



Heidelberg PHARMA

Focused Cancer Therapies

- First preliminary efficacy data from the clinical trial with HDP-101 in multiple myeloma published
- Presentation of preclinical and clinical data of the proprietary ADC technology platforms at the AACR meeting 2024
- Orphan drug designation for HDP-101 granted by the FDA
- Sale of a portion of future royalties for TLX250-CDx to HealthCare Royalty
- Professor Andreas Pahl takes over as Chief Executive Officer



HALF-YEAR FINANCIAL REPORT 2024

KEY FIGURES

	H1 2024 ¹ € '000	H1 2023 ¹ € '000
Earnings		
Sales revenue	4,055	4,391
Other income	2,227	277
Operating expenses	(15,551)	(20,704)
of which research and development costs	(10,583)	(14,772)
Operating result	(9,269)	(16,036)
Earnings before tax	(8,665)	(15,774)
Comprehensive income	(8,665)	(15,951)
Net loss for the period	(8,665)	(15,951)
Earnings per share in €	(0.19)	(0.34)
Balance sheet at end of period		
Total assets	71,974	77,965
Cash	42,619	57,379
Equity	41,163	50,891
Equity ratio ² in %	57.2	65.3
Cash flow statement		
Cash flow from operating activities	(16,924)	(18,153)
Cash flow from investing activities	(84)	(788)
Cash flow from financing activities	16,144	(5,008)
Employees (number)		
Employees as of the end of the period (headcount) ³	110	113
Employees as of the end of the period (full-time equivalents) ³	97	103

¹ The reporting period begins on 1 December and ends on 31 May.

² Equity/total assets

³ Including members of the Executive Management Board

Rounding of exact figures may result in differences in all tables of this report.

LETTER TO THE SHAREHOLDERS

Dear Ladies and Gentlemen, Dear Shareholders,

The last few months have been quite eventful. In March of this year, we signed a forward-looking agreement with HealthCare Royalty to sell part of the royalties from the portfolio candidate TLX250-CDx, which we developed up to the first Phase III clinical trial and out-licensed to our Australian partner Telix in 2017.

Telix conducted a second Phase III trial, which generated positive results. Based on these, Telix started a rolling Biologics License Application (BLA) submission to the US Food and Drug Administration (FDA) for the candidate TLX250-CDx in December 2023 for detection of clear cell renal cell carcinoma. Our partner announced in early June that it had completed the BLA submission. Telix hopes to achieve regulatory approval on the US market by the end of the year.

This agreement makes Heidelberg Pharma eligible for both milestone payments and royalties. We have now sold part of these future royalties to HealthCare Royalty. The agreed upfront payment of USD 25 million has already been collected. We expect to receive a further USD 75 million upon FDA approval of TLX250-CDx. A priority for us was to agree on a maximum cumulative repayable amount with HealthCare Royalty. As soon as this threshold has been reached, royalty payments will revert to Heidelberg Pharma. This means that we are already benefiting from the candidate's success and will continue to do so in the future.

On the scientific side, we were delighted to be able to release initial safety and preliminary efficacy data from the Phase I clinical trial with our ATAC development candidate HDP-101 back in December. Three patients from Cohort 5 were observed to be in partial remission. During treatment in Cohort 5, a temporary drop in thrombocyte count occurred, although this normalized within a few days. As a result, we will optimize the dosing regimen for Cohort 6.

We received some good news in March. The FDA has granted Orphan Drug Designation for the treatment of multiple myeloma to HDP-101. This provides further validation of the potential benefit of our Amanitin-based ADC candidate in this indication.

In the second half of the year, we will focus on recruiting patients for the clinical trial with HDP-101 and on submitting the trial application for the ATAC successor candidate HDP-102.

Based on current financial planning, the Company's financing is secured until mid-2025. Taking into account a further expected payment of USD 75.0 million from HealthCare Royalty upon the approval of TLX250-CDx, we assume based on the current medium-term planning that funding will be available until the end of 2026.

We are very optimistic that we will see further positive development of our clinical trial and that study participants will benefit from the therapy. Encouraging data, a dynamically developing pipeline and the achievement of some expected milestones should all have a positive impact on our valuation. We thank you for your trust and support.

Ladenburg, 11 July 2024

Yours sincerely,



Professor Andreas Pahl
Chief Executive Officer

INTERIM MANAGEMENT REPORT

Reporting period from 1 December 2023 to 31 May 2024

Introduction

Heidelberg Pharma is active in biopharmaceutical drug development, specializing in oncology. The company researches, develops and produces Antibody Drug Conjugates (ADCs), which combine the high affinity and specificity of antibodies with the efficacy of toxins. The focus of activities is on the patented and proprietary ATAC technology, which is based on the fungal toxin Amanitin and utilizes the biological mechanism of action of this toxin as a new therapeutic principle in cancer medicine. To Heidelberg Pharma's knowledge, it is the first company to develop the active ingredient Amanitin for cancer therapies. The ATAC technology platform is used for the development of proprietary therapeutic antibody-Amanitin conjugates as well as in collaborations with external partners.

In addition to the toxin Amanitin, which is known from the death cap mushroom, the company has been using other active substances such as the topoisomerase I inhibitor Exatecan or immunostimulatory active substances such as the toll-like receptor TLR7 since financial year 2023, thus supplementing the proprietary ATAC technology with additional ADC technologies ("toolbox") in order to develop the best possible ADCs for other target antigens and areas of application.

The most advanced development candidate HDP-101 is an Amanitin-based ADC and uses an antibody targeting the molecule BCMA on myeloma cells. HDP-101 is in Phase I clinical development for the treatment of patients with multiple myeloma (MM). Further ATAC candidates are being developed against various target molecules such as CD37, PSMA or GCC in the indications of non-Hodgkin's lymphoma, metastatic castration-resistant prostate cancer or gastrointestinal tumors such as colorectal cancer.

Key events in the first six months

HDP-101 (BCMA-ATAC) development program

The ATAC candidate HDP-101 is currently in a Phase I/IIa clinical trial for the treatment of relapsed or refractory multiple myeloma.

The first five patient cohorts and dose levels have been completed. The first four patient cohorts proved to be safe and well tolerated. Since September 2023, patients in the 5th cohort have been treated with a dose of 100 µg/kg HDP-101. After the first administration of HDP-101, all patients experienced a short-term reduction in platelet count, which completely normalized after a few days and was clinically inconspicuous.

To mitigate this transient effect, the clinical team has adjusted and optimized the medication regimen. Cohort 6 will consist of three arms, with at least three patients enrolled in each arm. In consultation with the clinical investigators, the dose will be 90 µg/kg in order to test these three arms with as little risk to the patients as possible.

Patients in Arm A will be treated with a single dose of HDP-101 on day 1 of each 21-day cycle following pre-medication. Arm B will receive a weekly dose of HDP-101, which means that the dose will be split and patients will be treated proportionally on days 1, 8 and 15 of each cycle. Arm C receives a partial dose of HDP-101 on days 1 and 8 of the first cycle and then a single dose on day 1 of each of the following 21-day cycles.

It is planned to continue further cohorts with the most promising dosage forms from cohort 6 and an increase in the dose.

The relevant authorities approved the listed protocol adjustments and the recruitment of the 6th cohort was prepared. First patients are currently being screened.

Fortunately, in cohort 5, three of the five patients treated with 100 µg/kg showed biological efficacy and an objective improvement in disease was detectable (“partial remission”). One of these patients is currently showing a further improvement in the course of the disease (“very good partial response”; VGPR).

One study participant from the third cohort received a total of 18 doses of HDP-101 without long-term side effects and showed stable disease progression over 15 months. A few weeks ago, progression of the disease was detected in this patient and treatment had to be discontinued.

New preclinical data of the ATAC technology platform presented at the AACR 2024 Annual Meeting

Heidelberg Pharma presented clinical and preclinical results of its ADC technologies at the American Association for Cancer Research (AACR) 2024 Annual Meeting in April. Initial safety and preliminary efficacy data from the Phase I clinical trial with the ATAC candidate HDP-101 were shown as well as preclinical data on the ATAC candidate HDP-102, an Amanitin-based ADC directed against the target molecule CD37. HDP-102 has shown excellent anti-tumor efficacy in *in vivo* studies after single administration. Initial preclinical studies show good tolerability, suggesting that HDP-102 represents a potential new treatment option for patients with non-Hodgkin’s lymphoma (NHL).

Another poster showed that ADC binding independent of the target antigen (off-target tox mechanisms) is responsible, for example, for the premature release of the transported cytotoxins and can thus cause side effects.

In the presented study, the off-target toxic mechanisms of Amanitin-based ADCs (ATACs) were deciphered. The data show that liver toxicity is caused by non-specific uptake of the ATACs into liver cells. By substituting two amino acids in the antibody (LALA mutation), which are responsible for the non-specific binding of ATACs, the off-target toxicity could be reduced. This significantly increases the tolerability of ATACs, while the antitumor efficacy is not affected, resulting in an improved therapeutic window of ATACs.

In addition, scientists from Heidelberg Pharma presented the first preclinical data from the new HDP-201 project, an exatecan-based ADC.

The posters are available on the company's website.¹

In April, Heidelberg Pharma hosted its first R&D webinar with key opinion leaders (KOLs) in the ADC field. In addition to presentations on the technology platform by the management team, preclinical data were presented and interpreted by Rakesh Dixit, CEO of Bionavigen, Gaithersburg, USA, and clinical data from the study with HDP-101 by Jonathan Kaufman, MD, Associate Professor of Hematology & Medical Oncology, Emory University School of Medicine, Atlanta, USA.

The event provided furthermore information on the other ADC platform technologies and the therapeutic product pipeline.

HDP-101 receives orphan drug designation from the FDA

At the end of March, Heidelberg Pharma announced that the US Food and Drug Administration (FDA) had granted orphan drug designation (ODD) to the ATAC candidate HDP-101. Orphan drug designation is granted to a drug or biological product intended for the prevention, diagnosis or treatment of rare diseases affecting fewer than 200,000 people in the United States. The status provides significant incentives to encourage development of the drug, including tax credits for qualified clinical trials, prescription drug fee waivers, and a potential seven years of market exclusivity after FDA approval.

Agreement concluded on the partial sale of license fees to 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 TLX250-CDx. Heidelberg Pharma received a non-refundable upfront payment of USD 25 million and is also entitled to receive up to an additional USD 90 million from the sale of royalties if defined milestones are reached. Of this amount, USD 75 million will be due upon approval of TLX250-CDx by the FDA. After HCRx has received a maximum cumulative amount, the royalties revert to Heidelberg Pharma, and HCRx receives a low single-digit percentage of Heidelberg Pharma's royalties.

TLX250-CDx is a radiolabeled form of the antibody girentuximab, which binds to the tumor-specific antigen CAIX on clear cell renal cell carcinoma. Heidelberg Pharma developed the antibody up to a first completed Phase III clinical trial before out-licensing it to Telix Pharmaceuticals Limited, a company based in Melbourne, Australia, (Telix) in 2017. Telix completed the submission of the marketing authorization application to the FDA in early June 2024 and expects to obtain marketing authorization for the product by the end of 2024. An accelerated review ("priority review") was also applied for in parallel.

¹ <https://heidelberg-pharma.com/de/forschung-entwicklung/wissenschaftliche-poster>

Professor Andreas Pahl becomes Chief Executive Officer

The Supervisory Board appointed Professor Andreas Pahl as the new Chief Executive Officer effective 1 February 2024 after Dr. Jan Schmidt-Brand, long-standing Chief Executive Officer of Heidelberg Pharma AG and Managing Director of the subsidiary Heidelberg Pharma Research GmbH, stepped down on 31 January 2024 upon reaching retirement age. Professor Pahl has simultaneously assumed the role of Managing Director of the subsidiary. Professor Pahl has been Head of Research & Development at Heidelberg Pharma since 2012 and has been a member of the Executive Management Board since 2016. He holds a doctorate in chemistry and has more than 25 years of experience in the pharmaceutical industry as well as in research and teaching.

Research and development activities

ADC technology (antibody drug conjugates)

Heidelberg Pharma is developing technology platforms for antibody drug conjugates (ADCs). ADCs that combine the specificity of antibodies with the efficacy of toxins to fight cancer. The core of this technology is to offer new approaches to antitumor therapy by exploiting a previously unused biological mode of action for cancer treatment.

Heidelberg Pharma is the first company to use the fungal toxin Amanitin for cancer therapy. The company uses the toxin's biological mechanism of action with its innovative ATAC technology as a new therapeutic principle. The toxin is a member of the amatoxin group of natural poisons, which occur in the death cap mushroom (*Amanita phalloides*), among others. By inhibiting RNA polymerase II, Amanitin triggers natural cell death (apoptosis). This novel principle in cancer therapy offers the possibility of breaking through drug resistance and destroying dormant tumor cells, which could produce major clinical advances.

Amanitin's mode of action also has the potential to be particularly effective against tumors that have changed due to so-called 17p deletion to bypass a special mechanism of cell protection. This change is found in most cancers, and especially in very aggressive forms. Tumors with 17p deletion could be a particularly effective target for the treatment with ATACs.

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, the company has been using other active substances such as the topoisomerase I inhibitor Exatecan or immunostimulatory active substances such as the Toll-like receptor TLR7 since financial year 2023, thereby supplementing the proprietary ATAC technology with additional ADC technologies ("toolbox") in order to develop the best possible ADCs for other target antigens and areas of application.

On the one hand, the business model focuses on building up the company's own product pipeline. In this pillar, proprietary ADC molecules based on licensed or self-generated antibodies are produced, tested as R&D candidates and further developed in-house.

On the other hand, the hybrid business model includes a business-to-business activity in which the drug-linker technologies developed by Heidelberg Pharma are to be licensed by pharmaceutical and biotech companies in order to make their antibodies more therapeutically effective against tumor diseases. Within this framework and integrated into license agreements, Heidelberg Pharma offers the cooperation partners not only licensing rights but also technological support in the production and purification of the conjugates, in the production and supply of the active ingredient and in selected preclinical studies. These ADC collaborations are intended to generate continuous sales and license payments.

The in-house developments and the intended out-licensing are each carried out exclusively for a specific antigen (biological target protein). As there are a large number of tumor-specific antigens, it is possible to develop our own product candidates and cooperate in parallel with various pharmaceutical and biotechnology companies. The resulting development candidates can be developed into different products for different indications.

Proprietary ATAC pipeline

Project HDP-101 (BCMA-ATAC)

HDP-101 is a BCMA-ATAC that will be tested in the indication multiple myeloma. BCMA (B-cell maturation antigen) is a surface protein that is highly expressed in multiple myeloma cells, to which BCMA antibodies specifically bind, bringing the Amanitin to the cancer cell.

In preclinical models, HDP-101 showed excellent anti-tumor activity including complete tumor remission, and very good tolerability in relation to the effective doses. Finally, the efficacy of HDP-101 was demonstrated for the first time *ex vivo* on human multiple myeloma tumor cells from patients.

Multiple myeloma is a cancer affecting bone marrow and the second most common hematologic cancer; it represents a major unmet medical need where new, more effective therapies are urgently required. HDP-101 also has potential in further hematologic indications.

The candidate is being evaluated since February 2022 in a Phase I/IIa clinical trial for treatment of relapsed or refractory multiple myeloma. The first part of this trial is a Phase I dose escalation study to determine a safe and optimal dosage of HDP-101 for the Phase IIa part of the study.

Project HDP-102 (CD37-ATAC)

HDP-102 is an ATAC targeting CD37 that is overexpressed on B-cell lymphoma cells. HDP-102 will be developed for specific indications of non-Hodgkin lymphoma (NHL). Preclinical studies have shown that this development candidate has a very large therapeutic window. This means that the distance between its therapeutic dose and a dose that leads to an unacceptable toxic effect is as large as possible. At the AACR Annual Meeting in April 2024, several Heidelberg Pharma scientists presented data showing excellent anti-tumor efficacy after a single dose in *in vivo* studies as well as good tolerability of HDP-102.

The production of the clinical investigational medicinal products in accordance with GMP (Good Manufacturing Practice) standards is proceeding according to plan and has largely been completed. In addition, further preclinical and toxicological studies have been completed and the data package required to initiate the first clinical trial on humans is expected to be completed in the fourth quarter of this year and submitted to the regulatory authority in a European country as a first step.

Project HDP-103 (PSMA-ATAC)

HDP-103 will be developed for the treatment of metastatic castration-resistant prostate cancer (mCRPC). The antibody used binds to PSMA, a surface antigen that is overexpressed on prostate cancer cells. This is a promising target for the ATAC technology because PSMA shows only very limited expression in normal tissue. Preclinical studies on *in vitro* and *in vivo* efficacy, tolerability and pharmacokinetics have shown that HDP-103 has a promising therapeutic window. This is confirmed by the fact that at 60% there is a very high prevalence of a 17p deletion in mCRPC. The increased sensitivity of prostate cancer cells with a 17p deletion has already been preclinically validated.² Since tumor cells with a 17p deletion are particularly sensitive to Amanitin, PSMA-ATACs might be particularly suitable for treating mCRPC.

In recent months, production of HDP-103 under GMP conditions was completed as planned. The preclinical and toxicology studies with HDP-103 have now been largely completed. A clinical study to investigate tolerability and efficacy is currently being planned and the clinical team is preparing the study protocol in the coming months.

Heidelberg Pharma plans to submit a trial application for HDP-103 to the regulatory authorities in 2025.

Project HDP-104 (GCC-ATAC)

The ATAC candidate HDP-104 targets guanylyl cyclase C or GCC, a receptor that is expressed on the surface of intestinal cells and cancer cells in various gastrointestinal tumors. The candidate is currently not being further developed at Heidelberg Pharma. The focus is on the HDP-201 project instead, which is being worked on in the same indication and with the same antibody but a different payload.

Project HDP-201

Since fall 2023, the company has been developing further ADC projects with other loading agents. The first candidate with a toxin other than Amanitin is HDP-201, an exatecan-based ADC. Exatecan is a topoisomerase I inhibitor that has proven itself in cancer therapy and is used in two already approved ADCs. It differs in its mode of action from that of Amanitin and thus expands the company's range of active ingredients.

HDP-201, targets guanylyl cyclase-C (GCC), a receptor that is expressed on the surface of intestinal cells and cancer cells in various gastrointestinal tumors. The company presented preclinical results to date at AACR 2024, where they met with a very large and very positive response. The results show that the tolerability and efficacy of HDP-201 is at least comparable to already approved exatecan ADCs.

The target protein to which the antibody used binds is overexpressed in over 95% of colorectal cancers and around 65% of esophageal and gastric tumors as well as pancreatic tumors. Since the GCC antibody has already been produced for the HDP-104 program, sufficient quantities of the antibody are available to supply two ADC projects. The short-term availability of the antibody shortened the research time and allowed Heidelberg Pharma to quickly start the development process of HDP-201. *In vitro/in vivo* tests and initial preclinical trials have now been completed.

² <https://www.nature.com/articles/s41467-018-06811-z>

ATAC collaborations

Collaboration with Takeda

Back in June 2017, Heidelberg Pharma signed an exclusive research agreement with Takeda Oncology, Cambridge, MA, USA, (Takeda), the subject of which is several targets for joint development of ADCs using the compound Amanitin. Under the terms of the exclusive research agreement, Heidelberg Pharma produced several ATACs using antibodies from Takeda's proprietary portfolio. As a result of this work, Takeda acquired an exclusive license in September 2022 to commercially develop an ATAC with a selected target. Takeda is responsible for further preclinical and clinical development, as well as potential commercialization, of the licensed product candidate. In August 2023, the Company's partner Takeda reached a development milestone by starting a GLP (Good Laboratory Practice) toxicology study.

Clinical portfolio

TLX250-CDx – diagnostic antibody

TLX250-CDx is a radiolabeled form of the antibody girentuximab, which binds to the tumor-specific antigen CAIX on clear cell renal cell carcinoma (ccRCC) and possibly other tumor types. Accumulation of this antibody in tumor tissue can be visualized by positron emission tomography (PET) scans. This could fundamentally change therapy planning for renal cancer patients and avoid potentially unnecessary surgery. The diagnostic agent may also prove suitable for monitoring response to treatment, detecting metastases and for diagnosing other kinds of tumors.

The antibody was developed at Heidelberg Pharma AG up to a first Phase III trial and outlicensed to the Australian company Telix in 2017.

Telix had conducted a second Phase III trial and, based on these positive Phase III results, began filing a rolling submission in the USA in December 2023 for the candidate TLX250-CDx for the identification of clear cell renal cell carcinoma. The partner announced at the beginning of June that the submission of the documents to the FDA had been completed.

As a Breakthrough Therapy Designation product candidate, TLX250-CDx has been granted a rolling review process that allows for phased submission and review of required modules on a pre-agreed schedule with the FDA. Telix has also applied for priority review. Telix plans a potential marketing authorization in the US by the end of this year.

Parallel to the preparations for market approval, Telix has introduced an "expanded access program" in the USA and a "named patient program" in Europe to give patients access to TLX250-CDx even before approval. Patients have already been accepted into this program in some European countries and in the USA.

Telix is conducting further clinical trials to potentially expand the indication of TLX250-CDx beyond kidney cancer, including triple-negative metastatic breast cancer (TNBC) and bladder cancer.

Heidelberg Pharma is entitled to milestone payments and royalties in the double-digit percentage range if the product receives marketing authorization. In March 2024, a portion of the future royalties from global sales of TLX250-CDx was sold to HealthCare Royalty.

TLX250 (girentuximab) – therapeutic antibody

In addition to further developing the TLX250-CDx antibody, Telix is also working on the advancement of a therapeutic radioimmunoconjugate (¹⁷⁷Lu-DOTA-girentuximab, TLX250) program based on the lutetium-177-labeled girentuximab antibody.

TLX250 is being tested in two Phase II combination studies (STARLITE 1 and 2) with immunotherapies. The US STARLITE 2 trial will evaluate TLX250 as a therapy in combination with the immunotherapy Opdivo® (nivolumab) in patients with advanced clear cell renal cell carcinoma (ccRCC). The aim is to assess tumor response compared to current standard of care.

RHB-107 (upamostat)

Developed by Heidelberg Pharma AG up to Phase II, RHB-107 (upamostat) is an oral serine protease inhibitor that is designed to block the activity of tumor-relevant serine proteases such as uPA, plasmin and thrombin to prevent tumor growth and metastasis.

The partner RedHill Biopharma Ltd., Tel Aviv, Israel, (RedHill; NASDAQ: RDHL) is developing the out-licensed serine protease inhibitor upamostat (RHB-107 at RedHill) for the treatment of COVID-19. RHB-107 has demonstrated both antiviral and potential tissue-protective effects, with RHB-107 strongly inhibiting SARS-CoV-2 replication in a preclinical human bronchial tissue study.

In early December 2023 the company announced that non-dilutive external funding had been committed for the RHB-107 arm of a platform trial for early COVID-19 outpatient treatment.³ In addition, the 300-patient Phase II RHB-107 arm of the PROTECT study received FDA clearance to start.⁴ The study is being conducted in the US, Thailand, Ivory Coast, South Africa and Uganda.

RHB-107 is also being tested in development programs against several viral diseases, including Ebola. RedHill announced in December that RHB-107 together with opaganib demonstrated synergistic effect when combined individually with remdesivir in a new *in vitro* Ebola virus study funded and conducted by the US Army, significantly improving efficacy while maintaining cell viability.⁵

³ RedHill press release, 4 December 2023: <https://www.redhillbio.com/news/news-details/2023/RedHill-Announces-New-Non-Dilutive-External-Funding-of-Entire-RHB-107-COVID-19-300-Patient-Phase-2-Study/default.aspx>

⁴ RedHill press release, 4 December 2023: <https://www.redhillbio.com/news/news-details/2023/RedHill-Announces-New-Non-Dilutive-External-Funding-of-Entire-RHB-107-COVID-19-300-Patient-Phase-2-Study/default.aspx>

⁵ RedHill press release, 20 December 2023: <https://www.redhillbio.com/news/news-details/2023/RedHill-and-U.S.-Army-Announce-Opaganib-and-RHB-107-Combinations-with-Remdesivir-Show-Distinct-Synergistic-Effect-Against-Ebola/default.aspx>

Market environment

For detailed information on the market environment for Heidelberg Pharma's product candidates and indications, see pages 28 to 37 of the 2023 Annual Report. No new ADCs have been approved by the FDA or EMA in 2024. The number of ADCs approved by the FDA therefore remains unchanged at twelve.⁶

The following tables show the most important events from the last six months in the areas of deals and financing as well as clinical trials and regulatory news:

Significant agreements, acquisitions and financings

Company	Partner	Event	Description
Mersana	Merck KGaA	Termination of agreement	Merck and Mersana terminate their license agreement from 2014. ⁷
Eisai	Bristol Myers Squibb (BMS)	Termination of agreement	BMS terminates ADC deal with Eisai (volume up to USD 3 billion). ⁸
SystImmune	Bristol Myers Squibb (BMS)	Agreement	Global license agreement for SystImmune's EGFRx-HER3 ADC with a total value of up to USD 8.4 billion. ⁹
Hansoh Pharma	GSK	Agreement	Exclusive license agreement for an ADC with an upfront payment of USD 185 million and up to USD 1.53 billion in milestone payments. ¹⁰
LegoChem Biosciences	Janssen Biotech, Inc.	Agreement	LegoChem Biosciences potentially receives up to USD 1.7 billion for LCB84 Trop2-targeted ADC. ¹¹
MediLink Therapeutics	Roche	Agreement	Global license agreement for the development of an ADC with a total volume of up to almost USD 1 billion. ¹²

⁶ BioCentury data base BCIQ, as of 19 December 2023

⁷ Fierce Biotech, 22 December 2023:

<https://www.fiercebiotech.com/biotech/merck-kgaa-mersana-abandon-adc-licensing-pact-new-year>

⁸ Biospace, 1 July 2024:

<https://www.biospace.com/article/eisai-assumes-sole-responsibility-for-adc-after-collaboration-with-bms-ends/>

⁹ Bristol Myers Squibb, press release, 11 December 2023:

<https://news.bms.com/news/details/2023/SystImmune-and-Bristol-Myers-Squibb-Announce-a-Global-Strategic-Collaboration-Agreement-for-the-Development-and-Commercialization-of-BL-B01D1/default.aspx>

¹⁰ GSK, press release, 20 December 2023: <https://www.gsk.com/en-gb/media/press-releases/gsk-enters-exclusive-license-agreement-with-hansoh-for-hs-20093/>

¹¹ LegoChem Biosciences, press release, 26 December 2023:

https://www.legochembio.com/media/press_view.php?lang=e&sc_seq=594

¹² MediLink Therapeutics, press release, 2 January 2024:

<https://www.prnewswire.com/news-releases/medilink-therapeutics-announces-worldwide-collaboration-and-license-agreement-with-roche-to-develop-next-generation-antibody-drug-conjugate-in-oncology-302024162.html>

Company	Partner	Event	Description
Biocytogen Pharmaceuticals	Gilead Sciences	Agreement	Agreement for the development of antibodies, including ADCs. ¹³
Biotheus	Hansoh Pharma	Agreement	Biotheus receives up to USD 690 million as part of the expansion of the ADC partnership with Hansoh. ¹⁴
Ipsen	Sutro Biopharma	Agreement	Ipsen and Sutro Biopharma enter into an exclusive global license agreement for up to USD 900 million for the preclinical ADC STRO-003. ¹⁵
Caris Life Sciences	Merck KGaA	Agreement	Multi-year strategic partnership for ADC development for up to USD 1.4 billion. ¹⁶
Alphamab	Arrivent	Agreement	Collaboration for the development of ADCs for up to USD 615.5 million. ¹⁷
MabCare Therapeutics	Day One Biopharmaceuticals	Agreement	License agreement for ADC MTX-13 for up to USD 1.6 billion. ¹⁸
ProfoundBio	Genmab	Acquisition	Genmab acquires ADC developer ProfoundBio for USD 1.8 billion including three clinical ADCs and ADC development platforms. ¹⁹
Abceutics	Merck KGaA	Acquisition	Merck acquires ADC developer Abceutics for up to USD 208 million. ²⁰
Ambrx	Johnson & Johnson	Acquisition	Johnson & Johnson acquires Ambrx for USD 2 billion. ²¹

¹³ Biocytogen Pharmaceuticals, press release, 19 February 2024:

<https://biocytogen.com/biocytogen-and-gilead-enter-into-a-multi-target-antibody-collaboration-agreement/>

¹⁴ Fierce Biotech, 15 March 2024: <https://www.fiercebiotech.com/biotech/hansoh-fresh-big-pharma-interest-signs-690m-adc-pact-fellow-chinese-biotech-biotheus>

¹⁵ Ipsen, press release, 2 April 2024: <https://www.ipsen.com/press-releases/ipsen-and-sutro-biopharma-announce-exclusive-global-licensing-agreement-for-an-adc-targeting-solid-tumors/>

¹⁶ Caris Life Sciences, press release, 4 April 2024: <https://www.carislifesciences.com/about/news-and-media/caris-life-sciences-announces-partnership-with-merck-kgaa-darmstadt-germany/>

¹⁷ Arrivent, press release, 5 June 2024:

<https://ir.arrivent.com/news-releases/news-release-details/arrivent-announces-multi-target-adc-collaboration-alphamab>

¹⁸ Day One Biopharmaceuticals, press release, 18 June 2024:

<https://ir.dayonebio.com/news-releases/news-release-details/day-one-expands-pipeline-potential-first-class-clinical-stage>

¹⁹ Genmab, press release, 3 April 2024:

<https://ir.genmab.com/news-releases/news-release-details/genmab-broaden-and-strengthen-oncology-portfolio-acquisition/>

²⁰ University of Buffalo, press release, 5 April 2024:

<https://www.buffalo.edu/news/releases/2024/04/Abceutics-acquired-by-Merck.html>

²¹ Johnson & Johnson, press release, 8 January 2024: <https://www.jnj.com/johnson-johnson-to-acquire-ambrx-advancing-next-generation-antibody-drug-conjugates-to-transform-the-treatment-of-cancer>

Company	Partner	Event	Description
Daiichi Sankyo		Expansion	Daiichi Sankyo invests €1 billion in the expansion of the Pfaffenhofen site in Germany, including for the development of ADCs. ²²
AstraZeneca		Expansion	AstraZeneca plans to build a USD 1.5 billion production facility for ADCs in Singapore. ²³
LegoChem Biosciences		Financing	Pan Orion Corp. from Korea invests approximately USD 415 million in LegoChem Biosciences. ²⁴
ProfoundBio		Financing	Oversubscribed Series B round of USD 112 million (pre-acquisition). ²⁵
Tubulis		Financing	Series B2 financing of €128 million. ²⁶
TORL BioTherapeutics		Financing	Oversubscribed USD 158 million Series B-2 round. ²⁷
Endeavor BioMedicines		Financing	Oversubscribed USD 132.5 million Series C round. ²⁸
ADC Therapeutics		Financing	Proceeds of USD 105 million. ²⁹
Pheon Therapeutics		Financing	Series B financing round of USD 120 million. ³⁰

²² Daiichi Sankyo, press release, 15 February 2024:

<https://www.daiichi-sankyo.eu/media/european-news/news-detail/daiichi-sankyo-investiert-ca-eine-milliarde-euro-in-deutschland-standort-pfaffenhofen-bayern-wird-zu-internationalem-innovationszentrum-ausgebaut/>

²³ AstraZeneca, press release, 20 May 2024:

<https://www.astrazeneca.com/media-centre/press-releases/2024/astrazeneca-to-manufacture-adcs-in-singapore.html>

²⁴ BioSpace, 16 January 2024:

<https://www.biospace.com/article/orion-invests-415m-in-korean-biotech-legochem-securesmajority-stake/>

²⁵ BioSpace, 14 February 2024:

<https://www.biospace.com/article/adc-focused-profoundbio-raises-112m-in-oversubscribed-series-b-to-advance-pipeline/>

²⁶ Tubulis, press release, 14 March 2024: <https://tubulis.com/news/tubulis-closes-upsize-e128-million-series-b2-to-accelerate-clinical-development-of-solid-tumor-focused-adc-pipeline/>

²⁷ TORL, press release, 10 April 2024:

<https://www.prnewswire.com/news-releases/torl-biotherapeutics-announces-158-million-oversubscribed-series-b-2-financing-to-advance-the-clinical-development-of-its-novel-antibody-drug-conjugate-adc-oncology-pipeline-302112553.html>

²⁸ Biospace, 24 April 2024: <https://www.biospace.com/article/endeavor-raises-132m-in-oversubscribed-series-c-to-advance-lung-disease-and-adc-candidates/>

²⁹ ADC Therapeutics, press release, 6 May 2024: <https://ir.adctherapeutics.com/press-releases/press-release-details/2024/ADC-Therapeutics-Announces-105-Million-Underwritten-Offering-of-Common-Shares-and-Pre-Funded-Warrants/default.aspx>

³⁰ Biospace, 22 May 2024:

<https://www.biospace.com/article/pheon-raises-120m-in-series-b-to-advance-adcs-for-hard-to-treat-cancers-/?s=80>

Clinical trials and regulatory decisions

Company	Candidate	Event	Description
Sanofi	tusamitamab ravtansine	Study suspension	Discontinuation of the study program for tusamitamab ravtansine announced after a Phase III study in NSCLC 2L did not meet the primary endpoint. ³¹
BioNTech, MediLink	BNT326/YL202	Study suspension	The FDA partially pauses the ongoing study of BioNTech’s ADC after the death of 3 patients. ³²
Merck KGaA and Daiichi Sankyo	patritumab deruxtecan	Denial of approval	FDA denied approval of ADC due to manufacturing issues. ³³
Gilead	Trodelyv (Sacituzumab govitecan)	Study results	The primary endpoint was not met in a phase III study in non-small cell lung cancer (NSCLC) ³⁴
MacroGenics	vobramitamab duocarmazine (vobra duo)	Study update	MacroGenics announces that 5 patients have died in the Phase II study for the treatment of prostate cancer. ³⁵
Gilead	Trodelyv (Sacituzumab govitecan)	Study results	The primary endpoint was not met in a Phase III study in urothelial carcinoma. ³⁶
AstraZeneca and Daiichi Sankyo	Enhertu (fam-trastuzumab deruxtecan-nxki)	Study results	Announcement of positive results from the Phase III study of Enhertu for the treatment of breast cancer with low HER2 expression. ³⁷

³¹ Sanofi, press release, 21 December 2023:

<https://www.sanofi.com/assets/dotcom/pressreleases/2023/2023-12-21-06-30-00-2799759-en.pdf>

³² Fierce Biotech, 17 June 2024:

<https://www.fiercebiotech.com/biotech/fda-halts-trial-biontech-medilink-adc-over-significant-risk-illness>

³³ Biospace, 27 June 2024:

https://www.biospace.com/article/merck-s-adc-pact-with-daiichi-hits-regulatory-setback-with-fda-rejection/?keywords=ADC&_gl=1*p42wbp*_up*MQ.*_ga*MTAzODcwODM1My4xNzlwMTc2Nz1*_ga_DXDFX4SY*MTcyMDE3NjcyNC4xLjAuMTcyMDE3Njc0NS4wLjAuMA..*_ga_Q90M6MWJZ4*MTcyMDE3NjcyNC4xLjAuMTcyMDE3Njc0NS4wLjAuMA..

³⁴ Biospace, 22 January 2024:

https://www.biospace.com/article/gilead-s-adc-trodelyv-fails-phase-iii-nsclc-study-stock-drops-10-percent-/?_gl=1*1dpmx5*_up*MQ.*_ga*MTAzODcwODM1My4xNzlwMTc2Nz1*_ga_Q90M6MWJZ4*MTcyMDE3NjcyNC4xLjAuMTcyMDE3NzAzMi4wLjAuMA..

³⁵ MacroGenics, press release, 9 May 2024:

<http://ir.macrogenics.com/news-releases/news-release-details/macrogenics-provides-update-corporate-progress-first-quarter>

³⁶ Biospace, 31 May 2024:

https://www.biospace.com/article/gilead-s-trodelyv-fails-to-reach-primary-endpoint-in-confirmatory-trial/?_gl=1*do8nfh*_up*MQ.*_ga*MTAzODcwODM1My4xNzlwMTc2Nz1*_ga_Q90M6MWJZ4*MTcyMDE3NjcyNC4xLjAuMTcyMDE3Njc4Ny4wLjAuMA..

³⁷ AstraZeneca, press release, 29 April 2024:

<https://www.astrazeneca.com/media-centre/press-releases/2024/enhertu-improved-pfs-in-her2-low-and-ultralow.html>

Company	Candidate	Event	Description
GSK	Blenrep (belantamab mafodotin)	Study results	Announcement of positive results from one of the two ongoing Phase III studies of Blenrep for the treatment of r/rMM. ³⁸
AstraZeneca and Daiichi Sankyo	datopotamab deruxtecan (Dato-DXd)	Marketing Authorization	Application filed for the treatment of adult patients with locally advanced or metastatic NSCLC. ³⁹
AstraZeneca and Daiichi Sankyo	Enhertu (fam-trastuzumab deruxtecan-nxki)	Approval for indication expansion	Enhertu receives US approval for the tumor-agnostic treatment of HER2-positive tumors. ⁴⁰
AbbVie	ELAHERE (mirvetuximab soravtansine-gynx)	Approval	ELAHERE receives full approval for the treatment of certain ovarian cancers following accelerated approval in 2022. ⁴¹

³⁸ GSK, press release, 2 June 2024:

<https://www.gsk.com/en-gb/media/press-releases/blenrep-combination-reduced-the-risk-of-disease-progression/>

³⁹ AstraZeneca, press release, 19 February 2024:

<https://www.astrazeneca.com/media-centre/press-releases/2024/fda-accepts-dato-dxd-bla-for-nonsquamous-nscl.html>

⁴⁰ AstraZeneca, press release, 6 April 2024:

<https://www.astrazeneca.com/media-centre/press-releases/2024/enhertu-approved-in-the-us-as-first-tumour-agnostic-her2-directed-therapy-for-previously-treated-patients-with-metastatic-her2-positive-solid-tumours.html>

⁴¹ AbbVie, press release, 22 March 2024:

<https://news.abbvie.com/2024-03-22-U-S-Food-and-Drug-Administration-FDA-Grants-Full-Approval-for-ELAHERE-R-mirvetuximab-soravtansine-gynx-for-Certain-Ovarian-Cancer-Patients>

Results of operations, financial position and net assets

The Heidelberg Pharma Group, which previously consisted of Heidelberg Pharma AG and its subsidiary Heidelberg Pharma Research GmbH as of the reporting date, reports consolidated figures. Two new companies, HDP G250 AG & Co. KG and HDP G250 Beteiligungs GmbH, were established as part of the HCRx agreement. These two companies are affiliated below the parent company Heidelberg Pharma AG and are not operationally active.

The reporting period referred to below relates to the period from 1 December 2023 to the balance sheet date of 31 May 2024 (H1 2024). The period-based comparative figures refer to the period from 1 December 2022 to 31 May 2023 (H1 2023). The reporting date-based comparative figures refer to 30 November 2023 or 31 May 2023.

Heidelberg Pharma does not have business units that differ materially in their risk/reward profiles and would therefore require segment reporting.

Due to rounding, it is possible that individual figures in this report may not add up exactly to the totals and that percentages given may not precisely reflect the absolute figures to which they relate.

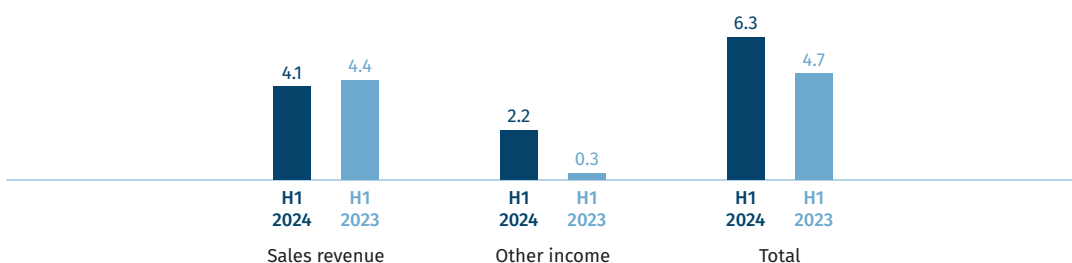
Sales revenue and other income

The Heidelberg Pharma Group generated sales revenue and income of €6.3 million in the first six months of the 2024 financial year (previous year: €4.7 million), this corresponds to an increase of 34%.

Sales revenue totaling to €4.1 million in both comparative periods and mainly comprised the group-wide cooperation agreements for ATAC technology (previous year: €4.4 million).

At €2.2 million, other income was significantly higher than the previous year's level of €0.3 million and consisted of government grants (€1.1 million), the reversal of unutilized accrued liabilities (€0.8 million) and other items (€0.3 million).

Income in € million¹

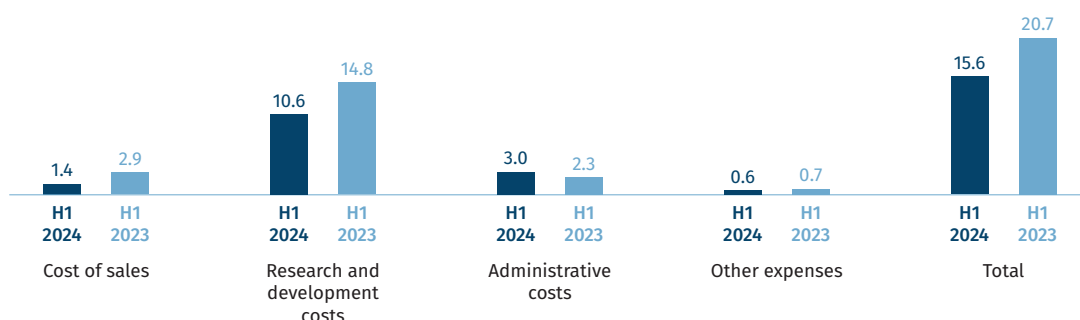


¹ rounded

Operating expenses

Operating expenses, including depreciation and amortization, amounted to €15.6 million in the reporting period (previous year: €20.7 million) and were almost 25% lower than in the previous year.

Operating expenses in € million¹



¹ rounded

The cost of sales relates to the Group's costs directly related to sales revenue. These are mainly expenses for the supply of Amanitin linker material to license partners. They were below the previous year's level, amounted to €1.4 million (previous year: €2.9 million) and corresponded to 9% of operating expenses.

Research and development costs of €10.6 million fell in comparison to the previous year (€14.8 million) due to the less cost-intensive external production for the ATAC projects and the ongoing clinical trial with HDP-101 compared to the same period in the previous year. At 68% of operating expenses, this category continued to represent the largest cost block.

Administrative expenses of €3.0 million (previous year: €2.3 million), which include the costs of holding activities and the stock exchange listing, amounted to 19% of operating expenses. The increase compared to the six-month period of 2023 is due to a higher headcount in this area as well as increased legal and consulting costs. However, this does not include any transaction costs for the HCRx agreement, as such expenses are offset against the transaction proceeds in accordance with IFRS 9.

At €0.6 million, other expenses for business development, marketing and commercial market supply activities, which mainly comprise staff and travel costs, were slightly below the previous year's level and accounted for 4% of operating expenses.

Financial result

In the first half of fiscal year 2024, the Group reported a financial result of €603 thousand (previous year: €262 thousand). The positive result is attributable to financing income from interest on cash and cash equivalents (€742 thousand; previous year: €767 thousand). The interest expense of €139 thousand (previous year: €506 thousand) of €136 thousand was largely incurred for the shareholder loan from dievini, which has now been repaid in full and for which interest expenses of €501 thousand were still due in the same period of the previous year.

The interest expenses for lease liabilities in connection with the application of IFRS 16 (€3 thousand; previous year: €5 thousand) were insignificant in the financing context.

Income taxes

In the comparative period of 2023, non-cash income taxes of €177 thousand were reported. This amount related to the withholding of capital gains tax (plus solidarity surcharge) from interest income. In the current financial year, the withholding was recognized as a receivable from tax authorities.

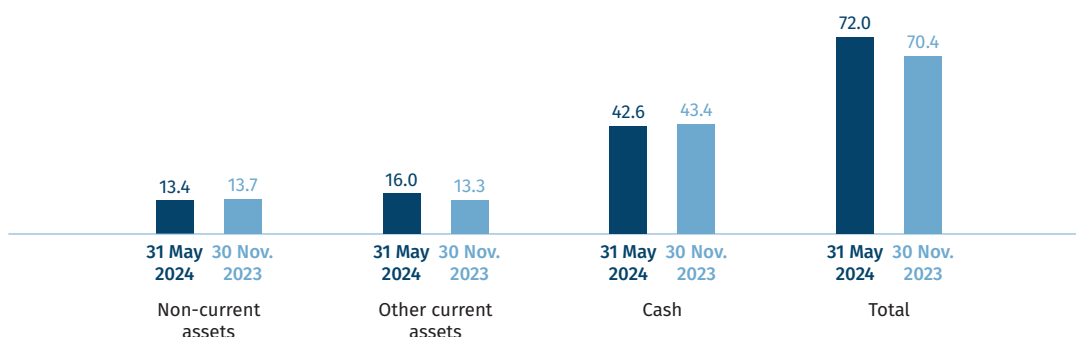
Profit/loss for the period

The Heidelberg Pharma Group’s net loss for the first six months of 2024 amounted to €8.7 million (previous year: €16.0 million). The significant increase is due to higher income and lower expenses. Earnings per share amounted to €−0.19 and, taking into account the average number of shares, developed positively compared to the previous year (€−0.34).

Assets

Total assets as of 31 May 2024 amounted to €72.0 million, up from €70.4 million as of the 30 November 2023 reporting date.

Balance sheet – assets in € million¹



¹ rounded

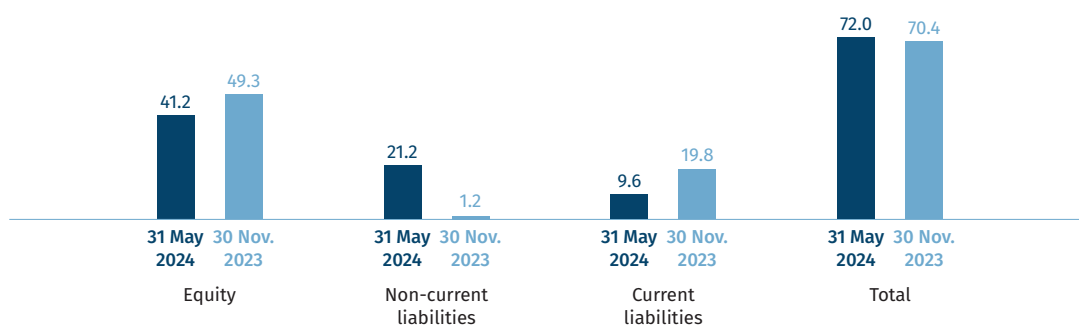
Non-current assets at the end of the reporting period amounted to €13.4 million and were therefore below the previous year's level (30 November 2023: €13.7 million) due to lower investments in fixed assets. This included property, plant and equipment (€3.5 million; previous year: €3.8 million), intangible assets, other non-current assets and the goodwill of Heidelberg Pharma Research (all unchanged from the previous year at €2.8 million, €1.0 million and €6.1 million respectively).

Current assets increased from €56.6 million in the previous year to €58.6 million. The cash included in this figure amounted to €42.6 million and were therefore slightly below the financial year-end 2023 figure of €43.4 million and below the half-year figure for the previous year as at 31 May 2023 (€57.4 million).

Equity

Equity at the end of the reporting period amounted to €41.2 million (30 November 2023: €49.3 million) and corresponded to an equity ratio of 57.2% (30 November 2023: 70.1%). Further information on the development of equity can be found in the notes to this report.

Balance sheet – equity and liabilities in € million¹



¹ rounded

Liabilities

As at the end of the reporting period, non-current lease liabilities amounting to €0.1 million were recorded, as at the 2023 reporting date.

Non-current contract liabilities fell from €1.2 million in the previous year to zero as at 31 May 2024 as a result of deferred income in accordance with IFRS 15 ("Revenue from Contracts with Customers") due to the passage of time.

The new balance sheet item of non-current financial liabilities (€21.2 million) is attributable to the upfront payment from HCRx, which was initially recognized as a liability less transaction costs. IFRS 9 ("Financial Instruments"), which is applicable in this case, provides for a gradual reduction of the liability through profit or loss only after the inflow of license payments (see comments on TLX250-CDx in the context of the clinical portfolio). It should be emphasized that this is not a payment-related financial liability, but a purely accounting requirement in accordance with IFRS 9. The advance payment received from HCRx in the amount of USD 25 million is neither repayable nor tied to obligations.

Current liabilities decreased to €9.6 million at the end of the reporting period (30 November 2023: €19.8 million).

This development is due in particular to the fully repaid shareholder loan from dievini, of which a final tranche of €5 million was repaid in the first half of the 2024 financial year.

While current lease liabilities remained stable at €0.1 million, trade payables fell noticeably from €7.9 million to €4.8 million.

Current contract liabilities (€3.6 million; 30 November 2023: €5.0 million) and other current financial liabilities (€1.1 million; 30 November 2023: €1.2 million) fell compared to the respective value on 30 November 2023.

Cash flow statement

At €16.9 million, the net cash outflow from operating activities in the six months of the current financial year was lower than in the same period of the previous year (€18.2 million).

Cash outflow from investing activities, which is attributable primarily to laboratory expansion, amounted to €0.1 million and was therefore significantly lower than in 2023 (€0.8 million).

In the first six months of the 2024 and 2023 financial years to be compared, there were changes in cash of €-5 million from financing activities due to the partial repayments of an interest-bearing shareholder loan granted by dievini.

In the reporting period, the HCRx payment of the equivalent of €23 million was also recorded, which, together with the separately disclosed outflows for associated transaction costs (€1.8 million), is to be added to financing activities.

Taking into account the impact on cash of exchange rate effects, the repayment portion of lease payments and the proceeds from exercised share options in 2023, the net cash outflow amounted to €0.8 million (previous year: €24.0 million).

At the end of the 2024 reporting period, Heidelberg Pharma had cash of €42.6 million (30 November 2023: €43.4 million; 31 May 2023: €57.4 million).

Cash flow ¹	H1 2024 € million	H1 2023 € million
Cash as of 1 December 2023 / 1 December 2022	43.4	81.3
Net change in cash from operating activities	(16.9)	(18.2)
Net change in cash from investing activities	(0.1)	(0.8)
Net change in cash from financing activities	16.1	(5.0)
Exchange rate effect/other	0.0	(0.0)
Cash as of 31 May 2024 / 31 May 2023	42.6	57.4

¹ rounded

Employees and remuneration system

Including the members of its Executive Management Board, the Heidelberg Pharma Group had 110 employees (97 FTEs) at the close of the reporting period (30 November 2023: 105 employees/95 FTEs; 31 May 2023: 113 employees/103 FTEs).

Heidelberg Pharma has a performance-related remuneration system for its employees comprising a fixed annual salary and a variable salary component. In addition, the stock option plans give employees a stake in the Company's performance.

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For more information, see section "C. Issue and measurement of stock options" in the notes.

Report on risks and opportunities

Heidelberg Pharma is exposed to the risks typical for a biotechnology company, namely those arising from the development and production of potential drug candidates for the treatment of cancer. The time between the commencement of drug development and marketing approval spans many years. There is a high risk that none of the out-licensed product candidates or ADC development candidates will receive regulatory approval. For Heidelberg Pharma, there is the risk that efficacy and safety data from animal models will not be confirmed in humans.

To date, neither Heidelberg Pharma nor a licensing partner has completed clinical development for any of the product candidates in the Heidelberg Pharma portfolio. However, an application for regulatory approval has been filed for one out-licensed project. Two projects (girentuximab and upamostat) have been completely transferred to a licensee for further development and marketing. The licensees are also exposed to the risks typical of the industry.

The Company is currently unable to finance itself solely through product sales and license revenue and is dependent on funding from equity providers or additional licensees. Risks and opportunities in connection with the Heidelberg Pharma Group's business are described in detail on pages 60 to 72 of the 2023 Annual Report. They remain unchanged unless otherwise noted below.

Report on post-balance sheet date events

No significant events occurred after the end of the reporting period.

Outlook

Heidelberg Pharma firmly believes that it is developing targeted and highly effective therapies for the treatment of cancer by leveraging its ADC technologies. In particular, the patented and proprietary ATAC platform based on the mushroom toxin Amanitin has a unique mode of action that could be of great medical benefit.

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.

The proprietary ATAC candidate HDP-101 is being tested in patients with multiple myeloma for the first time. Patients are currently being treated in a Phase I dose escalation study with increasing dose levels to determine a safe and optimum dosage for HDP-101. This concerns both the testing of different dosing regimens and the number of patients and leads to corresponding adjustments in the design of the study.

To date, 18 patients have been treated in the Phase I part, in five cohorts. During treatment in the fifth cohort, evidence of good biological efficacy with the initial dose was accompanied by a temporary drop in thrombocyte count, which is potentially dose-limiting. Modification of the dosing regimen is therefore expected to avoid this effect.

During the Phase IIa part, the recommended dose and dose regimen determined in Phase I will then be administered to at least 30 patients. Patients in this part will also be stratified based on the proportion of myeloma cells indicated by the biomarker, the 17p deletion status. According to the clinical trial plan, the first patients in the Phase IIa part will be treated around early 2025. The primary objective of the Phase I/IIa part of the trial is to assess the preliminary anti-tumor activity of HDP-101 along with evaluation of the safety of the drug.

After successful completion of the Phase I part, the data obtained will then be used by our partner Huadong to start on development of HDP-101 in China.

In order to further expand the therapeutic potential beyond the Antibody Targeted Amanitin Conjugates available at Heidelberg Pharma Research, additional research and option agreements are to be signed with pharmaceutical partners. The collaboration with existing partners is expected to be continued and expanded as planned, ideally culminating in one or more therapeutic candidates.

Takeda is developing a proprietary Antibody Targeted Amanitin Conjugate under exclusive license with a selected, yet undisclosed target and is responsible for its further preclinical and clinical development as well as for the potential commercialization of the licensed product candidate. The cooperation with Takeda is subject to confidentiality and is currently progressing within the framework of an intensive and detailed research plan.

The clinical product candidates outside the ATAC technology are being further developed at the partners Telix and RedHill. In the event of approval and marketing, Heidelberg Pharma will receive milestone payments and attractive royalties.

Heidelberg Pharma is not yet in a position to fully finance its own R&D activities using its own funds in the short to medium term. Stable revenue from the services business and increased payments from Heidelberg Pharma Research's technology cooperations or from license agreements are expected to help finance in-house development work. Due to current financial planning the Company's financing is secured until mid-2025. Taking into account a further expected payment of USD 75.0 million from HealthCare Royalty upon approval of Telix's diagnostic candidate, the company assumes, based on the current medium-term planning, that it will have sufficient financing until the end of 2026.

The full-year financial guidance issued on 25 March 2024 for the Heidelberg Pharma Group was adjusted on 18 June 2024.

The Heidelberg Pharma Group expects for the financial year 2024 sales and other income between €9.0 million and €12.0 million (previously: €11.0 million to €15.0 million). The reason for the lower sales is that expected sales are likely to be delayed due to developments at the license partners. In accordance with accounting regulations, the upfront payment received from HCRx is not yet reflected in the sales revenue guidance for financial year 2024. Heidelberg Pharma will be able to show pro rata sales revenue in the coming financial years only after the product has been approved, future sales revenue has been generated and license fees have been received from Telix. Operating expenses will remain between €36.0 million and €40.0 million. Based on these adjustments, an operating result (EBIT) between €-25.5 million and €-29.5 million is expected (previously: €-23.5 million to €-27.5 million).

For 2024, Heidelberg Pharma anticipates cash requirements of €18.0 million to €22.0 million (previously: €28.0 million to €32.0 million). Monthly cash consumption is expected to range between €1.5 million and €1.8 million per month (previously: €2.3 million and €2.7 million).

Financial outlook	Actual 2023 € million	Updated guidance 2024 € million	Original guidance 2024 € million
Sales revenue and other income	16.8	9.0–12.0	11.0–15.0
Operating expenses	38.0	36.0–40.0	36.0–40.0
Operating result	(21.2)	(25.5–29.5)	(23.5)–(27.5)
Total funding requirement ¹	37.9	18.0–22.0	28.0–32.0
Funds required per month ¹	3.2	1.5–1.8	2.3–2.7

¹ Not including any corporate actions

CONSOLIDATED BALANCE SHEET (IFRS)

as of 31 May 2024 and as of 30 November 2023

	31 May 2024 €	30 Nov. 2023 €
Assets		
Property, plant and equipment	3,557,201	3,847,160
Intangible assets	2,757,559	2,786,188
Goodwill	6,111,166	6,111,166
Other non-current assets	976,818	974,818
Non-current assets	13,402,744	13,719,332
Inventories	11,726,781	10,487,792
Prepayments	532,942	382,700
Trade receivables	1,342,180	978,836
Other receivables	2,350,183	1,345,451
Cash	42,618,847	43,438,922
Current assets	58,570,933	56,633,700
Total assets	71,973,677	70,353,032

	31 May 2024 €	30 Nov. 2023 €
Equity and liabilities		
Subscribed capital	46,604,977	46,604,977
Capital reserve	312,942,231	312,453,759
Other reserves	2,022,021	2,022,021
Accumulated losses	(320,406,349)	(311,740,961)
Equity	41,162,880	49,339,797
Lease liabilities (non-current)	57,359	70,407
Contract liabilities (non-current)	0	1,167,725
Financial liabilities (non-current)	21,197,265	0
Non-current liabilities	21,254,624	1,238,132
Trade payables	4,794,843	7,875,241
Lease liabilities (current)	113,855	113,193
Contract liabilities (current)	3,558,675	4,965,325
Financial liabilities (current)	0	5,647,778
Other current liabilities	1,088,799	1,173,566
Current liabilities	9,556,172	19,775,103
Total equity and liabilities	71,973,677	70,353,032

Rounding of exact figures may result in differences.

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME (IFRS)

Reporting period from 1 December 2023 to 31 May 2024

	H1 2024 €	H1 2023 €
Sales revenue	4,054,789	4,391,418
Other income	2,227,160	277,302
Income	6,281,950	4,668,720
Cost of sales	(1,355,093)	(2,964,548)
Research and development costs	(10,583,202)	(14,771,505)
Administrative costs	(2,975,531)	(2,284,404)
Other expenses	(636,692)	(684,024)
Operating expenses	(15,550,517)	(20,704,481)
Operating result	(9,268,568)	(16,035,761)
Finance income	742,034	767,392
Finance costs	(138,855)	(505,664)
Financial result	603,179	261,728
Earnings before tax	(8,665,388)	(15,774,033)
Income tax	0	(177,432)
Net loss for the period	(8,665,388)	(15,951,465)
Other comprehensive income	0	0
Comprehensive income	(8,665,388)	(15,951,465)
Earnings per share		
Basic earnings per share	(0.19)	(0.34)
Average weighted number of shares issued	46,604,977	46,591,120

Rounding of exact figures may result in differences.

Quarterly comparison	Q2 2024 €	Q1 2024 €	Q4 2023 €	Q3 2023 €	Q2 2023 €
Revenue	2,787,897	1,266,892	3,224,256	2,243,238	2,316,609
Other income	1,634,772	592,389	(316,313)	6,981,321	181,939
Operating expenses	(8,984,038)	(6,566,479)	(8,026,462)	(9,280,078)	(11,986,449)
of which cost of sales	(1,325,615)	(29,479)	(163,230)	(125,051)	(1,514,790)
of which research and development costs	(5,510,173)	(5,073,028)	(6,009,565)	(7,293,776)	(9,020,292)
of which administrative costs	(1,739,096)	(1,236,434)	(1,624,094)	(1,339,672)	(1,216,548)
of which other expenses	(409,154)	(227,538)	(229,574)	(521,579)	(234,818)
Operating result	(4,561,369)	(4,707,198)	(5,118,519)	(55,519)	(9,487,901)
Finance income	378,597	363,436	429,211	428,310	402,851
Finance costs	(37,269)	(101,586)	(96,252)	(159,684)	(204,896)
Financial result	341,329	261,851	332,959	268,626	197,954
Earnings before tax	(4,220,041)	(4,445,347)	(4,785,560)	213,108	(9,289,947)
Income tax	48,931	(48,931)	277,422	(99,990)	(98,074)
Net loss for the period	(4,171,110)	(4,494,278)	(4,508,138)	113,118	(9,388,021)
Net currency gain/loss from consolidation	0	0	2,022,021	0	0
Comprehensive income	(4,171,110)	(4,494,278)	(2,486,117)	113,118	(9,388,021)
Basic earnings per share	(0.09)	(0.10)	(0.10)	0.00	(0.20)
Average weighted number of shares issued	46,604,977	46,604,977	46,595,741	46,602,264	46,591,120

Rounding of exact figures may result in differences.

CONSOLIDATED CASH FLOW STATEMENT (IFRS)

Reporting period from 1 December 2023 to 31 May 2024

	H1 2024 €	H1 2023 €
Net loss for the year	(8,665,388)	(15,951,465)
Adjustment for items in the statement of comprehensive income		
Stock options	488,472	152,154
Depreciation, amortization and impairment losses	434,569	438,948
Gains (+) and losses (-) on disposal of non-current assets	10,050	74,447
Exchange rate effects	(44,158)	294,948
Finance income	(742,034)	(767,392)
Finance costs	138,855	505,664
	285,754	698,768
Changes in balance sheet items		
Inventories	(1,238,989)	(629,339)
Prepayments	(150,242)	(401,144)
Trade receivables	(363,344)	1,001,772
Other receivables	(1,004,732)	(928,984)
Other non-current assets	(2,000)	0
Trade payables	(3,080,398)	431,346
Contract liabilities	(2,574,375)	(2,714,973)
Other liabilities	(84,767)	762,829
	(8,498,848)	(2,478,493)
Cash flow from operating activities	(16,878,482)	(17,731,189)
Finance costs paid	(785,970)	(896,342)
Finance income received	740,201	474,979
Net cash flow from operating activities	(16,924,251)	(18,152,552)

	H1 2024 €	H1 2023 €
Cash flow from investing activities		
Proceeds from disposal of property, plant and equipment	960	9,000
Payments to acquire property, plant and equipment	(83,022)	(788,194)
Payments to acquire intangible assets	(2,057)	(8,776)
Net cash flow from investing activities	(84,119)	(787,970)
Cash flow from financing activities		
Change in shareholder loan	(5,000,000)	(5,000,000)
Income from financing activities	23,037,175	0
Transaction costs from financing activities	(1,839,910)	0
Proceeds from creating shares for stock options exercised	0	45,547
Principal portion of lease payments	(53,127)	(53,751)
Net cash flow from financing activities	16,144,138	(5,008,203)
Influence of exchange rate and other effects on cash	44,158	(2,119)
Net change in cash	(820,075)	(23,950,844)
Cash		
at beginning of period	43,438,922	81,329,482
at end of period	42,618,847	57,378,638

Rounding of exact figures may result in differences.

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY (IFRS)

Reporting period from 1 December 2023 to 31 May 2024

	Shares	Subscribed capital €	Corporate actions/ premium Capital reserve €	Stock options €	Other reserves €	Accumulated losses €	Total €
			304,740,219	6,714,208			
As of 1 December 2022	46,584,457	46,584,457	311,454,427		0	(291,394,475)	66,644,409
Measurement of stock options				152,154			152,154
Net loss for the period						(15,951,465)	(15,951,465)
Creation of shares for stock options exercised	15,140	15,140	30,407				45,547
Net change in equity							(15,753,764)
			304,770,626	6,866,362			
As of 31 May 2023	46,599,597	46,599,597	311,636,988		0	(307,345,940)	50,890,645
			304,778,906	7,674,853			
As of 1 December 2023	46,604,977	46,604,977	312,453,759		2,022,021	(311,740,961)	49,339,797
Measurement of stock options				488,472			488,472
Net loss for the period						(8,665,388)	(8,665,388)
Equity instruments through other comprehensive income							0
Net change in equity							(8,176,917)
			304,778,906	8,163,325			
As of 31 May 2024	46,604,977	46,604,977	312,942,231		2,022,021	(320,406,349)	41,162,880

Rounding of exact figures may result in differences.

SELECTED NOTES

A. General disclosures

The interim consolidated financial statements include the Group's parent, Heidelberg Pharma AG, Ladenburg, Germany, as well as its subsidiary Heidelberg Pharma Research GmbH, Ladenburg, Germany, – jointly, the "Group". As part of the HCRx agreement, two new companies were established, HDP G250 AG & Co. KG and HDP G250 Beteiligungs GmbH. These two companies are affiliated below the parent company Heidelberg Pharma AG and are not operationally active.

This report was prepared in accordance with the same accounting policies as the consolidated financial statements as of 30 November 2023. The Company's results of operations, financial position and net assets, as well as key items in these financial statements, are explained in detail in the interim management report. The Company's business activities are not subject to seasonal or macroeconomic influences.

The interim consolidated financial statements for the first half of fiscal year 2024 that appear in this report were prepared in accordance with the International Financial Reporting Standards (IFRS) endorsed and adopted by the European Union (EU), specifically in accordance with IAS 34 ("Interim Financial Reporting") issued by the International Accounting Standards Board (IASB) and in compliance with the Interpretations of the Standing Interpretations Committee (SIC) and the International Financial Reporting Interpretations Committee (IFRIC). New standards issued by the IASB and adopted by the EU are applied starting in the fiscal year in which their application becomes mandatory.

These interim financial statements have not been reviewed by the auditor, are condensed, do not include all the information and disclosures required for consolidated financial statements as of the end of a fiscal year, and should be read in the context of the IFRS consolidated financial statements as of 30 November 2023 published for the 2023 fiscal year. Pursuant to the Company's Declaration of Conformity issued in February 2024 concerning the German Corporate Governance Code, both the interim financial statements and the interim management report for the Group were made available to the Supervisory Board's Audit Committee prior to publication. This interim report was approved for publication by the Executive Management Board of Heidelberg Pharma AG on 11 July 2024.

B. Change in equity

As of the reporting date, the total number of shares issued (subscribed / share capital) remained at 46.604.977.

Equity of the Heidelberg Pharma Group at the end of the reporting period was €41.2 million (30 November 2023: €49.3 million). Capital reserves were €312.9 million (30 November 2023: €312.5 million) and the losses accumulated totaled €320.4 million (30 November 2023: €311.7 million). The equity ratio of the Heidelberg Pharma Group was 57.2% (30 November 2023: 70.1%).

C. Issue and measurement of stock options

Similar to the approach described in the Annual Report as of 30 November 2023, Heidelberg Pharma's obligation vis-à-vis the beneficiaries resulting from the issuance of options under the 2011, 2017, 2018 and 2023 Stock Option Plans was recognized in accordance with IFRS 2 in the reporting period. The estimated number of options expected to become exercisable is reviewed at each reporting date. The effects of any adjustments to be considered regarding initial estimates are recognized in the statement of comprehensive income as well as by adjusting equity accordingly.

The measurement of the stock options in the first six months of the 2024 fiscal year entailed staff costs of €488 thousand (previous year: €152 thousand).

As of the 31 May reporting date, no new options had been issued and no options were exercised by beneficiaries in the financial year 2023. However, 2,121 stock options were returned by employees leaving the company.

Heidelberg Pharma issued a total of 3,407,796 subscription rights to employees and members of the Executive Management Board under the 2011, 2017, 2018 and 2023 Stock Option Plans, of which 2,909,666 options (856,250 for Executive Management Board members and 2,053,416 for current or former employees) were outstanding as of the end of the reporting period. In addition, 59,120 options have been exercised and 439,010 options have been forfeited or expired.

A total of 31,750 options of the Executive Management Board and 136,368 options of employees vested in the first six months of the 2024 fiscal year.

D. Related party transactions

During the reporting period, three transactions by senior executives of Heidelberg Pharma AG were reported in accordance with Article 19 of the Market Abuse Regulation (Directors' Dealings).

The law firm Rittershaus invoiced services for legal advice amounting to approximately €1.1 thousand for the Heidelberg Pharma Group in the reporting period. Rittershaus is a related party of the Company because the Chairman of the Supervisory Board, Professor Christof Hettich, is a partner in this law firm.

There were no other related party transactions during the reporting period.

E. Nature and extent of items affecting profit or loss

In accordance with IAS 34.16A(c), items must be disclosed that are unusual in nature, extent or incidence and therefore have a significant effect on the balance sheet, income statement or cash flow. No such matters arose in the reporting period. For the current financial year, the advance payment of USD 25 million received from HCRx as part of the partial sale of license fees concluded in March 2024 is to be noted.

F. Key events after the interim reporting period (report on post-balance sheet date events)

Significant events that occurred after the end of the reporting period are explained in the report on post-balance sheet events that is part of the interim management report.

RESPONSIBILITY STATEMENT OF THE EXECUTIVE MANAGEMENT BOARD

“To the best of our knowledge, and in accordance with the applicable reporting principles, the financial statements for the first six months give a true and fair view of the assets, liabilities, financial position and profit or loss of the Heidelberg Pharma Group, and the interim management report includes a fair review of the development and performance of the business and the position of the Heidelberg Pharma Group, together with a description of the material opportunities and risks associated with the expected development of the Heidelberg Pharma Group.”

Ladenburg, 11 July 2024

The Executive Management Board of Heidelberg Pharma AG



Professor Andreas Pahl
Chief Executive Officer



Walter Miller
Chief Financial Officer

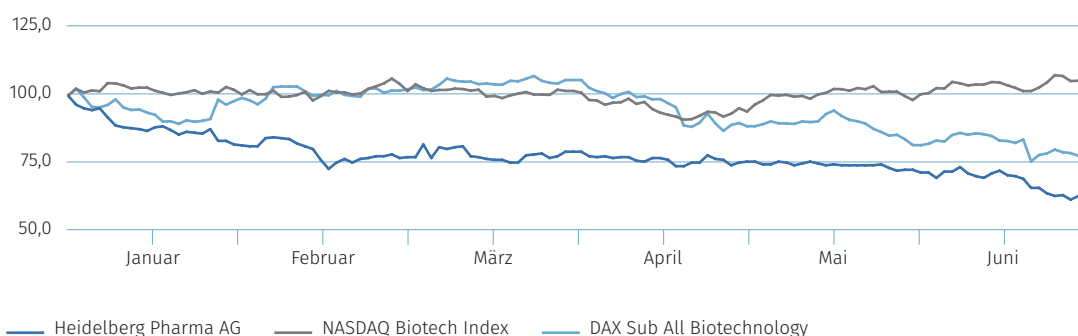
HEIDELBERG PHARMA'S SHARES

Share price performance in 2024

The year 2024 of the Heidelberg Pharma share began with a price of €3.64 and reached the half-year high of €3.73 on the same day. The share price fluctuated between €3.40 and €3.00 in the first few months and slipped below the €3.00 threshold from May onwards. The share closed the calendar half-year down 29% at €2.63.

The DAXsubsector Biotechnology Index closed down 18% and the NASDAQ Biotechnology Index ended the first half of the year up 3%. The German DAX and TecDax indices performed positively, up 9% and down 1% respectively.

Heidelberg Pharma's share price performance, indexed as of 1 January 2024



At the end of June, the market capitalization of Heidelberg Pharma corresponded to €122.6 million and was thus significantly lower than the previous year's figure of €173.4 million, which was still characterized by a lower number of shares. The average trading volume of Heidelberg Pharma shares in the first half of 2024 was 8,243 shares per day (previous year's volume: 3,083 shares).

Key share figures as of the end of the first six months of the year	1 Jan. to 30 June 2024	1 Jan. to 30 June 2023
Number of shares issued	46,604,977	46,599,597
Market capitalization in € million	122.6	173.35
Closing price (XETRA) in €	2.63	3.72
High ¹ in €	3.73 (2 Jan. 2024)	5.24 (5 Jan. 2023)
Low ¹ in €	2.40 (27 June 2024)	3.54 (29 June 2023)
Volatility (260 days ¹) in %	43.154	38.381
Average daily trading volume ¹ in shares	8,243	3,083
Average daily trading volume ¹ in €	25,497.27	13,832.10

¹ All stock exchanges

Source: Bloomberg

Annual General Meeting 2024

After the reporting period, the Annual General Meeting of Heidelberg Pharma AG was held in virtual format on 20 June 2024. The following draft resolutions of the administration were up for vote:

- Formal approval of the actions of the members of the Executive Management Board and the Supervisory Board for the fiscal year 2023
- Appointment of the auditor of the annual financial statements and the consolidated financial statements for the 2023/2024 fiscal year
- Cancellation of Authorized Capital 2022/I and creation of new Authorized Capital 2024/I with the option to exclude statutory subscription rights and corresponding amendments to the Articles of Association
- Approval of the remuneration report

Presence at the Annual General Meeting 2024 corresponded to 83.18% of the current share capital. Registered shareholders were able to follow the audio and video feed of the Annual General Meeting, to exercise their voting rights, to authorize representatives, to submit questions, ask questions, propose motions and nominations, exercise their right to information pursuant to section 131 AktG, submit comments pursuant to section 130a (1) to (4), exercise their right to speak or declare an objection to a resolution of the Annual General Meeting for the record or have their objections recorded in the minutes. The Annual General Meeting adopted the resolutions proposed by the management with a large majority (between 98.35% and 99.99%).

Shareholder structure of Heidelberg Pharma AG

Dietmar Hopp, parties related to him and companies controlled by them ^{1,2}	46%
Huadong Medicine Co., Ltd.	35%
Free float	19%

¹ Also includes dievini Hopp BioTech holding GmbH & Co. KG, DH-Holding Verwaltungs GmbH and DH-LT-Investments GmbH. All figures are assumptions by Heidelberg Pharma AG based on the most recent notifications in accordance with the German Securities Trading Act (Wertpapierhandelsgesetz – WpHG) and/or the voting rights reported at the most recent General Meeting.

² The former managing directors of dievini Hopp BioTech holding GmbH & Co. KG, Professor Christof Hettich and Dr. Friedrich von Bohlen und Halbach, and the managing director, Dr. Mathias Hothum, jointly hold 3.9% of Heidelberg Pharma shares and are affiliated with dievini via a pool agreement.

Analyst	Date	Valuation	Recommendation
Pareto Securities AG	25 March 2024	€8.80 per share	Buy
EQUITS GmbH	27 March 2024	€11.30 per share	Buy

Financial calendar 2024

Date	Type of report/event
10 October 2024	Interim management statement on the first nine months of 2024

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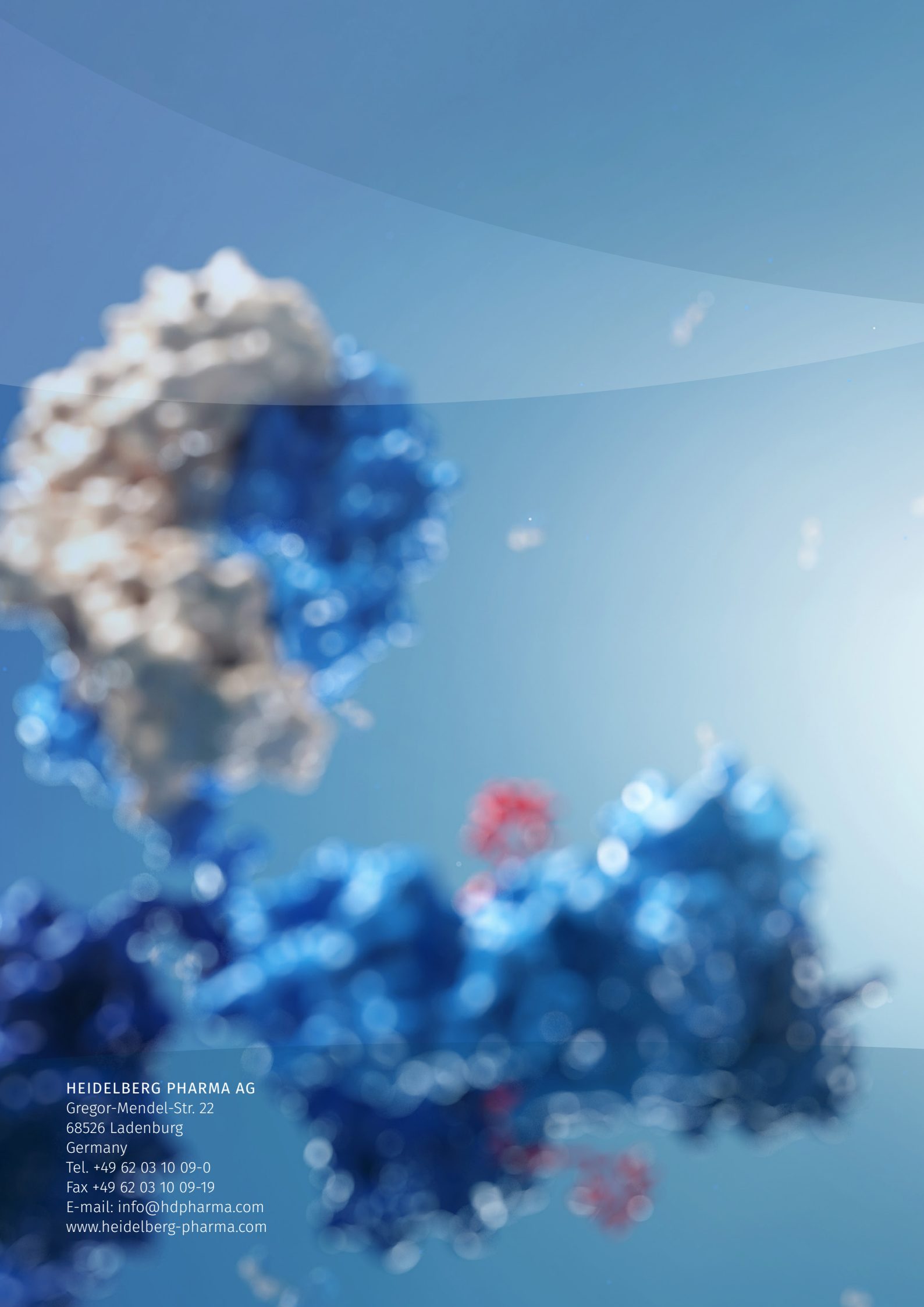
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The half-year financial report is also published in German and is available for download from our website at www.heidelberg-pharma.com.

The English translation of the half-year financial report is provided for convenience only. The German original is definitive.

As of: 10 July 2024



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