



CORPORATE NEWS

EARNINGS

PAION AG PUBLISHES GROUP QUARTERLY STATEMENT FOR THE FIRST QUARTER OF 2017

- Financial results in line with plan
- Cash position of EUR 28.7 million; cash reach at least until the end of 2018
- Positive data announced in U.S. safety trial with remimazolam in high-risk colonoscopy patients
- Patient recruitment in U.S. Phase III study with remimazolam in procedural sedation during bronchoscopy successfully completed
- Financing for regulatory filing activities in Japan secured
- Conference call (in English) today at 2:00 p.m. CEST (1:00 p.m. GMT/8:00 a.m. EDT)

Aachen (Germany), 10 May 2017 – 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 2017.

Dr. Wolfgang Söhngen, CEO of PAION AG, commented: *"2017 is off to a strong start for PAION. The recently completed rights offering demonstrates the strong support of our shareholders for our strategy for the Japanese market. Additionally, with the positive data from the ASA III/IV study and the completion of patient recruitment in the bronchoscopy study, we have achieved two other important milestones. We expect the results from the bronchoscopy study in mid-2017."*

Update on development activities and outlook

In the first quarter of 2017, PAION focused on advancing its Phase III development program for **remimazolam** in procedural sedation in the U.S.

U.S.

At the end of March 2017, PAION announced the completion of patient recruitment in the second pivotal U.S. Phase III clinical trial, which is evaluating remimazolam in procedural sedation during bronchoscopy. Headline data are expected in mid-2017.

Also at the end of the first quarter of 2017, PAION announced positive headline data from the U.S. clinical safety trial of remimazolam in ASA III/IV patients (American Society of Anesthesiologists classification) undergoing colonoscopy. The trial enrolled 79 patients and was designed to evaluate the efficacy and safety of remimazolam compared to placebo (with midazolam 'rescue' sedation) in patients undergoing proceduralist-supervised sedation for

colonoscopy. This study also included an open label arm in which midazolam was dosed according to U.S. label. The trial confirmed remimazolam's safety profile and tolerability shown in all previous studies in a more vulnerable patient population. Overall, remimazolam demonstrated good respiratory and cardiovascular stability as compared to placebo with midazolam rescue. No adverse events of concern were observed in either group. In addition, the efficacy and efficiency improvements were comparable to the positive pivotal U.S. Phase III trial in colonoscopy patients. Success of the procedure (including no requirement for rescue medication and the application of not more than five doses in any 15-minute interval) was achieved in 84.4% of patients in the remimazolam arm and 0% in the placebo arm. Other relevant endpoints showed a median time from start of medication to start of procedure of 5.0 minutes for remimazolam (placebo: 18.5 minutes) and a median time from end of procedure to return to full alertness of 3.0 minutes (placebo: 5.0 minutes). By comparison, procedural success was achieved in 12.9% of the midazolam patients. Midazolam patients showed a median time from start of medication to start of procedure of 19.0 minutes and a median time from end of procedure to return to full alertness of 7.0 minutes.

Based on the results of preclinical and Phase I studies and in consultation with the FDA, PAION is currently preparing additional Phase I studies to further assess the abuse potential of remimazolam. Two aspects will be studied: if remimazolam could inappropriately be used as a knock-out cocktail in combination with alcohol and if it could be abused intranasally. The studies will start shortly.

EU

In consultation with key opinion leaders in general anesthesia, PAION is currently preparing a Phase I study to determine the number of patients required for an EU Phase III study in general anesthesia. The Phase I study will start shortly.

Japan

Based on the positive pre-NDA meeting and the successful financing in February 2017, PAION has started to prepare a market approval dossier for remimazolam in Japan. The preparation includes, among other things, the necessary validation of commercial-scale production for the Japanese market. The dossier will be prepared by an experienced contract research organization (CRO) in close consultation with PAION.

Partner activities in other regions

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

Results of operations, financial position and net assets

Revenues in the first quarter of 2017 amounted to KEUR 2,051 compared to KEUR 3 in the prior-year period and mainly resulted from the upfront payment received from Cosmo under the remimazolam license agreement entered into in 2016.

Research and development expenses amounted to KEUR 4,079 in the first quarter 2017 and mainly relate to the Phase III development program for remimazolam in the U.S. The decrease of KEUR 2,423 compared to the prior-year period is mainly due to lower costs for Phase III studies.

General administrative and selling expenses decreased by KEUR 177 to KEUR 1,003 in the first quarter 2017. The decrease is mainly due to lower selling expenses.

Income taxes amounted to KEUR 822 in the first quarter 2017 (prior-year period: KEUR 1,330) and relate to tax claims for reimbursement of parts of the research and development costs from the British tax authorities. The decrease is mainly attributable to lower research and development costs.

The **net loss** for the first quarter 2017 amounted to KEUR 2,218. In the prior-year period, a net loss of KEUR 6,729 was reported. This means a decrease of the net loss in the amount of KEUR 4,511 compared to the prior-year period. The change is mainly attributable to higher revenues and lower research and development expenses than in the prior-year period.

Cash and cash equivalents decreased by KEUR 1,379 in the first quarter 2017. As of 31 March 2017, PAION's cash and cash equivalents amounted to KEUR 28,732.

The decrease of cash and cash equivalents primarily stems from **cash flows from operating activities** of KEUR -5,992 and **cash flows from financing activities** of KEUR 4,624. Cash flows from operating activities 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 revenues recognized from the upfront payment from Cosmo that already had a cash effect in 2016. Cash flows from financing activities primarily result from the capital increase with subscription rights conducted in February 2017.

Risks and opportunities

Material risks and opportunities relating to future development are presented in detail in the group management report for fiscal year 2016. Risks and opportunities have not changed significantly in the first quarter of 2017.

Outlook 2017

PAION confirms its outlook for 2017 made on 16 March 2017 with the publication of the 2016 financial results. PAION's major goals for 2017 are the continuation and completion of the ongoing clinical development program in the U.S. and the handover of the completed work to Cosmo.

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Key consolidated financial figures, IFRS (unaudited)

(all figures in KEUR unless otherwise noted)	Q1 2017	Q1 2016
Revenues	2,051	3
Research and development expenses	-4,079	-6,502
General administrative and selling expenses	-1,003	-1,180
Income taxes	822	1,330
Net result for the period	-2,218	-6,729
Earnings per share in EUR for the period (basic)	-0.04	-0.13
Earnings per share in EUR for the period (diluted)	-0.04	-0.13

Cash flows from operating activities	-5,992	-7,055
Cash flows from investing activities	-9	-137
Cash flows from financing activities	4,624	0
Change in cash and cash equivalents (incl. exchange rate differences)	-1,379	-7,218
Average number of group employees	30	39

	31 Mar. 2017	31 Dec. 2016
Intangible assets	2,651	2,688
Cash and cash equivalents	28,732	30,111
Equity	27,367	24,943
Current liabilities	10,210	13,040
Balance sheet total	37,577	37,983

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 10 May 2017 at 2 p.m. CEST (1 p.m. BST, 8 a.m. EDT) to present the financial results for the first quarter of 2017, highlight key achievements and provide a pipeline and strategy update and financial outlook.

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=m006f99be6d4e950f06d6928e900970e1>.

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 which is in Phase III clinical development for use in procedural sedation in the U.S. Currently,

PAION is mainly focusing its business and financial resources on successfully completing its ongoing clinical development program in procedural sedation. 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 and PAION is preparing filing in Japan. In the EU, PAION is currently planning to continue the clinical development program. 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 a further site in Cambridge (United Kingdom).

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

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This release contains certain forward-looking statements concerning the future business of PAION AG. These forward-looking statements contained herein are based on the current expectations, estimates and projections of PAION AG's management as of the date of this release. They are subject to a number of assumptions and involve known and unknown risks, uncertainties and other factors. Should actual conditions differ from the Company's assumptions, actual results and actions may differ materially from any future results and developments expressed or implied by such forward-looking statements. Considering the risks, uncertainties and other factors involved, recipients should not rely unreasonably upon these forward-looking statements. PAION AG has no obligation to periodically update any such forward-looking statements to reflect future events or developments.