.0%	-52.5%	-	-54.7%	-75.9%	-
EBIT	1.37	1.94	41.4%	-6.07	-21.05	n.a.
margin	6.7%	9.3%	-	-27.7%	-199.8%	-
Net income	2.37	2.94	23.9%	-5.45	-17.44	n.a.
margin	11.6%	14.0%	-	-24.8%	-165.5%	-
EPS (dil., in EUR)	0.04	0.04	23.9%	-0.08	-0.27	n.a.

Source: First Berlin Equity Research



Figure 4: 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	€64.4M	15,144K	€14	€208.6M	25%	€68.1M	30%	15%	12	1 Year
Remimazolam	PS US	€165.5M	22,000K	€20	€440.0M	40%	€223.2M	2%	12%	11	-
Remimazolam	PS CAN	€6.8M	1,056K	€20	€21.1M	50%	€13.4M	18%	15%	10	2 Years
Remimazolam	GA EU	€149.8M	15,144K	€45	€681.5M	20%	€179.8M	3 %	15%	11	2 Years
Remimazolam	GA US	€88.7M	23,925K	€40	€957.0M	20%	€242.7M	2%	15%	8	4 Years
Remimazolam	GA JAP	€99.3M	10,000K	€40	€400.0M	25%	€131.9M	8%	12%	13	-
Remimazolam	GA CHN	€17.3M	51,000K	€28	€1,405.0M	10%	€185. 4 M	10%	15%	15	3 Years
Remimazolam	PS CHN	€17.8M	33,260K	€10	€346.5M	10%	€45.7M	1%	15%	15	-
Remimazolam	GA KOR	€9.4M	3,750K	€28	€103.3M	25%	€34.1M	10%	5 %	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	2%	15%	7	5 Years
Remimazolam	ICU EU	€33.3M	2,439K	€167	€406.5M	25%	€136.8M	3 %	15%	8	4 Years
Remimazolam	ICU Japan	€4.7M	606K	€167	€101.0M	25%	€33.3M	18%	15%	9	5 Years
PACME PV		€729.6M									
Costs PV (4)		€453.5M									
NPV		€276.1M									
Milestones PV		€23.6M									
Pro forma net ca	sh	€24.5M									
Fair Value		€324.2M									
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

Source: First Berlin Equity Research

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



INCOME STATEMENT

All figures in EUR '000	2016	2017	2018	2019	2020E	2021E
Net revenues	0	0	0	0	937	7,536
Other op. inc. (including milestones)	4,262	5,811	2,766	8,000	20,000	3,000
Total revenue	4,262	5,811	2,766	8,000	20,937	10,536
Cost of goods sold	0	0	0	0	0	3,305
Gross profit	4,262	5,811	2,766	8,000	20,937	7,231
S,G&A	5,129	3,828	3,408	5,023	8,000	20,283
R&D	23,408	17,854	12,167	13,099	11,000	8,000
Other operating income (expense)	-807	-2	354	796	0	0
Operating income (EBIT)	-25,082	-15,872	-12,455	-9,326	1,937	-21,052
Net financial result	21	20	8	-122	-250	-750
Pre-tax income (EBT)	-25,061	-15,852	-12,447	-9,448	1,687	-21,802
Income taxes	4,944	3,759	2,510	2,432	1,250	4,360
Net income / loss	-20,118	-12,093	-9,937	-7,016	2,937	-17,441
Diluted EPS	-0.38	-0.20	-0.16	-0.11	0.04	-0.27
EBITDA	-24,758	-15,626	-12,265	-9,186	2,077	-20,912
Ratios						
EBIT margin	n.m.	n.m.	n.m.	n.m.	9.3%	-199.8%
EBITDA margin	n.m.	n.m.	n.m.	n.m.	9.9%	-198.5%
Net margin	n.m.	n.m.	n.m.	n.m.	14.0%	-165.5%
Cash Coverage of Expenses						
Cash / G&A	5.9x	6.5x	5.1x	3.7x	3.0x	1.1x
Cash / R&D	1.3x	1.4x	1.4x	1.4x	2.2x	2.4x
Y-Y Growth						
Total revenue	5851.0%	36.4%	-52.4%	189.2%	161.7%	-49.7%
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
<u>Assets</u>						
Current assets, total	35,128	29,357	22,037	22,650	29,132	29,428
Cash and cash equivalents	30,111	24,839	17,227	18,787	24,226	19,165
Short-Term Investments	0	0	0	0	0	0
Receivables	0	37	1,500	500	141	728
Inventories	0	0	0	0	2,015	7,536
Other current assets	5,017	4,481	3,311	3,363	2,750	2,000
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	31,286	31,516
Shareholders' equity & debt						
Current Liabilities, Total	13,040	6,656	3,501	10,154	8,964	6,645
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	5,818
Milestone	5,730	0	0	0	0	0
Provisions	555	391	630	270	2	15
Lease liabilities	0	0	0	55	63	72
Other current liabilities	403	344	654	632	900	740
Longterm liabilities, total	0	0	0	26	29	20,034
Convertible bond	0	0	0	0	0	0
Long-term debt	0	0	0	0	0	20,000
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	22,292	4,837
Total consolidated equity and debt	37,984	31,885	24,323	24,912	31,286	31,516
Ratios						
Current ratio (x)	2.69	4.41	6.29	2.23	3.25	4.43
Quick ratio (x)	2.69	4.41	6.29	2.23	3.02	3.29
Net gearing	-120.7%	-98.5%	-82.7%	-97.4%	-108.3%	19.4%
Book value per share (€)	0.45	0.41	0.33	0.23	0.34	0.07
Return on equity (ROE)	-66.5%	-48.2%	-43.2%	-39.5%	15.9%	-128.6%



CASH FLOW STATEMENT

All figures in EUR '000	2016	2017	2018	2019	2020E	2021E
Net result	-20,118	-12,093	-9,939	-7,016	2,937	-17,441
Depreciation and amortization	759	347	255	118	140	140
Changes in working capital	1,137	-911	-4,647	3,516	2,382	-7,699
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	5,459	-25,001
CAPEX	-192	-25	-13	-14	-32	-74
Free cash flow	-11,778	-17,745	-12,826	-2,861	5,428	-25,074
Debt financing, net	0	0	0	0	0	20,000
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	5,439	-5,061
Cash, start of the year	32,680	30,111	24,839	17,227	18,787	24,226
Cash, end of the year	30,111	24,839	17,227	18,787	24,226	19,165
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 $\in 0 - \in 2$ billion, and Category 2 companies have a market capitalisation of $> \in 2$ 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
238	\downarrow	↓	↓	↓
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
44	17 August 2020	€2.69	Buy	€4.90
47	Today	€2.45	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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