PAION AG

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

Q1 2016 results

RATING	**BUY**
PRICE TARGET	**€4.20**
Return Potential	112.3%
Risk Rating	High

HEADLINE DATA FOR US PHASE III COLONOSCOPY TRIAL IMMINENT

In Q1/16 Paion continued to focus on the phase III trials of Remimazolam in the US with the objective of approval for procedural sedation. The publication of headline data for the US phase III colonoscopy trial is expected in mid-2016. This will be a very significant event for Paion. We expect that positive data will move Remimazolam significantly closer to FDA approval and also allow the company to raise the c. €50m in capital required to fund filing and commercialisation in the US. We maintain our Buy recommendation and price target of €4.20.

Management maintains 2016 guidance Q1/16 results showed a net profit of €-6.7m (Q1/15: €-4.7m). Revenues were insignificant due to the focus on the US phase III trials of Remimazolam. R&D, which is by some distance the largest cost element in the P&L, was €6.5m (Q1/15: €5.8m). Management has maintained 2016 guidance for a narrowing in the net loss to €24.0-€27.0m (FY2015: a loss of €28.2m). Publication of headline data from the phase III colonoscopy trial in the US is expected in mid-2016. There is no reason to expect a near-term increase in R&D following publication of these data, and so H2/16 R&D should be below the H2/15 level, thus allowing Paion to reach its guidance.

Bronchoscopy trial required to secure full-range procedural sedation label Recruitment for the second US phase III trial in bronchoscopy remains moderate. Completion of recruitment for the trial was originally scheduled for 2016 but management signalled earlier in 2016 that this could be delayed into 2017. Paion has taken several steps to accelerate recruitment. The original study design prohibited certain co-medications. This prohibition was the major hurdle to recruitment and has now been removed. Paion is also opening additional study centres and intensifying support given to these centres. During the Q1 results conference call, CEO Wolfgang Söhngen explained the need for this second phase III trial with bronchoscopy patients in the US in addition to the trial with colonoscopy patients. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2013	2014	2015	2016E	2017E	2018E
Revenue (€m)	4.23	3.46	0.07	5.09	3.52	21.58
Y-o-y growth	-84.2%	-18.3%	n.a.	n.a.	-30.9%	513.2%
EBIT (€m)	-2.81	-11.64	-34.09	-25.16	-19.78	-10.16
EBIT margin	-66.5%	-336.8%	-47599.0%	-494.0%	-562.2%	-47.1%
Net income (€m)	-2.21	-9.10	-28.21	-19.56	-18.79	-9.45
EPS (diluted) (€)	-0.09	-0.23	-0.56	-0.39	-0.25	-0.12
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-1.75	-12.07	-26.32	-26.28	-13.49	-15.41
Net gearing	-99.7%	-94.1%	-91.9%	-87.1%	-91.1%	-73.2%
Liquid assets (€m)	13.29	58.91	32.68	56.40	42.91	77.50

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 anesthetic that is currently in Phase III clinical development for procedural sedation and general anesthesia.

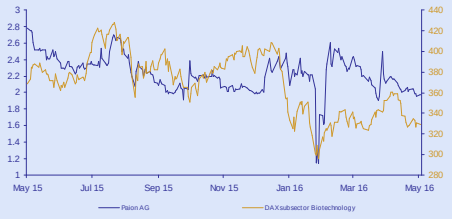
MARKET DATA

As of 17 May 2016

Closing Price	€ 1.98
Shares outstanding	50.66m
Market Capitalisation	€ 100.20m
52-week Range	€ 1.14 / 2.78
Avg. Volume (12 Months)	195,652

Multiples	2015	2016E	2017E
P/E	n.a.	n.a.	n.a.
EV/Sales	1043.7	14.7	21.2
EV/EBIT	n.a.	n.a.	n.a.
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 31 Mar 2016

Liquid Assets	€ 25.46m
Current Assets	€ 33.40m
Intangible Assets	€ 3.05m
Total Assets	€ 36.67m
Current Liabilities	€ 8.10m
Shareholders' Equity	€ 28.53m

SHAREHOLDERS

TIAA-CREF	3.0%
Free Float	97.0%

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This relates to the FDA's assumption that a label restricted to gastrointestinal indications (such as colonoscopy) would not be adhered to. Most colonoscopy patients are healthy whereas bronchoscopy patients typically suffer from lung cancer, tubercolosis or pneumonia. A successful bronchoscopy trial would demonstrate that Remimazolam can safely be used in procedural sedation with ill patients across a range of indications, also including dentistry, and not just with gastrointestinal patients.

Figure 1: Q1/16 results vs. our forecasts

in EURm	Q1/16A	Q1/16E	Delta	Q1/15A	Delta
Sales*	0.00	0.00	-	0.03	-100.0%
Pretax	-5.40	-5.50	-	-3.43	-
margin	*neg.*	*neg.*	-	*neg.*	-
Net income	-6.73	-7.00	-	-4.70	-
margin	*neg.*	*neg.*	-	*neg.*	-
EPS (dil., in EUR)	-0.13	-0.14	-	-0.09	-

* including other operating income such as milestone payments

Source: First Berlin Equity Research; Paion AG

Discontinuation of European phase III trial announced in February 2016 In early February 2016, Paion stated it had discontinued the European phase III trial with cardiac surgery patients due to difficulties in recruitment. Paion had planned the trial to include 530 patients at several European study centres. In Spring 2014 Paion reported the results of a successful phase II trial with 90 cardiac surgery patients at the Heart Centre in Leipzig. It appears that the higher number of participating study centres and patients as well as a more complex design made the phase III trial more difficult to execute than the phase II trial. We anticipate that near term positive newsflow will allow Paion to raise capital to fund a new phase III trial in the EU, this time with general anaesthesia patients.

Extension of Remimazolam's US patent life from 2027 to 2031 Also in February, Paion announced that an important further substance patent for Remimazolam had been granted in the USA. The patent relates to crystalline forms of the besylate salt of Remimazolam. The patent will extend the exclusivity claimed by Remimazolam in the US from 2027 to 2031.

Paion in talks with license partners in Japan Paion's former Japanese partner, Ono, terminated its Remimazolam license in November 2014. 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 fulfill Japanese filing requirements. The implication of this ruling is that Paion will 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. In mid-February 2016 Paion reported a positive pre-NDA meeting on Remimazolam with the Japanese PMDA. The PMDA stated that it regards Paion's non-clinical and clinical data package on Remimazolam as complete for filing. Paion's strategy continues to be to find license or distribution partners for all territories outside the US and EU. Management is currently holding talks with several parties regarding a Remimazolam license for Japan.

Additional €50m required from completion of US phase III trials to commercialisation With cash and cash equivalents of €25.5m at the end of Q1/16, management estimates that Paion's cash reach extends until the end of Q1/17. Management has pointed out that, in addition to the current cash position, funds of approximately €10m will be required until filing in the US and a further €10m until market approval.

Over and above this, the option of own commercialisation of Remimazolam in the US would require an additional €30m for the establishment of a commercial infrastructure including a distribution network and the production of market material. Management states that this spending would allow immediate market entry after approval.

We maintain our Buy recommendation and price target of €4.20 We are leaving our forecasts unchanged following the Q1 results. Our medium term forecasts continue to be based on the assumption of first revenues in Japan in general anaesthesia in 2018, first revenues in the US in procedural sedation in 2019, and first revenues in the EU in general anaesthesia in 2020. The publication of headline data for the US phase III colonoscopy trial is expected in mid-2016. This will be a very significant event for Paion. We expect that positive data will move Remimazolam significantly closer to FDA approval and also allow the company to raise the c. €50m in capital required to fund filing and commercialisation in the US. We maintain our Buy recommendation and price target of €4.20.

Figure 2: 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	€127.1M	15,950K	€20	€319.0M	50%	€185.2M	30%	15%	14	3 Years
Remimazolam	PS CAN	€3.4M	1,056K	€20	€21.1M	50%	€11.8M	15%	15%	9	5 Years
Remimazolam	GA EU	€195.9M	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	30%	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%	15%	8	4 Years
Remimazolam	GA CIS/MENA/TUR	€56.4M	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	15%	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		€716.8M									
Costs PV (4)		€492.7M									
NPV		€224.1M									
Milestones PV		€11.3M									
Pro forma net cash		€88.5M									
Fair Value		€324.0M									
Share Count		77,885K									
Price Target		€4.16									

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

INCOME STATEMENT

All figures in EUR '000	2013	2014	2015	2016E	2017E	2018E
Net revenues	**0**	**4**	**0**	**0**	**0**	**13,261**
Other op. inc. (including milestones)	**4,228**	**3,452**	**72**	**5,093**	**3,519**	**8,315**
Total revenue	**4,228**	**3,456**	**72**	**5,093**	**3,519**	**21,576**
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**	**5,093**	**3,519**	**9,641**
G&A	3,314	3,702	5,729	4,750	4,800	4,800
R&D	4,583	11,799	29,385	25,500	18,500	15,000
Other operating income (expense)	860	411	965	0	0	0
Operating income (EBIT)	**-2,810**	**-11,639**	**-34,088**	**-25,157**	**-19,781**	**-10,159**
Net financial result	-170	66	42	843	993	704
Pre-tax income (EBT)	**-2,980**	**-11,573**	**-34,046**	**-24,314**	**-18,788**	**-9,455**
Income taxes	768	2,468	5,834	4,750	0	0
Net income / loss	**-2,212**	**-9,105**	**-28,212**	**-19,564**	**-18,788**	**-9,455**
Diluted EPS	**-0.09**	**-0.23**	**-0.56**	**-0.39**	**-0.25**	**-0.12**
EBITDA	**-2,505**	**-11,327**	**-33,742**	**-24,857**	**-19,486**	**-9,814**
Ratios						
EBIT margin on PACME	-66.5%	-337.2%	-25767.8%	-494.0%	-562.2%	-105.4%
EBITDA margin on PACME	-59.3%	-328.2%	-25506.6%	-488.1%	-553.8%	-101.8%
Net margin on PACME	-52.3%	-263.8%	-21326.3%	-384.2%	-534.0%	-98.1%
Cash Coverage of Expenses						
Cash / G&A	4.0x	15.9x	5.7x	11.9x	8.9x	16.1x
Cash / R&D	2.9x	5.0x	1.1x	2.2x	2.3x	5.2x
Y-Y Growth						
Total revenue	-84.2%	-18.3%	-97.9%	7011.1%	-30.9%	513.2%
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	2016E	2017E	2018E
Assets						
Current assets, total	**14,433**	**63,032**	**40,051**	**68,726**	**46,289**	**92,816**
Cash and cash equivalents	13,292	58,912	32,680	56,398	42,911	77,497
Short-Term Investments	0	0	0	0	0	0
Receivables	0	467	0	509	563	3,452
Inventories	0	0	0	8,000	2,463	9,709
Other current assets	1,141	3,653	7,371	3,819	352	2,158
Non-current assets, total	**3,583**	**3,516**	**3,417**	**3,514**	**3,432**	**4,009**
Property, plant & equipment	89	76	56	153	70	647
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**	**72,241**	**49,721**	**96,825**
Shareholders' equity & debt						
Current Liabilities, Total	**4,659**	**3,924**	**7,901**	**7,009**	**2,287**	**7,120**
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	5,000	1,407	3,452
Provisions	2,508	306	224	1,500	352	432
Other current liabilities	236	280	344	509	528	3,236
Longterm liabilities, total	**28**	**17**	**6**	**509**	**352**	**52,158**
Convertible bond	0	0	0	0	0	50,000
Long-term debt	0	0	0	0	0	0
Provisions	0	0	0	0	0	0
Deferred revenue	28	17	6	509	352	2,158
Shareholders' equity	**13,329**	**62,607**	**35,562**	**64,722**	**47,082**	**37,547**
Total consolidated equity and debt	**18,016**	**66,548**	**43,468**	**72,241**	**49,721**	**96,825**
Ratios						
Current ratio (x)	3.10	16.06	5.07	9.81	20.24	13.04
Quick ratio (x)	3.10	16.06	5.07	8.66	19.16	11.67
Net gearing	-99.7%	-94.1%	-91.9%	-87.1%	-91.1%	-73.2%
Book value per share (€)	0.53	1.24	0.70	0.86	0.62	0.50
Net cash	13,292	58,912	32,680	56,398	42,911	27,497
Return on equity (ROE)	-15.3%	-24.0%	-57.5%	-39.0%	-33.6%	-22.3%

CASH FLOW STATEMENT

All figures in EUR '000	2013	2014	2015	2016E	2017E	2018E
Net result	**-2,212**	**-9,105**	**-28,212**	**-19,564**	**-18,788**	**-9,455**
Depreciation and amortization	390	93	125	300	296	345
Changes in working capital	457	284	3,999	-6,621	5,219	-5,382
Other adjustments	-381	-3,316	-2,198	0	0	0
Operating cash flow	**-1,746**	**-12,044**	**-26,287**	**-25,885**	**-13,273**	**-14,492**
CAPEX	-5	-26	-33	-398	-213	-922
Free cash flow	**-1,751**	**-12,070**	**-26,320**	**-26,282**	**-13,487**	**-15,414**
Debt financing, net	**-7,000**	**0**	**0**	**0**	**0**	**0**
Convertible bond financing, net	**0**	**0**	**0**	**0**	**0**	**50,000**
Equity financing, net	**0**	**57,618**	**22**	**50,000**	**0**	**0**
Other changes in cash	**-293**	**72**	**66**	**0**	**0**	**0**
Net cash flows	**-9,044**	**45,620**	**-26,232**	**23,718**	**-13,487**	**34,586**
Cash, start of the year	22,336	13,292	58,912	32,680	56,398	42,911
Cash, end of the year	**13,292**	**58,912**	**32,680**	**56,398**	**42,911**	**77,497**

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...27	↓	↓	↓	↓
28	20 November 2015	€2.02	Buy	€4.10
29	9 March 2016	€2.32	Buy	€4.60
30	31 March 2016	€2.18	Buy	€4.20
31	Today	€1.98	Buy	€4.20

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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:

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%.

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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.

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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**

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