PRESS RELEASE

Heidelberg Pharma concludes very successful financial year 2022 and reports on course of business

- Start of clinical trial and first safety data with HDP-101 in multiple myeloma
- Conclusion and implementation of a strategic partnership with Huadong Medicine
- Successful financing activities
- Financials in line with adjusted guidance
- Conference call to be held on 27 March 2023 at 03:00 pm CEST

Ladenburg, Germany, 24 March 2023 – Heidelberg Pharma AG (FSE: HPHA) today published its financial results and Annual Report for fiscal year 2022 (1 December 2021 – 30 November 2022) and its outlook for 2023.

Prof. Dr. Andreas Pahl, Chief Scientific Officer, commented: "With the treatment of the first patient in February 2022, we achieved our most important goal of the past year, the start of the clinical development with the world's first ATAC candidate, our HDP-101. The study is on track, patients have been treated in three dose cohorts and so far HDP-101 has been shown to be safe and well tolerated."

Dr. Schmidt-Brand, CEO and CFO, further commented: "Another highlight was marked by the strategic partnership with Huadong. The license and option agreements for various ATAC candidates and the investment totaling EUR 105 million underline Huadong's strategic interest in Heidelberg Pharma and significantly strengthen our financial position. Huadong is now the second largest shareholder after dievini with 35% and supports our ambition to successfully develop the ATAC technology and become a global ADC player.

We are pleased with the newly signed partnership with Chiome and the license agreement with Takeda for one ATAC candidate each. We can speak of a very successful fiscal year 2022, operationally and financially.

In early 2023, we received unfortunate news from our ATAC collaboration partner Magenta. After serious adverse events occurred in the study with the ATAC candidate MGTA-117, Magenta immediately and voluntarily paused dosing in the clinical trial. The company reported in early February 2023 that all ongoing programs were being halted and strategic alternatives were being evaluated. At the end of February, the Amanitin linker supply contract was terminated by Magenta, which will result in a loss of sales in the low single-digit millions in 2023.

Further consequences for the contract situation depend on the course of Magenta's strategic realignment and cannot be estimated at present. However, we assume that our partnership will not be continued."

Key events in fiscal year 2022

- **Clinical trial with HDP-101:** Since February 2022, the ATAC candidate HDP-101 is evaluated in a Phase I/IIa study for the treatment of relapsed or refractory multiple myeloma. The Phase I dose escalation part of the study is to determine a safe and optimal dose of HDP-101 for the Phase IIa part of the study. The first three patient cohorts and dose levels were concluded and HDP-101 has so far been shown to be safe and well tolerated. Six trial centers are up and running in the United States and Germany, and further centers in Europe are about to initiate operations.
- **Strategic partnership with Huadong:** Heidelberg Pharma and Huadong Medicine Co., Ltd., Hangzhou, China, (Huadong) announced at the end of February 2022 that the companies had entered into a strategic partnership with the signing of an exclusive licensing agreement as well as an investment agreement. This consists of an exclusive license to develop and commercialize the ATAC candidates HDP-101 and HDP-103 in parts of Asia[1] with an upfront payment of USD 20 million and milestone payments of up to USD 449 million, as well as tiered royalties ranging from single- to low double-digit percentages for each candidate. Huadong also receives an exclusive option for the research candidates HDP-102 and HDP-104 in parts of Asia with total milestone payments of up to USD 461 million. In addition, Huadong made a strategic equity investment in Heidelberg Pharma totaling EUR 105 million, representing 35% of total shares outstanding after the transaction.
- **Conclusion of a rights issue under the partnership with Huadong:** In August 2022, Heidelberg Pharma offered all shareholders a total of 12,408,648 new shares for subscription at a price of EUR 6.44 each. Huadong participated to a significant extent in the rights issue, acquiring 9,374,156 shares through pre-emption rights from the main shareholder dievini[2]. Huadong also acquired 2,464,496 shares that were not subscribed by other shareholders, bringing its equity interest in Heidelberg Pharma to 25%. To reach the targeted 35% shareholding, Huadong bought 4,465,908 more shares from dievini at a price of EUR 6.44 per share.

  The corporate action generated total gross issue proceeds of approximately EUR 80 million for Heidelberg Pharma, most of which will be used to carry out the ongoing Phase I trial of HDP-101 and to continue the development of the follow-on projects HDP-102 and HDP-103 as well as the proprietary ATAC technology. The new share capital is now EUR 46,584,457.00.
- **New preclinical data from the ATAC technology platform presented at the AACR 2022 Annual Meeting:** At the American Association for Cancer Research (AACR) Annual Meeting in April 2022, Heidelberg Pharma presented preclinical data on its ATAC technology. The Company presented data on the synergy of using ATACs together with immune checkpoint inhibitors, as well as data indicating that repeated treatment with ATACs in preclinical models results in better tolerability without compromising efficacy.

[1] Parts of Asia: (excl. Japan, India, Pakistan, Sri Lanka): PR China, Hong Kong, Macao, Taiwan, South Korea, Indonesia, Singapur, The Philippines, Thailand, Bangladesh, Bhutan, Brunei, Myanmar, Kambodia, Laos, Malaysia, Maledives, Mongolia, Nepal und Vietnam.
[2] dievini Hopp BioTech holding GmbH & Co. KG

- **ATAC cooperations**

  Partner **Magenta** Therapeutics, Cambridge, MA, USA, (Magenta) developed MGTA-117, an ATAC consisting of a CD117 antibody and Amanitin to be used for targeted preparation, or conditioning, of patients for stem cell transplants or gene therapy. In March 2022 the first patient was treated with MGTA-117 in a dose escalation clinical trial in patients with relapsed/refractory acute myeloid leukemia (AML) and myelodysplastic syndrome with excess blasts (MDS-EB). Further information can be found under “Events after the reporting period”.

  An exclusive research agreement with **Takeda** Oncology, Cambridge, MA, USA, (Takeda) has been in place since 2017 for several targets for joint development of ADCs using the compound Amanitin. Under the exclusive research agreement, Heidelberg Pharma manufactured several ATACs using antibodies from Takeda’s proprietary portfolio. As a result of this work, Takeda acquired an exclusive license in September 2022 for commercial development of an ATAC with a selected target.

  In July 2022, Heidelberg Pharma and **Chiome** Bioscience Inc., Tokyo, Japan, (Chiome) announced the signing of an exclusive research and option agreement which will combine one of Chiome’s monoclonal antibodies against one specific target with Heidelberg Pharma’s proprietary ATAC platform. Under the terms of the agreement, Chiome will have access to Heidelberg Pharma’s ATAC platform technology and has an option for an exclusive license for global development and commercialization rights to the product candidate resulting from the research collaboration.

- **Progress in the clinical legacy portfolio:** The Australian Partner Telix Pharmaceuticals Limited, Melbourne, Australia, (Telix) successfully completed its phase III ZIRCON trial on using positron emissions tomography (PET) imaging for diagnosing kidney cancer, which began in August 2019 and involved 300 patients in the third quarter of 2022.

  The study results reached all endpoints. Study data delivered 86% sensitivity and 87% specificity, to demonstrate the ability of TLX250-CDx to reliably detect the clear cell phenotype (ccRCC). Furthermore, the study has also met the key secondary endpoint, achieving 85% sensitivity and 89% specificity in detecting ccRCC in tumors smaller than 4cm (“T1a” classification), currently a significant clinical challenge in the diagnosis of ccRCC.

  Telix plans to submit applications for marketing approval as a diagnostic in kidney cancer to the FDA (Food and Drug Administration, USA) and other regulatory authorities worldwide. Potential future utility may include active surveillance, surgical staging and treatment response monitoring for renal cancer. Telix is conducting further clinical trials to expand the indication. At the same time, Telix is also preparing the launch of an Expanded Access Program (EAP) to provide patients with pre-approval access to TLX250-CDx.

Events after the reporting period

- **ATAC cooperation with Magenta:** After the reporting period had ended, Magenta presented positive preliminary safety and initial efficacy data from its clinical trial with MGTA-117 at the American Society of Hematology (ASH) Annual Meeting.[3] Shortly after making the promising preliminary data public, Magenta announced that dose-limiting toxicities were being observed in the fourth dose level.[4] On 25 January 2023, Magenta reported that in the third dose level of the MGTA-117 clinical trial, a grade 5 serious adverse event resulting in death occurred that deemed to be possibly related to MGTA-117. For safety reasons, Magenta subsequently paused dosing in the clinical trial until further notice.

  On 2 February 2023, Magenta decided to halt all ongoing programs and to conduct a comprehensive review of strategic alternatives. Meanwhile, the Amanitin linker supply contract was terminated by Magenta, which will result in Heidelberg Pharma losing sales revenue in the low single-digit million range for fiscal year 2023. Further consequences for the contract situation depend on the course of Magenta‘s strategic realignment and cannot be estimated at present.

- **Safety Review Committee meeting and implications for Heidelberg Pharma**

  Following completion of the third dose level, in March, a data review was conducted by the Safety Review Committee. The SRC concluded that the treatment with HDP-101 is safe and well-tolerated in these three cohorts and recommended to escalate the dose.

  Patient safety remains as the top priority for Heidelberg Pharma. Together with our Safety Review Committee, and based on the body of available data, we decided as an extra precaution to implement further safety measures for our patients, especially regarding the identification and exclusion of those patients who might be prone to develop respiratory events. Additional examination will be also included to detect any similar events early on.

  These additional measures will be included in the study and implemented with the fourth cohort at the trial sites.

Key financial figures of the Heidelberg Pharma Group for fiscal year 2022

The 2022 fiscal year concerns the period from 1 December 2021 to 30 November 2022. The Heidelberg Pharma Group includes two entities, Heidelberg Pharma AG and Heidelberg Pharma Research GmbH.

The Heidelberg Pharma Group generated **sales revenue and other income** totaling EUR 19.9 million in fiscal year 2022. The sharp increase compared with the previous year (EUR 2.3 million) is due in particular to higher sales revenue totaling EUR 8.2 million arising from the strategic partnership concluded with Huadong during the year, which involves out-licensing HDP-101 and HDP-103 for parts of Asia.

[3] Magenta press release, 12 December 2022: https://investor.magentatx.com/news-releases/news-release-details/magenta-therapeutics-presents-positive-mgta-117-clinical-data
[4] Magenta press release, 25 January 2023: https://investor.magentatx.com/news-releases/news-release-details/magenta-therapeutics-voluntarily-pauses-mgta-117-phase-12-dose

Sales revenue totaling EUR 18.5 million (previous year: EUR 1.7 million) comprised revenue from collaboration agreements for the ATAC technology (EUR 17.5 million; previous year: EUR 1.2 million) and the service business (unchanged at EUR 0.5 million) and one milestone payment for a previous out-licensing (EUR 0.5 million).

Other income amounted to EUR 1.4 million (previous year: EUR 0.6 million) and largely comprised exchange rate gains of EUR 1.0 million as a result of the appreciation of the US Dollar against the Euro in the period under review. There was no significant other income in the previous year.

Operating expenses including depreciation and amortization increased to EUR 37.0 million in 2022 compared with EUR 27.9 million in the previous year. **Research and development (R&D) costs** rose considerably year-over-year to EUR 26.4 million (previous year: EUR 18.7 million) due to the cost-intensive external manufacturing for the ATAC projects and the on-going clinical trial with HDP-101. The production of antibodies for HDP-102 and HDP-103 also contributed to the result. At 71% of operating expenses, R&D remained the largest cost item. The **cost of sales** amounted to EUR 4.7 million, representing 13% of operating expenses. **Administrative costs** were EUR 4.8 million, an increase on the prior year (EUR 4.0 million) and accounted for 13% of operating expenses. **Other expenses** for business development, marketing and commercial market supply activities, which mainly comprise staff and travel costs, were EUR 1.1 million. They were higher than in the previous year (EUR 0.5 million) and represented 3% of operating expenses.

The Heidelberg Pharma Group recognized **comprehensive income** of EUR -19.7 million (previous year: EUR -26.1 million) in the 2022 fiscal year. **Basic earnings per share** rose from EUR -0.80 in the previous year to EUR -0.53.

Monthly cash use increased to EUR 0.7 million exclusive of the capital increase (previous year: EUR 2.3 million). The Group had **cash** of EUR 81.3 million at the close of the fiscal year (30 November 2021: EUR 6.1 million). The addition resulted mainly from the strategic partnership with Huadong relating to the outlicensing of HDP-101 and HDP-103 for parts of Asia and from the capital increase implemented in the third quarter, which combined more than compensated for the outflow of liquidity due to the expanded operating activities. In addition, a further tranche of EUR 5 million was drawn down from the dievini shareholder loan in February 2022.

At the end of the fiscal year, **total assets** at EUR 100.6 million were several times higher than the prior-year figure (EUR 21.7 million), which is mainly attributable to the higher levels of cash and inventories.

Equity of the Heidelberg Pharma Group at the end of the reporting period was EUR 66.6 million (30 November 2021: EUR 6.7 million). This corresponds to an equity ratio of 66.3% (30 November 2021: 30.8%).

Financial outlook for 2023 and strategy

The Executive Management Board expects the Heidelberg Pharma Group to generate between EUR 7.0 million and EUR 10.0 million in sales revenue and other income (2022: EUR 19.9 million) in the 2023 fiscal year. Sales revenue generated by Heidelberg Pharma Research GmbH (especially from ATAC technology), as well as deferred revenue and potential

milestone payments to Heidelberg Pharma AG will contribute to this figure in roughly equal measure. Sales revenue from major potential license agreements was not included in this planning.

Based on current planning, operating expenses are expected to be in the range of EUR 37.0 million to EUR 41.0 million, slightly higher than in the reporting year (EUR 37.0 million). Earnings before interest and taxes (EBIT) in the 2023 fiscal year are expected to be between EUR -28.5 million and EUR -32.5 million (2022: EUR -17.2 million).

Funds used will be in the range of EUR 32.5 million to EUR 36.5 million. This corresponds to an average monthly use of cash of EUR 2.7 million to EUR 3.1 million (2022: EUR 0.7 million). The Group's financing is secured until mid-2025 based on current planning.

Heidelberg Pharma believes that Amanitin is an innovative toxin with attractive properties for the development of ATACs and will continue its strategy for the development and marketing of proprietary ATAC technology. The strategy's core elements are the expansion of the Company's own project pipeline, the development of the pipeline projects until clinical proof of concept, the initiation of further research and option agreements and their extension to include long-term license agreements, as well as the broadening of the technology base.

Invitation to the financial results press conference

On Monday, 27 March 2023, Heidelberg Pharma will hold a conference call for media, analysts, and investors in English at 3:00 pm CEST/9:00 am EDT. Please register at least 10 minutes in advance using the following link:

https://us06web.zoom.us/webinar/register/WN_YmSObiktT4qmb5kjSZ0Lvg

You will receive an e-mail with your registration confirmation, which contains the link to participate in the audio webcast as well as dial-in numbers for participation by phone. Please note that asking oral or written questions is only possible for online participants.

Key figures for the Heidelberg Pharma Group

In EUR million	2022 [1] EUR million	2021 [1] EUR million
Earnings		
Sales revenue	18.5	1.7
Other income	1.4	0.6
Operating expenses	(37.0)	(27.9)
of which research and development costs	(26.4)	(18.7)
Operating result	(17.2)	(25.6)
Earnings before tax	(17.8)	(26.1)
Total comprehensive income	(19.7)	(26.1)
Earnings per share in EUR (basic)	(0.53)	(0.80)
Balance sheet as of the end of the period		
Total assets	100.6	21.7
Cash and cash equivalents	81.3	6.1
Equity	66.6	6.7
Equity ratio[2] in %	66.3	30.8
Cash flow statement		
Cash flow from operating activities	(8.9)	(26.6)
Cash flow from investing activities	(0.6)	(1.4)
Cash flow from financing activities	84.0	29.2
Employees (number)		
Employees at year end[3]	110	96
Employees at year end[3] (full-time equivalents)	102	89

1) The reporting period begins on 1 December and ends on 30 November.
2) Equity / total assets
3) Including members of the Executive Management Board
Rounding of exact figures may result in differences.

The Annual Report, including the consolidated financial statements in accordance with International Financial Reporting Standards (IFRS), is available at https://heidelberg-pharma.com/en/press-investors/announcements/financial-reports.

About Heidelberg Pharma

Heidelberg Pharma is an oncology specialist and the first company to develop the toxin Amanitin into cancer therapies using its proprietary ATAC technology and to advance the biological mode of action of the toxin as a novel therapeutic principle. The proprietary technology platform is being applied to develop the Company's own therapeutic ATACs as well as in third-party collaborations. The lead candidate HDP-101 is a BCMA ATAC in clinical development for multiple myeloma. Further ATAC candidates are being developed against different targets such as CD37, PSMA or GCC each in the indications non-Hodgkin's lymphoma, metastatic castration-resistant prostate cancer or gastrointestinal tumors such as colorectal cancer.

Heidelberg Pharma AG is based in Ladenburg, Germany, and is listed on the Frankfurt Stock Exchange: ISIN DE000A11QVV0 / WKN A11QVV / Symbol HPHA. More information is available at http://www.heidelberg-pharma.com/.

ATAC® is a registered trademark of Heidelberg Pharma Research GmbH in the EU and the USA.

Contact

Heidelberg Pharma AG
Corporate Communications
Sylvia Wimmer
Tel.: +49 89 41 31 38-29
E-Mail: investors@hdpharma.com
Gregor-Mendel-Str. 22, 68526 Ladenburg

IR/PR support

MC Services AG
Katja Arnold (CIRO)
Managing Director & Partner
Tel.: +49 89 210 228-40
E-Mail: katja.arnold@mc-services.eu