

PAION AG

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Q3 Highlights

- Significant increase in share price and trading volume
- Feedback from the FDA on M6G regarding development program
- Recruitment of Phase Ib & IIa studies with CNS 7056 completed

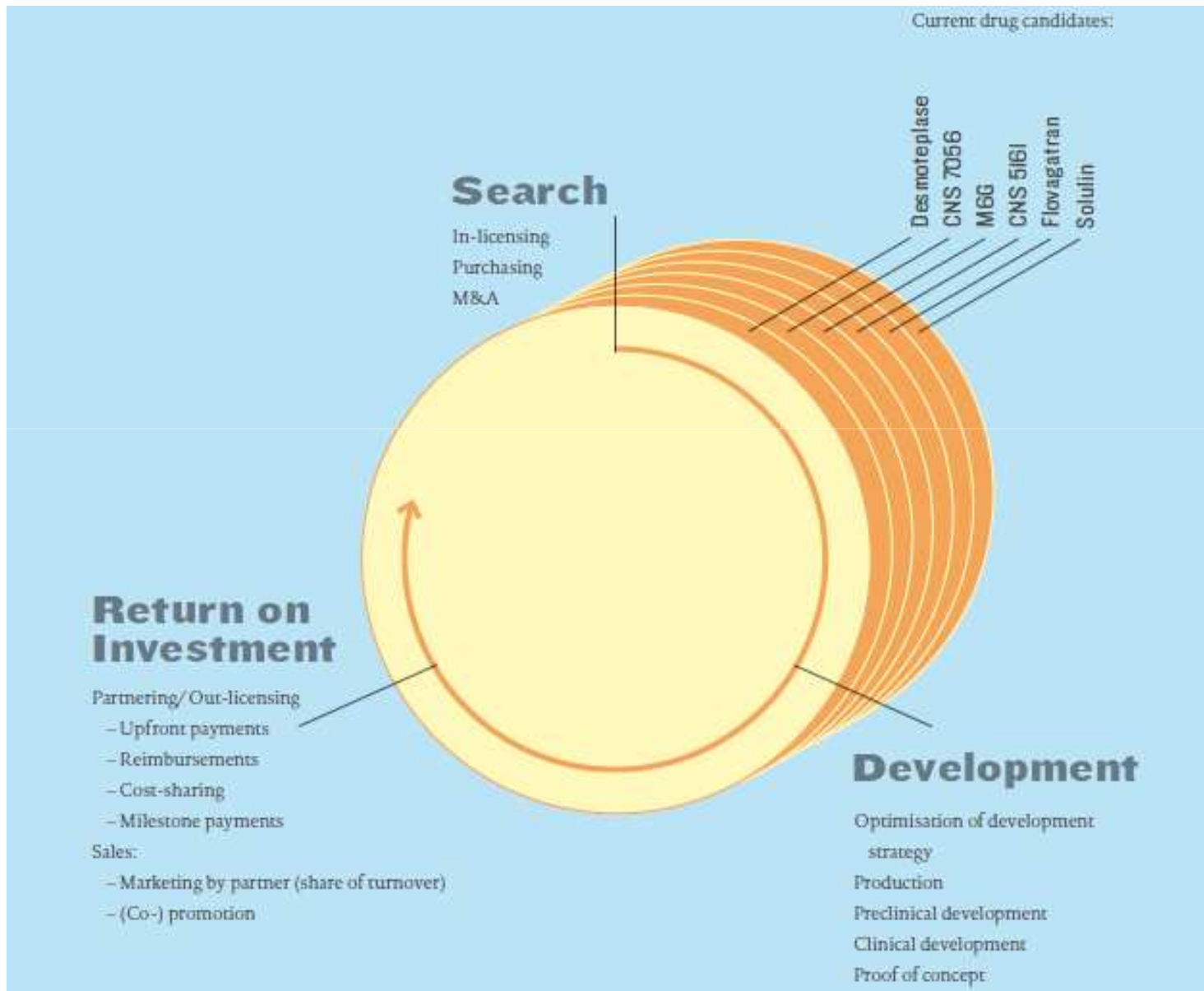
Events post reporting period:

- A. Vos leaves company
- Reporting of headline results of Phase Ib & IIa studies with CNS 7056

Corporate Overview

- **PAION is a publicly listed biopharmaceutical company headquartered in Aachen, Germany, with operations in Cambridge, UK. The company had 30 employees at the end of the first nine months 2009**
- **PAION has a track record of successful partnerships and has a strong potential for rapid R&D progression**
- **€ 27 million in cash & cash equivalents at the end of the first nine months 2009**
- **Substantial news-flow based on progress with CNS 7056**

The PAION Principle



Pipeline Overview

- PAION's **near-term value drivers** are
 - **CNS 7056**, an ultra-short acting anesthetic/sedative with disruptive market potential in phase II for procedural anesthesia
 - **M6G**, a short-term, low risk opportunity in acute pain care with superior side effect profile to morphine
 - **Desmoteplase**, a partnered and fully-funded phase III asset with estimated peak sales potential of US\$600 million
- PAION's **medium-term value drivers** are **CNS 5161, Solulin** and **Flovagatran**

Compound	Indication	Status of development				Expected launch	Estimated peak sales (US\$m)	Partners
		PC	PI	PII	PIII			
Desmoteplase IV plasminogen activator	Acute ischemic stroke	█	█	█	▶	2012	600 ²	Lundbeck (ww)
M6G IV opioid	Post operative pain	█	█	█	▶	2013	300	
CNS 5161 IV NMDA antagonist	Opioid refractory cancer pain	█	█	▶		2013+ ¹	300	
Flovagatran IV direct thrombin inhibitor	CABG	█	█	▶		2013+ ¹	200	
CNS 7056 IV sedative/anesthetic	Anesthesia/Sedation	█	█	▶		2013	500	ONO (Japan)
Solulin IV thrombomodulin	CV/Radiation injury	█	▶			2013+ ¹	200–400 ³	

Notes:

- 1 Launch dependent on funding and choice of indication
- 2 PAION estimates
- 3 Peak sales dependent on indication

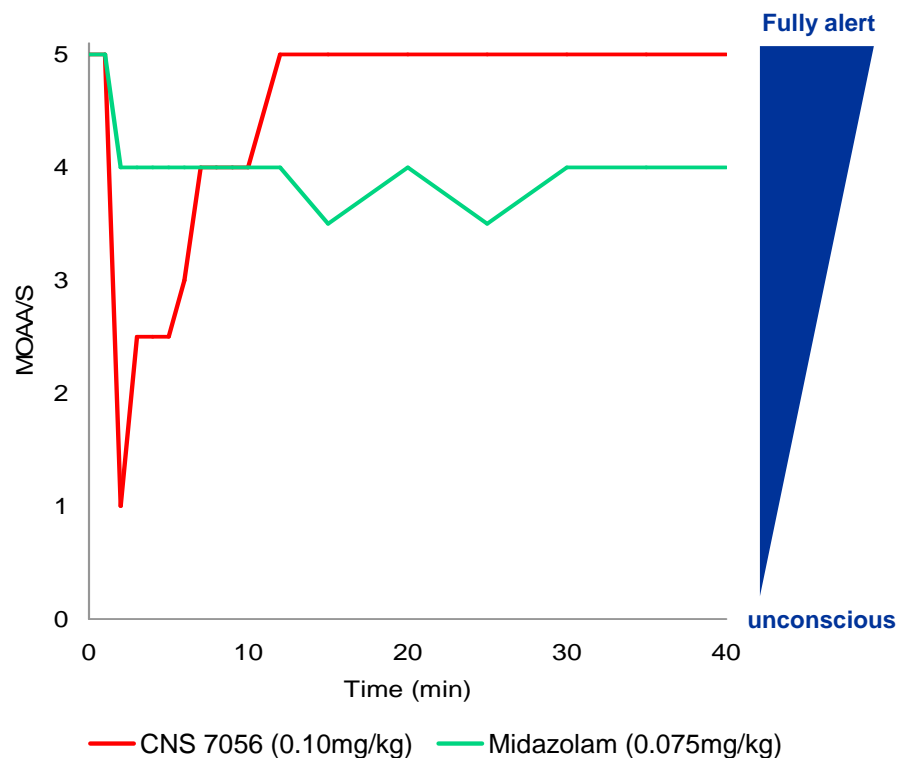
CNS 7056* – Product Highlights

Ultra-short acting anesthetic/sedative with disruptive market potential

- **CNS 7056 is an ultra short acting anesthetic/sedative**
- **Proof-of-Concept achieved confirming target profile**
 - **Low risk of over-sedation (antagonist available) or respiratory depression**
 - **Less resources needed for supervision in procedural sedation**
 - **More predictable pharmacokinetics when compared to midazolam and (fos)propofol due to metabolism by tissue esterases**
- **First target indication pursued by PAION: procedural sedation**
- **Additional attractive potential in induction and maintenance of anesthesia and sedation for ICU care or during imaging**
- **Phase Ib and IIa trials completed (headline data)**
- **First new entrant in field with chance to become new gold standard**

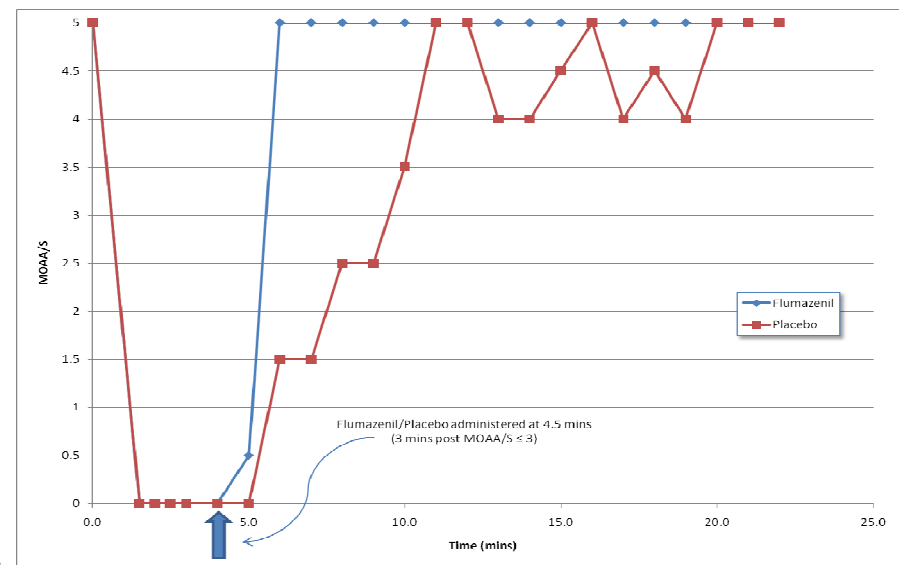
CNS 7056 – Predictable Sedation and Reversal

Rapid onset and offset (Ph I)



MOAA/S = modified observers' assessment of alertness and sedation

Flumazenil reversal without re-sedation after 0.25 mg/kg CNS 7056 (Ph Ib)



CNS 7056 – Outline of Clinical Program

- **Lead indication: sedation during procedures such as colonoscopy, endoscopy & short procedures (limb resetting, wound dressing)**
 - **Single dose first in man (versus midazolam) ✓**
 - **Phase Ib study**
 - **Part A: flumazenil reversal in volunteers ✓**
 - **Part B: bolus with top ups in volunteers undergoing colonoscopy ✓**
 - **Headline data ✓**
 - **Phase IIa study CNS 7056 vs. midazolam in patients undergoing gastroscopy**
 - **Headline data ✓**
 - **Phase IIb study CNS 7056 in patients undergoing colonoscopy under active preparation**
 - **Other interaction trials, pediatric trials (tbd)**
 - **Phase III trials:**
 - **Colonoscopy vs. propofol**
 - **Endoscopy vs. midazolam**
 - **Short procedures (trauma, limb resetting, wound dressing)**
- **ICU sedation**
- **Induction & maintenance of anesthesia**

CNS 7056 – Summary Phase Ib (Colonoscopy)

- 51 volunteers (6 in Part A and 45 in Part B)
- Part A: Flumazenil able to reverse the effects of CNS 7056 within approx. 1.5 min.
- Part B:
 - Approx. 2 min after the first dose of CNS 7056 sufficient sedation to commence procedure
 - 11 min mean time to recovery to full alertness after the last drug dose (top-up)
- Success rates for 30 min colonoscopy
 - 77% of all subjects across all cohorts
 - 83% in higher dose groups (0.075 and 0.1 mg/kg loading dose)
- Benzodiazepine-like safety profile
 - No serious adverse events and no unusual findings
 - Good cardiovascular and respiratory stability



Success Rates in Colonoscopy

Drug /dose Clinical Phase tested	Success rate n/N (%)
CNS 7056 (combined success rate of two highest doses) Phase Ib	24/29 (82.8%)
Fospropofol 6.5 mg/kg (labeled dose)* Phase II and Phase III	Phase II: 18/26 (69.2%) Phase III: 137/158 (86.7%)
Midazolam 0.02 mg/kg* Phase II and Phase III	Phase II: 21/26 (80.8%) Phase III: 36/52 (69.2%)

*Success rates taken from fospropofol NDA

MOAA/S – Recovery Phase Ib (Colonoscopy)

	Time (min) to recovery to MOAA/S 5* after last injection of study drug	Subjects re-sedated** n/N (%)
Cohort 1 0.04 mg/kg	9.8 ± 7.24	0/15 (0%)
Cohort 2 0.075 mg/kg	9.6 ± 3.27	0/15 (0%)
Cohort 3 0.10 mg/kg	6.9 ± 3.63	0/15 (0%)
Successful Procedures*** (From All 3 Cohorts)	11.1 ± 4.77	0/34 (0%)

* first MOAA/S 5, from 3 consecutive measurements

** MOAA/S < 5 following recovery

*** data from those subjects who underwent a successful procedure (n = 34 across all 3 cohorts)

- **Rapid recovery across all cohorts**
- **No re-sedation**



Safety Conclusions Phase Ib (Colonoscopy)

- **Flumazenil reverses sedative action of CNS 7056**
- **No re-sedation observed**
- **No dose-dependent drop of O₂ saturation, systolic and diastolic BP**
- **No serious adverse events**
- **No severe adverse events, low rate of moderate adverse events**
- **Two airway interventions (subjects on room air):**
 - **One chin lift, and one face mask with supplemental oxygen**

CNS 7056 Phase IIa in Gastroscopy – Study Design

- Phase IIa, midazolam-controlled, double-blind, dose-ranging study in patients undergoing diagnostic upper GI endoscopy (n=100)
 - 3 single dose levels of CNS 7056 (0.1 mg/kg, 0.15 mg/kg, 0.2 mg/kg)
 - Single dose of midazolam (0.075 mg/kg)
- Efficacy measurements
 - Success of the procedure
 - Composite of MOAA/S ≤ 4 on 3 consecutive measurements, completion of procedure, no requirement for rescue sedative, no ventilation
 - Measurement of sedation / memory / recall
- Safety measurements
 - Standard safety assessments, plus pulse oximetry & airways management monitoring and pain on injection
- DMC evaluated blinded data after approximately 40% of patients enrolled

Phase IIa (Gastroscopy) Efficacy Results

ITT Population (success = composite of MOAA/S \leq 4 on 3 consecutive measurements AND completion of the procedure AND no requirement for alternative sedative or ventilation)

	Success rate n/n (%) (ITT population)
CNS 7056 (0.10 mg/kg)	8/25 (32%)
CNS 7056 (0.15 mg/kg)	14/25 (56%)
CNS 7056 (0.20 mg/kg)	16/25 (64%)
Midazolam (0.075 mg/kg)	11/25 (44%)

Safety Conclusions Ph IIa (Gastroscopy)

- **No serious adverse events**
- **Rate of adverse events comparable to midazolam, no dose-dependency**
- **No dose dependent drop of O₂-saturation; no ventilation necessary**
- **Vital signs remained stable**
- **No clinically relevant changes in ECG**

Patient Comfort Shows Benzodiazepine-Like Profile

- **Approx. 80% of patients do not recall the procedure on CNS 7056 (similar rate for CNS 7056 in Phase Ib colonoscopy study) or midazolam**
- **There were no apparent differences in either the number of**
 - **Patients remembering events during the procedure**
 - **Patients dreaming during the procedure**
 - **Patients dissatisfied with the procedure**
- **No (low) pain on injection (comparable to midazolam, i.e. less than the reported rate for propofol)**

Conclusions from Phase Ib and Phase IIa Studies

- **CNS 7056**
 - Procedures up to 15 min can be performed with one bolus
 - Top-ups seem adequate for longer procedures up to 30 min
 - Benzodiazepine like safety profile in both trials
 - No serious adverse events and no unusual findings
 - Good cardiovascular and respiratory stability
- **Other learnings**
 - Consider increasing initial dose of fentanyl for colonoscopy
- **CNS 7056 delivers success rates at least as good as current gold standard or better**

CNS 7056* – Competitive Advantage

Product Profiles	*Remimazolam	Midazolam	Propofol	Fospropofol
Rapid time to peak effect	✓	✗	✓	✗
Rapid offset	✓	✗	✓	✓
Predictable recovery time	✓	✗	✓	✗
Early discharge	✓	✗	✓	?
Low respiratory depression	✓	✓	✗	✗
Less resources for supervision	✓	✗	✗	✗
Early recovery to full cognition	✓	✗	✗	✗
Reversal agent available	✓	✓	✗	✗
Low re-sedation risk after reversal	✓	✗	–	–
No (low) pain on injection	✓	✓	✗	

Significant near-term value drivers – M6G

Compound	M6G
Indication	Post-operative pain
Estimated peak sales	US\$ 300 million
Target product label	Well tolerated mono therapy for the treatment of post-operative pain
Expected launch	2013
Market exclusivity until	2021+
Partner	--
Status	Phase III

 ***Short-term low-risk opportunity in acute pain care***

M6G – Product Highlights

Short-term, low risk opportunity with unique properties in post-operative pain segment

- **M6G is a highly potent opioid with morphine replacement rather than morphine sparing potency (less nausea/vomiting/sedation)**
- **First target indication: post-operative pain**
- **About 1,000 patients on drug in clinical database**
- **Remaining development program is relatively small (budget, timelines)**
- **Project ready to continue Phase III trials**
 - **The program has been de-risked by meta-analysis and confirmation of effect size seen in latest Phase III trial**
 - **Rationale for future dose, administration scheme and design determined**
 - **PAION has reached an understanding with the FDA on the path to approval based on these data**
 - **Compound rated as New Medical Entity**
 - **Material for Ph III produced in Q3 2009**

M6G – Competitive Advantage

	i.v. M6G	i.v. Morphine
Efficacy		
Achievable Analgesia Level	++(+)	++
Onset of Analgesia (post-op)	++ (loading dose at induction of anesthesia)	++ (loading dose at conclusion of surgery)
Duration of action	+++	+
Side Effect Profile		
Reduced nausea	✓	✗
Reduced vomiting	✓	✗
Reduced anti-emetic use	✓	✗
Less sedation	✓	✗
Less respiratory depression	✓	✗

Desmoteplase – A Partnered and Fully-Funded Phase III Asset

Compound	Desmoteplase
Indication	Acute ischemic stroke
Estimated peak sales	US\$ 600 million (PAION estimates)
Target product label	Widening treatment window in stroke from 0-3 h up to 9 h in patients requiring reperfusion
Expected filing	2011+ (source: Lundbeck)
Market exclusivity until	2022+
Partner	Lundbeck (world-wide)
Status	Phase III

➔ Significant value driver for PAION without financial obligations

Desmoteplase – Product Highlights

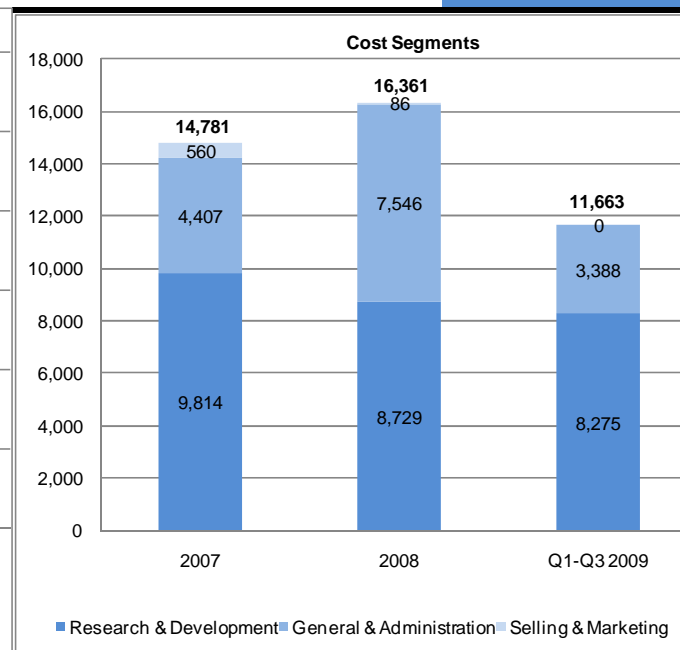
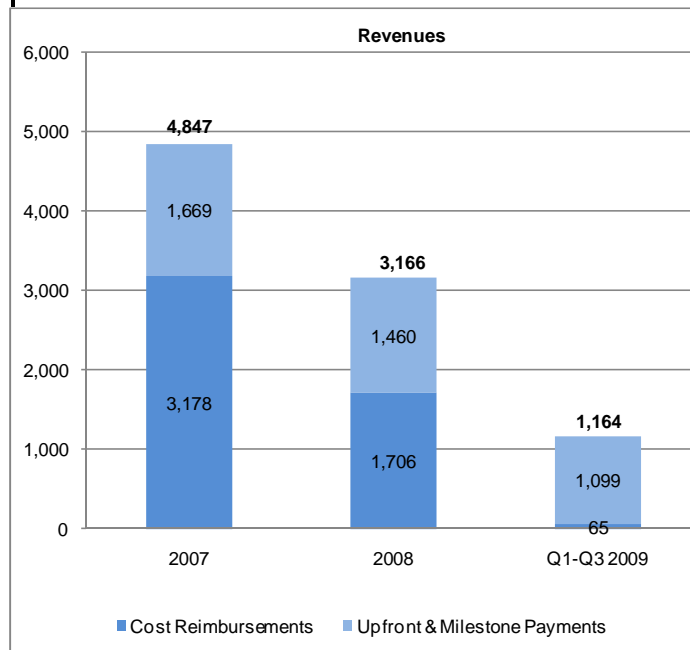
- **Desmoteplase is the most specific clot buster**
- **Treatment window up to 9 h (compared to rt-PA 3 h) with good safety profile**
- **No competitive reperfusion products in late-stage development in ischemic stroke**
- **Phase III program re-launched by Lundbeck in Q4 2008**
 - **Lundbeck has reported Nov 09 that sample size was adjusted (N = 400 in both trials) as lower effect size is considered relevant for FDA, time lines expected to be unaffected, if studies positive Desmoteplase could be eligible for Fast Track FDA review**
- **All development costs fully funded by Lundbeck**
- **Licensing terms**
 - **Future milestones of up to € 63 million (€ 38 million until approval, € 25 million on launch and pre-defined sales targets)**
 - **Double digit net royalties**
- **PAION retains co-promotion rights for the German-speaking countries, currently representing a major part of the European market in ischemic stroke**

Financials

Consolidated Statement of Comprehensive Income

In accordance with IFRS (all figures in EUR k if not otherwise noted)

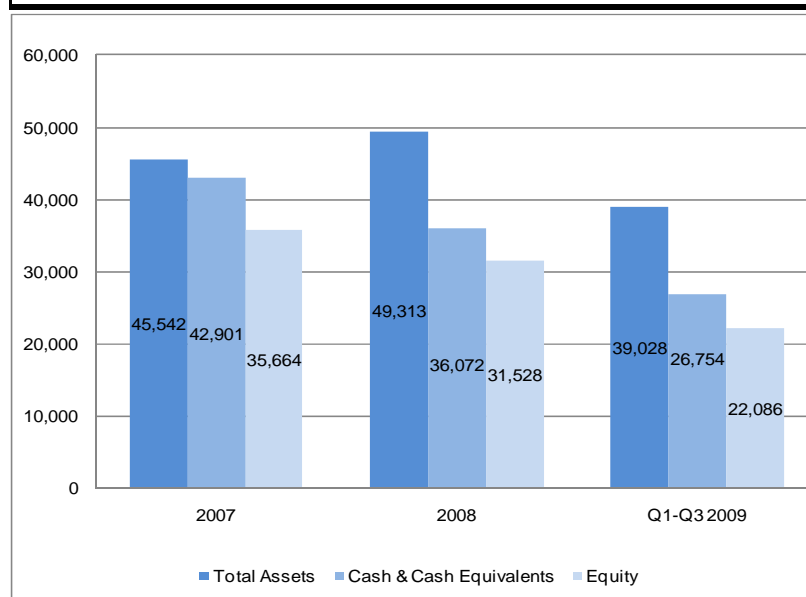
	FY 2007	FY 2008	Q1-Q3 2009
P&L Statement			
Revenues	4,847	3,166	1,164
Cost of revenues	-2,979	-780	-48
Research and development expenses	-9,814	-8,729	-8,275
General and administrative expenses	-4,407	-7,546	-3,388
Selling and marketing expenses	-560	-86	0
Operating result (EBIT)	-12,624	-13,799	-11,144
Financial result	2,112	813	-270
Net result	-10,512	-12,880	-10,043
EPS (in EUR, basic and diluted)	-0.63	-0.74	-0.41



Balance Sheet

In accordance with IFRS (all figures in EUR k if not otherwise noted)

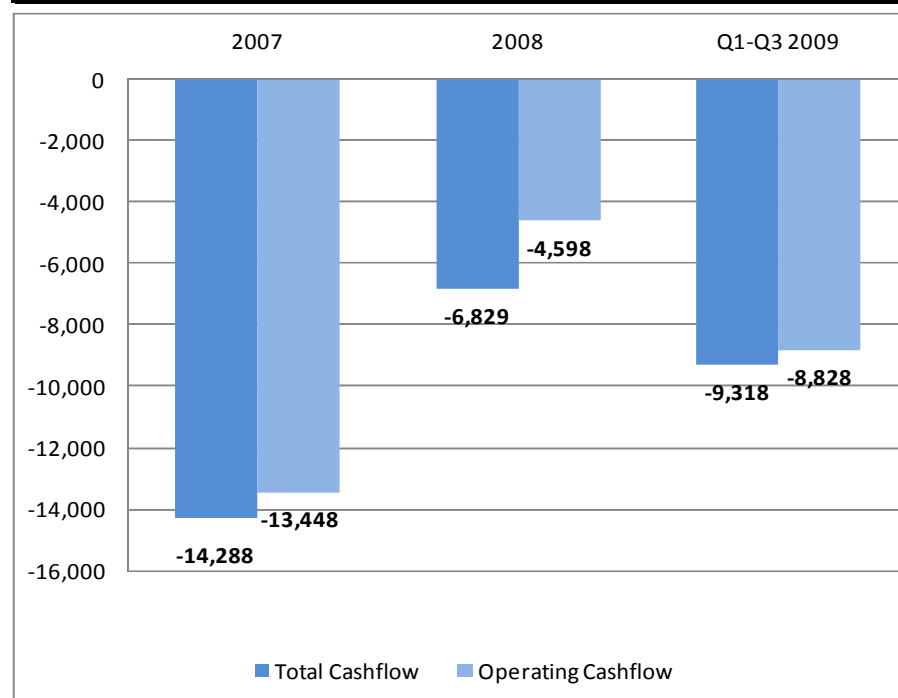
	12/31/2007	12/31/2008	09/30/2009
Balance Sheet			
Non-current assets	1,365	11,746	11,563
Current assets	44,177	37,567	27,465
<i>thereof Cash and cash equivalents</i>	<i>42,901</i>	<i>36,072</i>	<i>26,754</i>
Equity	35,664	31,528	22,086
Non-current liabilities	6,746	13,426	12,291
Current liabilities	3,132	4,359	4,651
Total assets	45,542	49,313	39,028
Equity ratio			
a) Equity / Total assets	78.3%	63.9%	56.6%
b) (Equity + Subordinate Loan + Deferred Income Lundbeck) / Total assets	92.9%	91.0%	88.1%



Cash Flow and Employees

In accordance with IFRS (all figures in EUR k if not otherwise noted)

	FY 2007	FY 2008	Q1-Q3 2009
Cash Flow Statement			
Cash flows from operating activities	-13,448	-4,589	-8,828
Cash flows from investing activities	-204	-436	-53
Cash flows from financing activities	-636	-1,638	-498
Employees			
FTE (average in period)	75	42	30
FTE (at period end)	53	33	30



Outlook (1)

- **Sustainable changes of cost structure**
 - Staff reductions in 2007 and 2008
 - Cost reductions in several areas
 - Development costs for Desmoteplase are completely borne by Lundbeck
 - Major development in 2009 was and continues to be on the development of CNS 7056. PAION has started preparation of a Phase IIb study in colonoscopy, which will be conducted in 2010
 - For 2009 a net loss is expected

- **Revenues**
 - Proportional release of deferred income

Outlook (2)

- **Cash and cash equivalents of EUR 27 million**
 - To implement value-generating steps especially conduct of a Phase IIb study with CNS 7056
 - This cash balance alone secures cash reach at least until mid 2011
- **Up to EUR 63 million milestone payments for Desmoteplase agreed, thereof**
 - Up to EUR 38 million until market approval
 - In total EUR 25 million upon commencement of marketing activities and the achievement of specific revenue targets
- **Additional milestone payments for the further development of CNS 7056 agreed from ONO, Japan**
- **Additional cash inflows from outlicensing targeted**

Achievements and expected newsflow 2009 / 2010

	2009			2010	
CNS 7056	Proof of concept & definition of dosages for Phase II ✓	Start Phase Ib and IIa studies ✓	Completion of Phase Ib and IIa studies ✓	Partnering	Start of Phase IIb
Solulin				Partnering	Start of Phase II with partner
M6G				Partnering	Restart of clinical development with partner
Desmoteplase	Lundbeck to start second Phase III study ✓				
CNS 5161	Decision to seek 3rd party funding ✓				
Flovagatran				Results of pre-clinical Studies	Decision on next step

Key objectives for 2009/2010

- **Keep momentum in CNS 7056**
- **Closing of one or more partnering deals to extend cash reach**
- **Continue to identify potential for cost savings**

Investment highlights

- ① **Significant near-term value drivers in key PAION compounds**
 - **CNS 7056 – ultra-short acting Phase II anesthetic/sedative with disruptive market potential and substantial news-flow**
 - **M6G – short-term, low risk opportunity in acute pain care with superior profile to morphine**
 - **Desmoteplase – fully-funded Phase III compound representing a large market opportunity (US\$ 600 million estimated peak sales) and significant potential revenues to PAION (€ 63 million of outstanding milestones plus royalties)**
- ② **Three other clinical stage compounds with medium-term upside potential**
- ③ **Strong management team with a track record of significant recent achievements**
- ④ **Strong financial position**



**Thank you very much
for your attention!**

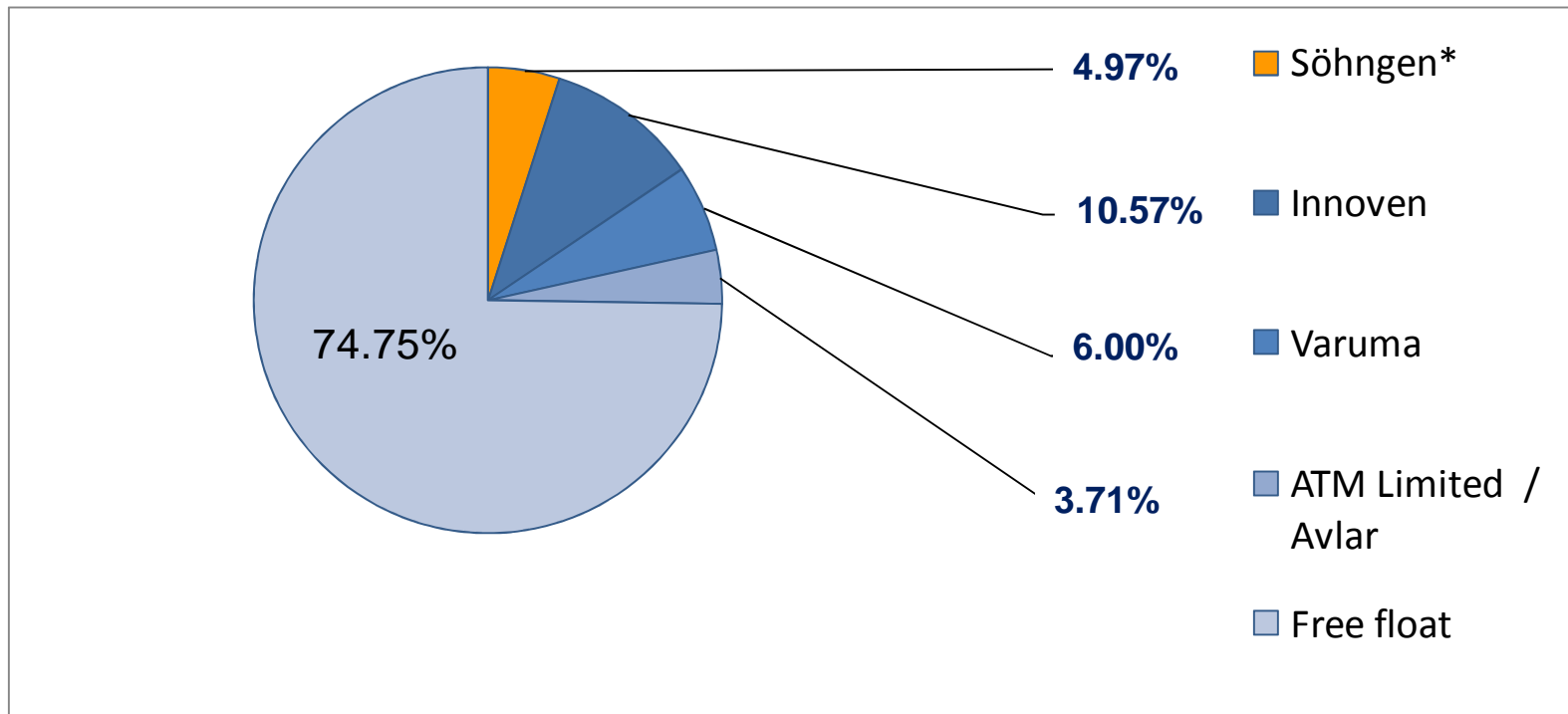
Contact:

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Shareholder structure (as of 10 November 2009)

24,602,919 shares outstanding



*Dr. Mariola Söhngen 2.62%, Dr. Wolfgang Söhngen 2.35%

Investor relations data

- **Total number of shares: 24,602,919**
- **ISIN DE000A0B65S3**
- **Listing Frankfurt Stock Exchange, Prime Standard Regulated Market**
 - **WKN A0B65S**
 - **SE Symbol: PA8 (Bloomberg: PA8 GR)**
 - **Most liquid trading on XETRA (PA8 GY)**
 - **Designated Sponsors: Close Brothers Seydler, Sal. Oppenheim**

- **Contact: Ralf Penner (Director Investor Relations & Public Relations)**
Phone +49 241 4453-152, e-mail: r.penner@paion.com

Corporate calendar 2010

16 March	Publication of the financial results 2008
11 May	Publication of the financial results for the first quarter 2010
19 May	Annual General Meeting, Aachen (Germany)
11 August	Publication of the financial results for the second quarter and the first half-year 2010
10 November	Publication of the financial results for the third quarter and the first nine months 2010
22-24 November	Analyst presentation

M6G - Analytical Effort Provided Missing Link and De-Risked Program

- **Conclusions of PK/PD modeling (n = 168 for PK and 345 for PD respectively):**
 - **Optimal loading dose identified: 45 mg (maintenance dose likely to be 15 mg in intervals of 8-12 h)**
 - **Optimal timing of drug administration: with premedication/induction of anesthesia**
 - **Sufficient evidence for a wider therapeutic margin for M6G compared to morphine, allowing further dose increase**
- **Conclusions of meta-analysis (based on 769 patients):**
 - **M6G has a longer duration of action than morphine**
 - **The analgesic effects of M6G are accompanied with significantly less nausea (p = 0.025; relative reduction 27%) and vomiting (p = 0.010; relative reduction 29%) as compared with morphine**
- **Study design discussed with FDA**

M6G vs. Morphine (Gold Standard)

M6G demonstrates a stronger, longer lasting effect at increased doses vs. morphine

Therapeutic target: VRS-score < 3

