

# PAION Q3#2011

Consolidated Financial Interim Report for the Third Quarter 2011  
and the Nine-Month Period ending 30 September 2011

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PAION AG



## About PAION AG

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

The company is specialised in developing and commercialising innovative drugs for the hospital-based treatment in indications for which there is a substantial unmet medical need. After proof of concept in humans the strategy is to out-license or co-develop the drug candidates with pharma partners. Thus 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 commercialisation activities.

## Key Figures

(all figures in KEUR unless otherwise noted)	Q3 2011	Q3 2010	Q1-Q3 2011	Q1-Q3 2010
Revenues	243	368	3,066	2,604
Research and development expenses	-1,347	-2,226	-4,380	-6,579
General administrative and selling expenses	-979	-1,082	-3,529	-3,312
Loss for the period	-2,164	-2,992	-5,056	-7,319
Earnings per share in EUR for the period (basic)	-0.09	-0.12	-0.20	-0.30
Earnings per share in EUR for the period (diluted)	-0.09	-0.12	-0.20	-0.30

	Q1-Q3 2011	Q1-Q3 2010
Cash flows from operating activities	-5,043	-7,390
Cash flows from investing activities	-41	-21
Cash flows from financing activities	179	-442
Change in cash and cash equivalents	-4,917	-7,838
Average number of group employees	25	29

	30 Sept. 2011	31 Dec. 2010
Intangible assets	10,022	10,571
Cash and cash equivalents	9,965	14,882
Equity	7,740	11,968
Non-current liabilities	10,132	10,483
Balance sheet total	21,093	26,836
Equity ratio	36.7%	44.6%

# Interim Group Management Report for the Nine-Month Period ending 30 September 2011

## The First Nine Months at a Glance

### April

Dr Gavin Kilpatrick stepped down from his position as a member of the Management Board and left the company.

### May

The Annual General Meeting elected Dr Harald F. Stock to the Supervisory Board.

PAION received second milestone payment of three million USD from Ono Pharmaceutical for the start of Japanese Phase II study with Remimazolam.

### August

PAION started Phase Ib study in haemophilia with Solulin.

## Developments of the Third Quarter 2011

- Due to reservations towards pharma sector investments and the currently difficult financial environment the partnering discussions with potential licensees for out-licensing of Remimazolam and M6G pose a greater challenge than expected
- Successful production of Remimazolam API for Phase III
- Start of a Phase Ib study with Solulin in the indication haemophilia
- Loss for the period reduced by EUR 2.3 million (30.9%) compared to the prior-year period
- Cash and cash equivalents of EUR 10.0 million secure a cash reach into the third quarter 2012 (without additional cash inflows and based on current structure)

## Development and Commercialisation Activities

In the first nine months of 2011 the efforts to find partners for Remimazolam and M6G were continued on an intensive basis.

Based on the excellent results of the Phase IIb trial with Remimazolam in colonoscopy, PAION is currently in discussion with interested parties. Findings from a marketing study conducted early 2011 confirm the market potential of Remimazolam and the current significant need for anaesthetics/sedatives with a high safety profile and a fast onset of action. In preparation of the further clinical development PAION has completed the production of Remimazolam API for Phase III.

Regarding the substance M6G for the treatment of peri-operative pain there are also discussions ongoing on continuing the development together with several partners in regional deal structures.

However, due to the difficult financial market conditions and current restrained investments of the pharma industry, negotiations pose a greater challenge to the company than expected. Therefore, the licensing agreements for Remimazolam and M6G are not likely

to be closed in 2011 and will be delayed due to the current unfavourable conditions. However, it is difficult to predict a clear time frame. The partnering of Remimazolam is being pursued with highest priority.

For the Japanese market Remimazolam is currently being developed in anaesthesia by PAION's partner Ono Pharmaceutical. In May 2011 Ono initiated the first Phase II trial with Remimazolam in Japan, which triggered a milestone payment to PAION of USD 3 million.

Following the announcement of positive preclinical data in the indication haemophilia in December 2010, PAION has selected haemophilia as the new lead indication for Solulin. Solulin has the potential to significantly improve the existing treatment modalities for the patients. In the first half year of 2011 a number of activities were undertaken to substantiate the safety and efficacy profile of Solulin in preclinical and ex vivo studies. On the basis of these data a clinical Phase Ib study was initiated in the indication haemophilia.

## Financial Overview

Revenues increased by KEUR 462 compared to the prior-year period. Research and development expenses decreased considerably compared to the prior-year period. The decrease is due to reduced development activities. The main research and development focus in the first nine months of 2011 was on Remimazolam and Solulin. General administrative and selling expenses increased compared to the prior-year period because of higher selling expenses in connection with partnering activities. The loss for the first nine months of 2011 of KEUR -5,056 was KEUR 2,263 lower than in the corresponding prior-year period (KEUR -7,319).

Cash and cash equivalents decreased by KEUR 4,917 in the first nine months 2011. As of 30 September 2011 PAION's cash and cash equivalents amounted to KEUR 9,965. The cash and cash equivalents secure a cash reach into the third quarter 2012. This does not account for further cash inflows from existing and future partners and does not account for cost cutting measures. Furthermore PAION has access to a remaining equity facility of EUR 13.2 million.

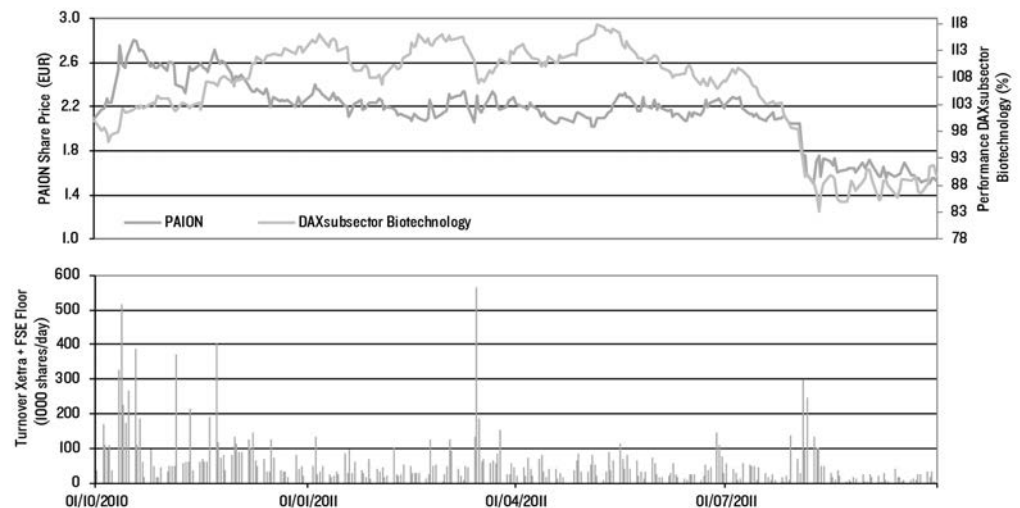
## Capital Market Environment and PAION Share Performance

Far-reaching global events influenced the behaviour on the financial markets during the first nine months of 2011. Besides the natural and nuclear disaster in Japan at the beginning of the year, the capital markets were impacted by the political unrest in the Arab countries. Also the ongoing EU government debt crisis contributes to the analysts' strong uncertainty. The current situation of the financial markets is characterised by anxiety and increased volatility. This environment has contributed to the restrained investments of the pharmaceutical industry. In this difficult environment not only the total market was at loss. Especially the German benchmark index DAXsubsector Biotechnology suffered a loss of more than 24% in value during the first nine months.

The PAION share started the year 2011 at a price of EUR 2.31 (Xetra), marking a peak price in the first nine months of 2011 on 4 January 2011 with a closing price of EUR 2.40 (Xetra) and marking a low price on 8 August 2011 with EUR 1.49 (Xetra). The closing price on 30 September 2011 was EUR 1.53 (Xetra). This corresponds to a decrease of 32% compared to the closing price of 2010 (EUR 2.24; Xetra).

The average daily trading volume (Xetra and Frankfurt Stock Exchange) amounted to 52,497 shares during the first nine months of 2011 (in the year 2010: 73,620 shares). Thereby 8.9 million shares (35.4% of total shares) were traded during the first nine months of 2011 (in the year 2010: 18.8 million shares and 76% of total shares, respectively).

### Development of the PAION Share Price (Xetra) in the First Nine Months 2011



## Overview of Research and Development Activities

### Remimazolam

Remimazolam is an innovative short-acting general anaesthetic/sedative that is being developed by PAION initially for use in minor medical interventions (procedural sedation). Sedatives are used, for example, in endoscopic procedures such as colonoscopies. After intravenous administration to over 300 human volunteers/patients in the course of the clinical trials performed, Remimazolam has clearly shown a controllable sedative effect with rapid onset and offset. This means that the patient can be selectively sedated for the duration of the intervention and rapidly regains full consciousness after the procedure. The rapid offset of the effect of the substance is due to its metabolism by tissue esterase enzymes that are widely distributed throughout the body.

Remimazolam has additional potential in anaesthesia, which is the initial indication being developed by PAION's partner Ono Pharmaceutical Co., Ltd. (Ono) for the Japanese market. Furthermore, Remimazolam could also be used as a sedative during artificial respiration in the Intensive Care Unit (ICU).

#### **Clinical Development**

The clinical studies performed with Remimazolam comprise two Phase I and two Phase II studies with single or multiple dose without an intervention or during endoscopy of the upper gastrointestinal tract or the colon.

The generated data indicate a good tolerability of Remimazolam. A rapid onset and offset of the sedative effect was observed during the procedures. It was also shown that it is possible to achieve the same (safety) or better (efficacy) results with single or multiple dosing of Remimazolam as compared to single or multiple dosing of the gold standard Midazolam. The effect of Remimazolam can be reversed by the benzodiazepine antagonist Flumazenil.

Based on the results of the Phase IIb study, the optimal dose regimens for Phase III studies can now be defined.

#### **Cooperation Agreements**

In 2007 Ono was granted the rights to develop and market Remimazolam for the Japanese market in return for the commitment of development milestone payments and royalties. Ono is developing Remimazolam for the indication anaesthesia, whereas PAION initially concentrates on indications requiring single or repeated bolus dosing to sedate patients for short procedures. In this co-operation, data and information are continually shared so that each party benefits from the development progress of the other party.

With the additional data the progress that has been made will help to support and accelerate the development of Remimazolam for the indication anaesthesia in the PAION territories.

PAION is currently in discussions with potential licence partners to advance the development of Remimazolam, preferably for multiple indications, as quickly as possible as well as to prepare for subsequent commercialisation.

## Morphine-6-glucuronide

Morphine-6-glucuronide (M6G), a highly potent opioid, demonstrated a strong analgesic effect in clinical Phase II and Phase III studies in the treatment of moderate to severe peri-operative pain. At the same time common opioid side effects, such as nausea and vomiting, were significantly reduced with M6G as compared to morphine.

### **Clinical Development**

PAION has performed various in-depth analyses of the available clinical data. The results support PAION's view that M6G has a wider therapeutic window than morphine at equi-analgesic dosages with a lower incidence of post-operative nausea and vomiting. Based on these findings a development plan has been agreed with the FDA for this New Chemical Entity, i.e. a novel, distinct substance. This improves the potential profitability for potential pharma partners as it provides the prospect for longer market exclusivity. The aim of the remaining Phase III programme is to show that M6G causes significantly less post-operative nausea and vomiting compared to equi-analgesic doses of morphine.

### **Cooperation Agreements**

The intellectual property rights for M6G are based on PAION's own development activities as well as rights acquired from third parties. In connection with this third party intellectual property, PAION has success-related obligations in the form of milestones and royalties.

Despite the positive results of the in-depth re-analysis and the encouraging FDA consultation PAION has so far not been able to conclude a global partnership for M6G. Currently PAION is in discussions on continuing the development together with several partners in regional deal structures.

## Desmoteplase

Desmoteplase is a recombinant protein (a so-called plasminogen activator) derived from the saliva of the vampire bat, *Desmodus rotundus*, which is intravenously administered to dissolve blood clots. It is currently being developed for the treatment of acute ischaemic stroke. The treatment is being carried out in a timeframe of three to nine hours post onset of stroke symptoms – a time window for which there currently is no approved drug treatment.

### **Clinical Development**

So far Desmoteplase has been tested in two Phase II studies and one Phase III study for the treatment of acute ischaemic stroke. In 2008 PAION's licence partner H. Lundbeck A/S (Lundbeck) took on the further development of Desmoteplase. In 2008 Lundbeck initiated a further Phase III development programme consisting of two comparable studies (DIAS-3 and DIAS-4). Furthermore, in 2010 Lundbeck initiated a Phase II study in Japan (DIAS-J).

On 10 August 2011 Lundbeck reported that the Phase III studies, DIAS-3 and DIAS-4, have now seen improved patient recruitment following several initiatives to speed up recruitment. The programme had as previously reported not developed at the expected pace and Desmoteplase will therefore be unable to deliver a filing as anticipated in the second half of 2012, but more likely in first half of 2014.

### **Cooperation Agreements**

PAION in-licensed Desmoteplase from Bayer HealthCare (formerly Schering AG) in 2001 in return for milestone payments and royalties. Today Lundbeck holds the exclusive global rights for research, development, production and marketing of Desmoteplase. The licence agreement came into effect in 2008 and was extended in 2010, to include potential follow-on compounds. Under these agreements, Lundbeck agreed to undertake the following payments:

- Payment of a non-refundable amount of EUR 8 million upfront payment, on the date the agreement took effect (January 2008; disclosed as deferred income and being released proportionally over the probable development period),
- Payment of a non-refundable purchase price of EUR 1.5 million, on the date the extended agreement took effect (October 2010),
- Milestone payments for Desmoteplase of up to EUR 68 million, of which up to EUR 40 million relate to milestones due before and including market approvals (regional splitting) and in total EUR 28 million are due upon commencement of marketing activities and the achievement of specific revenue targets,
- Milestone payments for the second generation molecules (follow-on compounds) of up to EUR 25 million for development and commercialisation,
- Assumption of all costs, especially for clinical development, production development, patent costs and marketing approval,
- Payment of licence fees (dependent on revenues) which amount to a low double-digit percentage following the deduction of the licence fees PAION has to pay to the original licensor, Bayer HealthCare.

PAION has reserved the option to co-promote Desmoteplase in Germany, Austria and Switzerland. If PAION decides to exercise this option it will receive a direct share of earnings rather than licence fees based on revenues.

## Solulin

Solulin is an improved variant of the human protein thrombomodulin, an important natural regulator of the clotting system. One of the functions of thrombomodulin is to stabilize the initial fibrin clot to stop bleeding. Other than native thrombomodulin which is anchored in the wall of blood vessels, Solulin can enter the blood stream to reach its potential site of action. In low concentrations Solulin is able to stabilise blood clots and to support coagulation. Haemophilia patients could benefit from this property.

According to the WHO about 400,000 people worldwide are currently affected by the hereditary disease haemophilia, including 10,000 in Germany. Therefore, the definition of an “orphan disease” is fulfilled. Solulin has the potential to significantly improve the existing treatment modalities for the patients.

Following the announcement of positive preclinical data PAION has selected haemophilia as the new lead indication for Solulin. In the first half year of 2011 a number of activities were undertaken to substantiate the safety and efficacy profile of Solulin in preclinical and ex vivo studies. Based on these data a clinical Phase Ib study could be initiated in August 2011.

Apart from the positioning in this indication, the possible use of Solulin for the treatment of radiation injury is being further evaluated.

### **Clinical Development**

Solulin already has been successfully tested in a Phase I study (first in man) which confirmed the excellent safety profile of the substance. In August 2011 an open label, randomized, multicenter, dose finding Phase Ib study was initiated evaluating the safety, pharmacokinetics and pharmacodynamics of single intravenous doses of Solulin in patients with severe haemophilia A receiving chronic therapy with coagulation factor VIII. First results of the study are expected in 2012.

## GGF2

GGF2 (Glial Growth Factor 2) is known to stimulate the growth and differentiation of a variety of cells including glial cells, the support cells of the nervous system. These glial cells form the myelin sheath that insulates nerve cells and is essential for their survival and proper functioning. In demyelinating diseases such as multiple sclerosis, the myelin sheath is damaged, leading to the degeneration of nerve cells.

In preclinical studies PAION's licence partner Acorda Therapeutics, Inc. (Acorda) demonstrated that GGF2 can stimulate the cell growth necessary to protect and regenerate a damaged myelin sheath. GGF2 is the lead neuregulin in Acorda's portfolio. Neuregulins have also shown the ability to restore cardiac function in preclinical models of heart failure caused by myocardial infarction, rapid pacing, viral and chemically induced cardiomyopathies.

In December 2010 Acorda announced the start of the first Phase I study. The early phase clinical research on GGF2 is funded by a USD 1 million Cardiac Translational Research Implementation Program (C-TRIP) grant awarded by the US National Heart, Lung and Blood Institute (NHLBI). Acorda expects to present initial study results at a meeting in the first half of 2012.

### Cooperation Agreements

The rights relating to the recombinant GGF2, rh GGF2, were licensed to Acorda in 2002 by PAION UK. In total, further milestone payments of USD 2.5 million prior to market approval and an additional milestone payment of USD 5 million are due upon market authorisation; after that PAION will receive revenue dependent royalties.

### Pipeline Overview

	Preclinical	Phase I	Phase II	Phase III	Partner
<b>Desmoteplase</b> (i.v. plasminogen-activator)	Acute ischaemic stroke				H. Lundbeck A/S (worldwide)
<b>M6G</b> (i.v. opioid)	Peri-operative pain				-
<b>Remimazolam</b> (i.v. anaesthetic/sedative)	Procedural sedation (PAION) Anaesthesia (Ono)				Ono Pharmaceutical (Japan)
<b>Solulin</b> (i.v. thrombomodulin)	Haemophilia				-
<b>GGF2</b> (i.v. glial growth factor)	Heart failure				Acorda Therapeutics (worldwide)

## Net Assets, Financial Position, and Results of Operations

### Results of Operations

	Q3 2011 KEUR	Q3 2010 KEUR	Q1-Q3 2011 KEUR	Q1-Q3 2010 KEUR
Revenues	243	368	3,066	2,604
Cost of revenues	0	-2	-1	-15
Gross profit	243	366	3,065	2,589
Research and development	-1,347	-2,226	-4,380	-6,579
General administrative and selling	-979	-1,082	-3,529	-3,312
Other income (expenses)	18	-28	35	70
Operating expenses	-2,308	-3,336	-7,874	-9,821
Operating result	-2,065	-2,970	-4,809	-7,232
Financial result	-183	-141	-499	-416
Income taxes	84	119	252	329
Loss for the period	-2,164	-2,992	-5,056	-7,319

**Revenues** in the first nine months of 2011 amounted to KEUR 3,066 and increased by KEUR 462 (17.7%) compared to the prior-year period. The revenues relate in the amount of KEUR 2,083 (USD 3 million) to a milestone payment from Ono for the start of the Phase II study with Remimazolam in Japan. Furthermore the revenues relate in the amount of KEUR 967 (prior-year period: KEUR 1,091) to the systematic release of deferred income in connection with the licence agreement concluded with Lundbeck. The monthly release of the deferred income was adjusted in August 2011 due to the delay of the expected filing date for Desmoteplase.

**Research and development expenses** amounted to KEUR 4,380 in the first nine months of 2011. This means a decrease of KEUR 2,199 (33.4%) compared to the prior-year period. The decrease is due to reduced development activities. The main research and development focus in the first nine months of 2011 was on Remimazolam and Solulin.

**General administrative and selling expenses** increased in the first nine months of 2011 by KEUR 217 (6.6%) to KEUR 3,529. The increase results from higher selling expenses in connection with partnering activities and market research.

The **financial result** for the first nine months of 2011 amounted to KEUR -499; a decrease of KEUR 83 compared to the prior-year period.

The **income taxes** are attributable to tax claims for reimbursement of parts of the research and development costs from the British tax authorities.

The **loss** for the first nine months of 2011 amounted to KEUR -5,056 meaning a decrease of KEUR 2,263 (30.9%) compared to the prior-year period.

## Net Assets

	30 Sept. 2011 KEUR	31 Dec. 2010 KEUR	Change KEUR
Non-current assets	10,211	10,768	-557
Current assets	10,882	16,068	-5,186
<b>Total Assets</b>	<b>21,093</b>	<b>26,836</b>	<b>-5,743</b>
Equity	7,740	11,968	-4,228
Non-current liabilities	10,132	10,483	-351
Current liabilities	3,221	4,385	-1,164
<b>Total Equity and liabilities</b>	<b>21,093</b>	<b>26,836</b>	<b>-5,743</b>

The **non-current assets** mainly comprise the development projects M6G (KEUR 6,058) and Remimazolam (KEUR 3,915).

The KEUR 5,186 decrease in **current assets** is mainly attributable to the decrease in cash and cash equivalents (KEUR 4,917).

The **equity** decreased mainly due to the loss for the period by KEUR 4,228 compared to 31 December 2010 and amounted to KEUR 7,740. As of 30 September 2011 the equity ratio is 36.7%, which means a decline compared to 31 December 2010 (44.6%). If the subordinate loan and the deferred non-refundable upfront payment from Lundbeck were recognised as economic equity, the equity ratio would increase to 82.2%.

The decrease of KEUR 351 in **non-current liabilities** is mainly attributable to the proportionate release of the deferred income in connection with the licence agreement concluded with Lundbeck. Because of the delay of the expected filing date for Desmotepase, KEUR 743 of the deferred income was reclassified from current liabilities into non-current liabilities.

The decrease of KEUR 1,164 in **current liabilities** is mainly attributable to the reclassification of deferred income as well as the decrease of trade payables and the decrease of other liabilities.

## Financial Position

Compared to 31 December 2010 **cash and cash equivalents** decreased by KEUR 4,917 to KEUR 9,965. The change in cash and cash equivalents stems from the following areas:

	Q1-Q3 2011 KEUR	Q1-Q3 2010 KEUR
Cash flows from operating activities	-5,043	-7,390
Cash flows from investing activities	-41	-21
Cash flows from financing activities	179	-442
Effects of exchange rate changes	-12	15
Change in cash and cash equivalents	-4,917	-7,838

The **cash flows from operating activities** in the first nine months of 2011 (KEUR -5,043) were mainly due to the loss for the period of KEUR -5,056.

The **cash flows from financing activities** in the first nine months of 2011 result mainly from a capital increase of KEUR 600 in return for the issue of 287,092 new shares as well as from interest payments for the subordinated loan (KEUR -442).

## Personnel Development

On average, PAION employed 25 employees in the first nine months of 2011 (fiscal year 2010: 28 employees).

## Risks and Opportunities

The risks and opportunities as mentioned in the "Risks and Opportunities Report" of the group management report for fiscal year 2010 remain unchanged for PAION for the current year. Potential effects of the development of particular material risks or opportunities are described in the appropriate sections of the quarterly report, for instance in the overview section on page 3 to 5, in the description of development activities and cooperations as well as in the forecast report.

## Significant Events Occurring After the Balance Sheet Date

No significant events occurred in the time period between the balance sheet date, 30 September 2011, and the finalisation of this report.

## Forecast Report

### Economic Conditions

The increased uncertainties of investors regarding the Euro zone debt crisis negatively impact the refinancing opportunities of the biotech industry. Investors are increasingly withdrawing from the biotechnology sector and pharmaceutical companies are more selective in terms of product acquisitions. Overall, this has led to a significant decline in investments but also to a considerable decline in deal flow. This also directly affects PAION.

### Development and Commercialisation Activities

PAION's major goals for 2011 and 2012 are the out-licensing of Remimazolam and M6G as well as further development of Solulin. Furthermore, PAION expects extensive development activities by the cooperation partners Lundbeck (Desmoteplase), Ono (Remimazolam) and Acorda (GGF2).

Based on the results of the Phase IIb study PAION intends to out-license the development and marketing rights for Remimazolam (outside Japan). In case of a successful out-licensing PAION expects to receive a substantial upfront payment, development milestone payments, a partial or complete assumption of future development costs until market approval and royalties from market approval onwards. Cooperation partner Ono started a Phase II study with Remimazolam in Japan in 2011. PAION benefits from the progress of development in the form of additional development data and benefits financially in the form of milestone payments and royalties from launch onwards.

Cooperation partner Lundbeck is currently conducting two Phase III studies (world-wide) and a phase II study (Japan) with Desmoteplase in stroke and expects to file marketing applications in the first half of 2014. Lundbeck bears all development costs and pays to PAION milestones of up to EUR 68 million, thereof up to EUR 40 million are due before and including market approvals, and with market entry a double-digit percentage net revenue share. If the further development is successful, based on Lundbeck's development plan, further milestone payments can be expected from 2013 onwards.

Acorda started a clinical Phase I study with GGF2 at the end of 2010. Milestone payments of up to USD 7.5 million before and including approval, and thereafter revenue-dependent licence fees are payable to PAION if the further development is successful.

### Financial Forecast

Revenues in 2011 will include the milestone payment of EUR 2.1 million received from Ono for the development progress with Remimazolam and the systematic release of deferred income in the amount of EUR 1.1 million. This results from the non-refundable milestone payment of EUR 8 million received in 2008 from Lundbeck; the monthly release was reduced from August 2011 onwards.

Research and development expenses will be considerably lower than the previous year. The out-licensing activities will lead to increased selling expenses compared to previous

years, especially in connection with consulting services. The budgeted expenses will lead to a significant net loss in 2011.

From the existing cooperations with Lundbeck, Ono and Acorda PAION expects the next cash inflows from 2012 onwards. Some of the milestone payments, which are expected in the future, are linked to milestone obligations for PAION, which would accordingly reduce the result. Furthermore, PAION expects in case of a successful out-licensing from 2012 onwards further cash inflows, in a substantial amount for Remimazolam and in a small amount from M6G.

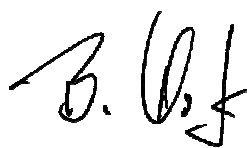
As of 30 September 2011 PAION's cash and cash equivalents amounted to EUR 10 million and the remaining equity facility amounted to EUR 13 million. The cash and cash equivalents alone secure a cash reach into the third quarter 2012. This does not account for further cash inflows from existing and future partners or from the equity facility and implies an unchanged structure. Further upfront payments, milestone payments, cost reimbursements or cost cutting measures as well as the use of the equity facility could expand the cash reach. Cash inflows may also be used fully or in part for funding of additional development activities within the existing portfolio or new strategic investments.

Aachen, Germany, 9 November 2011

PAION AG



Dr Wolfgang Söhngen



Bernhard Hofer



Dr Mariola Söhngen

## Condensed Consolidated Interim Financial Statements

### Consolidated Balance Sheet

ASSETS	30 Sept. 2011 EUR	31 Dec. 2010 EUR
<b>Non-current assets</b>		
Intangible assets	10,021,709.60	10,571,204.23
Equipment	189,156.70	196,223.77
Other assets	14.02	2.32
	<b>10,210,880.32</b>	<b>10,767,430.32</b>
<b>Current assets</b>		
Trade receivables	2,347.50	11,129.16
Prepaid expenses and other assets	915,162.56	1,175,118.30
Cash and cash equivalents	9,964,858.99	14,881,933.89
	<b>10,882,369.05</b>	<b>16,068,181.35</b>
<b>Total assets</b>	<b>21,093,249.37</b>	<b>26,835,611.67</b>

EQUITY AND LIABILITIES	30 Sept. 2011 EUR	31 Dec. 2010 EUR
<b>Equity</b>		
Share capital	25,379,906.00	25,073,684.00
Capital reserve	90,304,299.22	89,737,457.61
Translation reserve	-1,188,184.57	-1,142,438.22
Loss carryforward	-101,700,303.98	-92,446,174.58
Loss for the period	-5,055,691.48	-9,254,129.40
	<b>7,740,025.19</b>	<b>11,968,399.41</b>
<b>Non-current liabilities</b>		
Provisions	1,199,163.37	1,346,019.96
Financial liabilities	6,922,330.58	6,893,418.03
Deferred income	2,010,224.60	2,242,929.32
	<b>10,131,718.55</b>	<b>10,482,367.31</b>
<b>Current liabilities</b>		
Trade payables	1,497,406.06	1,835,290.75
Provisions	733,972.82	676,707.55
Other current liabilities	261,582.97	407,190.09
Current portion of deferred income	728,543.78	1,465,656.56
	<b>3,221,505.63</b>	<b>4,384,844.95</b>
<b>Total equity and liabilities</b>	<b>21,093,249.37</b>	<b>26,835,611.67</b>

## Consolidated Statement of Comprehensive Income

EUR	1 July – 30 Sept. 2011	1 July – 30 Sept. 2010	1 January – 30 Sept. 2011	1 January – 30 Sept. 2010
Revenues	242,938.04	368,304.14	3,066,447.49	2,603,713.48
Cost of revenues	-200.73	-1,827.31	-1,493.15	-14,865.50
<b>Gross profit</b>	<b>242,737.31</b>	<b>366,476.83</b>	<b>3,064,954.34</b>	<b>2,588,847.98</b>
Research and development expenses	-1,346,878.31	-2,226,134.39	-4,380,142.30	-6,578,949.82
General administrative and selling expenses	-979,751.61	-1,081,809.01	-3,529,514.57	-3,312,399.85
Other income (expenses), net	18,330.45	-28,662.05	35,290.25	69,877.39
<b>Operating expenses</b>	<b>-2,308,299.47</b>	<b>-3,336,605.45</b>	<b>-7,874,366.62</b>	<b>-9,821,472.28</b>
<b>Operating result</b>	<b>-2,065,562.16</b>	<b>-2,970,128.62</b>	<b>-4,809,412.28</b>	<b>-7,232,624.30</b>
Financial income	32,918.97	17,752.92	83,468.48	56,187.49
Financial expenses	-215,631.43	-158,732.12	-582,002.60	-471,881.90
<b>Financial result</b>	<b>-182,712.46</b>	<b>-140,979.20</b>	<b>-498,534.12</b>	<b>-415,694.41</b>
<b>Loss for the period before taxes</b>	<b>-2,248,274.62</b>	<b>-3,111,107.82</b>	<b>-5,307,946.40</b>	<b>-7,648,318.71</b>
Income taxes	84,170.78	118,781.88	252,254.92	328,946.46
<b>Loss for the period</b>	<b>-2,164,103.84</b>	<b>-2,992,325.94</b>	<b>-5,055,691.48</b>	<b>-7,319,372.25</b>
of which attributable to other shareholders	0.00	0.00	0.00	0.00
of which attributable to shareholders of PAION	-2,164,103.84	-2,992,325.94	-5,055,691.48	-7,319,372.25
Foreign currency translation of subsidiaries	390,129.65	-496,179.86	-45,746.35	318,920.18
<b>Other comprehensive income</b>	<b>390,129.65</b>	<b>-496,179.86</b>	<b>-45,746.35</b>	<b>318,920.18</b>
<b>Total comprehensive income</b>	<b>-1,773,974.19</b>	<b>-3,488,505.80</b>	<b>-5,101,437.83</b>	<b>-7,000,452.07</b>
of which attributable to other shareholders	0.00	0.00	0.00	0.00
of which attributable to shareholders of PAION	-1,773,974.19	-3,488,505.80	-5,101,437.83	-7,000,452.07
Earnings per share (basic)	-0.09	-0.12	-0.20	-0.30
Earnings per share (diluted)	-0.09	-0.12	-0.20	-0.30

## Consolidated Cash Flow Statement

EUR	1 January – 30 Sept. 2011	1 January – 30 Sept. 2010
<b>Cash flows from operating activities:</b>		
Net result for the period	-5,055,691.48	-7,319,372.25
<b>Reconciliation of net result for the period to cash flows from operating activities:</b>		
Amortization/depreciation and non-cash exchange rate changes of fixed assets	812,702.35	445,729.09
Loss/Profits from the disposal of non-current assets	-3,547.50	58,677.21
Interest expenses and interest income	498,534.12	415,694.38
Release of deferred income	-1,006,633.80	-1,119,218.94
Expenses from stock option plans	268,337.40	275,021.82
<b>Change in assets and liabilities which are not attributable to investing or financing activities:</b>		
Trade receivables	8,781.66	91,095.83
Prepaid expenses and other assets	-187,179.88	-613,637.10
Trade payables	-337,884.70	-323,158.93
Provisions	-201,277.90	78,648.44
Other current liabilities	-145,607.12	-100,443.39
Deferred income	36,816.30	0.00
Non-cash exchange losses/gains	-244,760.20	303,865.62
	<b>-5,557,410.75</b>	<b>-7,807,098.22</b>
Interest received	87,113.63	52,045.27
Tax payments received	427,767.94	364,651.44
<b>Cash flows from operating activities</b>	<b>-5,042,529.18</b>	<b>-7,390,401.51</b>
<b>Cash flows from investing activities:</b>		
Cash paid for investments in intangible assets and equipment	-44,642.64	-20,843.56
Cash received from the sale of intangible assets and equipment	3,550.00	0.00
Cash paid for investments	-11.70	0.00
<b>Cash flows from investing activities</b>	<b>-41,104.34</b>	<b>-20,843.56</b>
<b>Cash flows from financing activities:</b>		
Capital increase	306,222.00	0.00
Contributions to the capital reserve	315,012.30	0.00
Payments in connection with the raising of capital	-612.91	0.00
Interest paid	-441,576.19	-441,912.34
<b>Cash flows from financing activities</b>	<b>179,045.20</b>	<b>-441,912.34</b>
Change in cash and cash equivalents	-4,904,588.32	-7,853,157.41
Effect of exchange rate changes on cash	-12,486.58	15,061.77
Cash and cash equivalents at beginning of the period	14,881,933.89	22,871,407.20
<b>Cash and cash equivalents at end of the period</b>	<b>9,964,858.99</b>	<b>15,033,311.56</b>
<b>Composition of cash and cash equivalents at the end of the period:</b>		
Cash and cash equivalents	9,964,858.99	15,033,311.56

## Consolidated Statement of Changes in Equity

EUR	Share capital	Capital reserve	Translation reserve	Loss carryforward	Equity
31 December 2009	24,602,919.00	88,639,947.78	-1,492,295.41	-92,446,174.58	19,304,396.79
Total comprehensive income	0.00	0.00	318,920.18	-7,319,372.25	-7,000,452.07
Additional contribution to the capital reserve due to the issue of options	0.00	275,021.82	0.00	0.00	275,021.82
30 September 2010	24,602,919.00	88,914,969.60	-1,173,375.23	-99,765,546.83	12,578,966.54
Total comprehensive income	0.00	0.00	30,937.01	-1,934,757.15	-1,903,820.14
Issue of shares	470,765.00	0.00	0.00	0.00	470,765.00
Contribution to the capital reserve	0.00	687,845.00	0.00	0.00	687,845.00
Cost of raising capital	0.00	-30,693.87	0.00	0.00	-30,693.87
Additional contribution to the capital reserve due to the issue of options	0.00	165,336.88	0.00	0.00	165,336.88
31 December 2010	25,073,684.00	89,737,457.61	-1,142,438.22	-101,700,303.98	11,968,399.41
Total comprehensive income	0.00	0.00	-45,746.35	-5,055,691.48	-5,101,437.83
Issue of shares	306,222.00	0.00	0.00	0.00	306,222.00
Contribution to the capital reserve	0.00	315,012.30	0.00	0.00	315,012.30
Cost of raising capital	0.00	-16,508.09	0.00	0.00	-16,508.09
Additional contribution to the capital reserve due to the issue of options	0.00	268,337.40	0.00	0.00	268,337.40
30 September 2011	25,379,906.00	90,304,299.22	-1,188,184.57	-106,755,995.46	7,740,025.19

## Selected Explanatory Notes to the Consolidated Interim Financial Statements as of 30 September 2011

### General

The quarterly report of PAION AG includes interim consolidated financial statements and an interim group management report in accordance with the provisions of Secs. 37x (3) and 37w (2) to (4) WpHG [“Wertpapierhandelsgesetz”: German Securities Trading Act] in conjunction with Sec. 37y WpHG. The consolidated financial statements were prepared in accordance with the provisions of the International Financial Reporting Standards (IFRSs) for interim financial reporting. The interim group management report was prepared in accordance with the relevant provisions of the German Securities Trading Act.

The interim consolidated financial statements comprise PAION AG as the parent company, registered at Martinstrasse 10-12, 52062 Aachen, Germany, and the wholly-owned subsidiaries, which are fully consolidated:

- PAION Deutschland GmbH, Aachen/Germany
- PAION Holdings UK Ltd, Cambridge/UK
- PAION UK Ltd, Cambridge/UK
- CeNeS Drug Delivery Ltd, Cambridge/UK
- TheraSci Limited, Cambridge/UK
- CeNeS Pharmaceuticals Inc., Norwood/USA

### Basis of Accounting

The interim consolidated financial statements have been prepared in accordance with Sec. 315a HGB [“Handelsgesetzbuch”: German Commercial Code] and IFRSs, as adopted by the EU, and the interpretations of the International Financial Reporting Interpretations Committee (IFRIC). All IFRSs issued by the International Accounting Standards Board (IASB), London, UK, which were effective as of the balance sheet date of 30 September 2011 and applied by PAION, were adopted by the European Commission for application in the EU.

The following new announcements were published by the IASB during the reporting period and will be applied as soon as they come into effect if at that point an adoption by the European Commission has taken place.

- IFRS 10: In May 2011 the IASB has published IFRS 10 “Consolidated Financial Statements”. IFRS 10 provides a consistent definition of control and therefore provides

a consistent basis for the existence of control and the determination of the entities that should be included in the consolidated financial statements of the parent company. The new standard replaces the guidance in IAS 27 and SIC-12 that was applicable in this respect as yet. The standard is effective for fiscal years beginning on or after 1 January 2013.

- IFRS 11: In May 2011 the IASB has published IFRS 11 “Joint Arrangements”. IFRS 11 provides guidance on the accounting of joint ventures and joint operations. The new standard replaces the guidance in IAS 31 and SIC-13 that was applicable in this respect as yet. The standard is effective for fiscal years beginning on or after 1 January 2013.
- IFRS 12: In May 2011 the IASB has published IFRS 12 “Disclosure of Interests in Other Entities”. IFRS 12 provides guidance on disclosure requirements for all forms of interests in other entities in consolidated financial statements. The standard is effective for fiscal years beginning on or after 1 January 2013.
- IFRS 13: In May 2011 the IASB has published IFRS 13 “Fair Value Measurement”. IFRS 13 provides a precise definition of fair value and a single source of fair value measurement and disclosure requirements for use across IFRSs. The standard is effective for fiscal years beginning on or after 1 January 2013.

The provisions of IAS 34, “Interim Financial Reporting”, have been applied. The interim financial statements as of 30 September 2011 should be read in conjunction with the consolidated financial statements as of 31 December 2010.

The preparation of interim consolidated financial statements in accordance with IFRSs requires management to make estimates and assumptions which have an effect on the amount of recognised assets and liabilities, income and expenses and contingent liabilities. Actual amounts may differ from these estimates.

The interim consolidated financial statements do not contain any segment information as no material reportable segments could be identified.

## Consolidation Principles

The consolidation principles used in the interim consolidated financial statements as of 30 September 2011 were the same as those used in the consolidated financial statements as of 31 December 2010.

## Foreign Currency Translation

The consolidated financial statements are shown in Euro, which is the functional currency of PAION AG and the reporting currency of the Group. Each company within the Group defines its own functional currency. This is the Euro in the case of the German companies, whereas the UK-based companies use Pound Sterling as their functional currency. All items on the respective financial statements of each company are initially converted to the functional currency at the exchange rate applicable on the transaction date. Monetary assets and liabilities denominated in a foreign currency are converted to the functional currency on the reporting date at the exchange rate applicable on that date. All ensuing currency differences are recognised in profit or loss with the exception of exchange rate gains and losses from intra-Group loans classified in accordance with IAS 21 as net investments in foreign business operations; these are recognised in equity.

The assets and liabilities of the foreign companies are converted to Euro on the balance sheet reporting date at the exchange rate applicable on that date. These include all goodwill in connection with the acquisition of a foreign company and all fair value adjustments to the book values of the foreign company's assets and liabilities. Equity components are converted to Euro at historical rates at the time of initial consolidation. Expenses and income are converted to Euro at average monthly exchange rates. The resulting currency differences are accounted for separately within equity.

## Accounting Policies

The accounting policies used in the interim consolidated financial statements as of 30 September 2011 were the same as those used in the consolidated financial statements as of 31 December 2010.

## Tax Effects on Other Comprehensive Income

Because of the negative results of the PAION Group and the existing tax losses carried forward no income taxes are being paid at the moment. In the reporting period the Other Comprehensive Income (foreign currency translation of foreign subsidiaries) does not have any tax effects.

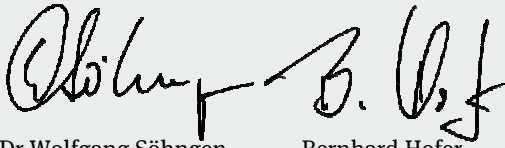
## Related Parties

On 8 February 2011 PAION concluded a know-how and licence agreement relating to the COMT programme with Mofo Thirty-Eight Limited. Under this programme, which PAION took into its portfolio in connection with the CeNeS acquisition in 2008, potential COMT inhibitors for Parkinson's disease were explored. Since the programme was not part of PAION's strategy, it was not further developed after the CeNeS acquisition as no lead structure was available. Alan Goodman, member of the Supervisory Board of PAION AG, holds 90% of Mofo Thirty-Eight Limited and PAION AG holds 10% of Mofo Thirty-Eight Limited. The spin-off is expected to facilitate funding for further development independently of PAION. PAION participates in future income via a revenue share.

Beyond that the relationships with related parties have not changed in comparison to those applied in the consolidated financial statements as of 31 December 2010.

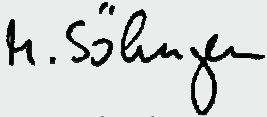
Aachen, Germany, 9 November 2011

PAION AG

Handwritten signatures of Dr. Wolfgang Söhngen and Bernhard Hofer. The signature of Dr. Wolfgang Söhngen is on the left, and the signature of Bernhard Hofer is on the right.

Dr Wolfgang Söhngen

Bernhard Hofer

Handwritten signature of Dr. Mariola Söhngen.

Dr Mariola Söhngen

# Review Report

## To PAION AG, Aachen:

We have reviewed the interim condensed consolidated financial statements, comprising the balance sheet, statement of comprehensive income, cash flow statement, statement of changes in equity and selected explanatory notes, and the interim group management report of PAION AG, Aachen, for the period from January 1, 2011 to September 30, 2011 which are part of the quarterly financial report pursuant to SEC 37x (3) WpHG ["Wertpapierhandelsgesetz": German Securities Trading Act]. The preparation of the interim condensed consolidated financial statements in accordance with the IFRSs on interim financial reporting as adopted by the EU and of the group management report in accordance with the requirements of the WpHG ["Wertpapierhandelsgesetz": German Securities Trading Act] applicable to interim group management reports is the responsibility of the Company's Management. Our responsibility is to issue a report on the interim condensed consolidated financial statements and the interim group management report based on our review.

We conducted our review of the interim condensed consolidated financial statements and the interim group management report in accordance with German generally accepted standards for the review of financial statements promulgated by the Institut der Wirtschaftsprüfer [Institute of Public Auditors in Germany] (IDW) and additionally in accordance with the International Standard on Review Engagements "Review of Interim Financial Information Performed by the Independent Auditor of the Entity" (ISRE 2410). Those standards require that we plan and perform the review to obtain a certain level of assurance in our critical appraisal to preclude that the interim condensed consolidated financial statements are not prepared, in all material respects, in accordance with IFRSs on interim financial reporting as adopted by the EU and that the interim group management report has not been prepared, in all material respects, in accordance with the provisions of the WpHG. A review is limited primarily to making inquiries of company personnel and applying analytical procedures and thus does not provide the assurance that we would obtain from an audit of financial statements. In accordance with our engagement, we have not performed a financial statement audit and, accordingly, we do not express an audit opinion.

Based on our review nothing has come to our attention that causes us to believe that the interim condensed consolidated financial statements are not prepared, in all material respects, in accordance with IFRSs on interim financial reporting as adopted by the EU and that the interim group management report has not been prepared, in all material respects, in accordance with the provisions of the WpHG applicable to interim group management reports.

Cologne, Germany, 9 November 2011

Ernst & Young GmbH

Wirtschaftsprüfungsgesellschaft

(s) Ueberschär

Wirtschaftsprüfer

[German Public Auditor]

(s) Galden

Wirtschaftsprüfer

[German Public Auditor]

## Information on PAION Shares

Market segment	Regulated market/Prime Standard Frankfurt
Ticker symbol	PA8
Reuters symbol	PA8G.DE (Xetra)
Bloomberg	PA8 GY (Xetra)
ISIN	DE000A0B65S3
First day of trading	11 February 2005
Designated sponsor	Close Brothers Seydler

Key figures	Q3 2011	2010
Number of shares at end of period	25,379,906	25,073,684
Average daily trading volume during the first nine months 2011 (Xetra, FSE)	52,497	73,620
Period high (Xetra closing price)	EUR 2.40 (4 January 2011)	EUR 3.27 (12 January 2010)
Period low (Xetra closing price)	EUR 1.49 (8 August 2011)	EUR 1.82 (29 June 2010)
Share price at end of period	EUR 1.53	EUR 2.24
Market capitalisation at end of period (Xetra)	EUR 38.8 million	EUR 56.2 million

## Corporate Calendar

23 March 2011	Publication of the financial results 2010
11 May 2011	Publication of the financial results for the first quarter 2011
24 May 2011	Annual General Meeting, Aachen
10 August 2011	Publication of the financial results for the second quarter / first half-year 2011
09 November 2011	Publication of the financial results for the third quarter / first nine months 2011
22 November 2011	Analyst Presentation at German Equity Forum Fall 2011, Frankfurt/Main (Germany)



"Polishing raw diamonds."  
PAION AG's advertising campaign in 2011

Date of publication: 9 November 2011

PAION AG

Martinstrasse 10-12

52062 Aachen Germany

Phone +49 241 4453-0

Fax +49 241 4453-100

info@paion.com [www.paion.com](http://www.paion.com)