

# PRESS RELEASE

# Heidelberg Pharma announces financial figures and reports on successful business performance in 2023

- First efficacy data from the clinical trial with HDP-101 in multiple myeloma
- Expansion of the ADC technology platform to include further payloads
- New Management Board team
- Successful financing activities; sales revenue and other income above plan
- Conference call to be held on 25 March 2024 at 03:00 pm CET/ 10:00 am EDT

**Ladenburg, Germany, 25 March 2024** – Heidelberg Pharma AG (FSE: HPHA) today published its financial results and Annual Report for fiscal year 2023 (1 December 2022 – 30 November 2023) and its outlook for 2024.

**Professor Andreas Pahl, Chief Executive Officer,** commented: "In 2023, we made significant progress both with our first clinical candidate as well as in broadening our proprietary pipeline and ADC technology platform. We are pleased that the results we've seen to date from our ongoing clinical trial with lead ATAC candidate HDP-101 provide first signs of the great potential of the unique compound Amanitin for the treatment of multiple myeloma. Over the past year, we have expanded our portfolio beyond Amanitin with further payloads, taking a decisive step towards developing a variety of targeted and highly effective ADCs for the treatment of a number of malignant hematological and solid tumors."

Walter Miller, Chief Financial Officer, commented further: "The year 2023 was highly successful from a scientific and clinical perspective, and we also have made good progress in financing our operating activities. The sale of our Emergence shares in summer 2023 and the royalty financing agreement we recently closed in March 2024 for the diagnostic Zircaix<sup>™</sup> provide significant funding support for our proprietary ADC projects and are enabling us to accelerate the development of our pipeline candidates. In addition, we have been able to repay part of the loan to our main shareholder dievini. We are in a strong financial position to pursue our plans in the year ahead."

# Key events in fiscal year 2023 and in recent months

Clinical trial with HDP-101: The ATAC candidate HDP-101 is being evaluated in a Phase I/IIa clinical trial for the treatment of relapsed or refractory multiple myeloma. The first four patient cohorts and dose levels have been completed and proved to be safe and well tolerated. Since September 2023, patients in the fifth cohort have been treated with a dose of 100 µg/kg HDP-101. After the initial administration of HDP-101, a temporary drop in thrombocyte count occurred in all patients. However, this normalized within a few days, with counts returning to clinically unremarkable levels. In order to mitigate the effect of the initial administration, an adjustment and optimization of the medication regimen was developed. The corresponding protocol adjustments were implemented and recruitment of the sixth cohort was started.



Encouragingly, the fifth cohort showed biological activity in three patients and an objective improvement in the disease was detected ("partial remission"). In addition, one of the study participants from the third cohort has been treated with HDP-101 as a monotherapy since January 2023 and showed a stabilization of the course of disease ("stable disease").

- Various preclinical data from the ATAC technology platform presented at the 2023 AACR Annual Meeting: Heidelberg Pharma presented preclinical results of its ATAC technology at the American Association for Cancer Research (AACR) Annual Meeting in April 2023, including demonstrating for HDP-103 that subcutaneous administration resulted in an improved therapeutic window compared to intravenous administration, i.e., better tolerability while maintaining antitumor efficacy.
- Heidelberg Pharma receives patent for the use of the Amanitin-based ADC technology platform: In November 2023, the subsidiary Heidelberg Pharma Research GmbH received a patent for site-specific ATAC conjugates from the European Patent Office (EPO), which also covers a method for synthesizing such conjugates and their use in the treatment of diseases. The patent protects the use of ATACs for research and development as well as for use in clinical trials and the commercialization of the resulting product candidates.
- New Management Board team established: Walter Miller was appointed to the Management Board with effect from 1 May 2023 and is responsible for finance as Chief Financial Officer. At the same time, he took on the role of Managing Director of the subsidiary Heidelberg Pharma Research GmbH. Walter Miller has more than 20 years of experience in the life science industry and more than 25 years of experience in corporate finance, mergers & acquisitions (M&A), strategic controlling, accounting and corporate development.

At the end of November 2023, the Company announced that Dr. Jan Schmidt-Brand, CEO of Heidelberg Pharma AG and Managing Director of the subsidiary Heidelberg Pharma Research GmbH, would step down from his positions on 31 January 2024 upon reaching retirement age. The Supervisory Board appointed Professor Andreas Pahl as CEO with effect from 1 February 2024. Professor Pahl also assumed the role of Managing Director of the subsidiary.

• **Minority interest in Emergence sold:** In summer 2023, Heidelberg Pharma sold its minority interest in Emergence Therapeutics AG, Duisburg, Germany, (Emergence). The pharma company Eli Lilly and Company, Indianapolis, Indiana, USA, acquired all shares in Emergence. In the reporting year, the Group received an inflow of cash of EUR 6.8 million as a result of the sale. The cash was mainly used for a partial repayment of EUR 5.0 million of the loan granted by the main shareholder dievini.

#### Extended ADC pipeline

 Partnership with Binghamton University: In December 2022, Heidelberg Pharma Research entered into a research and exclusive option agreement with Binghamton University, State University of New York, Binghamton, NY, USA, related to a novel and proprietary immunostimulatory technology platform. The platform includes potent novel immunostimulatory compounds (TLR-7 antagonists) and ADC technology for the specific delivery of these compounds to tumor tissue. The resulting immunostimulatory ADCs have the



potential to harness the patient's own immune system by making the tumor visible to the immune system to thus attack and eliminate malignancies. These immunostimulatory agents could be synergistic with cytotoxic agents, including ADCs generated by Heidelberg Pharma's ATAC technology.

 Project HDP-201: The new HDP-201 project was presented for the first time in fall 2023. HDP-201 targets guanylate cyclase C (GCC), a receptor that is expressed on the surface of intestinal cells or cancer cells in various gastrointestinal tumors. This is the first ADC candidate project to utilize Heidelberg Pharma's newly introduced drug payload, exatecan. The GCC antibody had already been produced for the ATAC HDP-104 in sufficient quantities to supply two ADC projects. Since the antibody was already available, research was completed quicker than usual, and Heidelberg Pharma was able to rapidly start the development process for HDP-201. The scientific team is currently working to identify a lead candidate from various exatecan-based ADC candidates.

# **ATAC** cooperations

- An exclusive research agreement for several target molecules had been in place with Magenta Therapeutics, Cambridge, MA, USA, (Magenta) since March 2018. At the beginning of 2023, Magenta reported that, in the third dose level of the MGTA-117 clinical trial, a grade 5 serious adverse event had occurred that was deemed to be possibly related to MGTA-117. The trial was suspended, and, shortly thereafter, Magenta announced a change in strategy, and discontinued all ongoing development programs and supply agreements. As a result, Heidelberg Pharma lost sales revenue in the low single-digit millions for the 2023 financial year. In April 2023, Heidelberg Pharma signed a termination agreement with Magenta under which all licensed ATAC rights and some Magenta patents were assumed by Heidelberg Pharma.
- Partner Takeda Oncology, Cambridge, MA, USA, (Takeda), with whom an exclusive research agreement for several target molecules for the joint development of ADCs with the active ingredient Amanitin has been in place since June 2017, reached a development milestone in August with the start of a GLP (Good Laboratory Practice) toxicology study for an antibody-Amanitin conjugate. This resulted in a payment to Heidelberg Pharma.

#### Progress in the outlicensed clinical portfolio

In December 2023, partner **Telix** Pharmaceuticals Limited, Melbourne, Australia, (Telix) submitted a Biologics License Application (BLA) with the US Food and Drug Administration (FDA) for its PET imaging agent Zircaix<sup>™</sup> (TLX250-CDx, <sup>89</sup>Zr-DFO-girentuximab) for the diagnosis of clear cell renal cell carcinoma.

The radiolabeled antibody was developed by Heidelberg Pharma AG up to an initial Phase III trial and licensed to Telix in 2017.

In addition to further developing the diagnostic antibody TLX250-CDx in other indications, Telix is also working on the development of a therapeutic radioimmune conjugate (<sup>177</sup>Lu-DOTA-girentuximab, TLX250) based on the lutetium-177-labeled antibody girentuximab.



### Events after the reporting period

 Royalty purchase agreement closed with HealthCare Royalty: In early March 2024, Heidelberg Pharma signed an agreement with HealthCare Royalty, Delaware, USA, (HCRx) for the sale of a portion of future royalties from global sales of Zircaix<sup>™</sup>. Heidelberg Pharma received a non-refundable upfront payment of USD 25 million and is also entitled to up to an additional USD 90 million from the sale of the royalties. Once HCRx has received a maximum cumulative amount, the royalties will revert to Heidelberg Pharma and HCRx will receive a low single-digit percentage of royalties.

# Key financial figures of Heidelberg Pharma Group for fiscal year 2023

The 2023 fiscal year concerns the period from 1 December 2022 to 30 November 2023. 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 16.8 million in fiscal year 2023 (2022: EUR 19.9 million).

**Sales revenue** totaled EUR 9.9 million (previous year: EUR 18.5 million) and includes revenue related to ATAC technology collaboration agreements of EUR 9.8 million (previous year: EUR 17.5 million) and to the service business of EUR 0.1 million (previous year: EUR 0.5 million). The previous year was characterized in particular by the out-licensing of HDP-101 and HDP-103 for certain territories to partner Huadong Medicine Co, Ltd, Hangzhou, China, (Huadong), of which the HDP-101 portion was fully recognized in revenue.

**Other income** amounted to EUR 6.9 million (previous year: EUR 1.4 million) and was primarily attributable to the disposal of Emergence shares (EUR 5.9 million), while 2022 saw considerable foreign exchange gains (EUR 1.0 million).

**Operating expenses** including depreciation and amortization increased slightly to EUR 38.0 million in 2023 compared to the previous year (EUR 37.0 million). **Research and development (R&D) costs** were slightly higher year-over-year at EUR 28.1 million (previous year: EUR 26.4 million). This increase was due in particular to the cost-intensive production of ADCs for successor candidates. At 74% of operating expenses, R&D remained the largest cost item.

**Cost of sales** was mainly related to expenses for customer-specific research and for the supply of Amanitin linkers to licensing partners. At EUR 3.3 million, these costs were down over the prior year (EUR 4.7 million) and accounted for 8% of operating expenses.

Administrative expenses amounted to EUR 5.2 million, which was above the previous year's level (EUR 4.8 million) and corresponded to 14% of operating expenses. Other expenses for business development, marketing and commercial market supply activities, which mainly comprised personnel and travel expenses, increased year-on-year to EUR 1.4 million (previous year: EUR 1.1 million) and corresponded to 4% of operating expenses.

The Heidelberg Pharma Group recognized **a net loss for the period** of EUR -20.3 million in the 2023 fiscal year (previous year: EUR -19.7 million). Undiluted **earnings per share** fell from EUR -0.53 in the previous year to EUR -0.44.



**Monthly cash use** increased to EUR 3.2 million. Monthly cash use excluding financing activities (mainly repayment of a portion of the dievini loan of EUR 10 million) amounted to EUR 2.3 million (previous year: EUR 0.7 million). At the end of the financial year, the Group had **cash** of EUR 43.4 million (30 November 2022: EUR 81.3 million).

At the end of the financial year, **total assets** amounted to EUR 70.4 million (previous year: EUR 100.6 million). Cash outflow and an increase in inventories were the main reasons for the reduction.

The Heidelberg Pharma Group's **equity** amounted to EUR 49.3 million at the end of the reporting period (30 November 2022: EUR 66.6 million), corresponding to an equity ratio of 70.1% (30 November 2022: 66.3%).

#### Financial outlook 2024 and strategy

For the 2024 financial year, the Executive Board expects sales and other operating income to total between EUR 11.0 million and EUR 15.0 million (2023: EUR 16.8 million). This does not yet include the upfront payment of USD 25 million received from HCRx and its effects on operational planning. Possible additional revenue from a potential further license agreement was not included in the 2024 earnings plan.

Operating expenses in 2024 are expected to be between EUR 36.0 million and EUR 40.0 million if business develops as planned, and thus roughly at the level of the 2023 reporting year (EUR 38.0 million). This guidance does not include any adjustments to the R&D budget due to the cash inflow from HCRx.

An operating result of between EUR -23.5 million and EUR -27.5 million is expected for 2024 (2023: EUR -21.2 million).

Funds used are expected to be between EUR 28.0 million and EUR 32.0 million in the 2024 financial year. This corresponds to an average monthly use of cash of between EUR 2.3 million and EUR 2.7 million (2023: EUR 3.2 million). Based on current planning, the Group is financed until mid-2025, but expects this financing range to be extended.

In recent years, Heidelberg Pharma has built up extensive expertise and a patent portfolio for the active ingredient Amanitin, which can be coupled with various tumor-specific antibodies, through its subsidiary Heidelberg Pharma Research GmbH. The strategy is aimed at validating the technology platform in clinical trials, broadening the application of the mechanism of action and developing new therapeutic options for patients. The company has a high level of expertise in the field of ADC development, which is to be broadened by incorporating new drug payloads.

#### Invitation to the financial results conference call

On Monday, 25 March 2024, Heidelberg Pharma will hold a conference call for media, analysts, and investors in English at 3:00 pm CET/10:00 am EDT. Please register at least 10 minutes in advance using the following link:

https://us06web.zoom.us/webinar/register/WN\_GRpMMZQHShuKhKn04vtyBA



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.



	2023 <sup>1</sup>	<b>2022</b> <sup>1</sup>
In EUR million	EUR million	EUR million
Earnings		
Sales revenue	9,859	18,514
Other income	6,942	1,346
Operating expenses	(38,011)	(37,042)
of which research and development costs	(28,075)	(26,377)
Operating result	(21,210)	(17,181)
Earnings before tax	(20,346)	(17,786)
Net loss for the year	(20,346)	(19,702)
Comprehensive income	(18,324)	(19,702)
Earnings per share in EUR (basic)	(0.44)	(0.53)
Balance sheet as of the end of the period		
Total assets	70,353	100,582
Cash and cash equivalents	43,439	81,329
Equity	49,340	66,644
Equity ratio <sup>2</sup> in %	70.1	66.3
Cash flow statement		
Cash flow from operating activities	(33,672)	(8,864)
Cash flow from investing activities	5,848	(598)
Cash flow from financing activities	(10,053)	84,001
Employees (number)		
Employees at year end <sup>3</sup>	105	110
Employees at year end <sup>3</sup> (full-time equivalents)	95	102

# Key figures for the Heidelberg Pharma Group

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/pressinvestors/announcements/financial-reports.



### **About Heidelberg Pharma**

Heidelberg Pharma develops novel drugs based on its ADC technologies for the targeted and highly effective treatment of cancer. ADCs are antibody-drug conjugates that combine the high affinity and specificity of antibodies with the efficacy of toxins to fight cancer. Selected antibodies are loaded with various payloads that are transported into diseased cells. The toxin then unleashes its effect within the cell and kills them.

Heidelberg Pharma is the first company to use the active ingredient Amanitin in cancer therapies. The company uses the toxin's biological mechanism of action with its innovative ATAC technology as a new therapeutic principle. It offers the opportunity to break through therapy resistance and also eliminate dormant tumor cells, which could lead to significant advances in cancer therapy - even for patients who no longer respond to any other treatment. The most advanced product candidate HDP-101 is a BCMA-ATAC for the indication multiple myeloma, which is currently in clinical development.

In addition to Amanitin, other payloads are expanding the ADC platforms to develop targeted and highly effective ADCs for the treatment of a variety of malignant hematologic and solid tumors.

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

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

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