



## CORPORATE NEWS

### EARNINGS

#### **PAION AG REPORTS CONSOLIDATED FINANCIAL RESULTS FOR THE FISCAL YEAR 2008**

Aachen (Germany), Cambridge (United Kingdom), 17 March 2009 – The biopharmaceutical company PAION AG (ISIN DE000A0B65S3; Frankfurt Stock Exchange, Prime Standard: PA8; London AIM: PAI) today reported its consolidated financial result according to International Financial Reporting Standards (IFRS) for the fiscal year ended 31 December 2008.

Cash and cash equivalents at the end of the reporting period amounted to EUR 36.1 million (2007: EUR 42.9 million). PAION is sufficiently funded to implement value-generating steps until the end of 2010, not accounting for potential additional future upfront and milestone payments from cooperation partners. At EUR 6.8 million the cash consumption in 2008 was significantly lower than in 2007 (EUR 14.3 million)

Group revenues decreased from EUR 4.8 million in 2007 to EUR 3.2 million due to lower reimbursements for research and development. The net loss for the period amounted to EUR 12.6 million, compared to EUR 10.5 million in 2007.

#### **Operational highlights:**

- In January 2008, the extended licensing agreement with H. Lundbeck A/S for the stroke drug Desmoteplase came into effect and PAION received a non-refundable upfront payment of EUR 8 million. PAION is eligible for up to EUR 63 million in future milestones plus royalties in the double-digit percentage range. In addition, PAION holds co-promotion options for Germany, Austria, and Switzerland. Mid-December 2008, Lundbeck announced the initiation of a new clinical Phase III program
- In June 2008, PAION successfully completed the acquisition of CeNeS Pharmaceuticals whose drug candidates were integrated into PAION's development pipeline
- In July 2008, PAION started a Phase I study with its intravenously administered anesthetic/sedative CNS 7056, including direct comparison with midazolam, the current gold standard for procedural sedation. The study was completed in November 2008 and results were reported in January 2009. The anticipated favourable profile was observed and no safety issues were reported
- At the beginning of November 2008, PAION reported positive results from a meta-analysis of clinical data on its pain drug M6G and announced the re-launch of partnering activities for the substance
- At the end of December 2008, PAION reported the completion of an open-label intravenous Phase IIa study with its NMDA receptor antagonist CNS 5161. The study was conducted in patients suffering from opioid-refractory cancer pain. Analgesic effects were detected while significant

side-effects or psychomimetic effects, often associated with NMDA receptor antagonists, were not observed

Dr. Wolfgang Söhngen, PAION's CEO commented: *"2008 marks a successful year for PAION. The fast and successful progress with CNS 7056 plus the re-start of the M6G program based on findings from the meta-analysis are proof for the inherent value of the acquisition. Our extended pipeline offers several attractive licensing opportunities for pharma partners and it is one of our key objectives to close at least one partnering deal in 2009 with the aim to achieve an expansion of our cash reach beyond the year 2010. With respect to our development activities, we intend to maintain the momentum for our near-term value driver CNS 7056. Following proof-of-concept already with the first Phase I study the next studies are already being lined up."*

**Consolidated financial results for the fiscal year 2008:**

Revenues for the full fiscal year 2008 amounted to EUR 3.2 million and mainly comprise reimbursements of development expenses from Lundbeck (EUR 1.7 million) and the systematic release of deferred income (EUR 1.5 million) in connection with the license agreement concluded with Lundbeck. As part of the outlicensing agreement between PAION and Lundbeck, Lundbeck made a non-refundable upfront payment of EUR 8 million, which is recognized as a deferred income item and is being released over the anticipated development period for Desmoteplase. The gross result in 2008 amounted to EUR 2.4 million.

Research and development expenses in the period declined by EUR 1.1 million to EUR 8.7 million compared to the corresponding period in the prior year. The decrease is primarily attributable to the new license agreement with Lundbeck, according to which Lundbeck will bear all development expenses for Desmoteplase. Furthermore, the development of Enecadin incurred much lower costs since the development was discontinued in April 2008. These cost savings were compensated by the substances acquired together with the PAION UK Group for which research and development expenses have been incurred since the acquisition date, 20 June 2008.

Compared with the previous year, the general and administrative expenses increased significantly by EUR 3.1 million to EUR 7.5 million because of one-off transaction and consulting fees incurred in connection with the acquisition of the PAION UK Group as well as one-off expenses relating to restructuring measures. The general and administrative expenses also include severance payments as well as one-off expenses relating to the technical settlement of the share swap and from the admission of all PAION shares to trading on AIM.

The net loss of the Group on 31 December 2008 was EUR 12.6 million, an increase of EUR 2.1 million compared to the prior year's period. This increase was mainly due to the one-off costs increase in general and administrative expenses as a result of the acquisition of the CeNeS Group.

At the end of the reporting period, 31 December 2008, cash and cash equivalents amounted to EUR 36.1 million. These were significantly strengthened by the non-refundable upfront payment of EUR 8 million paid by Lundbeck at the beginning of 2008.

The balance sheet as of 31 December 2008 contains the assets and liabilities acquired within the business combination of the PAION UK Group. Compared

to 31 December 2007, the total assets increased by EUR 3.8 million to EUR 49.3 million which was primarily due to the capitalization of the development projects as part of the purchase price allocation and to the non-refundable upfront payment by Lundbeck of EUR 8 million.

As of 31 December 2008, the equity ratio has declined to 63.9 % compared to 78.3 % on 31 December 2007. If the subordinate loan were taken into account and the deferred non-refundable upfront payment of Lundbeck were recognized as economic equity, the equity ratio would increase by 27.1 percentage points to 91.0 %.

As of 31 December 2008, PAION's headcount amounted to 33 employees, of which 8 work for the PAION UK Group. By comparison, the headcount as of 31 December 2007 amounted to 53 employees (German PAION Group only).

#### **Pipeline update:**

Through the acquisition of the PAION UK-Group, PAION was able to significantly broaden its portfolio which now comprises six product candidates in clinical development. The pipeline includes CeNeS' morphine-6-glucuronide (M6G), CNS 7056 and CNS 5161 programs. Together with Flovagatran, which was purchased by PAION in April 2008, these substances add to PAION's Desmoteplase and Solulin.

In July 2008, PAION started a clinical Phase I study with **CNS 7056**, an innovative short-acting anesthetic/sedative for intravenous administration. Among other indications, such compounds are used in endoscopic procedures including colonoscopies. In the course of this study, CNS 7056 was compared to placebo and a standard dose of Midazolam, which is currently the sedative of choice for procedural sedation. The study confirmed the anticipated positive profile of PAION's drug, with no safety problems occurring. In particular, the fast on/fast off sedation shown in pre-clinical studies was confirmed and thus proof-of-concept achieved. Therefore, PAION believes that the substance has a high potential for controllable sedation, especially in the field of outpatient procedures. In Japan, CNS 7056 is partnered with Ono Pharmaceuticals.

Morphine-6-glucuronide (**M6G**) was the most advanced project in the CeNeS portfolio. In clinical Phase II and Phase III studies this active morphine metabolite demonstrated an analgesic effect comparable to morphine, the current "gold standard" for the treatment of severe, post-operative pain. At the same time, the common side effects of morphine administration, such as nausea and vomiting, were significantly reduced with M6G. In total, more than 1,000 patients have already been treated with M6G. In the last Phase III study, however, M6G narrowly failed to demonstrate statistical significance with respect to the incidence and severity of nausea. Following the acquisition, PAION conducted a more in-depth analysis of the available clinical data which confirmed the analgesic effect of M6G. Furthermore, the data demonstrated a statistically significant reduction in nausea and vomiting. PAION believes that these findings will increase the probability of success of the clinical development programme and, as such, of out-licensing. Based on these results, PAION has now re-started the search for a development partner for M6G.

**Desmoteplase** is an intravenously administered substance for dissolving blood clots. Results from earlier Phase II studies suggested that the treatment window in acute ischemic stroke may be widened from currently three to up to nine hours after the occurrence of first stroke symptoms. A first Phase III study

did not meet the specified endpoint but on the basis of a further in-depth analysis, PAION was able to identify the reasons for the setback and secure the future development of the substance by an extended agreement with H. Lundbeck A/S. In December 2008, Lundbeck announced the initiation of a new Phase III program for which PAION was also involved in the preparation.

For the anticoagulant **Solulin**, results of a Phase I proof-of-concept study were reported in February and May 2008. The study confirmed the substance's good safety profile as well as its anticoagulant mode of action. The tested dosages did not reveal any relevant change in factors seen as key indicators for an increased bleeding propensity. Following the completion of the Phase I study, PAION has initiated a partnering process for the further development of Solulin.

**CNS 5161** is an NMDA receptor antagonist which may prove beneficial for the treatment of neuropathic pain, i.e. pain caused by irritation or damage of the nervous system. A second potential indication is the treatment of cancer pain. An open label clinical Phase IIa study with CNS 5161 in patients with opioid-refractory cancer pain, conducted by partner Ergomed Clinical Research Limited, Frankfurt, was completed in December 2008. Increasing analgesic effects were detected with increasing doses while significant side-effects or psychomimetic effects, often associated with the NMDA receptor antagonist compound class, were not observed. It is intended to seek third-party funding prior to initiating the next studies.

In April 2008 PAION purchased all rights to the anticoagulant **Flovagatran** for a one-off payment amounting to EUR 0.3 million plus a further milestone payment which will only be due in the event of receiving market authorization, out-licensing or re-sale. This substance could prove useful as an acute anticoagulant during major surgery such as coronary artery bypass grafting (CABG). PAION has initiated additional preclinical studies in preparation for clinical assessment in this new target indication.

**AIM delisting:**

On 18 February 2009, PAION AG announced the cancellation of the company's secondary listing on the Alternative Investment Market (AIM) of the London Stock Exchange, effective as of 19 March 2009. This delisting does not affect the company's primary listing in the Prime Standard segment of the Frankfurt Stock Exchange. In order to permit continued settlement in the UK Crest system, it is intended that the Depositary Interests (DI) instruments will remain in place following the cancellation date. As such, DI holders will not be required to take any action upon cancellation of the AIM listing.

**Outlook:**

Following the acquisition of CeNeS Pharmaceutical and the successful integration in 2008, PAION will continue to focus on the development of drugs for thrombotic/cardiovascular diseases as well as for the treatment of central nervous system (CNS) disorders.

PAION's primary development activities in 2009 will be centered around CNS 7056 and include a Phase Ib and a Phase IIa study in procedural sedation. PAION has initiated partnering activities for M6G and Solulin, aiming for at least one partnering deal in 2009.

The cash and cash equivalents amounting to EUR 36.1 million provide PAION with the necessary flexibility to implement value-generating steps while

securing the availability of sufficient cash until the end of 2010. This does not account for future upfront and milestone payments from cooperation partners, which would expand the cash reach but may also be used fully or in part for financing additional development activities.

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## Key Consolidated Financial Figures, IFRS

(all figures in KEUR unless otherwise noted)

|  | 2008       | 2007       |
|--|------------|------------|
| <b>Profit and Loss Statement</b>                           |            |            |
| Revenues   | 3,166      | 4,847      |
| Research and development expenses                          | -8,729     | -9,814     |
| General and administrative expenses                        | -7,546     | -4,407     |
| Selling and marketing expenses                             | -86        | -560       |
| Operating result   | -13,799    | -12,624    |
| Net loss for the period                                    | -12,580    | -10,512    |
| Personnel expenses included therein                        | -5,560     | -7,116     |
| Number of shares outstanding (weighted average, undiluted) | 20,853,621 | 16,755,552 |
| Number of shares outstanding (weighted average, diluted)   | 20,853,621 | 16,755,552 |
| Earnings per share in EUR (undiluted)                      | -0.74      | -0.63      |
| Earnings per share in EUR (diluted)                        | -0.74      | -0.63      |
| <b>Balance Sheet</b>                                       |            |            |
| Intangible assts   | 11,336     | 462        |
| Cash and cash equivalents                                  | 36,072     | 42,901     |
| Equity   | 31,528     | 35,664     |
| Non-current liabilities                                    | 13,426     | 6,746      |
| Total assets   | 49,313     | 45,542     |
| Equity ratio (percent)                                     | 63.9       | 78.3       |
| <b>Cash flow</b>   |            |            |
| Cash flow from operating activities                        | -4,589     | -13,448    |
| Cash flow from investing activities                        | -435       | -204       |
| Cash flow financing activities                             | -1,638     | -636       |
| <b>Employees</b>   |            |            |
| Group employees (average)                                  | 42         | 75         |

The full annual financial report 2008 will be available as from 17 March 2009 on our corporate website at <http://www.paion.com/reports>.

### **Earnings call and webcast**

On Tuesday, 17 March 2009 at 2 p.m. CET (1 p.m. GMT, 9 a.m. EDT), the Management Board of PAION will host a public conference call (conducted in English) to present the financial results of the fiscal year 2008, highlight the most important events in 2008 and provide further details on the company's latest developments. To access the call, participants from Germany may dial +49-30-213099779 (listen-only), from the UK +44-20-30432461 and from the US +1-866-8958561 (other countries: please choose from D/UK/US numbers). By dialing the number you will directly be transferred to the conference call. No participant passcode is necessary. To allow for smooth processing we suggest that you dial in 10 minutes before the beginning of the call. The conference call will be supplemented by a webcast presentation which can be accessed during the call under the following link: <https://www.anywhereconference.com>. In the field "Web Login" please enter 107272352 and in the field "Pin Code" 256799. After entering your name in the specified field please click on "Go". The dial-in details for the conference call and the webcast link are also available on our website <http://www.paion.com/investors>. The conference call will be recorded. Details on how to access the replay will be posted on the same web page after the call.

### **About PAION**

PAION is a biopharmaceutical company headquartered in Aachen, Germany. Since the acquisition of CeNeS Pharmaceuticals, which was completed in June 2008, the company has a second site in Cambridge, UK. The company is specializing in developing and commercializing innovative drugs for the hospital-based treatment of central nervous system (CNS) disorders and thrombotic/cardiovascular diseases, indications for which there is a substantial unmet medical need. PAION intends to further expand its portfolio of drugs by exploiting its core expertise in identifying high-potential compounds, licensing or otherwise acquiring them and advancing them through the clinical development and regulatory approval process. Where appropriate, particularly during the late stages of the clinical development and approval process and the commercialization phase, PAION seeks to collaborate with experienced partners.

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