CORPORATE NEWS

EARNINGS

PAION AG PUBLISHES GROUP QUARTERLY STATEMENT FOR THE FIRST QUARTER OF 2019

- Filing for market approval with remimazolam in the U.S. in April 2019
- Successful pre-submission meeting with EMA for the indication procedural sedation in the EU
- Cash and cash equivalents of EUR 15.6 million as of 31 March 2019
- Conference call (in English) today at 2:00 p.m. CEST (1:00 p.m. BST/9:00 a.m. EDT)

Aachen (Germany), 08 May 2019 – 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 2019.

Dr. Wolfgang Söhngen, CEO of PAION AG, commented: "*In the first quarter we worked full steam on filing for market approval for remimazolam in the U.S. together with our partner Cosmo. The NDA filing by Cosmo in early April was an important milestone for both parties. We also discussed the procedural sedation indication in the EU with the EMA at a pre-submission meeting and received positive feedback. We are now evaluating whether filing for market approval in procedural sedation based on the U.S. development program may be possible later this year. In addition, we will continue to work intensively on conducting the ongoing Phase III study in the EU in general anesthesia over the next few months, as well as on supporting our partners in further regulatory activities.*

Update on remimazolam development activities and outlook

U.S.

The New Drug Application (NDA) in procedural sedation was prepared together with Cosmo Pharmaceuticals (Cosmo) and submitted to the Food & Drug Administration (FDA) by Cosmo beginning of April 2019.

With a regular course of the approval process, the U.S. market approval and subsequent launch of remimazolam can be expected in 2020.

EU

Currently, a Phase III clinical trial for the induction and maintenance of general anesthesia is being conducted in the EU. The randomized, single-blind, propofol-controlled, confirmatory Phase III trial is expected to enroll approximately 500 ASA III/IV patients (American Society of Anesthesiologists classification III to IV) undergoing elective surgery at more than 20 European

trial centers. Patient recruitment is expected to be completed by the end of 2019.

At a pre-submission meeting with the EMA held in February 2019, the U.S. Phase III clinical development program, including key safety data and efficacy results, was discussed in relation to a potential regulatory filing in the EU. Based on the EMA feedback, PAION assumes that the existing data package is sufficient to be able to submit the Marketing Authorization Application (MAA) for remimazolam in procedural sedation in the EU. PAION is currently evaluating if filing for market approval for remimazolam in procedural sedation based on the completed U.S. development program could be possible still within this year.

Licensee activities in other territories
PAION's licensees are preparing the future filings of remimazolam in their respective territories through regulatory interactions.

Chinese remimazolam licensee Yichang Humanwell submitted a market approval dossier to the Chinese National Medical Products Administration (NMPA) for remimazolam in the indication procedural sedation in November 2018. A potential market approval could happen end of 2019 at the earliest.

Japanese remimazolam licensee Mundipharma submitted a market approval dossier to the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) for remimazolam in the indication general anesthesia in December 2018. Market approval could be granted end of 2019 at the earliest.

In November 2018, **Russian** remimazolam licensee R-Pharm announced the successful completion of a Phase III trial in general anesthesia. R-Pharm currently plans to file for market approval in Russia by the end of 2019.

For **Canada**, PAION expects its remimazolam licensee Pharmascience to use the U.S. market approval dossier as the basis for their own filing for market approval.

PAION's remimazolam licensee TR-Pharm (**Turkey, the Middle East** and **North Africa**) plans to file for market approval in Turkey based on the U.S. or Japanese dossier.

PAION's remimazolam licensee Hana Pharm successfully completed patient recruitment of a Phase III trial in general anesthesia in October 2018. Before filing for market approval, the production process for remimazolam needs to be established in **South Korea**. Accordingly, Hana Pharm plans to file for market approval in 2020.

Results of operations, financial position and net assets

In the first quarter of 2019, no **revenues** were realized. In the prior-year period, revenues amounted to KEUR 257 and mainly related to the remimazolam license agreement for Japan with Mundipharma.

Research and development expenses amounted to KEUR 3,063 in the first quarter of 2019 (prior-year period: KEUR 3,360) and mainly relate to the ongoing EU Phase III study in general anesthesia.

General administrative and selling expenses increased by KEUR 190 to KEUR 985 in the first quarter of 2019 compared to the prior-year period. General administrative expenses increased by KEUR 43 to KEUR 789 and selling expenses increased by KEUR 147 to KEUR 196.

Tax income amounted to KEUR 667 in the first quarter of 2019 (prior-year period: KEUR 749) and relates 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 2019 amounted to KEUR 3,241 and increased by KEUR 116 compared to the prior-year period (net loss in the prior-year period: KEUR 3,125).

Cash and cash equivalents decreased by KEUR 1,615 in the first quarter of 2019. As of 31 March 2019, PAION's cash and cash equivalents amounted to KEUR 15,612.

The decrease of cash and cash equivalents nearly entirely stems from **cash flows from operating activities** of KEUR -1,611. 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, receipt of the milestone payments from Mundipharma and Hana Pharm recognized as trade receivables at the beginning of the fiscal year as well as (further) changes of the working capital.

Risks and opportunities

Material risks and opportunities relating to future development were presented in detail in the group management report for fiscal year 2018. Risks and opportunities have not changed significantly in the first quarter of 2019.

Outlook 2019

PAION confirms its outlook for the current fiscal year given in March 2019 with the publication of the 2018 consolidated financial statements and group management report. PAION's focus for the rest of 2019 is on the development program in Europe, approval processes, commercial manufacture of and supply chain for remimazolam. In addition, it is expected that further development and approval activities in the various territories will also promote the other indications.

PAION also plans small-scale pre-marketing activities for the preparation of an own commercialization subject to possible dates for filing its own market approval dossiers for remimazolam in Europe.

###

Key consolidated financial figures, IFRS (unaudited)

(all figures in KEUR unless otherwise noted)	Q1 2019	Q1 2018
Revenues	0	257
Research and development expenses	-3,063	-3,360
General administrative and selling expenses	-985	-795
Tax income	667	749
Net result for the period	-3,241	-3,125
Earnings per share in EUR for the period (basic)	-0.05	-0.05
Earnings per share in EUR for the period (diluted)	-0.05	-0.05

Cash flows from operating activities	-1,611	-2,752
Cash flows from investing activities	0	-4
Cash flows from financing activities	-12	0
Change in cash and cash equivalents (incl. exchange rate differences)	-1,615	-2,755
Average number of group employees	42	37

	31 Mar. 2019	31 Dec. 2018
Intangible assets	2,247	2,212
Cash and cash equivalents	15,612	17,227
Equity	17,836	20,822
Current liabilities	4,072	3,501
Balance sheet total	21,952	24,323

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 08 May 2019 at 2 p.m. CEST (1 p.m. BST, 8 a.m. EDT) to present the financial results for the first quarter of 2019, 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=m4a804d5392d35e81f89dd501dcc8ad24

About PAION

PAION AG is a publicly listed specialty pharmaceutical company developing and aiming to commercialize innovative drugs for 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.

and its local licensee Cosmo Pharmaceuticals submitted a New Drug Application in April 2019. In Japan, licensee Mundipharma filed for market approval for remimazolam in general anesthesia in December 2018. In China, licensee Yichang Humanwell filed for market approval for remimazolam in procedural sedation in November 2018.

In Europe, PAION is currently focused on the development of remimazolam for general anesthesia, but is also evaluating the possibility of submitting a Marketing Authorization Application in procedural sedation based on the U.S. filing.

Development of remimazolam for intensive care unit (ICU) sedation is part of the longer-term life-cycle plan for remimazolam.

PAION's vision is to become an acknowledged “PAIONeer” in sedation and anesthesia. PAION is headquartered in Aachen (Germany) with an additional site in Cambridge (United Kingdom).

Contact

Ralf Penner
Vice President Investor Relations/Public Relations
PAION AG
Martinstrasse 10–12
52062 Aachen – Germany
Phone +49 241 4453-152
E-mail r.penner@paion.com
www.paion.com