PAION AG

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

Q2 results

RATING	**BUY**
PRICE TARGET	**€4.60**
Return Potential	114.3%
Risk Rating	High

US REMIMAZOLAM DEVELOPMENT FULLY FINANCED UNTIL FILING

Q2 numbers were close to our forecasts. Management raised guidance for 2016 net profit from a range of €-24.5m to €-27.5m to a range of €-21.5m to €-24.0m to reflect the booking later this year of €4m of the €10m upfront payment received from US commercialisation partner, Cosmo Pharmaceuticals, in July. Under the terms of the licensing deal announced on 24 June, Cosmo Pharmaceuticals will make payments of up to €62.5m (milestones of €52.5m, of which €10m are upfront, and an equity raise of €10m) to Paion. These payments should more than suffice to complete phase III development including preparation of filing of remimazolam in the US. However, Paion is currently evaluating the resumption of clinical development of remimazolam in the EU and management has pointed out that additional funding would be required for this. Against this background we have inserted a €15m equity raise into our valuation model in 2017. We maintain our Buy recommendation but lower the price target to €4.60 (previously: €4.70) to reflect dilution caused by the capital raise.

US phase III studies continued during Q2/16 Paion's Q2 results showed a pretax result of €-7.7m (Q2/15: €-7.9m) and were close to our expectations (see figure 1 overleaf). The €200k in revenues booked in Q2/16 stems from the license agreement for the US concluded with Cosmo Pharmaceuticals (Cosmo) at the end of June. The largest constituents of R&D costs of €5.7m (Q2/15: €6.2m) were the continuing US phase III trials of remimazolam with colonoscopy and bronchoscopy patients in the indication procedural sedation.

91.3% of patients met phase III study endpoint On 19 June, Paion published headline data from its U.S. phase III study with remimazolam in procedural sedation of colonoscopy patients. The study enrolled 461 patients at 13 sites and was designed to evaluate efficacy and safety of remimazolam compared to placebo with rescue by midazolam. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2013	2014	2015	2016E	2017E	2018E
Revenue (€m)	4.23	3.46	0.07	4.00	21.00	40.76
Y-o-y growth	-84.2%	-18.3%	n.a.	n.a.	425.0%	94.1%
EBIT (€m)	-2.81	-11.64	-34.09	-27.00	1.20	9.03
EBIT margin	-66.5%	-336.8%	-47599.0%	-675.0%	5.7%	22.1%
Net income (€m)	-2.21	-9.10	-28.21	-22.14	3.34	11.65
EPS (diluted) (€)	-0.09	-0.23	-0.56	-0.42	0.05	0.19
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-1.75	-12.07	-26.32	-21.99	3.25	11.24
Net gearing	-99.7%	-94.1%	-91.9%	-88.2%	-93.4%	-94.2%
Liquid assets (€m)	13.29	58.91	32.68	20.29	38.93	50.18

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

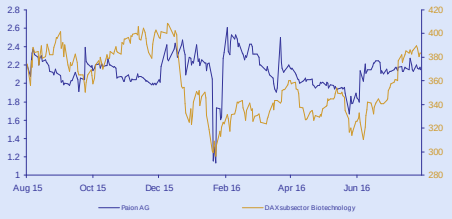
PAION is a specialty pharmaceutical company headquartered in Aachen (Germany) with operations in Cambridge (United Kingdom) and New Jersey (USA). PAION's lead substance, Remimazolam, is an intravenous ultra-short-acting benzodiazepine anesthetic that is currently in Phase III clinical development for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

MARKET DATA

As of 19 Aug 2016	
Closing Price	€ 2.15
Shares outstanding	55.74m
Market Capitalisation	€ 119.67m
52-week Range	€ 1.14 / 2.61
Avg. Volume (12 Months)	178,893

Multiples	2015	2016E	2017E
P/E	n.a.	n.a.	40.5
EV/Sales	1225.0	21.9	4.2
EV/EBIT	n.a.	n.a.	73.1
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 30 Jun 2016	
Liquid Assets	€ 32.10m
Current Assets	€ 35.52m
Intangible Assets	€ 2.84m
Total Assets	€ 38.55m
Current Liabilities	€ 7.51m
Shareholders' Equity	€ 31.36m

SHAREHOLDERS

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

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The study also included a non-comparative open label arm in which midazolam (likely to be the main competing product to remimazolam) was dosed according to its US label. 91.3% of patients met the study's primary endpoint which was success of the procedure.

Phase III results suggest >6 minute time saving versus midazolam Secondary study endpoints included time to start of procedure after administration of the first dose of medication and time to full alertness after the end of the procedure. These time-related secondary endpoints are very important. During commercialisation, the extent to which remimazolam facilitates shorter procedure times will be crucial in persuading physicians to switch from the long-established drugs used in procedural sedation such as midazolam and propofol. The results suggest the time saving through using remimazolam instead of its prospective main competing product, midazolam, is likely to exceed six minutes. This is a substantial time saving on a typical colonoscopy procedure time of 30-60 minutes. The US colonoscopy market is currently seeing trends towards lower reimbursement per procedure and "bundling" or a contracted flat fee for the total cost of each colonoscopy. In this environment, physicians are looking for ways to maintain their income. Remimazolam, which has the advantage over midazolam of shorter onset/offset times, and over its other main prospective competing product, propofol, of not requiring an anaesthetist, is a clear potential answer to this problem.

Figure 1: Q2/16 results vs. our forecasts

in EURm	Q2/16A	Q2/16E	Delta	Q2/15A	Delta
Sales*	0.20	0.00	-	0.01	1900.0%
Pretax	-7.67	-5.90	-	-7.90	-
margin	*neg.*	*neg.*	-	*neg.*	-
Net income	-6.47	-7.00	-	-6.64	-
margin	*neg.*	*neg.*	-	*neg.*	-
EPS (dil., in EUR)	-0.13	-0.14	-	-0.13	-

* including other operating income such as milestone payments

Source: First Berlin Equity Research; Paion AG

US license agreement concluded with Cosmo Pharmaceuticals The phase III headline results paved the way for a US license agreement for remimazolam with the Irish-headquartered company, Cosmo Pharmaceuticals N.V. which was announced on 24 June. Paion received €9.6m from a private placement to Cosmo at the end of June and a €10m upfront payment in July. €4m of the upfront payment will be booked as revenue in 2016 and management expects the remainder to be booked in 2017. Paion will also receive up to €42.5m in payments contingent on milestones related to the U.S. regulatory approval process. Following regulatory approval and once commercialisation gets underway, Paion will receive tiered royalties on net sales in the U.S, ranging from 20% to 25%, which may be adjusted under certain conditions, but not to below 15% of net sales.

Completion of bronchoscopy recruitment now expected for Q2/17 Recruitment for the second US phase III trial in bronchoscopy remains moderate. Completion of recruitment for the trial was originally scheduled for 2016. However, management signalled earlier in 2016 that this could be delayed into 2017 and stated in the Q2 report that completion of recruitment is now expected for Q2 2017. Paion has taken several steps to accelerate recruitment. The original study design prohibited certain co-medications. This prohibition was a major hurdle to recruitment and has now been removed. Paion is also opening additional study centres and members of management have visited some of the study centres to offer additional support.

We model a €15m capital raise in 2017 to cover EU remimazolam development costs With Cosmo now in charge of the US filing process, management is unwilling to comment on the likely timing of US filing. We continue to assume late 2017 for filing and late 2018 for approval. Paion had cash and cash equivalents of €32.1m as of end June 2016 and received the €10m upfront payment from Cosmo in July. Management believes that this money will more than suffice to complete phase III development including preparation of filing of remimazolam in the US. However, Paion is currently evaluating the resumption of clinical development of remimazolam in the EU and management has pointed out that additional funding would be required for this. Against this background we have inserted a €15m equity raise into our valuation model in 2017.

Figure 2: Changes to our forecasts

	2016E			2017E			2018E		
in EURm	**Old**	**New**	**Δ**	**Old**	**New**	**Δ**	**Old**	**New**	**Δ**
Sales*	10.00	4.00	-60.0%	15.00	21.00	40.0%	40.76	40.76	0.0%
EBIT	-20.25	-27.00	-	-4.80	1.20	-	9.03	9.03	0.0%
margin	*neg.*	*neg.*	-	*neg.*	*neg.*	-	*neg.*	*22.1%*	-
Net income	-14.95	-22.14	-	-4.29	3.34	-	9.59	11.65	21.5%
margin	*neg.*	*neg.*	-	*neg.*	*neg.*	-	*neg.*	*28.6%*	-
EPS (dil., in EUR)	-0.28	-0.42	-	-0.08	0.05	-	0.17	0.19	8.9%

* including other operating income such as milestone payments

Source: First Berlin Equity Research

We maintain our Buy rating but lower price target to €4.60 (previously €4.70) Figure 2 shows changes to our forecasts to 2018. In our note of 22 July, we assumed that all the €10m upfront payment from Cosmo would be booked as other operating income in 2016. In the Q2 report, management indicated that €6m of the €10m will not be booked until 2017. We have accordingly transferred €6m in sales from 2016 to 2017. Changes to net income in 2017 and 2018 are also influenced by our assumption that Paion will continue to book R&D spending-related tax credits during the next two years. Our 2018 EPS forecast rises by only 8.9%, despite a 21.5% increase in net income, due to our assumption of a €15m equity capital raise through the issue of an additional 7.0m shares at the current share price in 2017. Our NPV estimate (see figure 3 below) climbs by 8% because of reductions in our medium and long term R&D costs estimates. But our fair value per share estimate falls to €4.61 due to dilution caused by the €15m capital raise which we now model for 2017. We maintain our Buy recommendation but lower the price target to €4.60 (previously: €4.70).

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	22%	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	€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	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	€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	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		€648.4M									
Costs PV (4)		€451.0M									
NPV		€197.3M									
Milestones PV		€47.0M									
Pro forma net cash		€45.8M									
Fair Value		€290.0M									
Share Count		62,880K									
Price Target		€4.61									

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 our pipeline valuation model

	Old	New	Delta
PACME PV	**€648.4M**	**€648.4M**	**0.0%**
Costs PV	€465.7M	€451.0M	-3.1%
NPV	**€182.7M**	**€197.3M**	**8.0%**
Milestones PV	€47.0M	€47.0M	-0.1%
Pro Forma Net Cash	€35.4M	€45.8M	29.3%
Fair Value	€265.1M	€290.0M	9.4%
Diluted Share Count	55,878K	62,880K	12.5%
Fair Value Per Share	**€4.74**	**€4.61**	**-2.8%**

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**	**4,000**	**21,000**	**27,500**
Total revenue	**4,228**	**3,456**	**72**	**4,000**	**21,000**	**40,761**
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**	**4,000**	**21,000**	**28,826**
G&A	3,314	3,702	5,729	5,500	4,800	4,800
R&D	4,583	11,799	29,385	25,500	15,000	15,000
Other operating income (expense)	860	411	965	0	0	0
Operating income (EBIT)	**-2,810**	**-11,639**	**-34,088**	**-27,000**	**1,200**	**9,026**
Net financial result	-170	66	42	612	143	222
Pre-tax income (EBT)	**-2,980**	**-11,573**	**-34,046**	**-26,388**	**1,343**	**9,248**
Income taxes	768	2,468	5,834	4,250	1,997	2,400
Net income / loss	**-2,212**	**-9,105**	**-28,212**	**-22,138**	**3,340**	**11,648**
Diluted EPS	**-0.09**	**-0.23**	**-0.56**	**-0.42**	**0.05**	**0.19**
EBITDA	**-2,505**	**-11,327**	**-33,742**	**-26,764**	**2,964**	**9,678**
Ratios						
EBIT margin on PACME	-66.5%	-337%	-25768%	-675.0%	5.7%	31.3%
EBITDA margin on PACME	-59.3%	-328%	-25507%	-669.1%	14.1%	33.6%
Net margin on PACME	-52.3%	-264%	-21326%	-553.5%	15.9%	40.4%
Cash Coverage of Expenses						
Cash / G&A	4.0x	15.9x	5.7x	3.7x	8.1x	10.5x
Cash / R&D	2.9x	5.0x	1.1x	0.8x	2.6x	3.3x
Y-Y Growth						
Total revenue	-84.2%	-18.3%	-97.9%	5485.4%	425.0%	94.1%
Operating income	n.m.	n.m.	n.m.	n.m.	n.m.	652.2%
Net income/ loss	n.m.	n.m.	n.m.	n.m.	n.m.	248.7%

BALANCE SHEET

All figures in EUR '000	2013	2014	2015	2016E	2017E	2018E
Assets						
Current assets, total	**14,433**	**63,032**	**40,051**	**26,663**	**42,683**	**54,140**
Cash and cash equivalents	13,292	58,912	32,680	20,288	38,933	50,177
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	6,375	3,750	3,750
Non-current assets, total	**3,583**	**3,516**	**3,417**	**3,402**	**3,572**	**3,769**
Property, plant & equipment	89	76	56	40	210	408
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**	**30,064**	**46,255**	**57,909**
Shareholders' equity & debt						
Current Liabilities, Total	**4,659**	**3,924**	**7,901**	**7,064**	**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	6,375	3,750	3,750
Provisions	2,508	306	224	255	300	398
Other current liabilities	236	280	344	434	510	510
Longterm liabilities, total	**28**	**17**	**6**	**8**	**6**	**12**
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	8	6	12
Shareholders' equity	**13,329**	**62,607**	**35,562**	**22,993**	**41,688**	**53,239**
Total consolidated equity and debt	**18,016**	**66,548**	**43,468**	**30,064**	**46,255**	**57,909**
Ratios						
Current ratio (x)	3.10	16.06	5.07	3.77	9.36	11.62
Quick ratio (x)	3.10	16.06	5.07	3.77	9.36	11.62
Net gearing	-99.7%	-94.1%	-91.9%	-88.2%	-93.4%	-94.2%
Book value per share (€)	0.53	1.24	0.70	0.41	0.66	0.85
Net cash	13,292	58,912	32,680	20,288	38,933	50,177
Return on equity (ROE)	-15.3%	-24.0%	-57.5%	-75.6%	10.3%	24.5%

CASH FLOW STATEMENT

All figures in EUR '000	2013	2014	2015	2016E	2017E	2018E
Net result	**-2,212**	**-9,105**	**-28,212**	**-22,138**	**3,340**	**11,648**
Depreciation and amortization	390	93	125	236	1,764	652
Changes in working capital	457	284	3,999	130	75	-206
Other adjustments	-381	-3,316	-2,198	0	0	0
Operating cash flow	**-1,746**	**-12,044**	**-26,287**	**-21,772**	**5,179**	**12,094**
CAPEX	-5	-26	-33	-220	-1,934	-850
Free cash flow	**-1,751**	**-12,070**	**-26,320**	**-21,992**	**3,245**	**11,244**
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**	**-12,392**	**18,645**	**11,244**
Cash, start of the year	22,336	13,292	58,912	32,680	20,288	38,933
Cash, end of the year	**13,292**	**58,912**	**32,680**	**20,288**	**38,933**	**50,177**

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...28	↓	↓	↓	↓
29	31 March 2016	€2.18	Buy	€4.20
30	18 May 2016	€1.98	Buy	€4.20
31	5 July 2016	€2.15	Buy	€4.70
32	Today	€2.15	Buy	€4.60

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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%.

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