

# PAIONeers in progress

The PAION Principle

Search  
In-Licensing  
Purchasing  
M&A

return on  
investment

Partnering  
front pay  
reimbursement  
cost-sharing  
milestone payments  
incentives:  
marketing by partner  
(share of turnover)  
co-) promotion



**PAION**

# About PAION

PAION is a biopharmaceutical company headquartered in Aachen, Germany and has a second site in Cambridge, UK.

The company is focusing on the clinical development of drug candidates for diseases or interventions for which there is a substantial unmet medical need. The current development portfolio comprises inter alia substances for the treatment of acute ischaemic stroke, procedural sedation as well as pain treatment. After proof of concept in humans the strategy is to out-license or co-develop the drug candidates with pharma partners. Currently PAION is engaged in partnerships with H. Lundbeck A/S (Denmark), Ono Pharmaceutical Ltd (Japan) and Acorda Therapeutics (USA). Based on this business model revenues can be generated at an early stage, decreasing development costs and risks. The company further profits from the receipt of payments for reaching clinical and commercial milestones and receiving royalties after market approval of the drugs. Further upside can be generated from co-commercialisation activities.

PAION is listed at the Frankfurt Stock Exchange (Prime Standard Regulated Market, Stock Symbol PA8, ISIN DE000A0B65S3).

# Management

## Dr Wolfgang Söhngen, CEO

- PhD, Diploma in Pharmaceutical Medicine and Master of Business Communication
- Founder of PAION Deutschland GmbH (2000) and PAION AG (2004)
- Over 20 years experience in drug development and strategic planning at globally operating pharmaceutical companies



## Bernhard Hofer, CFO

- Bank officer
- Over 20 years experience in banking at various leading banks with a strong focus on corporate financing
- At PAION since 2001 (Head of Finance); member of the Management Board since 2004








## Dr Mariola Söhngen, CMO

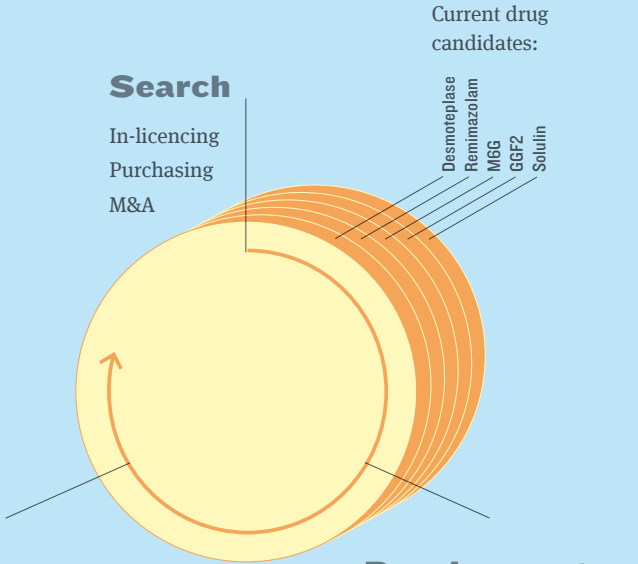
- PhD, Diploma in Pharmaceutical Medicine and Master of Business Communication
- Co-founder of PAION Deutschland GmbH (2000) and PAION AG (2004)
- Over 20 years experience in clinical development, licensing and strategic project evaluation at globally operating pharmaceutical companies



# Pipeline

	Preclinical	Phase I	Phase II	Phase III	Partner
<b>Desmotepase</b> (i.v. plasminogen activator)					H. Lundbeck A/S (worldwide)
<b>M6G</b> (i.v. opioid)					-
<b>Remimazolam</b> (i.v. anesthetic/sedative)					Ono Pharmaceutical (Japan)
<b>Solulin</b> (i.v. thrombomodulin)					-
<b>GGF2</b> (i.v. glial growth factor)					Acorda Therapeutics (worldwide)

# The PAION Principle



Current drug candidates:

## Search

- In-licencing
- Purchasing
- M&A

- Desmoteplase
- Remimazolam
- M6G
- GGF2
- Solulin

## Return on Investment

### Partnering/Out-licencing

- Upfront payments
- Reimbursements
- Cost-sharing
- Milestone payments

### Sales:

- Marketing by partner (share of turnover)
- (Co-) promotion

## Development

- Optimisation of development strategy
- Production
- Preclinical development
- Clinical development
- Proof of concept

# The PAION Principle

PAION AG is a biopharmaceutical company specialized in developing and commercializing innovative drugs for the hospital-based treatment in indications for which there is a substantial unmet medical need.

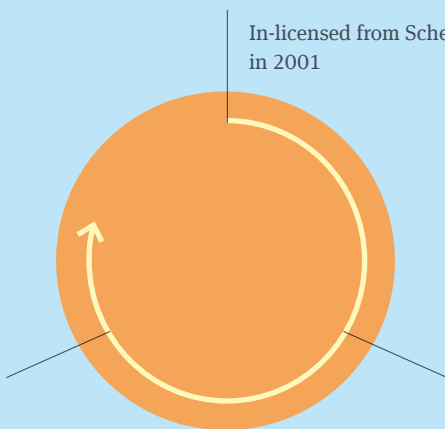
It is PAION's strategy to out-license the drug candidates to pharmaceutical companies after proof of concept in humans, or to enter a collaboration to further develop and to commercialise them. Thus financial income can be generated at an early development stage of the drug candidates, at the same time decreasing development costs and risks. The company profits by means of milestone payments for clinical and commercial successes as well as royalties after market approval of a drug. As soon as a drug is ready to be marketed, further revenues can be generated from co-commercialisation activities.

# Desmoteplase

**Indication:** Acute ischaemic stroke

## Search

In-licensed from Schering AG  
in 2001



## Return on Investment

**Pharma partner:** H. Lundbeck A/S (worldwide)

**Already received:** EUR 61.5 million upfront payments, milestone payments and cost-reimbursements

**Outstanding:** EUR 68 million milestone payments plus double-digit percentage net royalties

**Estimated peak sales:** US\$ 600 million (PAION estimate)

**Earliest filing:** 2012 (source: Lundbeck)

**Market exclusivity until:** 2022+

## Development

**Target product label:** Widening treatment window in stroke up to 9h in patients requiring reperfusion (currently 0–3h)

**Status:** Further Phase III trials launched by Lundbeck in 2008

**Development costs:** Fully funded by Lundbeck

# Desmoteplase

**Indication:**

Acute ischaemic stroke

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**Estimated peak sales:**

US\$ 600 million (PAION estimate)

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**Target product label:**

Widening treatment window in stroke up to 9 h in patients requiring reperfusion

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**Earliest filing:**

2012 (source: Lundbeck)

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**Market exclusivity until:**

2022+

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**Partner:**

H. Lundbeck A/S (worldwide)

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**Status:**

Phase III

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**Highlights:**

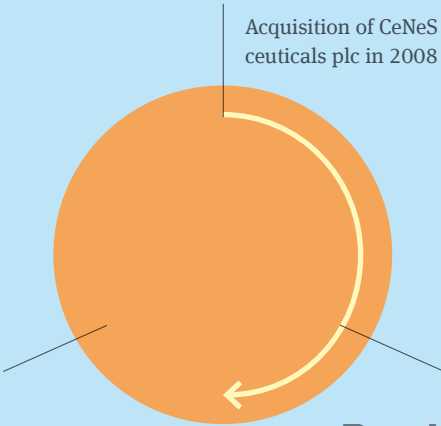
- Desmoteplase is the most specific clot buster
- Treatment window up to nine hours (compared to rt-PA three hours) with good safety profile
- No competitive reperfusion products in late-stage development in ischaemic stroke
- Further Phase III trials launched by Lundbeck in 2008
- All development costs fully funded by Lundbeck
- Licencing terms
  - Future milestones of up to EUR 68 million (EUR 40 million until approval, EUR 28 million on launch and pre-defined sales targets)
  - Double digit net royalties
  - PAION retains co-promotion rights for the German-speaking countries

# Remimazolam

**Indication:** Anaesthesia/procedural sedation

## Search

Acquisition of CeNeS Pharmaceuticals plc in 2008



## Return on Investment

**Pharma partner:** Ono Pharmaceutical Co., Ltd. (Japan)

**Estimated peak sales:** US\$ 500 million

**Earliest launch:** 2014

**Market exclusivity until:** 2027+

## Development

**Target product label:** Titrable and predictable anaesthesia/sedation with short wake-up time

**Status:** Phase-III-ready (procedural sedation); Phase II (anaesthesia, Japan)

# Remimazolam

**Indication:**

Anaesthesia/Sedation

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**Estimated peak sales:**

US\$ 500 million

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**Target product label:**

Titrable and predictable anaesthesia/sedation with short wake-up time

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**Earliest launch:**

2014

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**Market exclusivity until:**

2027+

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**Partner:**

Ono Pharmaceutical Co., Ltd. (Japan)

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**Status:**

Phase-III-ready (procedural sedation); Phase II (anaesthesia, Japan)

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**Highlights:**

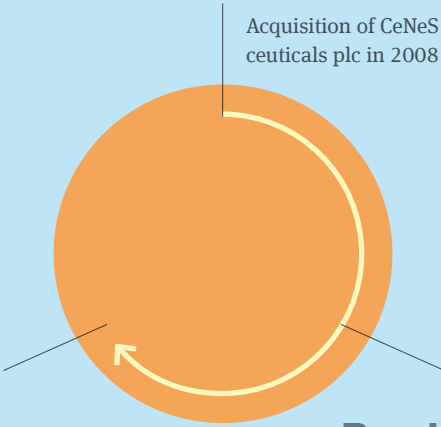
- Remimazolam is an ultra short acting anaesthetic/sedative activating the GABA<sub>A</sub> receptor
- Target profile substantiated by PAION in four clinical trials (two Phase I; two Phase II)
- Low risk of over sedation or respiratory depression, less monitoring required and earlier discharge expected
- More predictable pharmacokinetics when compared to the most commonly used short acting sedatives due to metabolism by tissue esterases
- First target indication pursued by PAION: procedural sedation. Attractive potential in induction and maintenance of anaesthesia (focus of our partner Ono) and sedation for ICU care or during imaging
- Low level of competitor development programmes
- Fast development programme with launch approx. 2014 (EU, US)

# M6G

**Indication:** Peri-operative pain

## Search

Acquisition of CeNeS Pharmaceuticals plc in 2008



## Return on Investment

**Estimated peak sales:**  
US\$ 300 million

**Earliest launch:** 2014

**Market exclusivity until:** 2020+

## Development

**Target product label:** Well tolerated mono therapy for the treatment of peri-operative pain

**Status:** About 1,000 patients on drug in clinical database; Phase III

# M6G

**Indication:**

Peri-operative pain

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**Estimated peak sales:**

US\$ 300 million

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**Target product label:**

Well tolerated mono therapy for the treatment of peri-operative pain

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**Earliest launch:**

2014 (with partner)

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**Market exclusivity until:**

2020+

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**Partner:**

Pending

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**Status:**

Phase III

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**Highlights:**

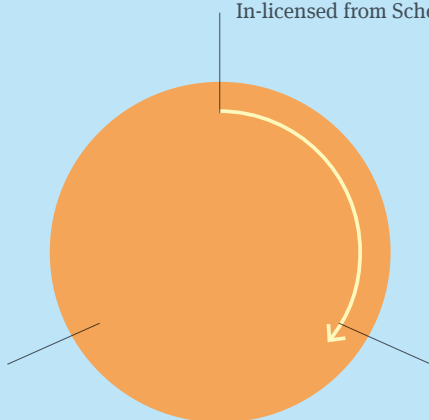
- M6G is a highly potent opioid with favorable pharmacokinetics resulting in a better safety profile (less nausea/vomiting/sedation)
- First target indication for PAION: peri-operative pain
- About 1,000 patients on drug in clinical database
- Meta analysis showed that M6G has a wider therapeutic window than morphine at equi-analgesic dosages with a lower incidence of post-operative nausea and vomiting; to be confirmed in Phase III
- Phase III development plan for this New Chemical Entity agreed with FDA
- Comprehensive market research shows premium pricing opportunity

# Solulin

**Indication:** Haemophilia; radiation injury

## Search

In-licensed from Schering AG in 2001



## Return on Investment

**Estimated peak sales:**  
US\$ 200–400 million  
(dependent on indication)

**Market exclusivity until:** 2030+

## Development

**Target product label:**  
Normalisation of hyper-fibrinolysis in haemophilic patients; protection against radiation injury

**Status:** Phase I

# Solulin

**Indication:**

Haemophilia; radiation injury

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**Estimated peak sales:**

US\$ 200–400 million

---

**Target product label:**

Normalisation of hyper-fibrinolysis in haemophilic patients; protection against radiation injury

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**Market exclusivity until:**

2030+

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**Partner:**

Pending

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**Status:**

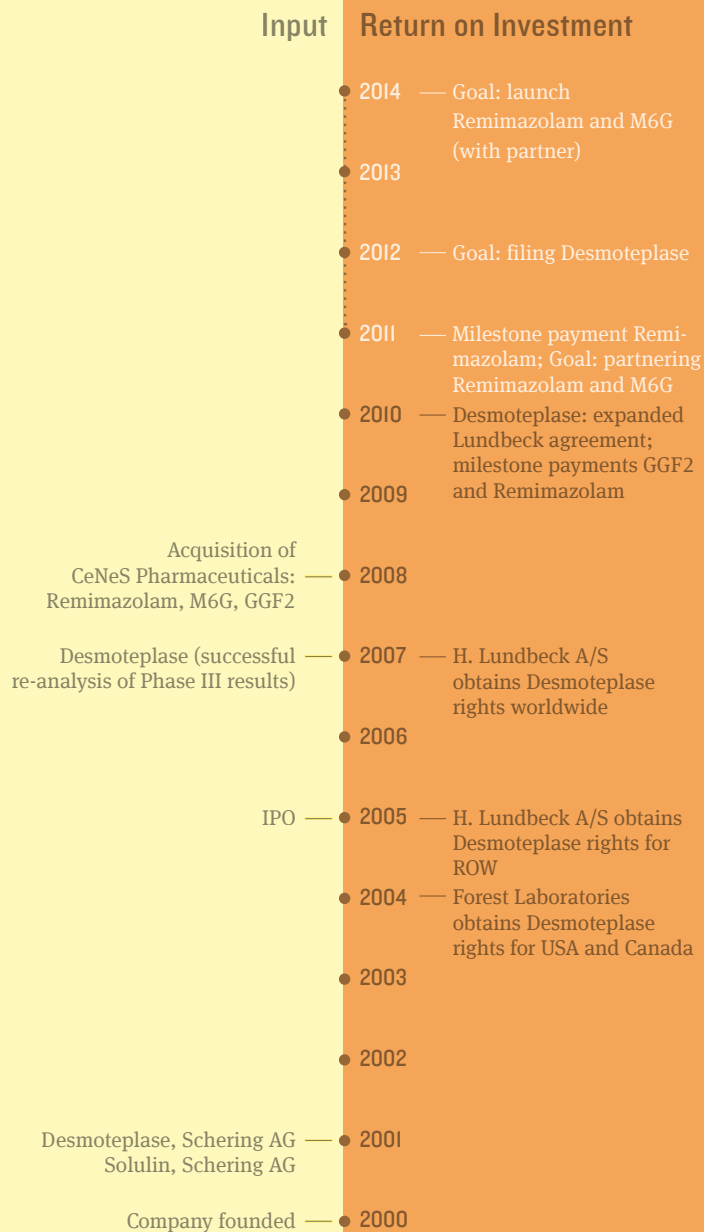
Phase I

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**Highlights:**

- Safety confirmed in first-in-man trial over a range of doses
- Pre-clinical data in haemophilia demonstrate promising approach
- Pre-clinical activities in the indication radiation injury
- Excellent pre-clinical data in stroke
- Protected internationally by substance and use patents

# Milestones



## Information on PAION shares

Market segment: Regulated Market/Prime Standard

Stock identification number: PA8

ISIN: DE000A0B65S3

First day of trading: 11. February 2005

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