

PAION AG

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

Update

RATING
PRICE TARGET **BUY**
€4.40
 Return Potential 79.4%
 Risk Rating High

€5M SHARE ISSUE TO FINANCE FILING FOR APPROVAL IN JAPAN

PAION is to raise €5m through a share issue to finance filing for approval of remimazolam in Japan. PAION will issue 2,439,023 new shares at €2.05 each, thereby increasing the share count by 4.4% to 58,196,117. An external contractor will be engaged to assemble a filing dossier for Japan. This means that no internal resources will be diverted from PAION's strategic priority - completion of the clinical development process in the US. PAION has also published preliminary full year 2016 numbers. Spending on R&D and S,G&A in 2016 was respectively 8% and 7% lower than we had expected, but management continues to expect completion of recruitment for the US phase III trial of remimazolam with bronchoscopy patients in Q2/17. The incorporation of the current share issue into a previously modelled capital raise means that no additional dilution has to be taken into account. However, we now take a more conservative view on the timing of future milestone payments from PAION's US marketing partner, Cosmo Pharmaceuticals. We now model a total of €42.5m over three years from 2018-2020 (previously: €42.5m during 2017 and 2018). The later timing of these payments causes us to reduce our price target from €4.60 to €4.40. We maintain our Buy recommendation.

Japanese PMDA sees remimazolam data package as ready for filing In late 2014, PAION's previous Japanese marketing partner, Ono, issued a profit warning with its H1 2014/15 results. Ono also announced that for strategic reasons it had abandoned plans to file for marketing approval of remimazolam for general anaesthesia in Japan. Ono had previously completed phase I, II and III studies in Japan. Transfer of know-how and technology from Ono to PAION was completed in July 2015. In October 2015, the Japanese regulatory authorities informed PAION that both the active ingredient of remimazolam produced by PAION in Europe as well as the finished formulation fulfil Japanese filing requirements. The ruling meant that PAION would not have to set up a new production process based on Ono's manufacturing process, which would have led to a significant delay in the Japanese filing. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2013	2014	2015	2016P	2017E	2018E
Revenue (€m)	4.23	3.46	0.07	4.30	5.70	33.26
Y-o-y growth	-84.2%	-18.3%	n.a.	n.a.	32.6%	483.5%
EBIT (€m)	-2.81	-11.64	-34.09	-24.20	-14.90	0.63
EBIT margin	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Net income (€m)	-2.21	-9.10	-28.21	-20.25	-7.93	3.06
EPS (diluted) (€)	-0.09	-0.23	-0.56	-0.38	-0.13	0.05
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-1.75	-12.07	-26.32	-12.14	-15.83	2.58
Net gearing	-99.7%	-94.1%	-91.9%	-121.0%	-91.9%	-91.5%
Liquid assets (€m)	13.29	58.91	32.68	30.14	29.70	32.28

RISKS

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

COMPANY PROFILE

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

MARKET DATA

As of 13 Feb 2017

Closing Price € 2.45
 Shares outstanding 55.74m
 Market Capitalisation € 136.67m
 52-week Range € 1.60 / 3.03
 Avg. Volume (12 Months) 200,965

Multiples	2016P	2017E	2018E
P/E	n.a.	n.a.	50.4
EV/Sales	24.8	18.7	3.2
EV/EBIT	n.a.	n.a.	170.0
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 30 Sep 2016

Liquid Assets € 35.91m
 Current Assets € 39.52m
 Intangible Assets € 2.68m
 Total Assets € 42.33m
 Current Liabilities € 13.41m
 Shareholders' Equity € 28.89m

SHAREHOLDERS

Cosmo Pharmaceuticals 9.1%
 TIAA-CREF 3.0%
 Free Float 87.9%



PAION reported a positive pre-NDA meeting on remimazolam with the Japanese PMDA (Pharmaceuticals and Medical Devices Agency) in early 2016. The PMDA stated that it regards PAION's non-clinical and clinical data package on remimazolam as complete for filing.

Start of filing process to bring new impetus to partnership discussions? PAION will use most of the proceeds of the share issue to engage an external contractor to assemble a filing dossier for Japan. This means that no internal resources will be diverted from PAION's strategic priority – completion of the clinical development process in the US. Filing in Japan is expected by mid-2018 at the latest. PAION has been evaluating partners for remimazolam in Japan since 2015 but so far a deal has not been concluded. Management believes that the start of the filing process may bring new impetus to partnership discussions.

2016 loss €2m smaller than we expected PAION has announced preliminary, unaudited figures for 2016. The net loss for 2016 was €2m smaller than we had forecast. As figure 1 shows, major cost items were not as high as we had expected or guidance had suggested. Publication of the annual report is scheduled for 16 March. Although costs came in below expectations during the latter part of 2016, management continues to expect completion of recruitment for the US phase III trial of remimazolam with bronchoscopy patients in Q2/17.

Figure 1: FY/16 results vs. our forecasts

in EURm	FY/16P	FY/16E	Delta	FY/15A	Delta
Sales*	4.30	4.00	7.5%	0.01	85900.0%
R&D expenses	-23.40	-25.50	-	-29.39	-
S,G&A expenses	-5.10	-5.50	-	-5.73	-
EBT	-25.15	-26.39	-	-34.05	-
Taxes	4.90	4.25	-	5.83	-
Net income	-20.25	-22.14	-	-28.21	-
margin	neg.	neg.	-	neg.	-
EPS (dil., in EUR)	-0.38	-0.42	-	-0.56	-

* including other operating income such as milestone payments

Source: First Berlin Equity Research; PAION AG

Approaches to resumption of clinical development in the EU under evaluation PAION is currently evaluating how to resume clinical development of remimazolam in the EU. Management has stated that details of a development plan for the EU will be published in the annual report. We inserted a capital raise of €15m in 2017 into our valuation model last August to cover the cost of further clinical development of remimazolam in the EU. In our view this sum will be sufficient to cover 2017 operating costs - including filing for approval in Japan. Our forecast for the 2017E cash position is €29.7m (2016P: €30.1m).

We now model later timing of milestone payments from Cosmo Pharmaceuticals

The terms of the U.S. licensing deal with Cosmo Pharmaceuticals (Cosmo) announced in June 2016 stipulated that Cosmo make milestone payments to PAION of up to €52.5m. €10m of this sum was already paid upfront in 2016. The timing of the payment of the balance of €42.5m is linked to the timing of filing for approval and the granting of approval for remimazolam in the U.S. in major indications including procedural sedation, general anaesthetic and intensive care unit sedation. Timing of filing for approval of remimazolam in all indications including procedural sedation is the responsibility of Cosmo. Cosmo has stated that remimazolam could be approved in the U.S. at the end of 2018, which would imply filing for approval at the end of 2017. However, we now take a more conservative view on the timing of the associated milestone payment and move this from 2017 to 2018. We now model a total of €42.5m of milestone payments over three years from 2018-2020 (previously: €42.5m during 2017 and 2018).



The milestones we model for 2019 and 2020 are linked to filing/approval in general anaesthetic and intensive care unit sedation. The impact of this change on our 2017 and 2018 forecasts is shown in the figure 2 below.

Figure 2: Changes to our forecasts

in EURm	2017E			2018E		
	Old	New	Δ	Old	New	Δ
Sales*	21.00	5.70	-72.9%	40.76	33.26	-18.4%
EBIT	0.40	-14.90	-	8.13	0.63	-92.3%
margin	1.9%	neg.	-	19.9%	1.9%	-
Net income	2.78	-7.93	-	10.74	3.06	-71.5%
margin	13.2%	neg.	-	26.3%	9.2%	-
EPS (dil., in EUR)	0.04	-0.13	-	0.17	0.05	-71.4%

* including other operating income such as milestone payments

Source: First Berlin Equity Research; PAION AG

Buy recommendation maintained but price target lowered to €4.40 (previously: €4.60)

The incorporation of the current share issue into a previously modelled capital raise means that no additional dilution has to be taken into account. However, the changes in the timing of the milestone payments discussed above cause us to lower our price target to €4.40 (previously: €4.60). 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	€51.7M	25,300K	€15	€387.2M	25%	€108.0M	30%	15%	9	4 Years
Remimazolam	PS US	€105.7M	15,950K	€20	€319.0M	50%	€185.2M	2%	15%	14	3 Years
Remimazolam	PS CAN	€3.4M	1,056K	€20	€21.1M	50%	€11.8M	15%	18%	9	5 Years
Remimazolam	GA EU	€159.4M	37,800K	€40	€1,512.0M	20%	€337.4M	30%	15%	9	4 Years
Remimazolam	GA US	€127.5M	23,925K	€40	€957.0M	20%	€222.2M	3%	15%	12	5 Years
Remimazolam	GA JAP	€79.2M	26,000K	€40	€1,040.0M	25%	€290.1M	10%	15%	11	2 Years
Remimazolam	GA CHN	€33.4M	51,000K	€31	€1,561.1M	10%	€188.6M	10%	15%	14	4 Years
Remimazolam	GA KOR	€5.0M	3,750K	€31	€114.8M	25%	€32.0M	10%	5%	8	4 Years
Remimazolam	GA CIS/MENA/TUR	€45.9M	55,247K	€32	€1,740.7M	10%	€194.2M	15%	15%	9	4 Years
Remimazolam	ICU US	€14.4M	3,988K	€184	€733.7M	10%	€85.2M	1%	15%	9	4 Years
Remimazolam	ICU EU	€10.7M	3,988K	€120	€478.5M	10%	€53.4M	30%	15%	6	5 Years
Other	HF/HPH	€12.1M	1,333K	€926	€1,234.3M	20%	€292.3M	5%	15%	10	8 Years
PACME PV		€648.4M									
Costs PV (4)		€447.3M									
NPV		€201.0M									
Milestones PV		€30.5M									
Pro forma net cash		€44.9M									
Fair Value		€276.5M									
Share Count		63,368K									
Price Target		€4.36									

Source: First Berlin Equity Research

Figure 4: Changes to pipeline valuation model

	Old	New	Delta
PACME PV	€648.4M	€648.4M	0.0%
Costs PV	€450.8M	€447.3M	-0.8%
NPV	€197.6M	€201.0M	1.7%
Milestones PV	€47.0M	€30.5M	-35.0%
Pro Forma Net Cash	€50.0M	€44.9M	-10.1%
Fair Value	€294.6M	€276.5M	-6.1%
Diluted Share Count	63,422K	63,368K	-0.1%
Fair Value Per Share	€4.64	€4.36	-6.0%

Source: First Berlin Equity Research



INCOME STATEMENT

All figures in EUR '000	2013	2014	2015	2016P	2017E	2018E
Net revenues	0	4	0	0	0	13,261
Other op. inc. (including milestones)	4,228	3,452	72	4,300	5,700	20,000
Total revenue	4,228	3,456	72	4,300	5,700	33,261
Cost of goods sold	0	4	11	0	0	11,935
Gross profit	0	0	61	0	0	1,326
PACME	4,228	3,452	132	4,300	5,700	21,326
G&A	3,314	3,702	5,729	5,100	5,600	5,700
R&D	4,583	11,799	29,385	23,400	15,000	15,000
Other operating income (expense)	860	411	965	0	0	0
Operating income (EBIT)	-2,810	-11,639	-34,088	-24,200	-14,900	626
Net financial result	-170	66	42	50	150	30
Non-operating expenses	0	0	0	-1,000	0	0
Pre-tax income (EBT)	-2,980	-11,573	-34,046	-25,150	-14,750	656
Income taxes	768	2,468	5,834	4,900	6,825	2,400
Net income / loss	-2,212	-9,105	-28,212	-20,250	-7,925	3,056
Diluted EPS	-0.09	-0.23	-0.56	-0.38	-0.13	0.05
EBITDA	-2,505	-11,327	-33,742	-23,946	-14,421	1,158
Ratios						
EBIT margin on PACME	n.m.	n.m.	n.m.	n.m.	n.m.	2.9%
EBITDA margin on PACME	n.m.	n.m.	n.m.	n.m.	n.m.	5.4%
Net margin on PACME	n.m.	n.m.	n.m.	n.m.	n.m.	14.3%
Cash Coverage of Expenses						
Cash / G&A	4.0x	15.9x	5.7x	5.9x	5.3x	5.7x
Cash / R&D	2.9x	5.0x	1.1x	1.3x	2.0x	2.2x
Y-Y Growth						
Total revenue	-84.2%	-18.3%	-97.9%	5904.3%	32.6%	483.5%
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	2013	2014	2015	2016P	2017E	2018E
Assets						
Current assets, total	14,433	63,032	40,051	33,687	33,454	36,243
Cash and cash equivalents	13,292	58,912	32,680	30,137	29,704	32,281
Short-Term Investments	0	0	0	0	0	0
Receivables	0	467	0	0	0	212
Inventories	0	0	0	0	0	0
Other current assets	1,141	3,653	7,371	3,550	3,750	3,750
Non-current assets, total	3,583	3,516	3,417	3,405	3,419	3,694
Property, plant & equipment	89	76	56	43	57	333
Goodwill & other intangibles	3,494	3,440	3,362	3,362	3,362	3,362
Other Assets	0	0	0	0	0	0
Total assets	18,016	66,548	43,468	37,091	36,873	39,937
Shareholders' equity & debt						
Current Liabilities, Total	4,659	3,924	7,901	12,182	4,560	4,658
Convertible bond	0	0	0	0	0	0
Short-term debt	0	0	0	0	0	0
Accounts payable	1,914	3,338	7,332	5,850	3,750	3,750
Milestone				5,700		
Provisions	2,508	306	224	234	300	398
Other current liabilities	236	280	344	398	510	510
Longterm liabilities, total	28	17	6	7	2	10
Convertible bond	0	0	0	0	0	0
Long-term debt	0	0	0	0	0	0
Provisions	0	0	0	0	0	0
Deferred revenue	28	17	6	7	2	10
Shareholders' equity	13,329	62,607	35,562	24,902	32,311	35,269
Total consolidated equity and debt	18,016	66,548	43,468	37,091	36,873	39,937
Ratios						
Current ratio (x)	3.10	16.06	5.07	2.77	7.34	7.78
Quick ratio (x)	3.10	16.06	5.07	2.77	7.34	7.78
Net gearing	-99.7%	-94.1%	-91.9%	-121.0%	-91.9%	-91.5%
Book value per share (€)	0.53	1.24	0.70	0.45	0.51	0.56
Net cash	13,292	58,912	32,680	30,137	29,704	32,281
Return on equity (ROE)	-15.3%	-24.0%	-57.5%	-67.0%	-27.7%	9.0%



CASH FLOW STATEMENT

All figures in EUR '000	2013	2014	2015	2016P	2017E	2018E
Net result	-2,212	-9,105	-28,212	-20,250	-7,925	3,056
Depreciation and amortization	390	93	125	254	479	532
Changes in working capital	457	284	3,999	2,394	-2,193	-204
Milestone	0	0	0	5,700	-5,700	0
Other adjustments	-381	-3,316	-2,198	0	0	0
Operating cash flow	-1,746	-12,044	-26,287	-11,902	-15,339	3,384
CAPEX	-5	-26	-33	-241	-493	-808
Free cash flow	-1,751	-12,070	-26,320	-12,143	-15,832	2,576
Debt financing, net	-7,000	0	0	0	0	0
Convertible bond financing, net	0	0	0	0	0	0
Equity financing, net	0	57,618	22	9,600	15,400	0
Other changes in cash	-293	72	66	0	0	0
Net cash flows	-9,044	45,620	-26,232	-2,543	-432	2,576
Cash, start of the year	22,336	13,292	58,912	32,680	30,137	29,704
Cash, end of the year	13,292	58,912	32,680	30,137	29,704	32,281

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
2...30	↓	↓	↓	↓
31	22 August 2016	€2.15	Buy	€4.60
32	28 October 2016	€2.66	Buy	€4.60
33	18 November 2016	€2.38	Buy	€4.60
34	Today	€2.45	Buy	€4.40

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

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STRONG BUY: An expected favourable price trend of more than 50% combined with sizeable confidence in the quality and forecast security of management.

BUY: An expected favourable price trend of more than 25% percent.

ADD: An expected favourable price trend of between 0% and 25%.

REDUCE: An expected negative price trend of between 0% and -15%.

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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: <http://firstberlin.com/disclaimer-english-link/>

SUPERVISORY AUTHORITY: Bundesanstalt für Finanzdienstleistungsaufsicht (German Federal Financial Supervisory Authority) [BaFin], Graurheindorferstraße 108, 53117 Bonn and Lurgiallee 12, 60439 Frankfurt

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