

# Heidelberg Pharma Reports on the First Nine Months of Financial Year 2025

- Leading ADC candidate HDP-101 continues to demonstrate favorable safety and tolerability profile; clinical trial progresses into ninth cohort with increased dose of 175 µg/kg
- Delay in significant milestone payment leads to extensive cost-saving measures, including a 75% reduction in workforce and focus on leading ADC project HDP-101
- Presentation of new clinical data of HDP-101 at the International Myeloma Society (IMS) Annual Meeting; several patients from cohort 8 show initial objective efficacy after only a few doses
- Adjustment of guidance following strategic focus

**Ladenburg, Germany, 9 October 2025 –** Heidelberg Pharma AG (FSE: HPHA) reported today on its operational progress as well as on the Group's financial figures for the first nine months of fiscal year 2025 (1 December 2024 – 31 August 2025).

**Professor Andreas Pahl, CEO of Heidelberg Pharma AG, commented**: "In light of the delayed milestone payment, we have decided to prioritize our projects and implement a comprehensive cost-saving program. We deeply regret having to take these measures and would like to thank all affected colleagues for their many years of commitment, dedication, and valuable contributions to Heidelberg Pharma.

The measures we've decided on also affect our guidance, which we adjusted a few days ago.

The clinical development of our leading project HDP-101 remains promising. In cohorts 5 to 8, we observed an overall response rate of 36%, and in cohort 8, the preliminary overall response rate is 50%. HDP-101 has a strong safety and tolerability profile, and these data underscore the therapeutic potential of HDP-101 in heavily pretreated patients with relapsed or refractory multiple myeloma."

#### Key operational developments within the company and among its partners

- Developments at partner Telix unrelated to the ATAC technology: On 27 August 2025, partner Telix Pharmaceuticals Limited, Melbourne, Australia (Telix) received a Complete Response Letter (CRL) from the FDA for the diagnostic agent TLX250-CDx. The FDA identified deficiencies in the CMC (Chemistry, Manufacturing and Controls) package. According to Telix, the company immediately began addressing the deficiencies and will promptly request a Type A meeting with the FDA. New timelines will be communicated as soon as they are available.
  - Under the license agreement with Telix, Heidelberg Pharma is entitled to milestone payments and double-digit royalties if the product receives marketing approval. In 2024, Heidelberg Pharma sold a portion of the future royalties to HealthCare Royalty (HCRx) and is entitled to receive USD 70 million from HCRx following FDA approval of TLX250-CDx, with reductions if approval is granted after the end of 2025. As the payment condition has not yet been met, the milestone payment is delayed accordingly.
- Strategic focus and cost-saving measures: Due to the delayed milestone payment, Heidelberg Pharma announced on 25 September 2025, after the end of the reporting period, a comprehensive program to streamline operations and reduce costs. As the milestone payment from HCRx is still expected, but delayed and potentially lower than anticipated, this measure was necessary to extend the company's cash runway.



In the future, Heidelberg Pharma will focus on the further development of its lead ADC candidate HDP-101, which is currently in a Phase I/IIa clinical trial. The second clinical program, HDP-102, will be temporarily paused. For the third ADC, HDP-103, the company still plans to prepare the documentation for a clinical trial application.

Early research activities will be phased out. Heidelberg Pharma will explore opportunities to outlicense its preclinical programs.

The current workforce will be reduced companywide by approximately 75% by mid-2026.

• HDP-101 development program: HDP-101, an Amanitin-based antibody-drug conjugate targeting the BCMA antigen, is being tested in a Phase I/IIa open-label, multicenter study for the treatment of relapsed or refractory multiple myeloma, a cancer of the bone marrow. The first part of the study is a Phase I dose escalation study to determine the safe and optimal dosage of HDP-101 for the Phase IIa part of the study. The first eight patient cohorts and dose levels were completed with no evidence of dose-limiting toxicities.

The eighth cohort, with a dose of  $140 \,\mu g/kg$ , proved to be safe and well tolerated. All patients were dosed and have completed the observation period. HDP-101 consistently demonstrated a very good safety and tolerability profile. In addition, there are promising signs of clinical efficacy. In half of the patients, initial efficacy was observed after the first doses. Two patients achieved partial response and one patient achieved very good partial response. This builds on earlier positive results, including a patient from cohort 5 who had previously undergone several different therapies and has now achieved complete response with no detectable tumor cells while on ongoing monotherapy with HDP-101. In addition, several patients from different cohorts showed objective improvements and promising antitumor activity, further supporting the therapeutic potential of HDP-101 in heavily pretreated patients with relapsed or refractory multiple myeloma.

Based on these results, the Safety Review Committee recommends continuing the study in cohort 9 with an increased dose of 175  $\mu$ g/kg in one dosing arm. The cohort has already been started, and the first patient dosed.

HDP-102 development program: HDP-102 is an ADC targeting CD37, which is overexpressed
on B-cell lymphoma cells. Preclinical studies have shown excellent anti-tumor efficacy in in vivo
studies as well as good tolerability. Heidelberg Pharma intends to develop HDP-102 for specific
indications of non-Hodgkin lymphoma.

At the end of May, Heidelberg Pharma announced the dosing of the first patient with HDP-102. Three patients were treated with 40  $\mu$ g/kg in the first cohort. Initial data showed promising results. The treatment is well tolerated, and initial signs of biological activity were observed even at the very low dose. Two patients showed stabilization of the disease with regression and reduction of lymph nodes. The safety committee recommended increasing the dose of HDP-102 to 65  $\mu$ g/kg in cohort 2.

Due to the current financial situation of the company, the study is being temporarily paused, and no further cohorts are being opened at this time. Patients in cohort 1 will continue to be treated with HDP-102 as long as there is no progression of the disease.

• **HDP-103 development program:** HDP-103 is being developed for the treatment of metastatic castration-resistant prostate cancer (mCRPC). The antibody used binds to PSMA, a membrane antigen that is overexpressed on prostate cancer cells. It is a promising target for ATAC technology as it has limited expression in normal tissues.



The clinical team is working on the study application for a Phase I clinical trial. As part of the current focus, partners are being sought for the clinical development of HDP-103 outside China. This does not affect the development cooperation with Huadong in its license territory.

HDP-104 and HDP-201 development program: The ADC projects HDP-104 and HDP-201 target guanylyl cyclase-C (GCC), a receptor that is expressed on the surface of intestinal cells and cancer cells in various gastrointestinal tumors. HDP-104 uses Amanitin as its payload, while HDP-201 uses the topoisomerase inhibitor exatecan. Heidelberg Pharma is currently not pursuing further development of either project, and is seeking a partnership.

#### Events after the end of the reporting period

• New clinical data on HDP-101 presented at International Myeloma Society Annual Meeting 2025: At the Annual Meeting of the International Myeloma Society (IMS) in Toronto, Canada, in mid-September, Professor Jonathan L. Kaufman, clinical investigator for the study and David Bankes Glass Professor, Department of Hematology and Medical Oncology, Emory University, Atlanta, USA, presented new results from eight patient cohorts in the ongoing study evaluating HDP-101 in multiple myeloma. In cohort 8, HDP-101 consistently demonstrated a very good safety and tolerability profile and encouraging signs of clinical efficacy. Biological activity of HDP-101 was observed in several patients, and one patient has already achieved very good partial remission.

# Adjustment of the risk and opportunity report Financial risks – Liquidity – Risk of insolvency

An expected milestone payment of USD 70 million from HCRx did not materialize, as the payment condition – market approval of the diagnostic agent TLX250-CDx by the FDA – is currently not fulfilled. The lack of cash inflow jeopardizes the continued existence of the Group and/or the consolidated companies.

To enable the companies of the Heidelberg Pharma Group to meet their payment obligations, a decision was made on 25 September 2025, to strategically focus on the leading ADC candidate HDP-101, discontinue all early-stage research activities, and reduce the workforce by 75%.

Once these measures have been implemented and based on the current planning, the company's financing range will be extended until mid-2026.

In addition to the liquidity risk that threatens the company's existence, it cannot be ruled out that other risks, including general risks (business model) and financial risks (impairment of short- or long-term assets) will also increase.

## Results of operations, financial position and net assets

The Heidelberg Pharma Group, as of the reporting date consisting of Heidelberg Pharma AG and its three subsidiaries Heidelberg Pharma Research GmbH, HDP G250 AG & Co. KG, and HDP G250 Beteiligungs GmbH, reports consolidated figures. The two latter companies, which were newly established in the previous year, are not operationally active and affiliated to the parent company like Heidelberg Pharma Research GmbH.

The reporting period referred to below relates to the period from 1 December 2024 to 31 August 2025 (9M 2025).

In the first nine months of the 2025 financial year, the Group generated sales revenues and income totaling EUR 6.4 million (previous year: EUR 7.6 million) and is in line with the updated planning.



The **sales revenues** included in this figure fell from EUR 5.2 million the previous year to EUR 1.4 million. **Other income** amounted to EUR 5.0 million and was thus significantly higher than the previous year's level of EUR 2.4 million due exchange rate gains (EUR 3.2 million).

Operating expenses, including depreciation, amounted to EUR 28.2 million in the reporting period (previous year: EUR 22.8 million) and are broken down as follows: Cost of sales decreased to EUR 0.2 million (previous year: EUR 1.5 million) and corresponds to 1% of total costs. Research and development costs of EUR 21.0 million increased compared to the same period last year (EUR 15.7 million). This increase is due to the planned significantly higher costs for the Phase I/Ila study with HDP-101. R&D costs continue to represent the largest cost item, accounting for 74% of operating expenses. Administrative costs, which include the costs of holding activities, the stock exchange listing and the executive management board, increased to EUR 5.0 million compared to the same period last year (EUR 4.7 million), which is mainly due to higher personnel costs. Administrative costs account for 18% of operating expenses. Other expenses for business development, marketing and commercial market supply activities, which mainly include personnel and travel expenses, but also expenses for exchange rate differences (EUR 1.1 million), doubled compared to the previous year from EUR 1.0 million to EUR 2.0 million and represented 7% of operating expenses.

**The financial result,** which is mainly made up of interest income on bank balances, amounted to EUR 0.7 million (previous year: EUR 1.0 million). Despite the full repayment of the shareholder loan last year, the decrease is attributable to a lower investment volume and lower interest rates.

The **net loss** for the first nine months of the financial year increased to EUR 21.1 million compared to the previous year's figure of EUR 14.3 million. The increase is mainly due to higher operations expenses. **Earnings per share** deteriorated accordingly from EUR -0.31 in the previous year to EUR -0.45 in the reporting period.

**Cash** amounted to EUR 22.9 million at the end of the third quarter (30 November 2024: EUR 29.4 million; 31 August 2024: EUR 36.6 million). Excluding financing effects (shareholder loans, sale of receivables), Heidelberg Pharma recorded an average cash outflow of EUR 2.8 million per month in the first nine months of the fiscal year (previous year: EUR 2.6 million).

**Total assets** as of 31 August 2025 amounted to EUR 54.1 million and were therefore below the figure at the comparative reporting date of 30 November 2024 (EUR 60.7 million). **Equity** (EUR 10.5 million) also decreased as a result of the loss for the period compared to the end of the 2024 financial year (EUR 30.9 million).

#### Financial outlook for 2025

The guidance issued on 21 March 2025 for the current financial year was adjusted on 6 October 2025.

The Heidelberg Pharma Group expects sales and other income for the financial year 2025 between EUR 7.5 million and EUR 9 million (previously: EUR 9 million to EUR 11 million). Operating expenses are expected to range between EUR 36 million and EUR 40 million (previously: EUR 40 million to EUR 45 million).

Based on these adjustments, an operating result (EBIT) between EUR -28.5 million and EUR -31 million is expected (previously: EUR -30 million to EUR -35 million).

As part of the strategic focus, long-term and short-term assets are still being reviewed for impairment. They could prove to be only partially or no longer recoverable, resulting in value adjustments. Such non-cash depreciation on assets would lead to additional operating expenses in



the current fiscal year, which in turn could have a negative impact on the operating result beyond the aforementioned range of between EUR -28.5 million and EUR -31 million.

For 2025, Heidelberg Pharma anticipates cash requirements of EUR 14 million to EUR 17 million (previously: EUR 50 million to EUR 55 million anticipated inflow). Monthly cash outflow is expected to range between EUR 1.2 million and EUR 1.5 million per month (previously: EUR 4.2 million and EUR 4.6 million inflow). Based on current planning and available funds, the Company's financing is secured until mid-2026.

The Executive Management Board, in accordance with the Supervisory Board, is in talks with the main shareholders and other parties to secure financing in the medium term.

The complete set of figures for the interim financial statements is available at <a href="http://www.heidelberg-pharma.com/">http://www.heidelberg-pharma.com/</a> "Press & Investors > Announcements and Reports > Financial Reports > Interim announcement of 9 October 2025. A conference call on this interim announcement will not be offered.



# **Key figures for the Heidelberg Pharma Group**

In EUR thsd.	9M 2025 <sup>1</sup> EUR thsd.	9M 2024 <sup>1</sup> EUR thsd.
Earnings		
Sales revenue	1,436	5,248
Other income	4,988	2,368
Operating expenses	(28,179)	(22,849)
of which research and development costs	(21,042)	(15,650)
Operating result	(21,756)	(15,233)
Earnings before tax	(21,054)	(14,259)
Net loss for the period / Comprehensive income	(21,054)	(14,259)
Basic earnings per share in EUR	(0.45)	(0.31)
Balance sheet as of the end of the period		
Total assets	54,052	65,775
Cash	22,869	36,569
Equity	10,530	35,823
Equity ratio <sup>2</sup> in %	19.5	54.5
Cash flow statement		
Cash flow from operating activities	(24,818)	(22,749)
Cash flow from investing activities	(179)	(266)
Cash flow from financing activities	18,428	16,106
Employees (number)		
Employees as of the end of the period <sup>3</sup>	126	109
Full-time equivalents as of the end of the period <sup>3</sup>	114	98

<sup>1</sup> The reporting period begins on 1 December and ends on 31 August. 2 Equity / total assets 3 Including members of the Executive Management Board Rounding of exact figures may result in differences.



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### **About Heidelberg Pharma**

Heidelberg Pharma is a biopharmaceutical company working on a new treatment approach in oncology and developing novel drugs based on its ADC technologies for the targeted and highly effective treatment of cancer. ADCs are antibody-drug conjugates that combine the specificity of antibodies with the efficacy of toxins to fight cancer. Selected antibodies are loaded with cytotoxic compounds, the so-called payloads, that are transported into diseased cells. Inside the cells, the toxins then unleash their effect and kill the diseased cells.

Heidelberg Pharma is the first company to use the compound Amanitin from the green death cap mushroom in cancer therapy. The biological mechanism of action of the toxin represents a new therapeutic modality and is used as a compound in the Amanitin-based ADC technology, the so-called ATAC technology.

The lead candidate HDP-101 is a BCMA ATAC in clinical development for multiple myeloma. A second ATAC candidate, HDP-102, has recently started clinical development in Non-Hodgkin Lymphoma and is currently on a temporary hold. HDP-103 against metastatic castration-resistant prostate cancer and HDP-104 targeting gastrointestinal tumors such as colorectal cancer have completed preclinical development. Heidelberg Pharma is open for partnering.

The company is based in Ladenburg, Germany, and is listed on the Frankfurt Stock Exchange: ISIN DE000A11QVV0 / WKN A11QVV / Symbol HPHA. More information is available at <a href="https://www.heidelberg-pharma.com">www.heidelberg-pharma.com</a>

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