PAION AG

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

Comprehensive phase III US colonoscopy trial results

RATING	**BUY**
PRICE TARGET	**€4.60**
Return Potential	73.1%
Risk Rating	High

SPECTACULAR CONFIRMATION OF HEADLINE DATA

Paion has published comprehensive peer-reviewed results of its phase III trial of remimazolam in procedural sedation of colonoscopy patients in the USA. The results spectacularly confirm the conclusion we drew in June following the headline results - that remimazolam will produce substantial time savings for physicians in comparison with its prospective main competing product, midazolam. While the headline phase III results in combination with the phase IIb results published in 2010 suggested a time saving on a typical 30-60 minute colonoscopy procedure of over six minutes, the comprehensive phase III results show a total combined onset/offset time saving versus midazolam of over 23 minutes! The US colonoscopy market is currently seeing trends towards lower reimbursement per procedure. 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 rival product, propofol, of not requiring an anaesthetist, is a clear potential answer to this problem. In June Paion signed a U.S. licensing deal with Cosmo Pharmaceuticals on the strength of the headline phase III data. We continue to expect late 2017 for filing and late 2018 for approval of remimazolam in the U.S. We maintain our Buy recommendation and price target of €4.60.

Final data show results of midazolam arm 461 patients at 13 U.S. sites participated in the phase III colonoscopy trial. The primary outcome measure was a composite endpoint defined as: no need for rescue medication, completion of the procedure and no more than 5 top-up doses within any 15-minute window. As figure 1 overleaf shows, the primary endpoint was reached in 91.3% of the patients in the remimazolam arm, 1.7% in the placebo arm and 25.2% in the midazolam (open label arm). Important secondary endpoints were median time from start of medication to start of procedure and mean time from end of procedure to return to full alertness. The headline data released in June did not contain data from the midazolam arm of the trial. (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

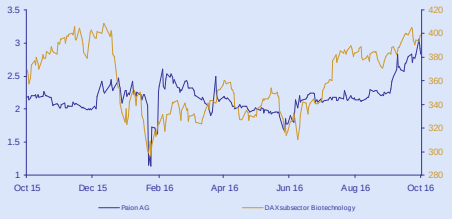
PAION is a specialty pharmaceutical company headquartered in Aachen (Germany) with operations in Cambridge (United Kingdom) and New Jersey (USA). PAION's lead substance, Remimazolam, is an intravenous ultra-short-acting benzodiazepine anesthetic that is currently in Phase III clinical development for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

MARKET DATA

As of 21 Oct 2016	
Closing Price	€ 2.66
Shares outstanding	55.74m
Market Capitalisation	€ 148.09m
52-week Range	€ 1.14 / 3.06
Avg. Volume (12 Months)	200,888

Multiples	2015	2016E	2017E
P/E	n.a.	n.a.	60.1
EV/Sales	1619.6	29.0	5.5
EV/EBIT	n.a.	n.a.	290.0
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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So we based our conclusion that the time saving using remimazolam instead of midazolam exceeds six minutes on a comparison of the remimazolam phase III data with data from the remimazolam phase IIb trial which also included a midazolam arm.

Figure 1: Overview procedural results

	Remimazolam (phase III)	Placebo (phase III)	Midazolam (phase III)	Midazolam (phase IIb)
Procedural success	91.3%	1.7%	25.2%	75.0%
Use of rescue sedation	3.4%	95.0%	64.7%	25.0%
Average fentanyl dose	88.9 mcg	121.3 mcg	106.9 mcg	119.0 mcg
Start of medication to start of procedure (median)	4.0 minutes	19.5 minutes	19.0 minutes	6.4 minutes*
End of procedure to fully alert (mean)	7.2 minutes	21.3 minutes	15.7 minutes	15.2 minutes
Mean time 1st dose to discharge	58 minutes	86 minutes	75 minutes	n.a.

**mean value*

Source: Paion AG

Midazolam dosed above label in practice; but we still expect over 15 min. time saving
In figure 1 above, we show final data from all three arms of the phase III trial as well as midazolam data from the phase IIb trial. The biggest deviation between phase IIb and phase III in the midazolam data is with respect to onset time (start of medication to start of procedure). Phase IIb data showed onset time of 6.4 minutes for midazolam whereas phase III showed 19.0 minutes. This difference accounts for most of the increase in time saving from over six minutes to 23 minutes mentioned above. Midazolam was dosed according to label in both the phase IIb and phase III trials. However, at the time of the phase IIb trial in 2010, the midazolam label stipulated a dose of 2.5mg. The midazolam label currently recommends a dosage of 1.5mg, and this was the quantity administered in the phase III trial. As figure 1 shows, the dose of fentanyl administed together with midazoplam was also lower at phase III than phase IIb. We believe that the increase in onset time for midazolam between phase II and III is attributable to the difference in the doses of miazolam and fentanyl administered. Offset time outcomes for midazolam in phase III (15.7 minutes) are similar to phase IIb (15.2 minutes) despite the lower dose administered in phase III. As we explained in our July note, 25% of the midazolam patients in the phase IIb study could not be successfully sedated and were given propofol as a sedative rescue. In phase III additional midazolam was used as a sedative rescue. Recovery time from sedation with propofol is substantially shorter than with midazolam and so the recovery time for midazolam patients in phase IIb was artificially short. As we wrote in our July note, in practice physicians generally dose midazolam at <5mg to <6mg. At this dose level, the recovery time with midazolam is generally substantially longer than 15.7 minutes. The onset time at <5mg to <6mg may be shorter than the final phase III date show, but the offset time is likely to be longer and so we still expect the overall time difference between procedures with remimazolam and midazolam to be over 15 minutes.

Phase III results confirm favourable safety profile The phase III results confirmed the favourable safety profile demonstrated by earlier trials. There were no treatment-emergent serious events in the trial. Hypotension occurred in 44.3% of patients given remimazolam, in 47.5% of patients on placebo and in 67.3% of patients given midazolam. Hypoxia (depressed levels of oxygen in the arterial blood) occurred in 1.0% of remimazolam patients, 3.4% of patients in the placebo arm and 1.0% of midazolam patients.

Phase III data will not be on label but will play role in pharmacoeconomic modelling
Management states in the phase III press release that the results will not be part of the label claims, but that they will serve as valuable data to plan future studies and perform pharmacoeconomic modelling. As we have pointed out above and in our July study,

pharmacoeconomic considerations (i.e. 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. In our view, the final results of the phase III trial with colonoscopy patients provide a compelling argument to make this switch. We are leaving our forecasts largely unchanged and maintain our Buy recommendation and €4.60 price target.

Figure 2: Pipeline valuation

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		€46.1M									
Fair Value		€290.4M									
Share Count		62,884K									
Price Target		€4.62									

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

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...28	↓	↓	↓	↓
29	18 May 2016	€1.98	Buy	€4.20
30	5 July 2016	€2.15	Buy	€4.70
31	22 August 2016	€2.15	Buy	€4.60
32	Today	€2.66	Buy	€4.60

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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%.

SELL: An expected negative price trend of more than -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/

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