

# Annual General Meeting of PAION AG

Aachen, 24 May 2011



## Disclaimer

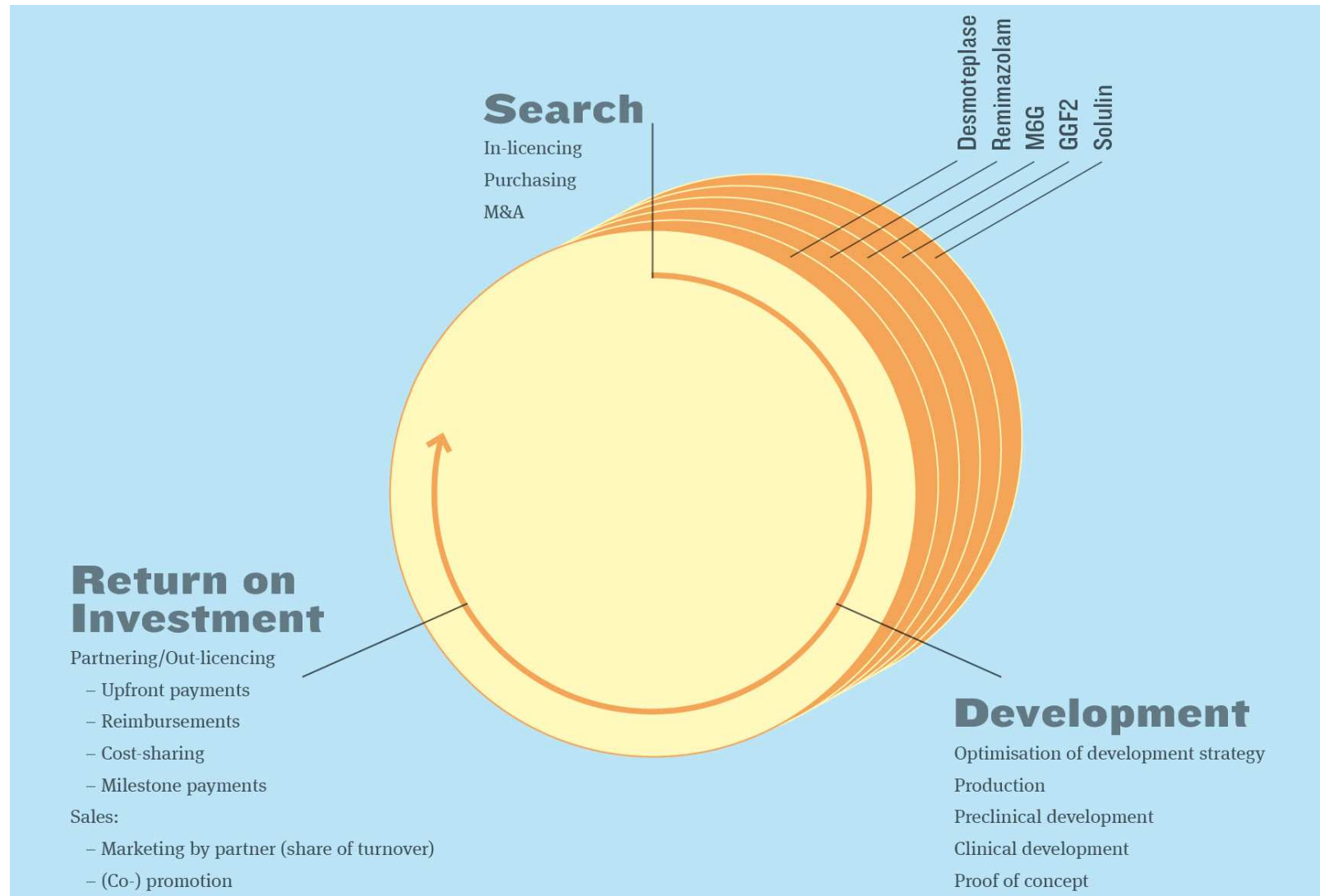
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# Agenda

- **Review 2010** **Dr Wolfgang Söhngen**
- **Development progress** **Dr Mariola Söhngen**
- **Financial overview** **Bernhard Hofer**
- **Outlook** **Dr Wolfgang Söhngen**

# The PAION principle



## Highlights 2010 (1)

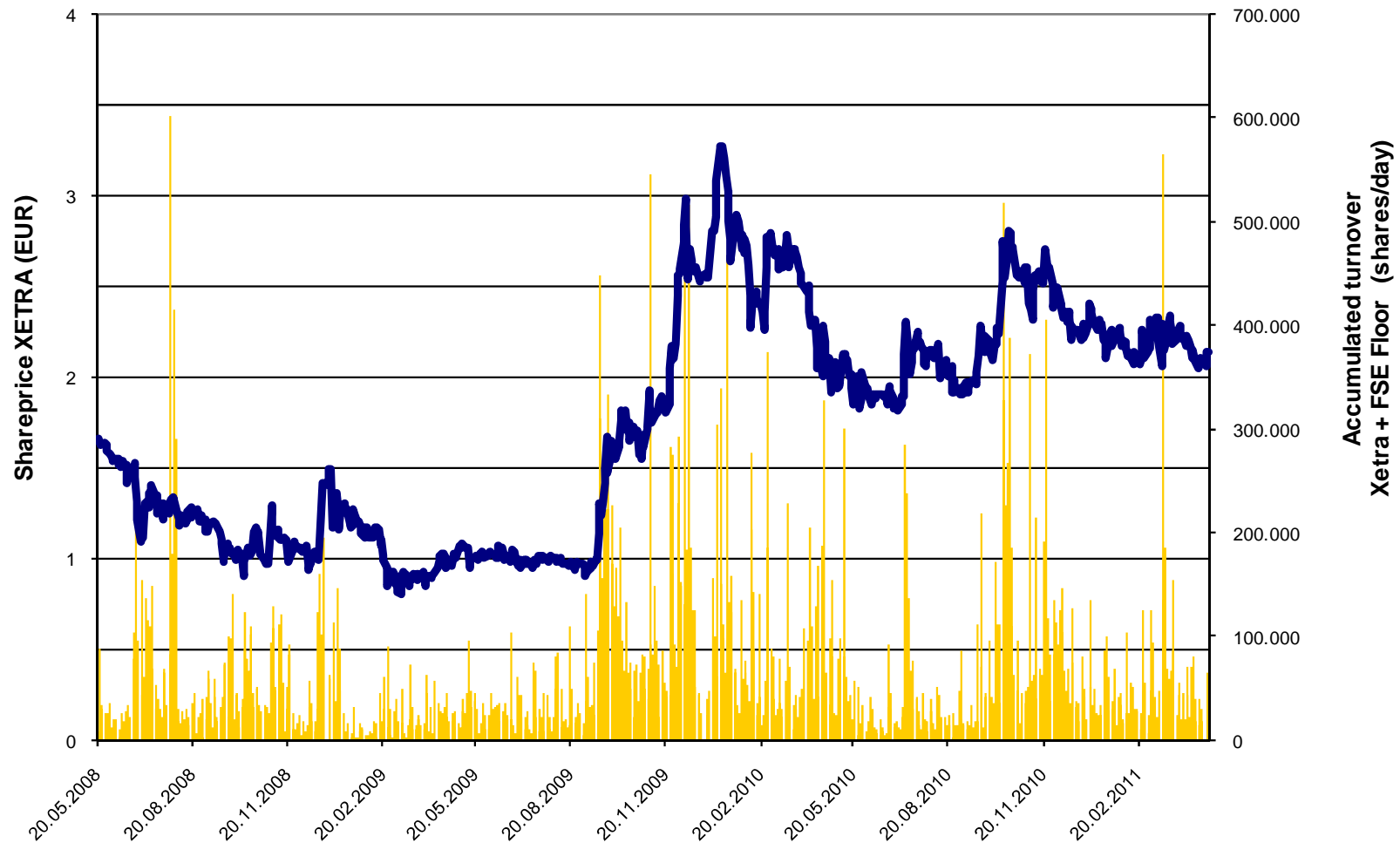
- **Remimazolam**
  - Phase IIb (procedural sedation) successfully completed
  - US\$ 1 million milestone received from Ono for start of Japanese development in second indication (anesthesia)
  
- **Desmoteplase**
  - Japanese Phase II initiated
  - Lundbeck agreement amended to include follow-on substances
    - EUR 1,5 million upfront payment received
    - EUR 5 million additional Desmoteplase milestones
    - EUR 25 million for Desmoteplase follow-on substances

## Highlights 2010 (2)

- **Solulin**
  - Positive preclinical results in the indication hemophilia
- **GGF2**
  - US\$ 1 million milestone received from Acorda for IND approval
- **Increasing financial reach**
  - Equity facility agreement for EUR 15 million, thereof EUR 1 million utilized in 2010
  - Milestone payments of EUR 3 million in total from Lundbeck, Ono and Acorda

# Shareprice development of the past three years

(20 May 2008 – 19 May 2011)



## Share information & analyst coverage

- 76.4% of total shares traded in 2010
- 193% of total shares traded in the last 3 years
- Closing price PAION shares Xetra on 30 December 2010: EUR 2.24
  - Average price 2008: EUR 1.42
  - Average price 2009: EUR 1.29
  - Average price 2010: EUR 2.31

Report by	Current rating	Date of last update	Last change	Year end 2010	Year end 2009	Year end 2008
LBBW	Buy / € 4.00	11 May 2011	23 Mar 11 - € 4.50 to 4.00	Buy / € 4.50	Buy / € 4.00	Buy / € 3.50
First Berlin/DZ Bank**	Buy / € 4.00	12 May 2011	18 Oct 10 - € 3.85 to 4.00	Buy / € 4.00	Buy / € 2.80	Buy / € 1.90
Edison	€ 4.06*	23 Mar 2011	25 Nov 10 - € 3.17 to 4.81	€ 4.06*	€ 2.88	n/a
Seydler	Buy / € 3.90	11 May 2011	20 Jan 10 - € 1.94 to 3.90	Buy / € 3.90	Buy / € 1.94	Buy / € 2.15
MIDAS	Not available	24 Nov 2009	18 Dec 08 - € 3.50 to 4.17	Not available	Buy / € 4.17	Buy / € 4.17

\* Based on NPV of EUR 102 million

\*\* DZ Bank since 1 Jan 2010

## PAION's value drivers

- PAION's short-term value drivers are
  - Remimazolam, an ultra-short acting anesthetic/sedative with significant market potential; Phase-III-ready for procedural sedation and in Phase I for anesthesia
  - M6G for the treatment of peri-operative pain, well tolerated and with superior side effect profile to opioids
  - 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 Solulin and GGF2

Compound	Indication	Status of development				Earliest launch	Estimated peak sales (US\$m)	Partners
		PC	PI	PII	PIII			
Desmoteplase IV plasminogen activator	Acute ischemic stroke	█	█	█	▶	1	600 <sup>2</sup>	Lundbeck (ww)
M6G IV opioid	Peri-operative pain	█	█	█	▶	2014	300	
Remimazolam IV anesthetic/sedative	Anesthesia/Sedation	█	█	▶		2014	500	ONO (Japan)
Solulin IV thrombomodulin	Hemophilia	█	▶					
GGF2 IV glial growth factor	Heart failure	█	▶					Acorda (ww)

Notes:

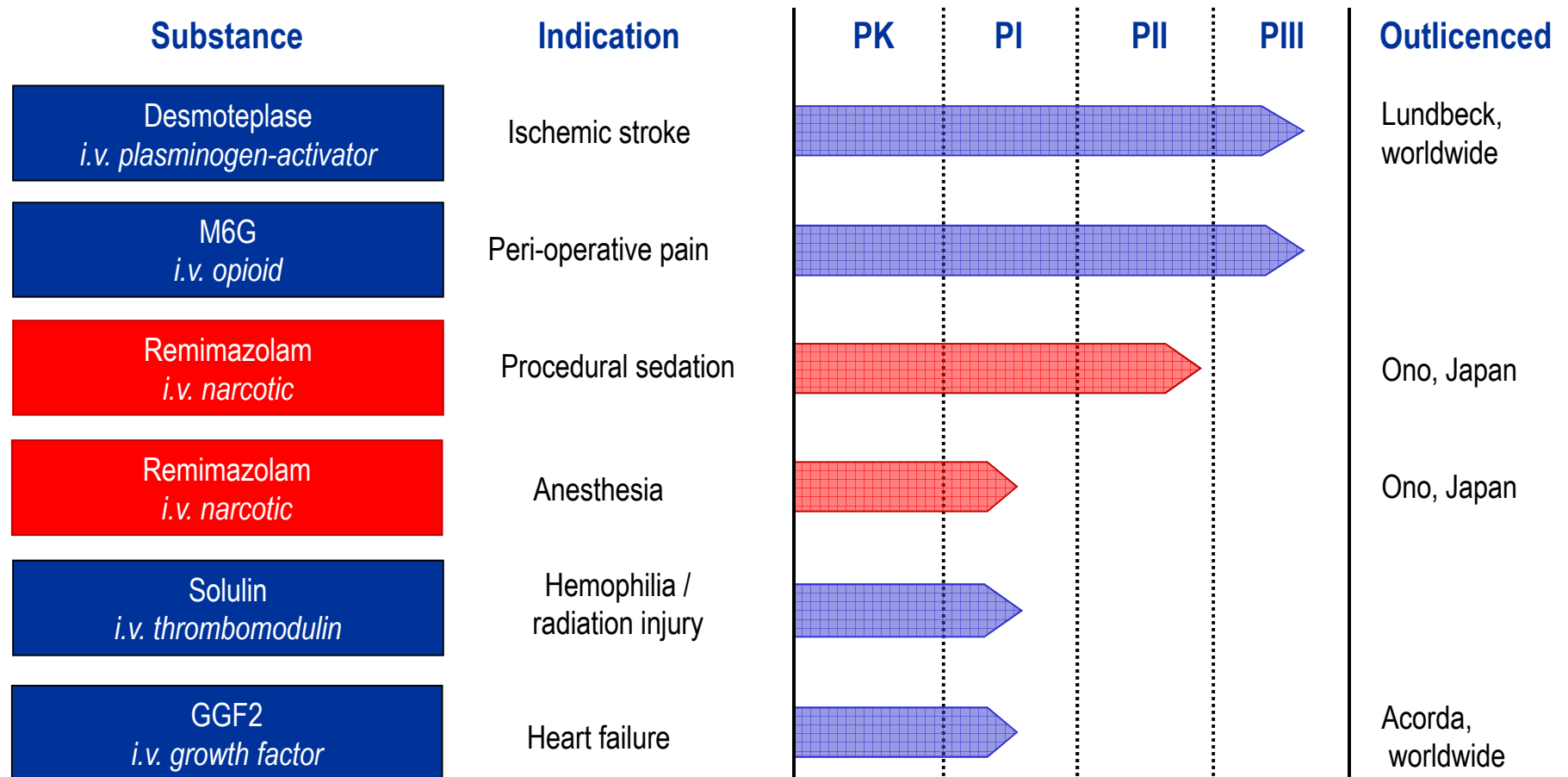
1 Filing (Lundbeck guidance): 2012

2 PAION estimates

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# Pipeline acc. to stage of development



## Remimazolam – product highlights

- **Remimazolam is an ultra-short acting anesthetic/sedative**
- **Low risk of over-sedation or respiratory depression and early discharge expected**
- **Metabolism by tissue esterases (enzymes), therefore effect more predictable compared to competitors**
- **Target indications:**
  - **Procedural sedation (PAION)**
  - **Induction and maintenance of anesthesia (Ono)**
  - **Sedation for ICU (Intensive Care Unit) care**
- **Hardly any competitors with comparable efficacy profile**

## Superior response rate for Remimazolam

	Success rate n/N (%) (ITT)
Remimazolam – 8.0/3.0 mg	37/40 (92.5%), p = 0.066*
Remimazolam – 7.0/2.0 mg	38/40 (95.0%), p = 0.025*
Remimazolam – 5.0/3.0 mg	39/40 (97.5%), p = 0.007*
Midazolam – 2.5/1.0 mg	30/40 (75.0%), p = 0.007**

\* Descriptive p values for Remimazolam represent pair-wise comparisons between each group and Midazolam

\*\* Descriptive p value for Midazolam represents comparison to Remimazolam groups combined

## Short time to fully alert

MOAA/S	Time to fully alert (mins) Mean (SD)
	ITT population
Remimazolam – 8.0/3.0 mg	13.6 (7.48)
Remimazolam – 7.0/2.0 mg	11.3 (5.69)
Remimazolam – 5.0/3.0 mg	13.3 (7.21)
Midazolam – 2.5/1.0 mg	15.2 (7.43)

## Efficacy

- **Faster onset of sedation for Remimazolam, compared with Midazolam → procedures can be started earlier**
- **Higher procedure success rate (95% overall) for Remimazolam, compared with Midazolam (75%)**
- **Rapid offset of sedation**
- **Short time to ready for discharge**
- **Remimazolam requires less resource use and better patient flow**
  
- **Remimazolam fixed dose regimen successfully established (ease of use)**

## Safety

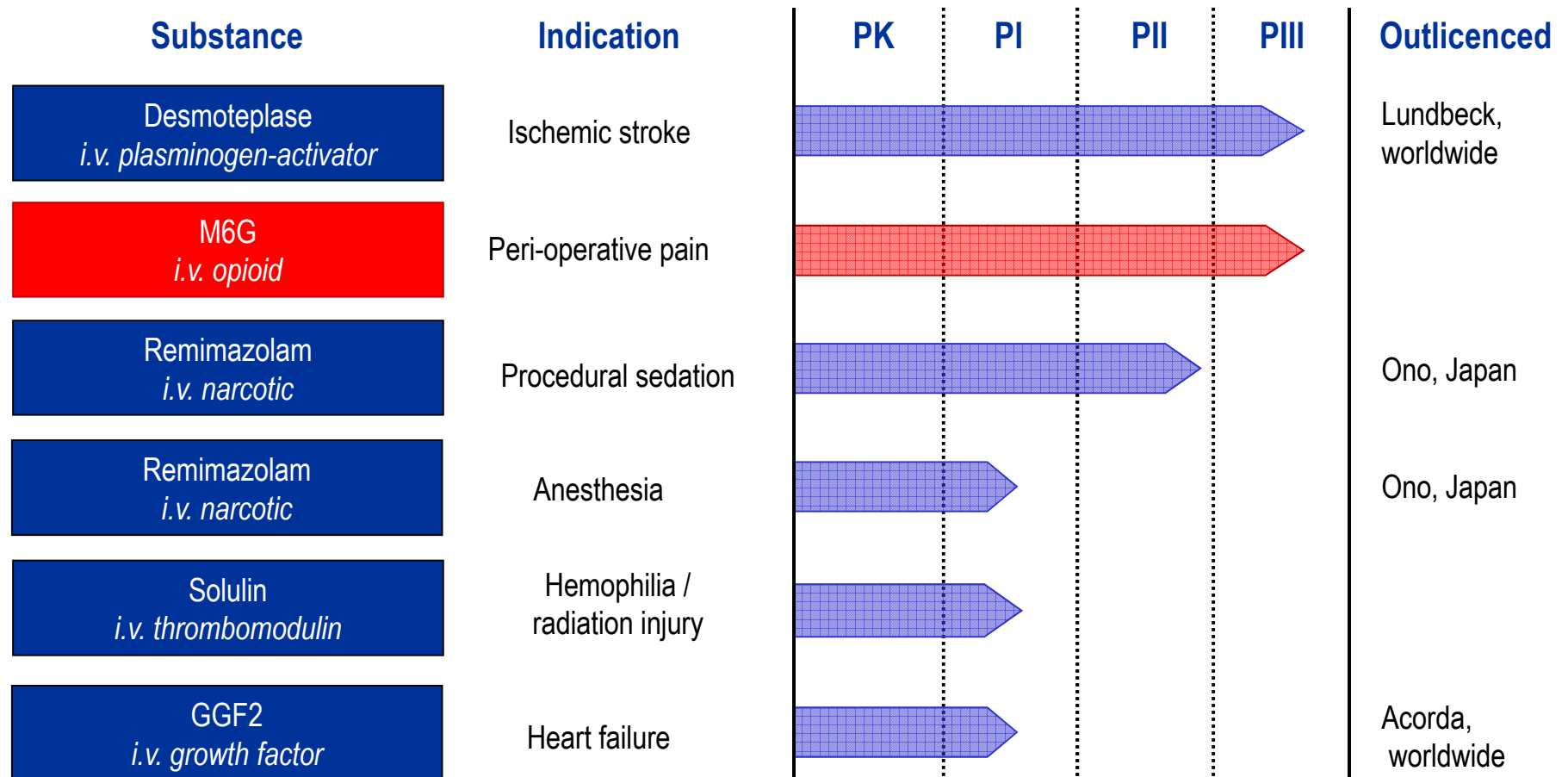
- Overall good tolerability
- No treatment emergent serious adverse events
- No apparent differences in oxygen saturation (values remained stable at a mean of 97% throughout)
- Airway interventions (similar between all groups)
- No ventilation necessary
- Adverse events were considerably less frequent than in previous studies

## Market needs

- Rapid “street-readiness” of patients (not necessarily driving)
- Target Controlled Infusion (TCI)
- Predictable pharmacokinetics and efficacy
- Rapid awakening to full alertness on demand following sedation or anesthesia
- Improved cost-efficiency
- Faster patient flow
- Less nursing supervision
- Good cardio/respiratory safety
- Availability of reversal agent
- Reduced pain on injection
- Amnestic effect and high patient satisfaction

...can all be addressed with Remimazolam

# Pipeline acc. to stage of development



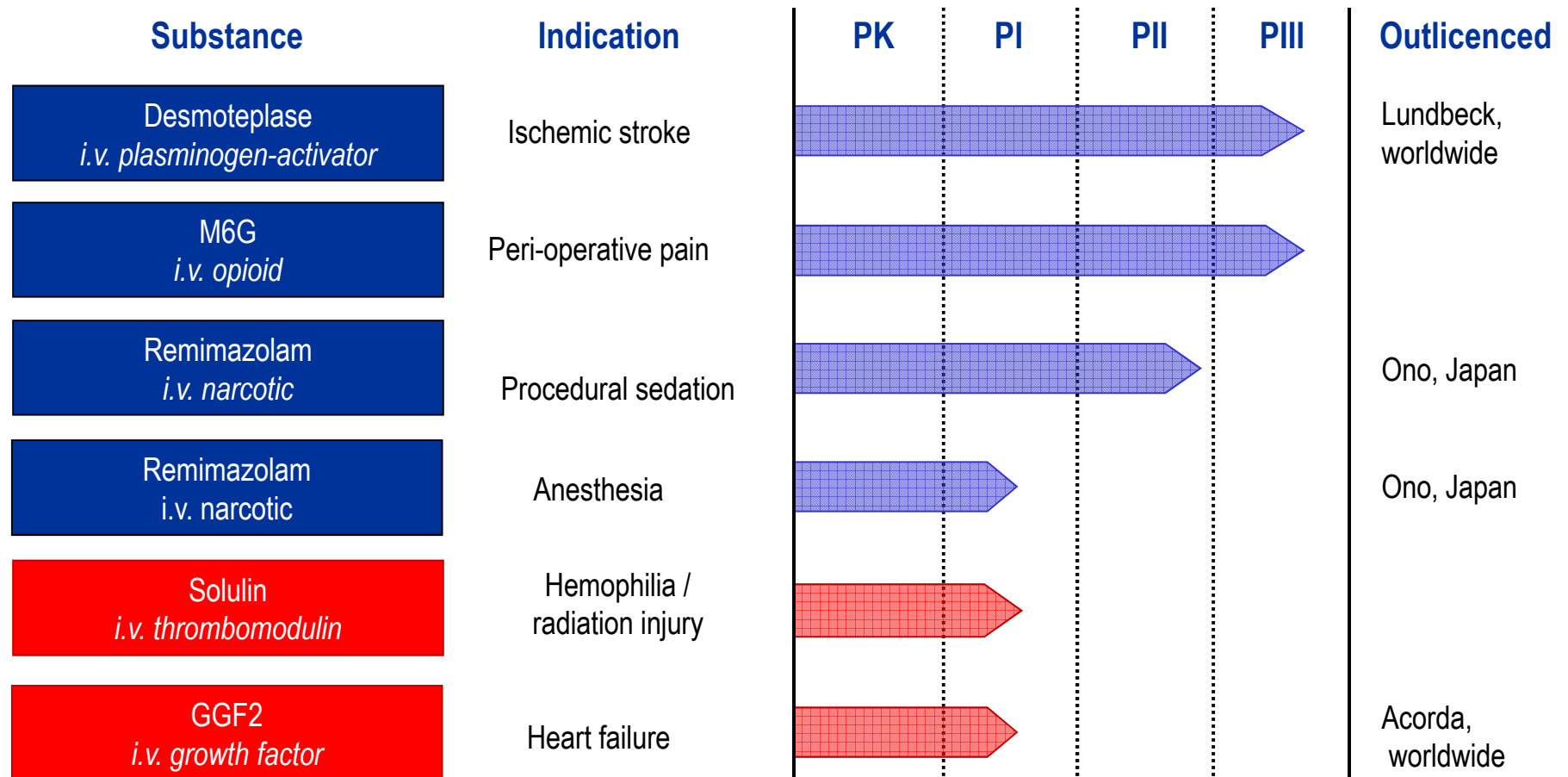
## M6G – product highlights

- **M6G is a major morphine metabolite with an improved safety profile (less nausea/vomiting/sedation)**
- **First target indication for PAION: peri-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**

# Our partner's activities

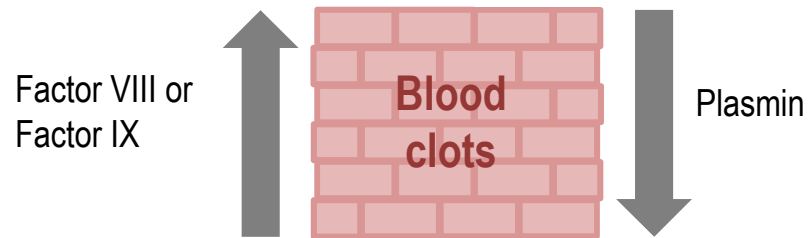
Substance	Indication	PK	PI	PII	PIII	Outlicenced
Desmoteplase <i>i.v. plasminogen-activator</i>	Ischemic stroke	[Red arrow spanning PK, PI, PII, and PIII]				Lundbeck, worldwide
M6G <i>i.v. opioid</i>	Peri-operative pain	[Blue arrow spanning PK, PI, PII, and PIII]				
Remimazolam <i>i.v. narcotic</i>	Procedural sedation	[Red arrow spanning PK, PI, and PII]				Ono, Japan
Remimazolam <i>i.v. narcotic</i>	Anesthesia	[Red arrow spanning PK and PI]				Ono, Japan
Solulin <i>i.v. thrombomodulin</i>	Hemophilia / radiation injury	[Blue arrow spanning PK and PI]				
GGF2 <i>i.v. growth factor</i>	Heart failure	[Red arrow spanning PK and PI]				Acorda, worldwide

# Pipeline acc. to stage of development

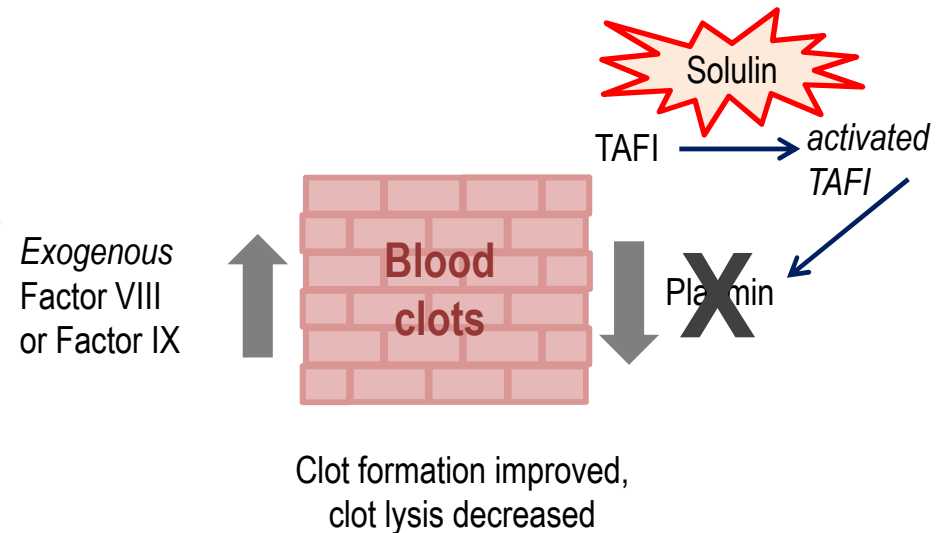


# Solulin makes clots firmer

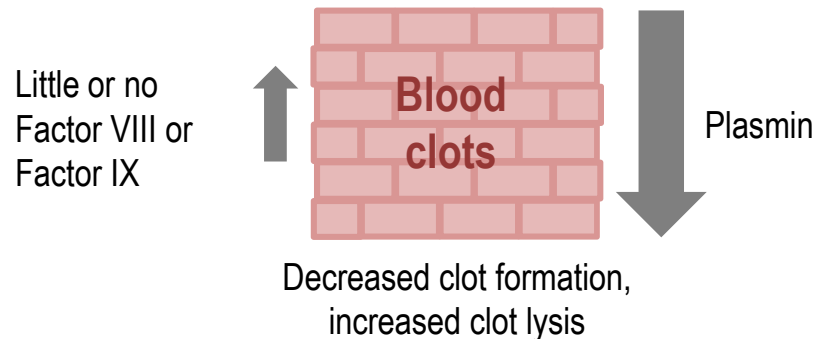
## Normal blood



## Treated hemophilic blood



## Hemophilic blood



- Safety in man demonstrated in Phase I study
- Preclinical data → positioning in hemophilia
- Market exclusivity with good product differentiation facilitates attractive commercial potential

## Summary development activities 2010

Desmoteplase	<ul style="list-style-type: none"><li>• Continuation of worldwide Phase III development as well as start of Phase II development in Japan by Lundbeck</li></ul>
Remimazolam	<ul style="list-style-type: none"><li>• Performance of Phase IIb study by PAION (colonoscopy)</li><li>• Phase I study by Ono (anesthesia)</li></ul>
Solulin	<ul style="list-style-type: none"><li>• Preclinical work for positioning in hemophilia</li></ul>
GGF2	<ul style="list-style-type: none"><li>• Start of Phase I by Acorda</li></ul>

# Agenda

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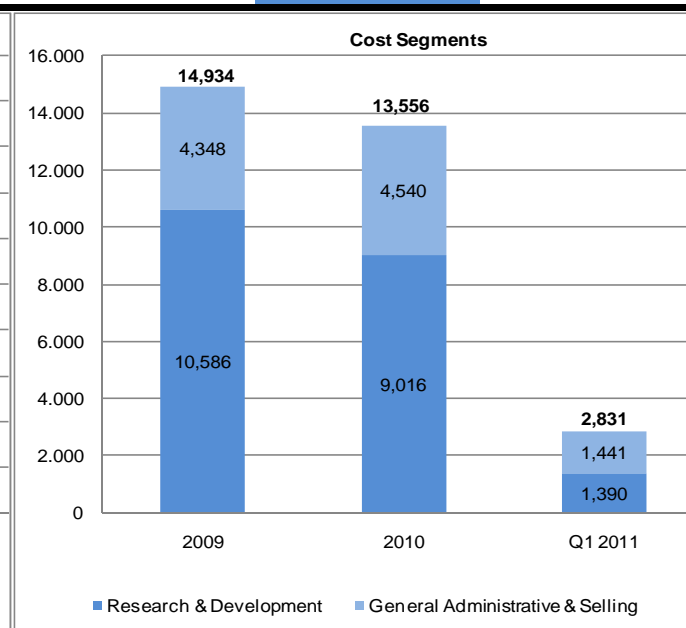
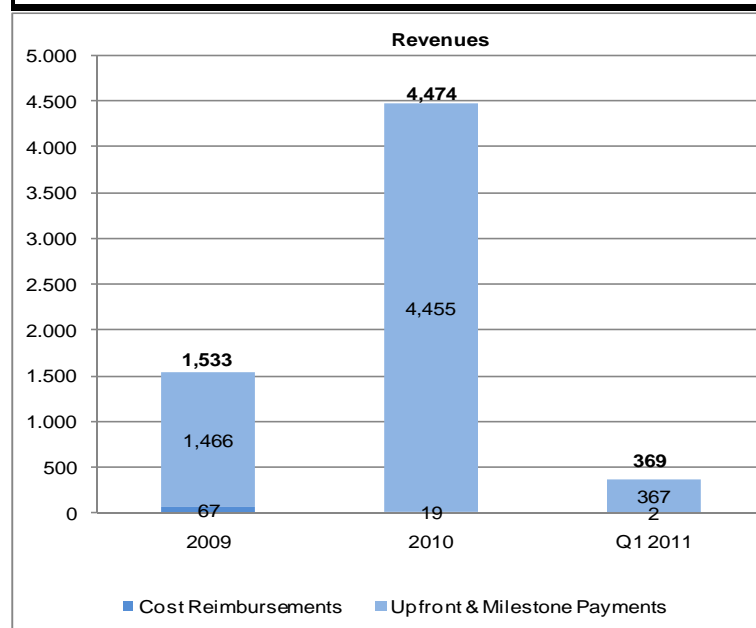
## Financial items

- **Statement of comprehensive income**
- **Balance sheet**
- **Cash flow and employees**
- **Financial outlook**
- **References regarding the report by the Management Board pursuant to Section 289 (4) and (5) as well as Section 315 (4) HGB**
- **Explanation of certain agenda items**

# Consolidated statement of comprehensive income

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

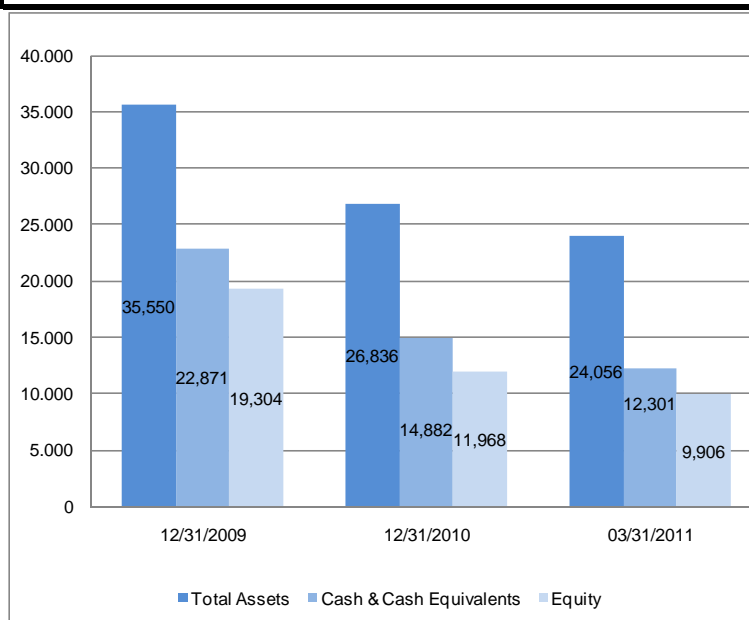
	FY 2009	FY 2010	Q1 2011
<b>Statement of comprehensive income</b>			
<b>Revenues</b>	<b>1.533</b>	<b>4.474</b>	<b>369</b>
Research and development expenses	-10.586	-9.016	-1.390
General administrative and selling	-4.348	-4.540	-1.441
<b>Operating result (EBIT)</b>	<b>-12.996</b>	<b>-9.033</b>	<b>-2.464</b>
Financial result	-381	-660	-143
<b>Net result</b>	<b>-13.037</b>	<b>-9.254</b>	<b>-2.528</b>
EPS basic (in EUR)	-0,53	-0,38	-0,10



# Balance sheet

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

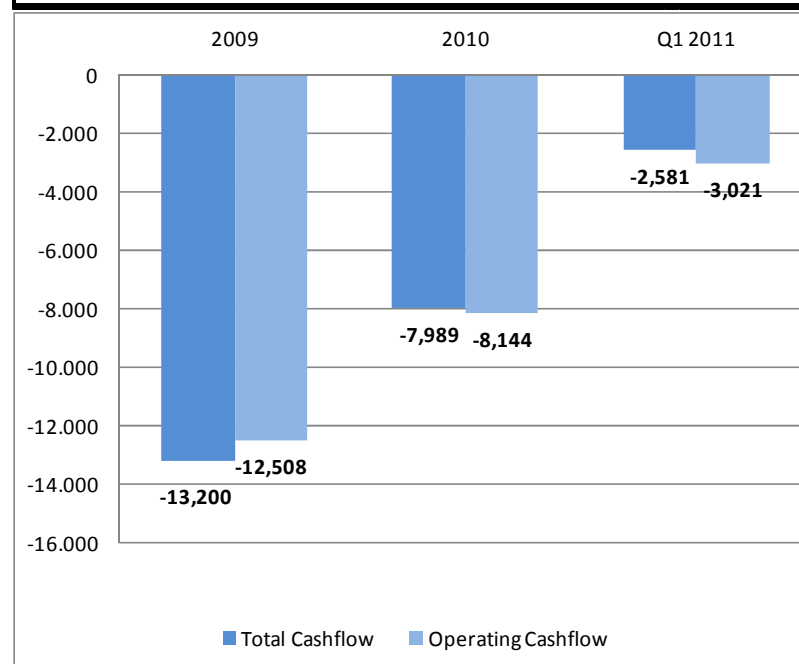
	12/31/2009	12/31/2010	03/31/2011
<b>Balance Sheet</b>			
Non-current assets	11.671	10.768	10.310
Current assets	23.879	16.068	13.746
<i>thereof Cash and cash equivalents</i>	22.871	14.882	12.301
Equity	19.304	11.968	9.906
Non-current liabilities	12.033	10.483	10.007
Current liabilities	4.213	4.385	4.143
<b>Total assets</b>	<b>35.550</b>	<b>26.836</b>	<b>24.056</b>
<b>Equity ratio</b>			
a) Equity / Total assets	54,3%	44,6%	41,2%
b) (Equity + Subordinate Loan + Deferred Income Lundbeck) / Total assets	87,9%	83,8%	83,5%



# Cash flow and employees

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

	FY 2009	FY 2010	Q1 2011
<b>Cash Flow Statement</b>			
Cash flows from operating activities	-12.508	-8.144	-3.021
Cash flows from investing activities	-108	-44	-3
Cash flows from financing activities	-658	170	454
Change in cash and cash equivalents	-13.200	-7.989	-2.581
<b>Employees</b>			
FTE (average in period)	30	28	26
FTE (at period end)	30	27	26



## Financial outlook 2011

- **Revenues**
  - Proportional release of deferred income (EUR 1.5 million)
  - Single-digit million revenues from development activities of partners
  - Further revenues from intended out-licensing (substantial amount for Remimazolam and a smaller amount for M6G)
- R&D expenses lower than previous year
- Partnering activities lead to an increase of selling expenses
- The budgeted expenses lead to a significant net loss in 2011
- **Financing activities**
  - Partial use of the equity facility (current authorisation for 1.7 million shares)

## Medium-term financial outlook

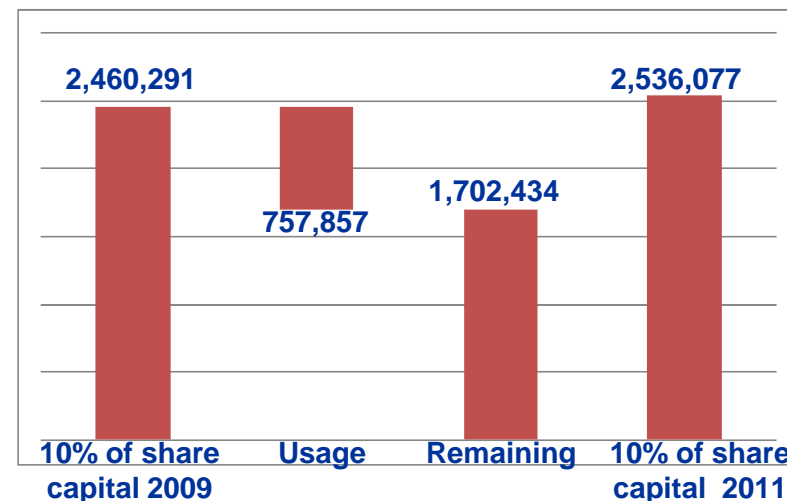
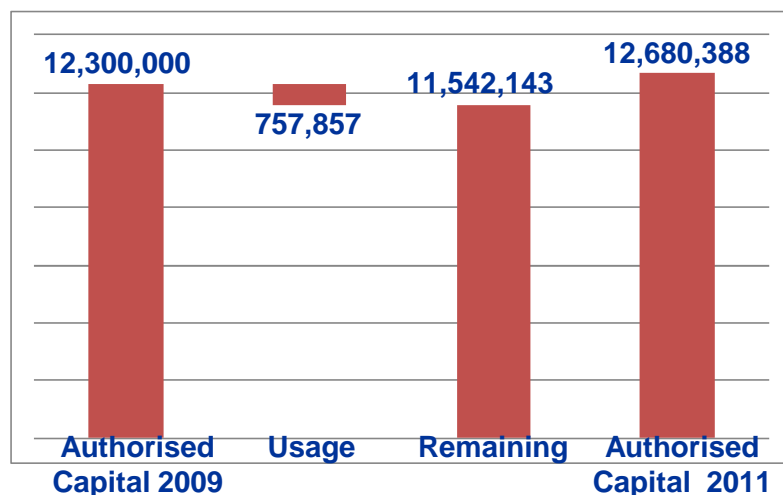
- **Cash reach until the middle of 2012**
  - Cash and cash equivalents of EUR 12 million as of 31 March 2011
  - Cash reach until the middle of 2012 based on current cash position plus inflows from a partial use of the equity facility
- **Potential for significant funds**
  - Up to EUR 68 million milestone payments from Lundbeck agreed, thereof up to EUR 40 million until market approval
  - Development milestone payments from Ono
  - Up to USD 7.5 million milestone payments until market approval from Acorda
  - Out-licensing of Remimazolam
  - Out-licensing of M6G
  - Usage of remaining EUR 13 million equity facility

## References regarding the report by the Management Board pursuant to Section 289 (4) and (5) as well as Section 315 (4) HGB

- The complete report by the Management Board pursuant to Section 289 (4) and (5) as well as Section 315 (4) HGB is available for review at the desk
  - Composition of subscribed capital
  - Restrictions relating to voting rights or the transfer of shares
  - Shareholdings which exceed 10% of voting rights
  - Shares with special rights conferring control
  - Type of control of voting rights when employees are shareholders and do not directly exercise their control rights
  - Legal provisions and provisions of the Articles of Incorporation on the appointment and removal of members of the Management Board and amendments to the Articles of Incorporation
  - Authority of the Management Board to issue or buy back shares
  - Material arrangements dependent on a change in control in the wake of a takeover bid
  - Compensation agreements entered into by the company with members of the Management Board and employees in the event of a takeover bid

## Agenda item 6: Authorised Capital

- Primary goal is the renewal of the authorisation to be able to issue new shares up to 10% of the share capital without a prospectus and by excluding subscription rights
- Removal of the existing Authorised Capital in the amount of EUR 11,542,143
- Creation of a new Authorised Capital 2011 in the amount of EUR 12,680,388
  - This is 50% of the current share capital
  - Authorisation includes up to 10% (2,536,077 shares) of the share capital by excluding subscription rights



# Agenda

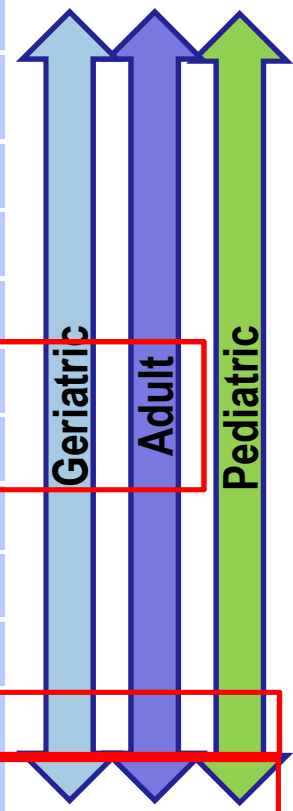
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## Topics

- **Market potential Remimazolam**
- **Partnering**
- **Strategic alignment**
- **Summary**

## 2011 – Market research Remimazolam (Europe)

Procedure	Annual procedures in million	Avg. % sedated	Sedated procedures	Size of physician group
Bone fracture reduction	8,6	10%	862,334	Very Large
Wound care (including lacerations)	5,9	17%	1,128,439	Very Large
Extraction of foreign body	0,8	20%	159,512	Very large
Bladder catheterization	1,6	20%	323,894	Medium
Bronchoscopy	0,9	80%	729,304	Small
Colonoscopy	9,9	90%	8,966,585	Medium
GI endoscopy		72%		Medium
Interventional cardiology	4,1	60%	2,469,154	Very Small
Lumbar puncture	0,5	10%	45,257	Small
Cataract	2,9	40%	1,157,579	Medium
ICU Sedation	*7,6	50%	3,784,896	Small
Anesthesia	35,2	100%	35,200,000	Large



# Fast onset and recovery could save 80 to 90 minutes per day (statement of anesthesiologist)

## Important

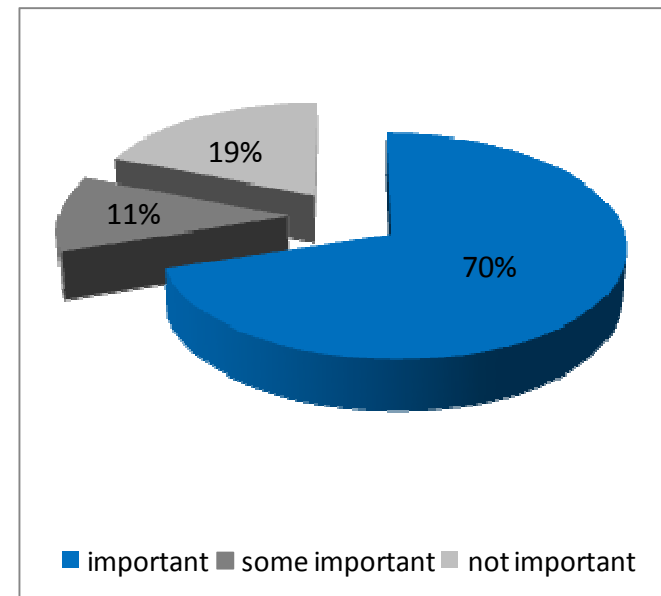
- ✓ Patients wake quicker so transferred quicker - higher throughput
- ✓ Short onset of action and a short duration would be ideal
- ✓ Very important - will expedite cases
- ✓ Useful for diagnostic procedures/ day case surgery
- ✓ Better for the patient, faster recovery
- ✓ Saves time, Could save 80 - 90 minutes per day
- ✓ Would make life easier

## Some importance

- ✓ Important - but not sure currently delayed as a result of sedation
- ✓ Important to discharge to ward fast- but not too fast or they'll come back
- ✓ Already fast

## Not important

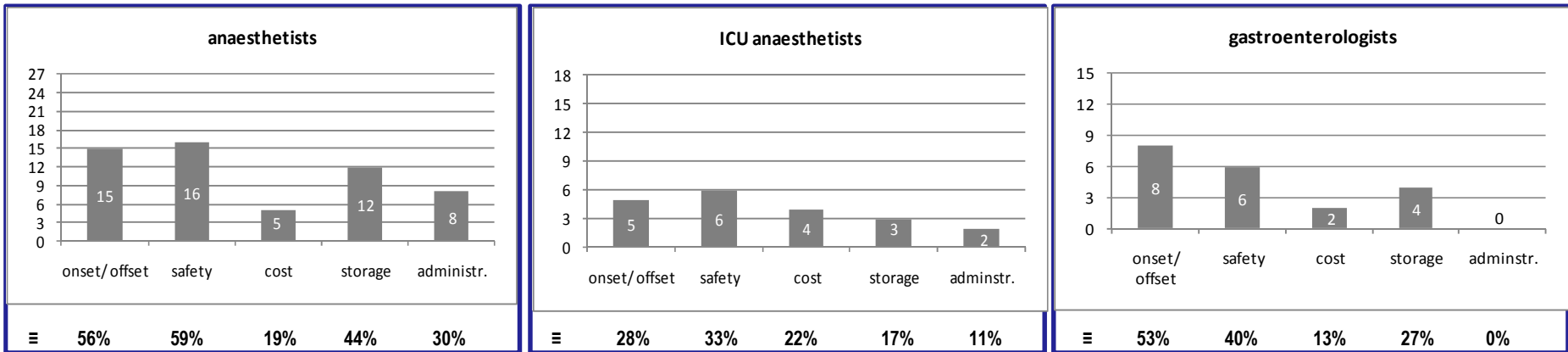
- ✓ It's not something that holds us up at any stage
- ✓ Not apply to Neurological setting
- ✓ Don't work on a production line
- ✓ Not a need, already good
- ✓ Possibility not considered
- ✓ Satisfied with what we have - don't need anything else



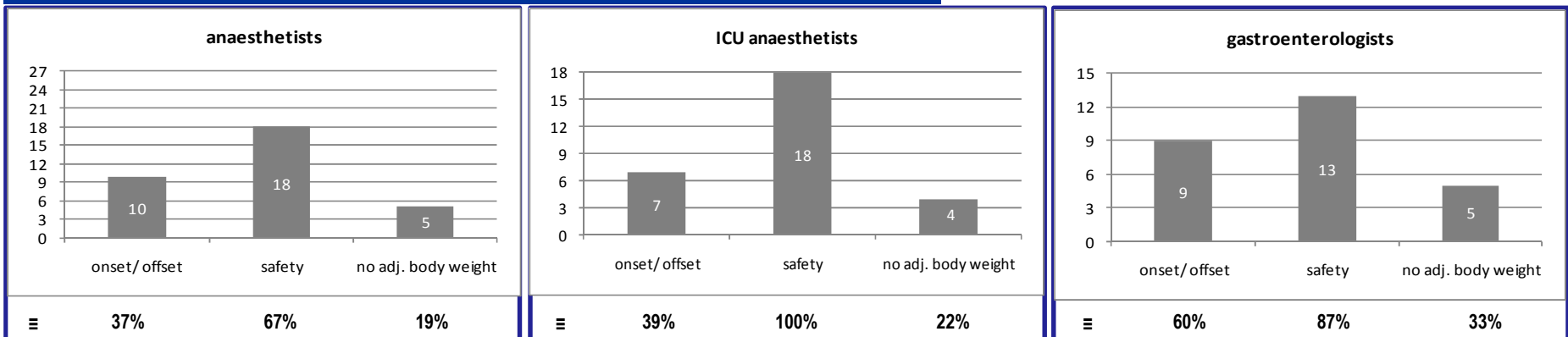
Percentage of interviewees estimating the importance of faster onset and recovery

# Remimazolam addresses most important needs

## Unmet needs regarding anaesthetic drugs

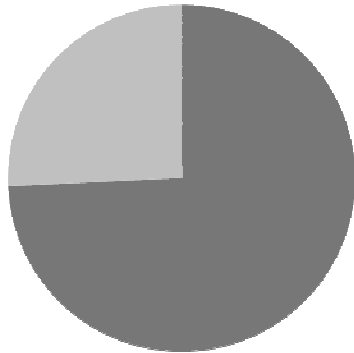


## Perceived main advantages of Remimazolam

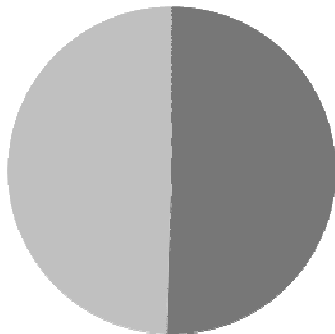


Total number of answers and percentage due to total number of interviewees; multiple answers possible

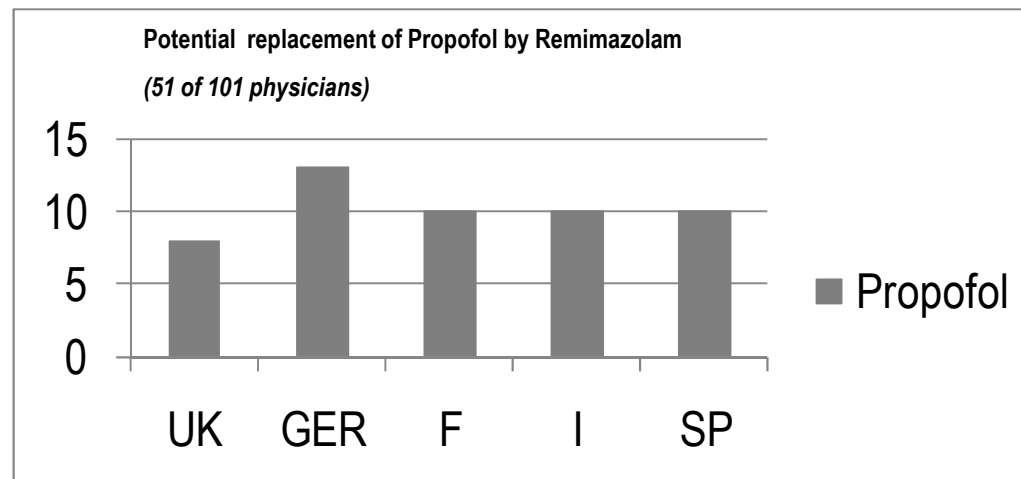
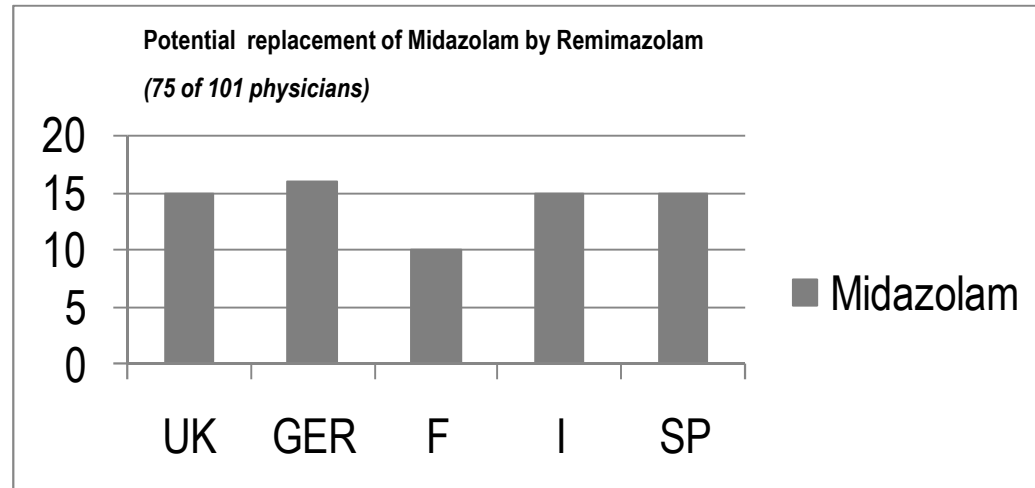
# More than 50% of the physicians would choose Remimazolam



74% willing to switch from Midazolam to Remimazolam



51% willing to switch from Propofol to Remimazolam



## Total hospital market opportunity

Top 15 EU

Numbers in million	2008	2009	2010	2011
Sum of dosages (Midazolam & Propofol) EU15	126	132	137	143
Remimazolam market share	40%	40%	40%	40%

**The total hospital opportunity is based on two main assumptions:**

- In time, Remimazolam will achieve a broad label for IV hospital usage
- Remimazolam will achieve a 40% share of Propofol and Midazolam's usage in the hospitals as physicians indicated a willingness to change by more than 50% across Europe

# Partnering

- **Remimazolam**
  - **Potential deal structures**
    - **Worldwide development**
    - **Regional deals**
      - **US partner with co-development (EU market potential remains at PAION)**
      - **US and EU partner take over complete development**
  - **Conclusion of licence agreement targeted for second half of 2011**
  
- **M6G**
  - **Potential deal structures**
    - **Worldwide development (highly unlikely)**
    - **Focus on regional deals**

## Strategic alignment

- **Apart from development, the mid- and long-term goal is the commercialization in the hospital market**
- **Remimazolam determines strategic alignment and options**
  - **Remimazolam as basis for a EU commercialization**
    - **Worldwide / US partner with co-commercialization**
    - **Market research results confirm potential in EU**
    - **Market access with focused infrastructure**
    - **Co-commercialization of Desmoteplase has synergistic effects**
- **M6G follows the strategy set by Remimazolam**
- **Positioning of Solulin in hemophilia and possibly in the indication radiation injury**

## Summary

- **Financial position**
  - Cash reach until mid 2012
  - EUR 13 million equity facility
  - Significant potential from existing partnerships (> EUR 75 million)
  - Significant potential from future partnerships (M6G & Remimazolam)
- **Progress in several development assets**
  - Remimazolam – PAION (procedural sedation), Ono (anesthesia)
  - Desmoteplase – Lundbeck
  - Solulin (hemophilia)
  - GGF2 – Acorda
- **Potential for corporate development**
  - Co-commercialization rights for Desmoteplase
  - EU commercialization rights Remimazolam



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

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