PAION AG

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

Q3/2016 results

RATING	**BUY**
PRICE TARGET	**€4.60**
Return Potential	93.7%
Risk Rating	High

EXCELLENT PHASE III RESULTS, COSMO DEAL DERISK THE COMPANY

Q3/16 results were close to our expectations. Management's full year guidance of a net loss of €-21.5m to €-24.0m is unchanged. The loss is driven primarily by costs of the phase III trials of remimazolam in the indication procedural sedation in the U.S. Excellent results from the phase III trial of remimazolam with colonoscopy patients paved the way for a U.S. licensing deal with Cosmo Pharmaceuticals and have largely derisked the company. €19.6m already received from Cosmo Pharmaceuticals have supported the company's liquidity position which stood at €35.9m at end September. Paion stands to receive milestones of up to a further €42.9m ahead of U.S. commercialisation and will not require additional funds to bring remimazolam to the market in the U.S. Next steps are likely to be the resumption of clinical development in the EU and a decision on whether to partner in Japan before or after filing for approval. We maintain our Buy recommendation and price target of €4.60.

Lower R&D costs in Q3/16 due to discontinuation of EU phase III study Q3/16 sales of €2.0m (Q3/15: €0.0m) stemmed from the first part of a total €10.0m upfront license fee due from US commercialisation partner, Cosmo Pharmaceuticals, under the terms of the agreement concluded in June. Paion's Q3/16 net loss was €2.9m (Q3/15: a net loss of €9.1m). As figure 1 shows, the narrowing of the net loss was driven by declines in both selling, general and administrative costs and R&D expenses. S,G&A costs in Q3/15 covered market research, pre-marketing and market access activities whereas in Q3/16 this item was restricted mainly to the preparation of license agreements. Q3/16 R&D expenses were below the prior year quarter level mainly because of the discontinuation of the EU phase III study of remimazolam with patients undergoing major cardiac surgery.

Time saving of over 15 minutes on colonoscopy procedure Paion published comprehensive peer-reviewed results of its phase III trial of remimazolam in procedural sedation of colonoscopy patients in October. (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	0.40	8.13
EBIT margin	-66.5%	-336.8%	-47599.0%	-675.0%	1.9%	19.9%
Net income (€m)	-2.21	-9.10	-28.21	-22.14	2.78	10.74
EPS (diluted) (€)	-0.09	-0.23	-0.56	-0.42	0.04	0.17
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-1.75	-12.07	-26.32	-21.99	2.68	10.34
Net gearing	-99.7%	-94.1%	-91.9%	-88.2%	-93.3%	-94.1%
Liquid assets (€m)	13.29	58.91	32.68	20.29	38.37	48.71

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 17 Nov 2016	
Closing Price	€ 2.38
Shares outstanding	55.74m
Market Capitalisation	€ 132.37m
52-week Range	€ 1.14 / 3.06
Avg. Volume (12 Months)	208,080

Multiples	2015	2016E	2017E
P/E	n.a.	n.a.	53.8
EV/Sales	1347.0	24.1	4.6
EV/EBIT	n.a.	n.a.	241.2
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW

COMPANY DATA

As of 30 Sep 2016	
Liquid Assets	€ 35.91m
Current Assets	€ 39.47m
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%

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The results suggest a time saving on a typical 30-60 minute colonoscopy procedure of over 15 minutes. Headline figures from this study released in June paved the way for a US license agreement for remimazolam with the Irish-headquartered company, Cosmo Pharmaceuticals N.V. (Cosmo). Under the terms of the licensing deal Cosmo agreed to make payments of up to €62.5m (milestones of €52.5m, of which €10m are upfront, and an equity raise of €10m) to Paion ahead of remimazolam's US commercialisation. Paion received the €10m upfront payment in July. As described above, €2m of this was booked as revenue in Q2/16. A further €2m will be recorded as revenue in the current quarter and the balance of €6m in 2017. Paion received €9.6m of the equity raise in June. The remaining €0.4m will be paid at a later date.

Figure 1: Q3/16 results vs. our forecasts

in EURm	Q3/16A	Q3/16E	Delta	Q3/15A	Delta	9M/16A	9M/15A	Delta
Sales*	2.03	2.00	1.5%	0.01	40500.0%	2.23	0.00	-
R&D expenses	-4.28	-4.50	-	-8.93	-	-16.43	-20.91	-
S,G&A expenses	-0.94	-1.00	-	-1.81	-	-4.19	-4.54	
Net income	-2.86	-3.00	-	-9.05	-	-16.06	-20.39	-
margin	*neg.*	*neg.*	-	*neg.*	-	*neg.*	*neg.*	
EPS (dil., in EUR)	-0.05	-0.05	-	-0.18	-	-0.31	-0.40	-

* including other operating income such as milestone payments

Source: First Berlin Equity Research; Paion AG

Completion of bronchoscopy phase III recruitment expected in Q2/17 Paion is carrying out a second US phase III trial with bronchoscopy patients. Most colonoscopy patients are healthy whereas bronchoscopy patients typically suffer from lung cancer, tubercolosis or pneumonia. A successful bronchoscopy trial will 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. Recruitment for the bronchoscopy trial was originally moderate. However, steps to accelerate recruitment such as opening additional study centres and intensifying support given to these centres have proven effective and more than half of the target number of 420 patients have now been recruited. Management has confirmed that completion of patient recruitment is expected for Q2/17.

Management evaluating how to resume clinical development in the EU Paion is currently evaluating how to resume clinical development in the EU. During the conference call following the release of the Q3/16 results, management indicated that it will give a clear statement on this in the first quarter of next year.

Partnering discussions in Japan In February 2016 Paion reported a positive pre-NDA meeting on Remimazolam with the Japanese Pharmaceuticals and Medical Devices Agency (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 partnering discussions and is evaluating whether to partner before or after filing for approval.

We maintain our Buy recommendation and €4.60 price target Full year guidance is unchanged on the Q2/16 report published in August and is for a net result of €-21.5m to €-24.0m. We are leaving our forecasts unchanged and maintain our Buy recommendation and price target of €4.60.

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	€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)		€450.8M									
NPV		€197.6M									
Milestones PV		€47.0M									
Pro forma net cash		€50.0M									
Fair Value		€294.6M									
Share Count		63,422K									
Price Target		€4.64									

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**	**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	5,600	5,700
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**	**400**	**8,126**
Net financial result	-170	66	42	612	141	217
Pre-tax income (EBT)	**-2,980**	**-11,573**	**-34,046**	**-26,388**	**541**	**8,343**
Income taxes	768	2,468	5,834	4,250	2,238	2,400
Net income / loss	**-2,212**	**-9,105**	**-28,212**	**-22,138**	**2,779**	**10,743**
Diluted EPS	**-0.09**	**-0.23**	**-0.56**	**-0.42**	**0.04**	**0.17**
EBITDA	**-2,505**	**-11,327**	**-33,742**	**-26,764**	**2,164**	**8,778**
Ratios						
EBIT margin on PACME	n.m.	n.m.	n.m.	n.m.	1.9%	28.2%
EBITDA margin on PACME	n.m.	n.m.	n.m.	n.m.	10.3%	30.5%
Net margin on PACME	n.m.	n.m.	n.m.	n.m.	13.2%	37.3%
Cash Coverage of Expenses						
Cash / G&A	4.0x	15.9x	5.7x	3.7x	6.9x	8.5x
Cash / R&D	2.9x	5.0x	1.1x	0.8x	2.6x	3.2x
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.	1931.5%
Net income/ loss	n.m.	n.m.	n.m.	n.m.	n.m.	286.6%

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**	**42,122**	**52,673**
Cash and cash equivalents	13,292	58,912	32,680	20,288	38,372	48,710
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**	**45,693**	**56,442**
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**	**41,127**	**51,772**
Total consolidated equity and debt	**18,016**	**66,548**	**43,468**	**30,064**	**45,693**	**56,442**
Ratios						
Current ratio (x)	3.10	16.06	5.07	3.77	9.24	11.31
Quick ratio (x)	3.10	16.06	5.07	3.77	9.24	11.31
Net gearing	-99.7%	-94.1%	-91.9%	-88.2%	-93.3%	-94.1%
Book value per share (€)	0.53	1.24	0.70	0.41	0.65	0.82
Net cash	13,292	58,912	32,680	20,288	38,372	48,710
Return on equity (ROE)	-15.3%	-24.0%	-57.5%	-75.6%	8.7%	23.1%

CASH FLOW STATEMENT

All figures in EUR '000	2013	2014	2015	2016E	2017E	2018E
Net result	**-2,212**	**-9,105**	**-28,212**	**-22,138**	**2,779**	**10,743**
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**	**4,618**	**11,189**
CAPEX	-5	-26	-33	-220	-1,934	-850
Free cash flow	**-1,751**	**-12,070**	**-26,320**	**-21,992**	**2,684**	**10,339**
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**	**18,084**	**10,339**
Cash, start of the year	22,336	13,292	58,912	32,680	20,288	38,372
Cash, end of the year	**13,292**	**58,912**	**32,680**	**20,288**	**38,372**	**48,710**

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...29	↓	↓	↓	↓
30	5 July 2016	€2.15	Buy	€4.70
31	22 August 2016	€2.15	Buy	€4.60
32	28 October 2016	€2.66	Buy	€4.60
33	Today	€2.38	Buy	€4.60

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

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- **key sources of information in the preparation of this research report**
- **valuation methods and principles**
- **sensitivity of valuation parameters**

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