CORPORATE NEWS

EARNINGS

PAION AG PUBLISHES GROUP QUARTERLY STATEMENT FOR THE FIRST NINE MONTHS OF 2019

- NDA for remimazolam accepted for review by the FDA – PDUFA date set for 05 April 2020
- After positive pre-submission meeting with EMA, the MAA submission for procedural sedation in the EU is planned in 2019
- Financial position strengthened through loan agreement for up to EUR 20 million and convertible notes agreement for up to EUR 15 million
- Cash and cash equivalents of EUR 22.8 million as of 30 September 2019
- Dr. Jim Phillips started as new CEO in October 2019

Aachen (Germany), 06 November 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 nine months of 2019.

Dr. Jim Phillips, CEO of PAION AG, commented: *"PAION has made solid progress in the year to date on both the financial and development fronts. We have the resources to advance remimazolam to the next stage, including submitting a marketing application in Europe for procedural sedation in 2019 and continuing pre-commercialization activities. In the event marketing authorizations are granted, we should see the first product launches of remimazolam next year. It is an exciting time for PAION, and I am very happy to be part of the team now. We look forward to announcing more achievements in the months ahead."*

Update and outlook on remimazolam development

U.S.

The New Drug Application (NDA) in procedural sedation was prepared together with licensee Cosmo Pharmaceuticals (Cosmo) and submitted to the FDA by Cosmo in April 2019. The FDA informed Cosmo in June 2019 that the filing had been accepted and that a target decision date under the Prescription Drug User Fee Act (PDUFA) of 05 April 2020 had been set.

Under this timeline, market approval and subsequent launch is expected in 2020 assuming a regular approval process.

EU

In Europe, PAION is seeking approval for remimazolam in general anesthesia and in procedural sedation.

Procedural sedation: PAION plans to submit a Marketing Authorization Application (MAA) for procedural sedation in 2019. In a pre-submission meeting with the European Medicines Agency (EMA) held in February 2019, the EMA indicated that the existing data package from the U.S. Phase III clinical development program will be sufficient for submitting an MAA in procedural sedation. An essential task to be completed prior to the MAA submission is EMA approval of the Pediatric Investigation Plan (PIP), which has been agreed with the Pediatric Committee of the EMA in October 2019.

General anesthesia: PAION is conducting a randomized, single-blind, propofol-controlled, confirmatory Phase III trial with remimazolam for the induction and maintenance of general anesthesia. The trial is expected to enroll approximately 500 ASA III/IV patients (American Society of Anesthesiologists classification III to IV) in Europe undergoing non-emergency surgery. The opening of additional sites has accelerated the recruitment process. Currently, more than half of the necessary patients have been recruited and patient enrolment is expected to complete in the first half of 2020.

Assuming approval in procedural sedation and positive results in the Phase III trial in general anesthesia, PAION plans to submit an extension of the marketing authorization, a so-called type-II-variation, for remimazolam for general anesthesia. The review process for an extension is generally significantly faster than for an MAA.

The complete data from the EU Phase III study in general anesthesia, which are required for the submission of an extension of marketing authorization, are expected to be available at the time of the regulatory decision on the MAA in procedural sedation.

Licensee activities in other territories

PAION's licensees are actively advancing remimazolam in their respective territories.

Japanese licensee Mundipharma submitted a market approval dossier for remimazolam for general anesthesia in December 2018, which is currently being assessed by the Japanese Pharmaceuticals and Medical Devices Agency (PMDA). Market approval is currently expected early in 2020.

Chinese licensee Yichang Humanwell submitted a market approval dossier for remimazolam for procedural sedation to the Chinese National Medical Products Administration (NMPA) in November 2018. Market approval is currently expected in 2020.

Russian licensee R-Pharm announced the successful completion of a Phase III trial with remimazolam in general anesthesia in November 2018. R-Pharm is currently preparing to file the marketing dossier in Russia. For the license territory **Turkey, Middle East and North Africa**, R-Pharm plans to file for market approval based on the U.S. dossier.

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

PAION's **South Korean** licensee Hana Pharm successfully completed patient recruitment of a Phase III trial with remimazolam in general anesthesia in

October 2018. Hana Pharm is currently preparing to file the marketing dossier in South Korea.

Funding activities

In June 2019, PAION and the European Investment Bank (EIB) signed a loan agreement for up to EUR 20 million. The loan will be available until June 2021 and can be drawn down in a total of three tranches based on certain conditions, such as the achievement of operational milestones. PAION plans to draw down the first tranche of EUR 5 million before the end of the year.

In August 2019, PAION and Yorkville signed an agreement for a growth financing via convertible notes with a nominal amount of up to EUR 15 million, expected to be issued in up to three tranches. The first tranche with a nominal amount of EUR 5 million was issued in September 2019.

Changes in the Management Board

On 16 October 2019, Dr. James (Jim) Phillips joined PAION AG as the new Chief Executive Officer (CEO). Dr. Wolfgang Söhngen, co-founder and long-standing CEO of the company, will be leaving the Management Board in November 2019 as he reaches the age limit foreseen in the company bylaws.

Results of operations, financial position and net assets

Revenues in the first nine months of 2019 amounted to KEUR 7,500 and entirely resulted from the milestone payment from U.S. licensee Cosmo in connection with the submission of the NDA for remimazolam in the indication procedural sedation in the U.S. Revenues in the prior-year period primarily resulted from the license agreement with Japanese remimazolam licensee Mundipharma.

Research and development expenses amounted to KEUR 9,686 in the first nine months of 2019 (prior-year period: KEUR 9,118) and mainly relate to the EU Phase III trial in general anesthesia.

General administrative and selling expenses increased by KEUR 1,063 to KEUR 3,631 in the first nine months of 2019 compared to the prior-year period. General administrative expenses increased by KEUR 396 to KEUR 2,721 and selling expenses increased by KEUR 667 to KEUR 910. The increase of general administrative expenses mainly relates to the two financing agreements entered into in 2019, while selling expenses particularly increased in the course of setting up the supply chain and conducting pre-commercial activities for remimazolam.

Other income (expenses) includes (net) foreign exchange gains of KEUR 256 in the first nine months of 2019 (prior-year period: KEUR 3).

Tax income amounted to KEUR 1,995 in the first nine months of 2019 (prior-year period: KEUR 2,066) and relates to research and development tax credit claims.

The **net loss** for the first nine months of 2019 amounted to KEUR 3,380 compared to a net loss of KEUR 8,764 in the prior-year period. This means an increase of the net result in the amount of KEUR 5,384 compared to the prior-year period which is mainly attributable to higher revenues partly offset by

higher general administrative and selling expenses than in the prior-year period.

Cash and cash equivalents amounted to KEUR 22,796 as of 30 September 2019, an increase of KEUR 5,569 compared to 31 December 2018.

The increase of cash and cash equivalents primarily stems from **cash flows from operating activities** of KEUR 1,141 and **cash flows from financing activities** of KEUR 4,428. Cash flows from operating activities mainly result from the net loss, 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. Cash flows from financing activities primarily result from the gross proceeds of the convertible note of KEUR 4,750 and transaction costs incurred in this regard.

Risks and Opportunities

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

Outlook 2019

Development and commercialization activities

PAION's major focus for the remainder of 2019 is preparing the MAA submission in Europe for remimazolam in procedural sedation, which is expected to be completed by year-end, as well as advancing the European Phase III trial in general anesthesia. In addition, PAION will continue to support its licensees around the globe as they go through the regulatory review process in their respective territories.

PAION will also continue ongoing manufacturing and supply chain activities for remimazolam and small-scale pre-commercialization activities as preparation for the planned own commercialization of remimazolam in selected European markets.

Financial outlook

PAION expects revenues of about EUR 8 million in 2019, of which EUR 7.5 million already were recognized in connection with the regulatory filing for remimazolam in the U.S. by Cosmo. EUR 0.5 million are related to revenues from R-Pharm in connection with the transfer of the U.S filing dossier and are expected in the fourth quarter of 2019.

Due to the ongoing investment in the development of remimazolam including the EU Phase III study, PAION expects research and development expenses to amount to between approx. EUR 13 million and approx. EUR 15 million, depending on the progress of development. Income from tax credits on parts of research and development expenses from British tax authorities is expected to amount to approx. EUR 2 million. General administrative and selling expenses are expected to amount to between approx. EUR 4 million and approx. EUR 5 million depending on the volume of pre-commercial activities. Net loss is expected to amount to between approx. EUR 7 million and approx. EUR 10 million in 2019.

Based on current planning, available cash and cash equivalents secure a cash runway into 2021. PAION expects that additional funds will be required in the next years for the planned own commercialization in selected European

markets as well as the intended development of the indication ICU sedation and for the multi-year PIP. The magnitude of the required funds will be dependent on the actual setup of commercialization and which European countries PAION will initially focus on as well as the timing and the amount of milestone payments and royalties from licensees.

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Key consolidated financial figures, IFRS (unaudited)

(all figures in EUR thousand unless otherwise noted)	Q3 2019	Q3 2018	Q1-Q3 2019	Q1-Q3 2018
Revenues	0	241	7,500	758
Research and development expenses	-3,513	-2,574	-9,686	-9,118
General administrative and selling expenses	-1,310	-807	-3,631	-2,568
Income taxes	829	577	1,995	2,066
Net result for the period	-3,966	-2,521	-3,380	-8,764
Earnings per share in EUR for the period (basic)	-0.06	-0.04	-0.05	-0.14
Earnings per share in EUR for the period (diluted)	-0.06	-0.04	-0.05	-0.14

	Q1–Q3 2019	Q1–Q3 2018
Cash flows from operating activities	1,141	-10,219
Cash flows from investing activities	-4	-13
Cash flows from financing activities	4,428	5,214
Change in cash and cash equivalents (incl. exchange rate differences)	5,569	-5,019
Average number of employees	43	39

	30-09-2019	31-12-2018
Intangible assets	2,091	2,212
Cash and cash equivalents	22,796	17,227
Equity	17,644	20,822
Current liabilities	5,388	3,501
Non-current liabilities	5,187	0
Total assets	28,219	24,323

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. PAION has completed clinical development for use in procedural sedation in the U.S. and its licensee Cosmo Pharmaceuticals submitted a New Drug Application in April 2019, for which a PDUFA decision date of 05 April 2020 has been set. 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 seeking approval of remimazolam for general anesthesia and for procedural sedation. PAION plans to submit a Market Approval Authorization for procedural sedation by the end of 2019. A Phase III trial in general anesthesia is ongoing in Europe.

Development 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).

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