PAION AG

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

Update

RATING	**BUY**
PRICE TARGET	**€ 4.40**
Return Potential	44.5%
Risk Rating	High

REMIMAZOLAM CLEARS ANOTHER HURDLE ON ROAD TO U.S. APPROVAL

PAION has published headline data of its U.S. phase III trial of remimazolam in procedural sedation of patients undergoing bronchoscopy. Remimazolam met the trial's primary efficacy endpoint and performed very well in important secondary endpoints including median onset and offset times. The trial also confirmed the drug's excellent safety profile. These data follow similarly positive results of the pivotal U.S. phase III trial in procedural sedation of colonoscopy patients released last year. We continue to expect approval of remimazolam in the U.S. in the key procedural sedation indication towards the end of 2018. We maintain our Buy recommendation and price target of €4.40.

FDA required trial in non-gastrointestinal and sicker patients PAION's original primary goal for remimazolam on the U.S. market was to gain approval for the product in colonoscopy. With 15m procedures performed annually, colonoscopy is the most commercially attractive segment of the U.S. procedural sedation market. 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. However, the FDA assumed that remimazolam will also be used in other areas of procedural sedation. As well as trials on typical cohorts of colonoscopy patients, the FDA also required the phase III programme to include >100 patients aged over 65, and >100 high-risk ASA III/IV patients (American Society of Anesthesiologists' classification III: patients with severe systemic disease; ASA IV: patients with severe systemic disease that is a constant threat to life). The FDA further stipulated that PAION carry out a study of remimazolam in a non-gastrointestinal indication with sicker patients than are typically encountered in colonoscopy. (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	n.a.	n.a.	n.a.	n.a.	n.a.	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 03 Jul 2017	
Closing Price	€ 3.04
Shares outstanding	58.26m
Market Capitalisation	€ 177.33m
52-week Range	€ 2.08 / 3.60
Avg. Volume (12 Months)	193,730

Multiples	2016	2017E	2018E
P/E	n.a.	n.a.	57.5
EV/Sales	34.8	25.9	4.5
EV/EBIT	n.a.	n.a.	237.0
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW

COMPANY DATA

As of 31 Mar 2017	
Liquid Assets	€ 28.73m
Current Assets	€ 35.13m
Intangible Assets	€ 2.65m
Total Assets	€ 37.58m
Current Liabilities	€ 10.21m
Shareholders' Equity	€ 27.37m

SHAREHOLDERS

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

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PAION carried out the ASA III/IV and bronchoscopy trials (500-600k bronchoscopy procedures are performed annually in the US) to fulfil these requirements.

Headline ASA III/IV readout comparable with phase III colonoscopy data The ASA III/IV trial enrolled 79 patients undergoing a colonoscopy into a remimazolam, midazolam or placebo (including midazolam 'rescue' sedation) treatment group. The primary objective was to assess the safety of remimazolam compared to placebo and midazolam, following administration of a standard dose of fentanyl. Headline data released at the end of March showed that administration of remimazolam to these patients is safe and that efficacy and efficiency gains are comparable to the phase III trial with colonoscopy patients.

Primary endpoint of phase III broncoscopy trial achieved in 82.5% of patients The phase III trial of remimazolam for procedural sedation of patients undergoing bronchoscopy enrolled 446 patients and was conducted at multiple sites throughout the U.S. It was prospective, double-blind, randomized, midazolam- and placebo-controlled. The primary outcome measure was successful completion of the bronchoscopy procedure, no requirement for a rescue sedative medication, no more than five doses of study medication within any 15-minute window for placebo and remimazolam, no more than 3 doses of study medication within any 12-minute window for midazolam. Figure 1 below summarises the headline results of the trial. As figure 1 shows, the procedure was successful in 82.5% of patients who received remimazolam, compared with 3.4% for placebo and 34.8% for midazolam.

Figure 1: Headline results of the phase III bronchoscopy trial

	Remimazolam	Placebo	Midazolam (Open Label)
Procedural Success	82.5%	3.4%	34.8%
Use of Rescue Sedation	16.2%	96.6%	56.5%
Time from First Dose to Start of Procedure (onset)	5.0 min	17.0 min	16.0 min
End of Procedure to Fully Alert (offset)	6.0 min	14.0 min	12.0 min
Total onset + offset time	11.0 min	31.0 min	28.0 min
Time to "back to normal"	404.0 min	935.0 min	478.5 min
Incidence of hypotension	41.9%	62.7%	49.3%
Incidence of hypoxia	21.8%	20.3%	18.8%

Source: Paion

17 minute time saving vs. midazolam The trial also confirmed remimazolam's superior efficiency vs. midazolam, one of its two main prospective rival products (the other rival drug is propofol). As figure 1 shows, the time saving entailed by use of remimazolam instead of midazolam (total onset + offset time) is 17 minutes. Given that a bronchoscopy procedure typically lasts 30 minutes, this is a substantial time saving. As was the case with the phase III colonoscopy trial, onset and offset data for midazolam were distorted by the difference between the trial dosage level and the dosage level administered by physicians in practice. The trial dosage of midazolam of 1.75mg initial and 1mg top-ups is based on the FDA label. However, physicians generally dose midazolam at 5mg to 6mg. At this dose level, the onset time is shorter than the headline phase III data show, but the offset time is likely to be longer. We therefore still expect the overall time difference between bronchoscopy procedures with remimazolam and midazolam to be around 17 minutes. The time saving indicated by the phase III colonoscopy trial was around 20 minutes.

The trial also confirmed remimazolam's excellent safety profile Overall adverse events, treatment-emergent adverse events and, in particular, incidents of hypotension (low blood pressure) and bradycardia (slow heartbeat) occurred less frequently with remimazolam compared to midazolam. Twenty-one patients across all treatment groups experienced a total of 26 treatment-emergent serious adverse events (SAEs). Out of these 26 SAEs, only two were considered related to treatment with remimazolam and occurred in a single patient after administration of fentanyl at twice the dose allowed by the study protocol.

Filing for approval in Japan expected by mid-2018 The February equity raise to finance filing for approval of remimazolam in Japan raised gross proceeds of €5.0m. Most of the proceeds of this share issue are being used for the necessary validation of commercial-scale production for the Japanese market and to pay an external contractor to assemble a filing dossier for Japan. Filing in Japan is expected by mid-2018 at the latest. PAION has been evaluating partners for remimazolam in Japan since 2015, but so far a deal has not been concluded.

We expect filing for approval in the U.S. in early 2018 Timing of filing for approval of remimazolam in all indications in the U.S. including procedural sedation is the responsibility of Cosmo. Cosmo has stated that remimazolam could be approved in the U.S. at the end of 2018. We expect filing for approval in mid-2018.

We maintain our Buy recommendation and price target of €4.40 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 U.S. market. However, we continue to model a further capital raise of €10m later this year to partially fund the €20-25m estimated cost of the E.U. 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 €10-15m from cash on hand and/or the next milestone payment from Cosmo. A phase I study to support sample size calculation for the E.U. phase III study will start shortly. We maintain our Buy recommendation and price target of €4.40.

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	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 Year
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		€32.2M									
Pro forma net cash		€44.4M									
Fair Value		€278.9M									
Pro forma share count		63,399K									
Price Target		€4.40									

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	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
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...32	↓	↓	↓	↓
33	18 November 2016	€2.38	Buy	€4.60
34	14 February 2017	€2.45	Buy	€4.60
35	27 March 2017	€2.19	Buy	€4.40
36	Today	€3.04	Buy	€4.40

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

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