PAION AG

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

Final 2016 results

RATING	**BUY**
PRICE TARGET	**€4.40**
Return Potential	101.3%
Risk Rating	High

FILING FOR APPROVAL IN THE U.S. AND JAPAN IN 2018

Final 2016 numbers were close to the preliminary figures published on 7 February ahead of the recently completed €5m capital raise to finance filing for approval of remimazolam in Japan. The two most important events at PAION in 2016 were the publication of data from the phase III trial of remimazolam with colonoscopy patients in the U.S. and the ensuing U.S. commercialisation agreement with Cosmo Pharmaceuticals. PAION has already received €20.0m as a result of this deal and stands to receive up to €42.5m more in milestone payments. These payments should ensure that PAION is fully financed until remimazolam's U.S. launch as Cosmo will finance the filing and approval processes. The licensing agreement with Cosmo has thus substantially derisked the equity story. We expect filing for approval of remimazolam in the U.S. in the indication procedural sedation in mid-2018 and in Japan for general anesthesia by mid-2018 at the latest. The resumption of clinical development of remimazolam in the EU, also for general anesthesia, is likely to entail a phase III trial starting in 2018 modelled on the phase trial completed in Japan in 2013. We maintain our Buy recommendation and price target of €4.40.

PAION has already received €20.0m of potential €62.5m from Cosmo The terms of the licensing deal announced with Cosmo entail payments of up to €62.5m (milestones of €52.5m - of which €10m upfront - and an equity raise of €10m) as well as tiered royalties following commercialisation. PAION received the €10m upfront payment and €9.6m of the equity capital increase last year. The outstanding €0.4m was invested in the course of the February capital increase. €4.3m of the above-mentioned upfront payment was booked as revenue for 2016 (see figure 1 overleaf). Revenue recognition of the €5.7m balance is dependent on the progress of certain development components, but management expects this figure to be booked by the end of 2017.

R&D costs down 20.4% in 2016 vs. 2015 2016 R&D costs at €23.4m were 20.4% below the 2015 figure of €29.4m. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2013	2014	2015	2016	2017E	2018E
Revenue (€m)	4.23	3.46	0.07	4.26	5.73	33.26
Y-o-y growth	-84.2%	-18.3%	n.a.	n.a.	34.5%	480.5%
EBIT (€m)	-2.81	-11.64	-34.09	-25.08	-17.02	0.63
EBIT margin	-66.5%	-336.8%	-47599.0%	-588.5%	-297.0%	1.9%
Net income (€m)	-2.21	-9.10	-28.21	-20.12	-13.12	3.33
EPS (diluted) (€)	-0.09	-0.23	-0.56	-0.38	-0.21	0.05
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-1.75	-12.07	-26.32	-11.78	-18.21	3.76
Net gearing	-99.7%	-94.1%	-91.9%	-120.7%	-99.6%	-101.2%
Liquid assets (€m)	13.29	58.91	32.68	30.11	27.30	31.06

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 24 Mar 2017	
Closing Price	€ 2.19
Shares outstanding	58.20m
Market Capitalisation	€ 127.22m
52-week Range	€ 1.65 / 3.03
Avg. Volume (12 Months)	162,404

Multiples	2016	2017E	2018E
P/E	n.a.	n.a.	41.3
EV/Sales	22.8	16.9	2.9
EV/EBIT	n.a.	n.a.	155.1
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW

COMPANY DATA

As of 31 Dec 2016	
Liquid Assets	€ 30.11m
Current Assets	€ 35.13m
Intangible Assets	€ 2.69m
Total Assets	€ 37.98m
Current Liabilities	€ 13.04m
Shareholders' Equity	€ 24.94m

SHAREHOLDERS

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

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The decline was mainly attributable to lower expenses for phase I studies and for production development and preparation of the market approval dossier in the course of the US development program. Expenses for phase III development increased due to the successful measures taken to accelerate the US bronchoscopy study.

Figure 1: FY/16 results vs. our forecasts

in EURm	FY/16A	FY/16P	Delta	FY/15A	Delta
Sales*	4.26	4.30	-0.9%	0.01	85100.0%
R&D expenses	-23.41	-23.40	-	-29.39	-
S,G&A expenses	-5.13	-5.10	-	-5.73	-
EBT	-25.06	-25.15	-	-34.04	-
Taxes	4.94	4.90	-	5.83	-
Net income	-20.12	-20.25	-	-28.21	-
margin	*neg.*	*neg.*	-	*neg.*	-
EPS (dil., in EUR)	-0.38	-0.38	-	-0.56	-

* including other operating income such as milestone payments

Source: First Berlin Equity Research; PAION AG

General, administrative and selling costs fell 10.4% to €5.1m (2015: €5.7m). Selling costs fell in 2016 primarily because of higher prior year spending on market research, pre-marketing and market access activities. However, administrative costs rose due to preparation of capital raising measures, which were ultimately not implemented because of the agreement with Cosmo. The swing in the other income (expenses) figure to €-0.8m (2015: €1.0m) stemmed from foreign exchange losses in 2016 after corresponding gains in 2015. The operating result came in at €-25.1m (2015: €-34.1m).

2016 tax credit lower because of link to R&D costs PAION booked an income tax credit of €4.9m in 2016 (2015: €5.8m). The credits relate to tax claims for partial reimbursement of R&D costs from the British tax authorities. The tax charge credit was below the prior year level because of the decline in R&D costs discussed above. The net result was €-20.1m (2015: €-28.2m). EPS, which amounted to €-0.38 (2015: €-0.56), was influenced by a 5.2% increase in the average number of shares outstanding to 53.245m (2015: 50.653m) as a result of the issue to Cosmo.

EU Phase III trial of remimazolam in general anesthesia from 2018 In February 2016 PAION discontinued a phase III study of remimazolam in the EU with cardiac surgery patients in the indication general anesthesia. The trial was discontinued due to recruitment challenges caused by the study's complex design. During Q4 last year, management stated that in early 2017 it would provide details on the further development of remimazolam in the EU. The annual report states that a phase I study will be conducted during 2017 to determine the number of patients required for a further EU Phase III study in general anesthesia, which is expected to start in 2018. The study design is likely to resemble the successfully completed phase III program in general anesthesia in Japan. Management expects the phase III study in the EU to require funding of €20-€25m.

Completion of recruitment for US phase III trial with bronchoscopy patients in Q2/17 Management expects PAION's net loss to narrow to €12-€14m in 2017 (FY2016: a loss of €20.1m). The main driver of the reduced loss will be R&D which is expected to be in the range €18-€20m this year after €23.4m in 2015. R&D expenses should be lower than in 2016 because of the completion of the phase III study of remimazolam in the US with colonoscopy patients. The US phase III study of remimazolam with bronchoscopy patients is continuing and completion of recruitment is expected shortly. The budget also includes a tax credit of €3.5- €4.0m (FY2016: €5.0m). The decline reflects lower R&D spending.

We model €15m equity raise in 2017 to partially fund EU phase III trial PAION's cash position amounted to €30.1m at the end of 2016. There was no debt on the balance sheet. The February equity raise to finance filing for approval of remimazolam in Japan raised gross proceeds of €5.0m. On the assumption that development, filing and approval go according to plan, we anticipate that PAION will not need additional funding to bring remimazolam to the US market. However, we continue to model a further capital raise of €15m later this year to partially fund the €20-€25m estimated cost of the EU phase III trial of remimazolam in the indication general anesthesia. This trial is expected to begin in 2018. We expect PAION to source the remaining €5-€10m from cash on hand and/or the next milestone payment from Cosmo.

Figure 2: Changes to our forecasts

	2017E			2018E		
in EURm	**Old**	**New**	**Δ**	**Old**	**New**	**Δ**
Sales*	5.70	5.73	0.5%	33.26	33.26	0.0%
EBIT	-14.90	-17.02	-	0.63	0.63	0.0%
margin	*neg.*	*neg.*	-	*1.9%*	*1.9%*	-
Net income	-7.93	-13.12	-	3.06	3.33	8.8%
margin	*-139.1%*	*neg.*	-	*9.2%*	*10.0%*	-
EPS (dil., in EUR)	-0.13	-0.21	-	0.05	0.05	5.7%

* including other operating income such as milestone payments

Source: First Berlin Equity Research; PAION AG

We maintain our Buy recommendation and price target of €4.40 Figure 2 shows changes to our forecasts. We have lowered our 2017E EBIT forecast by €1.5m mainly because management guidance on R&D and general, administrative and selling costs is respectively €4m higher and nearly €2m lower than the figures we previously modelled. Our net income forecast is €5.1m lower because of a €3m reduction in our forecast of this year's tax rebate. We are leaving our 2018 forecasts largely unchanged. Despite the €5.1m reduction in our 2017 net profit forecast, our projection of the year-end 2017 cash position is only €2.3m below the forecast in our previous note. This relates mainly to higher accounts payable in connection with the upward revision in our R&D forecast. Meanwhile, rolling our valuation model forward into 2017 reduces the present value of costs and milestone payments by another €2m. We continue to see fair value at €4.40. Our recommendation remains at Buy.

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	3 Years
Remimazolam	PS US	€105.7M	15,950K	€20	€319.0M	50%	€185.2M	22%	15%	14	2 Years
Remimazolam	PS CAN	€3.4M	1,056K	€20	€21.1M	50%	€11.8M	15%	15%	9	4 Years
Remimazolam	GA EU	€159.4M	37,800K	€40	€1,512.0M	20%	€337.4M	30%	15%	9	3 Years
Remimazolam	GA US	€127.5M	23,925K	€40	€957.0M	20%	€222.2M	30%	15%	12	4 Years
Remimazolam	GA JAP	€79.2M	26,000K	€40	€1,040.0M	25%	€290.1M	10%	15%	11	1 Years
Remimazolam	GA CHN	€33.4M	51,000K	€31	€1,561.1M	10%	€188.6M	10%	15%	14	3 Years
Remimazolam	GA KOR	€5.0M	3,750K	€31	€114.8M	25%	€32.0M	10%	15%	8	3 Years
Remimazolam	GA CIS/MENA/TUR	€45.9M	55,247K	€32	€1,740.7M	10%	€194.2M	15%	15%	9	3 Years
Remimazolam	ICU US	€14.4M	3,988K	€184	€733.7M	10%	€85.2M	15%	15%	9	3 Years
Remimazolam	ICU EU	€10.7M	3,988K	€120	€478.5M	10%	€53.4M	30%	15%	6	4 Years
Other	HF/HPH	€12.1M	1,333K	€926	€1,234.3M	20%	€292.3M	5%	15%	10	7 Years
PACME PV		€648.4M									
Costs PV (4)		€446.1M									
NPV		€202.3M									
Milestones PV		€31.0M									
Pro forma net cash		€45.2M									
Fair Value		€278.5M									
Share Count		63,371K									
Price Target		€4.39									

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 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
PACME PV	**€648.4M**	**€648.4M**	**0.0%**
Costs PV	€447.3M	€446.1M	-0.3%
NPV	**€201.0M**	**€202.3M**	**0.6%**
Milestones PV	€30.5M	€31.0M	1.6%
Pro Forma Net Cash	€44.9M	€45.2M	0.6%
Fair Value	€276.5M	€278.5M	0.7%
Diluted Share Count	63,368K	63,371K	0.0%
Fair Value Per Share	**€4.36**	**€4.39**	**0.7%**

Source: First Berlin Equity Research

INCOME STATEMENT

All figures in EUR '000	2013	2014	2015	2016	2017E	2018E
Net revenues	**0**	**4**	**0**	**0**	**0**	**13,261**
Other op. inc. (including milestones)	**4,228**	**3,452**	**72**	**4,262**	**5,730**	**20,000**
Total revenue	**4,228**	**3,456**	**72**	**4,262**	**5,730**	**33,261**
Cost of goods sold	**0**	**4**	**11**	**0**	**0**	**11,935**
Gross profit	**0**	**0**	**61**	**4,262**	**0**	**1,326**
PACME	**4,228**	**3,452**	**132**	**8,524**	**5,730**	**21,326**
G&A	3,314	3,702	5,729	5,129	3,750	4,000
R&D	4,583	11,799	29,385	23,408	19,000	16,700
Other operating income (expense)	860	411	965	-807	0	0
Operating income (EBIT)	**-2,810**	**-11,639**	**-34,088**	**-25,082**	**-17,020**	**626**
Net financial result	-170	66	42	21	150	27
Non-operating expenses	0	0	0	-1,000	0	0
Pre-tax income (EBT)	**-2,980**	**-11,573**	**-34,046**	**-25,061**	**-16,870**	**654**
Income taxes	768	2,468	5,834	4,944	3,750	2,672
Net income / loss	**-2,212**	**-9,105**	**-28,212**	**-20,118**	**-13,120**	**3,326**
Diluted EPS	**-0.09**	**-0.23**	**-0.56**	**-0.38**	**-0.21**	**0.05**
EBITDA	**-2,505**	**-11,327**	**-33,742**	**-24,831**	**-16,539**	**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.	15.6%
Cash Coverage of Expenses						
Cash / G&A	4.0x	15.9x	5.7x	5.9x	7.3x	7.8x
Cash / R&D	2.9x	5.0x	1.1x	1.3x	1.4x	1.9x
Y-Y Growth						
Total revenue	-84.2%	-18.3%	-97.9%	5851.0%	34.5%	480.5%
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	2016	2017E	2018E
Assets						
Current assets, total	**14,433**	**63,032**	**40,051**	**35,128**	**31,123**	**34,016**
Cash and cash equivalents	13,292	58,912	32,680	30,111	27,300	31,059
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	5,017	3,824	2,746
Non-current assets, total	**3,583**	**3,516**	**3,417**	**2,855**	**2,439**	**2,180**
Property, plant & equipment	89	76	56	167	57	100
Goodwill & other intangibles	3,494	3,440	3,362	2,688	2,382	2,080
Other Assets	0	0	0	0	0	0
Total assets	**18,016**	**66,548**	**43,468**	**37,984**	**33,563**	**36,196**
Shareholders' equity & debt						
Current Liabilities, Total	**4,659**	**3,924**	**7,901**	**13,040**	**6,163**	**5,481**
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	6,353	5,156	4,532
Milestone				5,730		
Provisions	2,508	306	224	555	380	398
Other current liabilities	236	280	344	403	627	551
Longterm liabilities, total	**28**	**17**	**6**	**0**	**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	0	2	10
Shareholders' equity	**13,329**	**62,607**	**35,562**	**24,943**	**27,398**	**30,705**
Total consolidated equity and debt	**18,016**	**66,548**	**43,468**	**37,984**	**33,563**	**36,196**
Ratios						
Current ratio (x)	3.10	16.06	5.07	2.69	5.05	6.21
Quick ratio (x)	3.10	16.06	5.07	2.69	5.05	6.21
Net gearing	-99.7%	-94.1%	-91.9%	-120.7%	-99.6%	-101.2%
Book value per share (€)	0.53	1.24	0.70	0.45	0.44	0.49
Return on equity (ROE)	-15.3%	-24.0%	-57.5%	-66.5%	-50.1%	11.4%

CASH FLOW STATEMENT

All figures in EUR '000	2013	2014	2015	2016	2017E	2018E
Net result	**-2,212**	**-9,105**	**-28,212**	**-20,118**	**-13,120**	**3,326**
Depreciation and amortization	390	93	125	759	481	532
Changes in working capital	457	284	3,999	1,137	-970	-904
Milestone	0	0	0	5,730	-5,730	0
Net taxes received	-693	-3,988	-3,269	585	1,194	1,078
Other items	312	672	1,071	321	0	0
Operating cash flow	**-1,746**	**-12,044**	**-26,287**	**-11,586**	**-18,146**	**4,032**
CAPEX	-5	-26	-33	-192	-66	-273
Free cash flow	**-1,751**	**-12,070**	**-26,320**	**-11,778**	**-18,212**	**3,759**
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**	**9,212**	**15,400**	**0**
Other changes in cash	**-293**	**72**	**66**	**-2**	**0**	**0**
Net cash flows	**-9,044**	**45,620**	**-26,232**	**-2,568**	**-2,812**	**3,759**
Cash, start of the year	22,336	13,292	58,912	32,680	30,111	27,300
Cash, end of the year	**13,292**	**58,912**	**32,680**	**30,111**	**27,300**	**31,059**

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...31	↓	↓	↓	↓
32	28 October 2016	€2.66	Buy	€4.60
33	18 November 2016	€2.38	Buy	€4.60
34	14 February 2016	€2.45	Buy	€4.40
35	Today	€2.19	Buy	€4.40

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INFORMATION PURSUANT TO SECTION 34B OF THE GERMAN SECURITIES TRADING ACT [WPHG], TO REGULATION (EU) NO 596/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF APRIL 16, 2014, ON MARKET ABUSE (MARKET ABUSE REGULATION) AND TO THE GERMAN ORDINANCE ON THE ANALYSIS OF FINANCIAL INSTRUMENTS [FINANV]

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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:

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%.

SELL: An expected negative price trend of more than -15%.

RISK ASSESSMENT

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