



## CORPORATE NEWS

### EARNINGS

#### PAION AG PUBLISHES GROUP QUARTERLY STATEMENT FOR THE FIRST QUARTER OF 2018

- Financial results in line with plan
- Cash position of EUR 22.1 million; cash reach into the second half of 2019
- Remimazolam market approval applications in preparation for the U.S. and Japan
- Phase III trial initiated in South Korea
- EU Phase III study planned to start in the second half of 2018
- Conference call (in English) today at 2:00 p.m. CEST (1:00 p.m. GMT/8:00 a.m. EDT)

Aachen (Germany), 09 May 2018 – The specialty pharmaceutical company PAION AG (ISIN DE000A0B65S3; Frankfurt Stock Exchange, Prime Standard: PA8) today reports its consolidated financial results according to International Financial Reporting Standards (IFRS) for the first quarter of 2018.

Dr. Wolfgang Söhngen, CEO of PAION AG, commented: *"We expect the coming months to be busy as we and our partners steadily advance the development of remimazolam around the world. Importantly, the PAION team is working closely with partners Cosmo in the U.S. (procedural sedation) and Mundipharma in Japan (general anesthesia) to ensure they receive all the necessary data and documentation to complete the first market approval dossiers for remimazolam. In parallel, we will start the Phase III trial in general anesthesia still required for market approval in the EU for which preparations are going according to plan."*

#### **Update on development activities**

##### **U.S.**

Following the successful completion of the U.S. clinical development program for remimazolam in procedural sedation in 2017, in the first quarter of 2018 PAION focused on the work to complete the data package and documentation necessary to enable the U.S. license partner **Cosmo Pharmaceuticals (Cosmo)** to prepare the market approval dossier and to submit for regulatory approval as planned in the fourth quarter of 2018/first quarter of 2019.

##### **EU**

Based on the results of the Phase I trial conducted in 2017, subsequent simulations and Scientific Advice obtained from the European Medicines Agency (EMA) in January 2018 for defining the new European Phase III program, PAION currently assumes that approximately 500 patients will be required for the EU Phase III study in general anesthesia.

PAION is planning a study in general surgery close in design to the successfully completed Phase III program in general anesthesia in Japan, but in sicker patients, where the medical need to reduce hypotensive events is higher. The study is currently planned to start in the second half of 2018.

#### Partner activities in other territories

All remimazolam license partners have activities ongoing to support future filings in their respective territories with a focus on clinical studies and regulatory interactions.

In August 2017, PAION's remimazolam license partner for Russia, **R-Pharm**, announced the start of a Phase III study in general anesthesia in Russia. Completion of the study is expected still in the first half of 2018. Subsequently, R-Pharm plans filing for market approval which is currently planned end of 2018.

In December 2017, PAION entered into a license agreement with **Mundipharma** for Japan. Based on the positive pre-NDA meeting with the Japanese regulatory authority, PAION had started preparations for a market approval dossier for remimazolam. Mundipharma has now taken over this work with PAION's support. Mundipharma currently plans to file for market approval in 2018.

PAION's South Korean remimazolam license partner **Hana Pharm** has started a Phase III study with remimazolam in general anesthesia in South Korea in March 2018. Completion of the study is expected in 2018.

PAION's Chinese remimazolam license partner **Yichang Humanwell** is going to conduct a Phase II study with remimazolam in general anesthesia and a Phase III study with remimazolam in procedural sedation in China.

#### Results of operations, financial position and net assets

**Revenues** in the first quarter of 2018 amounted to KEUR 257 compared to KEUR 2,051 in the prior-year period and relate primarily to the upfront payment received from Mundipharma in January 2018 under the remimazolam license agreement for Japan entered into in 2017. Revenues in the prior-year period mainly resulted from the license agreement with U.S. license partner Cosmo.

**Research and development expenses** amounted to KEUR 3,360 in the first quarter of 2018 and mainly related to preparatory activities for filing for market approval for remimazolam in procedural sedation in the U.S. The decrease of KEUR 719 compared to the prior-year period was mainly due to lower costs for Phase III studies as the recruitment and reporting activities of our external service providers are completed.

**General administrative and selling expenses** decreased by KEUR 208 to KEUR 795 in the first quarter of 2018.

**Income taxes** amounted to KEUR 749 in the first quarter of 2018 (prior-year period: KEUR 822) and relate to tax claims for reimbursement of a portion of research and development costs from the British tax authorities.

**Net loss** for the first quarter of 2018 amounted to KEUR 3,125 (prior-year period: KEUR 2,218). This means an increase of the net loss in the amount of KEUR 907 compared to the prior-year period. The change is mainly attributable to lower revenues on the one hand and lower research and development expenses than in the prior-year period on the other hand.

**Cash and cash equivalents** decreased by KEUR 2,755 in the first quarter 2018. As of 31 March 2018, PAION's cash and cash equivalents amounted to KEUR 22,084.

The decrease of cash and cash equivalents nearly entirely stems from **cash flows from operating activities** of KEUR -2,752. These primarily result from the net loss adjusted for the current tax credit claim towards the British tax authorities which has not had a cash effect yet, as well as adjusted for the part of the upfront payment of EUR 1 million received from Mundipharma in January 2018 which has had a cash effect already but has not been recognized as revenues yet.

#### **Risks and opportunities**

Material risks and opportunities relating to future development were presented in detail in the group management report for fiscal year 2017. Risks and opportunities did not change significantly in the first quarter of 2018.

#### **Outlook 2018**

PAION confirms its outlook for 2018 given in March 2018 with the publication of the 2017 financial results. PAION's major goals for 2018 are the completion and transfer of all data and documentation related to the U.S. remimazolam development program to Cosmo and the start of a new EU Phase III study in general anesthesia. In addition, PAION will continue to work on production development for the commercial product of remimazolam.

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## Key consolidated financial figures, IFRS (unaudited)

(all figures in KEUR unless otherwise noted)	Q1 2018	Q1 2017
Revenues	257	2,051
Research and development expenses	-3,360	-4,079
General administrative and selling expenses	-795	-1,003
Income taxes	749	822
Net result for the period	-3,125	-2,218
Earnings per share in EUR for the period (basic)	-0.05	-0.04
Earnings per share in EUR for the period (diluted)	-0.05	-0.04

Cash flows from operating activities	-2,752	-5,992
Cash flows from investing activities	-4	-9
Cash flows from financing activities	0	4,624
Change in cash and cash equivalents (incl. exchange rate differences)	-2,755	-1,379
Average number of group employees	37	30

	31 Mar. 2018	31 Dec. 2017
Intangible assets	2,402	2,415
Cash and cash equivalents	22,084	24,839
Equity	22,174	25,229
Current liabilities	7,686	6,656
Balance sheet total	29,860	31,885

### Conference call and webcast

In addition to the publication of the results, the Management Board of PAION AG will host a public conference call (conducted in English) on 09 May 2018 at 2 p.m. CEST (1 p.m. BST, 8 a.m. EDT) to present the financial results for the first quarter of 2018, highlight key achievements and provide a pipeline and strategy update.

To access the call, participants should dial:

- Germany +49 (0) 69 7104 45598,
- UK +44 (0) 20 3003 2666 and
- U.S. +1 212 999 6659
- Other countries: please use the UK number

When prompted, give the password "PAION". The conference call will include a slide presentation which can be accessed during the call at: <https://paion-events.webex.com/paion-events/j.php?MTID=m80f358cc31e1f6c0bff0a60b9456018f>.

### About PAION

PAION AG is a publicly listed specialty pharmaceutical company developing and aiming to commercialize innovative drugs to be used in out-patient and hospital-based sedation, anesthesia and critical care services. PAION's lead compound is remimazolam, an intravenous, ultra-short-acting and controllable benzodiazepine sedative/anesthetic drug candidate for which PAION has completed the clinical development for use in procedural sedation in the U.S.

Outside the U.S., PAION has so far focused on the development of remimazolam in the indication general anesthesia. A full clinical development program for general anesthesia was completed in Japan. In the EU, PAION is currently planning to continue the clinical development program by starting a Phase III trial in the second half of 2018. Development of remimazolam in the indication intensive care unit (ICU) sedation is also part of the longer-term life-cycle plan for remimazolam.

PAION is headquartered in Aachen (Germany) with an additional site in Cambridge (United Kingdom).

PAION's vision is to become an acknowledged "PAIONeer" in sedation and anesthesia.

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