

KEY FIGURES

	2023 ¹ €'000	2022 ¹ €'000
Earnings		
Sales revenue	9,859	18,514
Other income	6,942	1,346
Operating expenses	(38,011)	(37,042)
of which research and development costs	(28,075)	(26,377)
Operating result	(21,210)	(17,181)
Earnings before tax	(20,346)	(17,786)
Net loss for the year	(20,346)	(19,702)
Comprehensive income	(18,324)	(19,702)
Earnings per share in € (basic)	(0,44)	(0,53)
Balance sheet at end of period		
Total assets	70,353	100,582
Cash	43,439	81,329
Equity	49,340	66,644
Equity ratio ² in %	70.1	66.3
Cash flow statement		
Cash flow from operating activities	(33,672)	(8,864)
Cash flow from investing activities	5,848	(598)
Cash flow from financing activities	(10,053)	84,001
Employees (number)		
Employees as of the end of the period (headcount) ³	105	110
Employees as of the end of the period (full-time equivalents) ³	95	102

¹ The reporting period begins on 1 December and ends on 30 November.

² Equity/total assets

³ Including members of the Executive Management Board

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



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Ultra-High Performance

CONTENTS




About us


- 5 Mission
- 7 Portfolio
- 9 Highlights in 2023

Values

- 10 Introducing our new management duo
- 14 Report of the Supervisory Board
- 19 Investor relations



 = Glossary (term marked in blue) or cross reference

 = Internet reference



Combined management report

- 24 Company overview
- 28 Economic environment in 2023
- 37 Course of business in 2023
- 47 Non-financial performance indicators
- 48 Results of operations, financial position and net assets of the Group
- 54 Overall assessment of the course of business and position of the Group by the Executive Management Board
- 56 Corporate governance
- 60 Risk report
- 72 Report on post-balance sheet date events
- 73 Heidelberg Pharma – Report on expected developments and on opportunities 2023
- 79 Disclosures on Heidelberg Pharma AG (HGB)

Consolidated financial statements

- 88 Consolidated statement of comprehensive income
- 89 Consolidated balance sheet
- 90 Consolidated cash flow statement
- 92 Consolidated statement of changes in equity
- 93 Notes to the Consolidated financial statements

- 166 Responsibility statement of the Executive Management Board
- 167 Independent auditor's report
- 176 Glossary
- 180 Financial calendar, contact and publishing information









HIGHLIGHTS IN 2023

April

Presentation of new preclinical data at the AACR Annual Meeting providing positive evidence of the efficacy and tolerability of the company's proprietary ATAC technology

May

- Walter Miller was appointed Chief Financial Officer
- Virtual Annual General Meeting

June

Selling of minority shareholding in Emergence to Eli Lilly

August

Partner Takeda initiated a GLP toxicology study with an antibody-amanitin conjugate, thus triggering a milestone payment

September

Positive update on the Phase I/IIa clinical trial with the candidate HDP-101 and start of the fifth cohort

December

- Presentation of positive safety data of HDP-101 at the ASH Annual Meeting
- Granting of a patent for site-specific ATAC conjugates
- Announcement that Professor Andreas Pahl will take over from Dr. Jan Schmidt-Brand as Spokesman of the Executive Board as of 1 February 2024

INTRODUCING OUR NEW MANAGEMENT DUO



Professor Andreas Pahl, Chief Executive Officer

Professor Andreas Pahl, 59, joined Heidelberg Pharma in 2012 and served on the Executive Management Board as Chief Scientific Officer from 2016 up to and including January of this year. A keen surfer and skier, Professor Pahl previously worked in the pharmaceutical industry and has around 25 years of research and teaching experience.

Professor Pahl, we know you to be a passionate scientist. What made you decide to take on your new role as CEO?

In my more than 12 years with Heidelberg Pharma, I have been responsible for significantly expanding our research and development activities and worked with my colleagues to keep enhancing our very special ADC technology and lay the foundation for the continued development of our portfolio. In recent years, we've established an experienced and motivated leadership team to fully leverage Heidelberg Pharma's considerable potential. Using sound scientific results to deliver safe, effective therapies for patients while demonstrating the appeal of our business model to investors is what drives me. I want to build bridges between the interests of the research community and the capital markets.

On behalf of all of our employees, I'd like to take this opportunity to thank my predecessor, Dr. Schmidt-Brand, for many years of dedicated service to the Company. We enjoyed a constructive, trust-based collaboration, and worked together to keep Heidelberg Pharma on the right track. I wish him all the best for his retirement and plenty of wonderful experiences and activities that he so often didn't have time for before.

You were dubbed the Pilzprofessor ("mushroom professor") in an interview some time ago. Do you like this title?

Not really, but the interview was conducted at the German Equity Forum in November 2023 and the journalists coined this attention-grabbing term to show what Heidelberg Pharma stood for – our unique expertise in the mushroom toxin Amanitin.

Why did you choose the past tense there? Is Heidelberg Pharma no longer focusing its research on Amanitin?

We're still the world's leading experts in this area and will remain so. Over the past year, however, we have expanded our ATAC technology that relies on the Amanitin mushroom toxin to include additional ADC technology with other payloads.

“I want to build bridges between the interests of the research community and the capital markets.”

Can you help us understand what that looks like? What has changed?

We’re now working with a toolbox that contains additional ADC technology with different compounds in addition to our ATAC platform. ADCs consist of antibodies that point the way to tumor cells and are linked to a cytotoxin by a linker molecule. An ADC’s particular mode of action is that the cytotoxic payload is transported directly to the diseased cells and does not attack healthy cells. The drug is only released in the tumor cells to unleash its toxic effect, destroying the cancer cells in the process.

Our scientific teams have built up wide-ranging expertise in these ADCs over the years. In addition to Amanitin, we are now using this knowledge for other toxins and immunostimulants and rolling it out commercially to licensing partners as part of our technology partnerships.

How is the trial of the first clinical candidate, HDP-101, going?

The fifth cohort with HDP-101 is now complete and we are very encouraged to see some initial indications of efficacy. Three patients exhibited a demonstrable improvement in their disease in what is known as a “partial response”. A patient from the third cohort has now been receiving HDP-101 as a monotherapy for more than a year. His disease progression is stable and he is tolerating the medication very well. Although this is still an individual case, we see the fact that one patient can already benefit from one of our product candidates as a major success.

Our US trial centers are currently recruiting the first patients for the sixth cohort.

Can you give us an outlook for the coming fiscal year?

We are about to start clinical trials for two further ATAC candidates. The clinical trial application for HDP-102, which we are aiming to test for non-Hodgkin lymphoma, is very close to being submitted. We are also preparing a clinical trial application for our PSMA candidate HDP-103 and plan to submit this in 2025.

We are about to take the next development step in our HDP-201 project, which uses a compound – Exatecan – that is new to us, and will identify lead candidates by the fall.

One traditional interview question to finish: where do you see the Company’s projects five years from now?

ADCs represent the future of highly effective and targeted cancer therapy. I am very optimistic that we will have a well-filled pipeline of different ADC candidates in five years and that one or two ADCs will have already become established methods for treating cancer.



Walter Miller, Chief Financial Officer

Walter Miller, 56, was appointed Chief Financial Officer of Heidelberg Pharma in May 2023. He has more than 20 years of experience in the life sciences industry and over 25 years of experience in corporate finance, mergers and acquisitions (M&A) and strategic controlling as well as accounting and corporate development in both listed biotech companies and clinical research organizations (CROs). Before joining Heidelberg Pharma, Mr. Miller, who is an avid runner, was CFO of the Optimapharm Group headquartered in Croatia.

Mr. Miller, you moved from Zagreb to the Rhine-Neckar region ten months ago.

What were your impressions of your first few months here?

I have gotten to know a formidable and innovative group of people and am delighted to have become part of the Heidelberg Pharma team at such an exciting time. As a developing biotech company we face many different challenges, particularly in terms of finance. Our business activities require significant levels of investment, and it usually takes years to achieve lasting financial success. As CFO, I see my primary responsibility as ensuring that we can fund our activities – both on the cost and income side.

Heidelberg Pharma expanded its research activities during the past year.

Has the Company's finance strategy also changed as a result?

Research and finance strategies go hand-in-hand. We are confident that our portfolio will be a success. Our aim is to make Heidelberg Pharma a leading global player in ADC technology over the next few years. We need additional financial resources to safeguard the further investment required to do this.

Selling the minority stake in Emergence and, most importantly, the recently completed transaction with HealthCare Royalty have swelled the Company's coffers.

What are you doing with this inflow of funds?

Selling our stake in Emergence was an unplanned yet highly welcome development. Most of the funds were used for a loan repayment to our main shareholder dievini. We are also using it to support and accelerate our own pipeline candidates and ADC technologies. This is also the thinking behind our agreement with HealthCare Royalty regarding the sale of royalties.

Heidelberg Pharma developed the girentuximab antibody as a therapeutic and diagnostic agent through the first Phase III clinical trial and licensed it to Australian company Telix Pharmaceuticals for further development in 2017. This licensing agreement made us eligible for both milestone payments and royalties. We have now sold part of these rights to HealthCare Royalty. By signing this agreement, we receive capital earlier than we would have done from the planned royalties and will invest it in developing our own candidates.

One key element of this contract was to agree on a maximum sum for royalties. Once HealthCare Royalty has received a specific cumulative amount of royalties, a large portion of any royalties over and above this amount revert back to Heidelberg Pharma. The agreement allows us to profit from global product sales both now and later while reducing our residual approval and market risk. For example, the first payment of USD 25 million does not include any repayment obligation in the event that the FDA approval we are all expecting and hoping for does not materialize. The second payment of USD 75 million upon approval enables us to continue developing our portfolio at maximum speed and extend our cash reach, assuming that our current expectations prove correct and that we receive the second payment.

Running and biotechnology have one thing in common – you need great stamina for both.

Where do you see Heidelberg Pharma in five years' time?

Nobody can look into a crystal ball and predict the future accurately. Yet, as in running and sports in general, it's all about making sure you've done the right preparations and have the necessary staying power. We've done our homework, we have a strong and experienced team, and we're looking to the future with confidence. I'm very optimistic that the past and, hopefully, continued success of our clinical trials will also be reflected in commercial success in the near future. This is in the interest of our stakeholders. Patients benefit from the therapies while shareholders profit from the increase in Heidelberg Pharma's value.

“Our aim is to make Heidelberg Pharma a leading global player in ADC technology over the next few years.”

REPORT OF THE SUPERVISORY BOARD

During the reporting year, the Supervisory Board performed all its duties in accordance with the law, the Company's Articles of Association and its Internal Rules of Procedure.

The Supervisory Board worked closely with the Executive Management Board, regularly advising it on the management of the Company and monitoring the Executive Management Board's activities. The Executive Management Board presented all significant strategic and operational measures to the Supervisory Board and agreed their implementation in advance with the Supervisory Board. The Supervisory Board obtained regular reports on the situation and development of the Company, both at regular Supervisory Board meetings, which were held either virtually or in person, and in additional conference calls. It also received regular, comprehensive and timely information on all major business developments and basic issues relating to business policy, corporate management and planning (including financial, investment and personnel planning). Discussions included, in particular, the following topics: partnership with Huadong Medicine Co. Ltd., Hangzhou, China, (Huadong), the development strategy for HDP-101, potential follow-up projects, negotiations with HealthCare Royalty, Delaware, USA, (HCRx), licensing negotiations, technology partnerships, M&A matters and financing options. Without exception, the Supervisory Board examined all documents submitted and prepared by the Executive Management Board and the related departments. The parties providing the information, in particular the members of the Executive Management Board, were consulted on significant matters.

The Supervisory Board also obtained information about all significant events that were particularly important for the assessment of the status, implementation of strategy and achievement of goals, as well as for the development and management of Heidelberg Pharma AG and its subsidiary Heidelberg Pharma Research GmbH. The Chairman of the Supervisory Board regularly discussed the strategy and reviewed the progress of the business with the Chief Executive Officer. The Chairman of the Supervisory Board was advised promptly of all important resolutions taken by the Executive Management Board and, when necessary, arranged for the discussion of important issues by the Supervisory Board or the appropriate Supervisory Board subcommittees.

Supervisory Board meetings in the 2023 fiscal year

In the 2023 fiscal year (1 December 2022 to 30 November 2023), the Supervisory Board met for four regular meetings and several extraordinary meetings. All meetings were held in either virtually or in person. The Supervisory Board is made up of international members. The members based in Germany attended the Supervisory Board meetings in person wherever possible, while the two members based in China took part via video conference.

Attendance overview

Date	Hettich	Baur	Hothum	Von Bohlen und Halbach	Kudlek	Liu	Xia
22 March 2023	X	X	X (in person)	X	X (in person)	X	Not yet in office
13 July 2023	X	X	X (in person)	X	–	X	X
28 Sep. 2023	X	X	X (in person)	X	X	X	X
23 Nov. 2023	X (in person)	X	X (in person)	X	X (in person)	X	X

Main topics at the meetings of the Supervisory Board in the 2023 fiscal year

In the 2023 fiscal year, the Supervisory Board discussed and approved the following items requiring its approval:

- Evaluation of corporate objectives for the 2023 fiscal year and definition of corporate objectives for the 2024 fiscal year
- Budget for the 2024 fiscal year
- Approval of the 2022 annual and consolidated financial statements
- Agenda and proposed resolutions for the 2023 Annual General Meeting
- Events at former partner Magenta Therapeutics and impact on the proprietary ATAC technology
- Clinical development strategy of HDP-101
- Further development of the successor candidates HDP-102 and HDP-103
- Introduction of new payload technologies (Exatecan and immunostimulatory agents)
- Nomination of development candidate with new payload HDP-201
- Contract negotiations with Carbogen on the material supply model
- Preparation and conclusion of a license agreement with HealthCare Royalty
- Negotiation mandates for potential contractual partnerships
- Adaptation and revision of the existing risk management system
- Adoption of the share option plan 2023
- Appointment of the Chief Financial Officer Walter Miller and conclusion of a corresponding contract
- Reappointment of Executive Board member Professor Andreas Pahl and appointment as Chief Executive Officer, as well as conclusion of a corresponding contract
- Compensation system for the Executive Board and Supervisory Board

The full Supervisory Board approved all of the actions submitted for approval following in-depth review and discussion.

The Supervisory Board was informed, regularly and comprehensively, about the Company's financial situation, its future funding requirements and the risk management system and discussed the Company's future strategy with the Executive Management Board. Establishing its own pipeline is becoming an increasingly important aspect of the Company's overall strategy. In addition to the development candidate HDP-101, an antibody drug conjugate directed against the target molecule BCMA, which is already in clinical development, development activities for the other ATAC candidates were intensified with the approval of the Supervisory Board. The committee also discussed the addition of further loading technologies to the ADC technology.

The Supervisory Board was regularly informed about activities at Heidelberg Pharma AG's licensees for Zircaix™ (TLX250-CDx) and upamostat.

The Executive Management Board also regularly briefed the Supervisory Board on the business activities of the Company's subsidiary Heidelberg Pharma Research GmbH, which is focused on refining and marketing its technology platform for therapeutic antibody drug conjugates.

Virtual 2023 Annual General Meeting

The Annual General Meeting of Heidelberg Pharma AG was held on 25 May 2023 in a virtual format. All proposed resolutions were adopted by majorities ranging from 96,30% and 99,99%.

Corporate governance

The Supervisory Board together with the Executive Management Board decided on 1 February 2024 to implement the recommendations and suggestions of the German Corporate Governance Code (GCGC) to a large extent. The new joint Declaration of Conformity by the Executive Management Board and the Supervisory Board was adopted on the same day and is available at the Company's website under "Press & Investors > Corporate Governance > Declaration of Conformity". More information on corporate governance at Heidelberg Pharma is available on the Company's website under "Press & Investors" > "Corporate Governance".



Conflicts of interest on the Supervisory Board

Any conflicts of interest affecting members of the Supervisory Board pursuant to recommendation E.1 of the GCGC were disclosed to the other members of the Supervisory Board, and the Supervisory Board members affected by the given conflict of interest acted as follows during the respective deliberations and resolutions of the Supervisory Board:

Professor Christof Hettich, Chairman of the Supervisory Board, is a partner at Rittershaus law firm, which provides various legal consulting services to the Heidelberg Pharma Group. This relationship has been identified as a potential conflict of interest. To the extent that the services provided by the Rittershaus law firm were the subject of deliberations of the Supervisory Board, the Chairman of the Supervisory Board did not take part in these deliberations and abstained from any votes taken.

While a large part of the Supervisory Board members also holds positions on supervisory boards of other companies in the pharmaceutical and biotech sectors, none of these companies can be considered major competitors of Heidelberg Pharma, which complies with GCGC requirements.

Activities of the Committees

The Supervisory Board established two committees to efficiently fulfill its responsibilities; each committee is responsible for preparing issues within its purview for the full Supervisory Board. At the regular Supervisory Board meetings, each committee chairman reported to the Supervisory Board on the work of his committee.

For efficiency, a joint Compensation and Nomination Committee was established, which covers both areas separately in its meetings. The Compensation Committee met twice in fiscal year 2023. At the beginning of the year, the committee conducted numerous interviews with candidates for the position of Chief Financial Officer. The subsequent appointment of Walter Miller and the extension of Professor Andreas Pahl's contract were decided by the full Supervisory Board.

The Audit Committee met two times in the fiscal year. The Audit Committee discussed the 2022 annual financial statements with the auditor Deloitte GmbH Wirtschaftsprüfungsgesellschaft, Frankfurt, Germany, (Deloitte). At the proposal of the Supervisory Board, Deloitte was elected by the Annual General Meeting on 25 May 2023 and subsequently commissioned by the Supervisory Board to audit the 2023 financial statements. In advance, the Supervisory Board obtained a declaration of independence from the auditor. The Audit Committee also discussed the half-year report for 2023 with the Executive Board prior to publication. The committee also dealt in detail with the Company's risk management system. In addition, the tender for and the appointment of a new auditor for the 2024/25 financial year were discussed in detail.

Adoption of the annual financial statements

The auditors Deloitte audited the combined management report, the annual financial statements of Heidelberg Pharma AG and the consolidated financial statements as of 30 November 2023, including the underlying accounting, and issued an unqualified auditor's report. The lead auditor of these consolidated financial statements was Mr. Steffen Schmidt, who has held this position since the 2023 consolidated financial statements. The auditors conducted their audit in compliance with the generally accepted German standards for the audit of financial statements of the German Institute of Public Auditors (IDW). The combined management report, the annual financial statements of Heidelberg Pharma AG and the consolidated financial statements were each prepared pursuant to the principles of the German Commercial Code and in accordance with the International Financial Reporting Standards (IFRSs) as adopted by the EU, taking into account Section 315a (1) of the German Commercial Code. The Statement on Corporate Governance was updated to reflect new targets for the proportion of women on the Executive Management Board and published as amended on 19 March 2024.

The aforementioned documents as well as the dependent company report and the audit reports of Deloitte were made available to all members of the Supervisory Board in a timely manner and discussed in detail with the auditors both at the meeting of the Audit Committee held on 12 March 2024 and today's accounts meeting of the Supervisory Board. The auditors reported to the Supervisory Board on the material findings of their audit, that the combined management report presents a true and fair view of the risks and opportunities and that the measures taken by the Executive Management Board in accordance with Section 91(2) of the German Stock Corporation Act were suitable for identifying at an early stage any developments which could jeopardize the Company's existence. The auditors also discussed the audit's scope, focal points and costs.

The Audit Committee discussed the audit result in detail and proposed to the Supervisory Board that it approve the financial statements as prepared by the Executive Management Board. The Supervisory Board also reviewed the audit result and examined both sets of annual financial statements and the combined management report, as well as the proposed appropriation of accumulated loss (under the German Commercial Code) in accordance with legal provisions and concurred with the results of the audit. Based on the conclusive findings of its examination, the Supervisory Board has no objections and at today's meeting approved the financial statements as prepared by the Executive Management Board; they are hereby adopted.

The Report by Heidelberg Pharma AG on Relationships with Affiliated Companies in Accordance with Section 312 (1) of the German Stock Corporation Act (dependent company report) prepared by the Executive Management Board was also reviewed by Deloitte in accordance with Section 313 (3) of the German Stock Corporation Act.

The auditors issued the following unqualified auditor's report on 21 March 2024:

"On completion of our review and assessment in accordance with professional standards, we confirm that

1. the actual disclosures contained in the report are accurate, and
2. that the consideration paid by the Company for the transactions listed in the report was not inappropriately high."

The dependent company report prepared by the Executive Management Board and the audit report prepared by the auditors for this dependent company report were examined and discussed in detail by the members of the Supervisory Board. The representative of the auditors reported in detail on the main findings of the audit. He also addressed questions from the Supervisory Board and was available to provide additional information. At the meeting to discuss the financial statements, the Supervisory Board concurred with the findings of the audit of the dependent company report and raised no objections. Following its own examination, the Supervisory Board raised no objections to the dependent company report.

Following the examination by the Supervisory Board, there were no objections to the statement by the Executive Management Board at the end of the dependent company report.

Recognition of commitment

The Supervisory Board would like to take this opportunity to thank the Executive Management Board and all employees of Heidelberg Pharma AG and its subsidiary Heidelberg Pharma Research GmbH for the impressive commitment they showed in the 2023 fiscal year.

Ladenburg, 21 March 2024

For the Supervisory Board



Professor Christof Hettich
Chairman of the Supervisory Board

INVESTOR RELATIONS

Market development

Compared to the turbulent previous year, investors can look back on the 2023 trading year with satisfaction. Despite ongoing geopolitical crises and high inflation, the equity markets calmed down in the fourth quarter,¹ with all of the major indices recording gains. The NASDAQ closed the year up 55%², Germany's DAX benchmark index gained 19% by year-end thanks to a price rally. The TecDAX technology index finished the year up 14%.

Several key interest rate hikes over the course of the year helped to make more conservative forms of investment more attractive³ again at the expense of riskier stocks on biotechnology indices. The German DAX subsector Biotechnology Index recorded losses of over 7% on the prior-year figure. While a rebound in the second half of the year meant the US NASDAQ Biotechnology Index ended the year up 3%, it continued to lag far behind previous years.

Biotechs completed 46 IPOs in 2023 (2022: 53), including 17 in the USA and just one in the EU, even lagging well behind the weak previous year.⁴ The IPO market is expected to gradually pick up in 2024, particularly for biotech companies able to present initial clinical data.⁵

Share price performance of Heidelberg Pharma's shares in 2023

Heidelberg Pharma's shares started 2023 trading at €4.96, reaching their high for the year of €5.24 on 5 January 2023. While the stock hovered around the €5 mark in the first few months of the year, it began a steady decline in March and settled between €3.80 and €3.40 by mid-year. The shares dropped below €3 in mid-October before reaching their annual low of €2.60 on 30 October 2023. Progress in our clinical trial of HDP-101 and the presentation of preliminary data at the ASH Annual Meeting fueled a share price recovery, with the stock ending the year at €3.74.

¹ <https://www.zdf.de/nachrichten/wirtschaft/boersenjahr-2023-rueckblick-100.html>

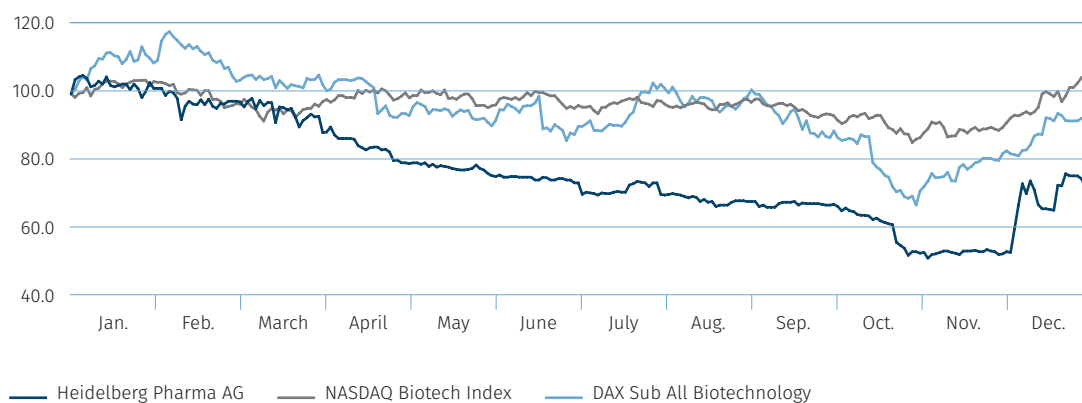
² <https://www.nasdaq.com/articles/2023-review-2024-outlook>

³ <https://www.zdf.de/nachrichten/wirtschaft/boersenjahr-2023-rueckblick-100.html>

⁴ BCIQ database, 30 January 2024

⁵ BioCentury, 21 December 2023: Diamonds in a rough 2023, predictions for 2024

Heidelberg Pharma's share price performance, indexed as of 1 January 2023



Trading and liquidity

The average daily trading volume of Heidelberg Pharma's shares across all German stock exchanges in 2023 (1 January to 31 December) was 5,453 shares (previous year: 6,874 shares). The Company's market capitalization at the end of December 2023 was €174.30 million (2022: €229.60 million).

Key share figures	FY 2023	FY 2022
Period under review: 1 January to 31 December 2023 ¹		
Market capitalization in € million	174.30	229.66
Number of shares issued	46,604,977	46,584,457
Closing price (XETRA) in €	3.740	4.930
High ² in €	5.240 (on 5 Jan. 2023)	6.500 (on 13 Dec. 2022)
Low ² in €	2.600 (on 30 Oct. 2023)	3.400 (am 25 Jan. 2022)
Volatility (260 days; XETRA) in %	41.47	61.22
Average daily trading volume ² in shares	5,453	6,874
Average daily trading volume ² in €	20,071	36,018

¹ As of the end of the reporting period

² All stock exchanges

Source: Bloomberg

Annual General Meeting

The Annual General Meeting of Heidelberg Pharma AG took place in a virtual format on 25 May 2023. Of the Company's share capital at that time (46,584,457 no par value bearer shares), 39,243,625 shares, or 84.24%, were represented with the same number of votes.

In addition to dealing with standard agenda items such as the approval of the annual financial statements, the formal approval of the actions of the members of the Executive Management Board and Supervisory Board and the election of the auditor, the following agenda items were adopted:

- Elections to the Supervisory Board, specifically one representative of Huadong
- Resolution on amendments to the Articles of Association with regard to the authorization to hold a virtual Annual General Meeting and with regard to the virtual participation of Supervisory Board members in an Annual General Meeting
- Amendment to the Articles of Association with regard to the quorum of the Supervisory Board
- Resolution on the Heidelberg Pharma Stock Option Plan 2023, on the reduction of conditional capital, and on corresponding amendments to the Articles of Association
- Approval of the remuneration report

All proposed resolutions were adopted by a significant majority of between 96.30% and 99.99%.

Shareholder structure of Heidelberg Pharma AG¹

Dietmar Hopp, parties related to him and companies controlled by them ^{2,3}	45.7%
Huadong Medicine Co., Ltd.	35.0%
Free float	19.3%

¹ As of 30 November 2023

² Shares of dievini Hopp BioTech holding GmbH & Co. KG, DH-Holding Verwaltungs GmbH, Walldorf, and DH-LT-Investments GmbH (as of 30 November 2023)

³ The former managing directors of dievini Hopp BioTech holding GmbH & Co. KG, Prof. 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

General information¹

Listed:	Regulated Market (Prime Standard)
Stock exchange symbol:	HPHA
WKN/ISIN:	A11QVV/DE000A11QVV0
Share capital:	€46,604,977
Admitted capital:	46,604,977 bearer shares of common stock
Designated sponsors:	Pareto Securities AS, Stifel Europe Bank AG

¹ As of 30 November 2023

Please see page 180 for the financial calendar. The current conference calendar is available on the website.

COMBINED MANAGEMENT REPORT

for the fiscal year from 1 December 2022
to 30 November 2023



24	Company overview
28	Economic environment in 2023
37	Course of business in 2023
47	Non-financial performance indicators
48	Results of operations, financial position and net assets of the Group
54	Overall assessment of the course of business and position of the Group by the Executive Management Board
56	Corporate governance
60	Risk report
72	Report on post-balance sheet date events
73	Heidelberg Pharma – Report on expected developments and on opportunities 2023
79	Disclosures on Heidelberg Pharma AG (HGB)

COMBINED MANAGEMENT REPORT

for the Heidelberg Pharma Group and Heidelberg Pharma AG, Ladenburg

for the fiscal year from 1 December 2022 to 30 November 2023

1 Company overview

Reporting is based on a combined management report for the Heidelberg Pharma Group (IFRS) and Heidelberg Pharma AG (HGB). Joint reporting is based on the entities' common activity profile, risks that almost match and consolidated financial reporting.

 Pages 60–79 and 60

Chapters 1 through 6 and chapter 11 of this management report provide an overview of business activities in the past fiscal year, while chapters 8 through 11 outline the current situation and predict future developments. Reference is made particularly to chapter 8, "Risk report."

"Heidelberg Pharma" will be used as a synonym for the Group hereinafter. The entity's specific corporate name is stated whenever facts specific to Heidelberg Pharma AG as the parent company are reported. If information specifically concerns the subsidiary Heidelberg Pharma Research GmbH, its full corporate name or "Heidelberg Pharma Research" are used.

1.1 Corporate structure, locations and reporting

The Company is domiciled in Ladenburg near Heidelberg, Germany. Since October 2017, the Company has been doing business as Heidelberg Pharma AG and has been registered in the Commercial Register of Mannheim Local Court under HRB 728735. Until 31 January 2024, the Company's Executive Management Board consisted of Dr. Jan Schmidt-Brand, Professor Andreas Pahl and Walter Miller (since 1 May 2023). Dr. Jan Schmidt-Brand stepped down as a member of the Executive Management Board on 31 January 2024 as part of the retirement-related succession plan. Since then, Professor Andreas Pahl and Walter Miller have been the Executive Management Board members of Heidelberg Pharma AG. The Company (formerly WILEX AG) has been listed on the Regulated Market (Prime Standard, stock exchange symbol HPHA, ISIN DE000A11QVW0) of the Frankfurt Stock Exchange since November 2006.

The only subsidiary Heidelberg Pharma Research GmbH has been part of the Heidelberg Pharma Group since March 2011. Its Managing Directors are Walter Miller (since 1 May 2023) and Professor Andreas Pahl (since 1 February 2024). Dr. Jan Schmidt-Brand held the position of Managing Director until his retirement on 31 January 2024. Heidelberg Pharma Research is also domiciled in Ladenburg, Germany. From November 2019 until June 2023, the subsidiary was a shareholder of Emergence Therapeutics AG, Duisburg, Germany (Emergence). Until the 2021 fiscal year, Emergence was classified as an associate, over which significant influence could be exerted. As Heidelberg Pharma's share in this entity was reduced to 1.49% in the reporting period and it no longer has significant influence, Emergence is now reported as an equity investment within the meaning of IFRS 9. On 29 June 2023, Heidelberg Pharma announced that its minority interest in Emergence, including the shares from converting the Emergence convertible bond, had been sold to the US pharmaceutical company Eli Lilly and Company.¹

¹ Press release, 29 June 2023: <https://heidelberg-pharma.com/en/press-investors/announcements/press-releases-and-ad-hoc-announcements/ah-heidelberg-pharma-sells-minority-shareholding-in-emergence-therapeutics>

These consolidated financial statements were prepared in accordance with the International Financial Reporting Standards (IFRSs) of the International Accounting Standards Board (IASB), London, United Kingdom, as applicable in the European Union (EU), taking into account the recommendations of the International Financial Reporting Standards Interpretation Committee (IFRS IC). The provisions applicable in accordance with Section 315e German Commercial Code (Handelsgesetzbuch – HGB) were also taken into account. The IFRS consolidated financial statements include Heidelberg Pharma AG as the parent company as well as the subsidiary Heidelberg Pharma Research GmbH for the full 2023 fiscal year (1 December 2022 to 30 November 2023).

1.2 Business activities

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 potency of toxins. Its activities focus on an its patented and proprietary ATAC technology that is based on the mushroom toxin Amanitin and uses the biological mode of action of this **toxin** as a novel therapeutic principle in cancer medicine. To the best of the Company's knowledge, Heidelberg Pharma is the first company to develop the compound **Amanitin** for cancer therapies. The **ATAC** technology platform is being applied to develop the Company's proprietary therapeutic Antibody Targeted Amanitin Conjugates as well as in third-party collaborations.

 Glossary

In addition to the toxin Amanitin, which is known from the green death cap mushroom, the Company has been using other active ingredients such as the **topoisomerase inhibitor exatecan** or **immune-stimulating** active ingredients such as the Toll-like receptor TLR7 since the fiscal year 2023, thereby supplementing its proprietary ATAC technology with further ADCs technologies ("toolbox") to develop the best possible ADCs for additional target antigens and applications.

Heidelberg Pharma AG is responsible for the development phase of the Group's internal projects. For this it continues projects, i.e. the development of potential product candidates, on completion of the research phase performed by the subsidiary Heidelberg Pharma Research GmbH, taking over their further **preclinical** and clinical development. Heidelberg Pharma AG also performs functions relating to Group and research strategy, finance, investor and public relations, business development, project management, human resources, legal and regulatory matters, and contract management. Alliance and data management, as well as intellectual property rights are also covered.

The subsidiary Heidelberg Pharma Research GmbH take care of the Group's research activities. Focusing on the proprietary ATAC technology, it researches various drug loadings in the field of therapeutic antibody drug conjugates. The loadings are combined with tumor-specific antibodies designed to target the highly potent compound to the cancer cell. The goal is to develop a cancer treatment that has fewer side effects and is more effective based on the ATAC and ADC candidates resulting from this process.

Heidelberg Pharma also collaborates with production partners to supply its licensing partners with **good manufacturing practice** (GMP) quality Amanitin **linker** material for their own development projects as required.

Detailed information regarding the projects and the current status of development is presented in chapter 3, "Course of business in 2023."

 Page 37

1.3 Business model, corporate strategy and goals

In recent years, Heidelberg Pharma through its subsidiary Heidelberg Pharma Research GmbH has developed extensive expertise and an extensive patent portfolio for the compound Amanitin, which can be linked with different tumor-specific types of antibodies. The strategy is to validate the technology platform in clinical trials, broaden its application based on its mode of action and use it to develop new therapeutic options for patients. The company boasts a high level of expertise in ADC development, which will be broadened going forward by incorporating new drug loadings.

A hybrid business model that comprises both developing a proprietary product pipeline and licensing the technology to other companies provides the commercial basis for this.

Glossary

The first pillar of the business model involves producing proprietary ADC [molecules](#) based on licensed or internally generated antibodies, testing these as [R&D](#) candidates and further refining them. At present, the most advanced of the Company's pipeline projects is [HDP-101](#), an ATAC based on an antibody targeting the protein BCMA that is connected to the Amanitin toxin via a linker. Since February 2022, patients in a [Phase I/IIa](#) clinical trial in [multiple myeloma](#) have been treated with HDP-101. Alongside developing HDP-101, Heidelberg Pharma continuously examines additional ATAC candidates in preclinical tests for efficacy and tolerability to identify further potential development candidates. The successor candidates [HDP-102](#) and [HDP-103](#) as well as [HDP-104](#) are in preclinical testing. Heidelberg Pharma is also working on ADC candidates that will be loaded with new active ingredients. The first development candidate resulting from this work is HDP-201, which is currently in preclinical development.

The business model's second pillar involves working with partners in early-stage research collaborations to produce ATACs using the partners' antibodies. Going forward, potential partners will also be offered other ADC technologies. The goal is to enter into license agreements based on which the partners would make payments for technology support, granting licenses and supplying GMP material. Heidelberg Pharma expects such ADC alliances to continually generate sales revenue and royalties.

Heidelberg Pharma's own development activities and envisaged out-licensing take place exclusively for a specific [antigen](#) (biological target protein) in each case. Given that numerous tumor-specific antigens exist, this enables the development of the Company's own product candidates as well as parallel collaboration with various pharmaceutical and biotech companies for their candidates. The development candidates resulting from these activities can be developed as different products and for different indications.

Outside of ADC technologies, there are already out-licensed clinical product candidates that are developed solely by licensing partners. In addition to milestone payments during development, Heidelberg Pharma is entitled to royalties following successful market approval.

Since the total income generated to date has not been sufficient to finance Heidelberg Pharma's ongoing research and development activities, the Company will require additional funding in the next years as well.

1.4 Internal management system

Cash funds, cash reach, sales revenue and other income, as well as operating expenses and the operating result, are reviewed at least monthly and are the key control variables of Heidelberg Pharma. Research and development (R&D) expenses are a particularly important measure of performance. These expenses still significantly exceed income and will probably continue to do so in the next few years. Hence the average change in cash funds – i.e. the cash flow in a given period – is a key financial indicator. The ratio of liquid funds to cash usage shows how long sufficient cash will be available to fund operations based on the Company's planning. Chapter 5, "Results of operations, financial position and net assets of the Group", contains a qualitative and quantitative assessment of the Company's internal control system.

 Page 48

1.5 Intellectual property

The ADC technology as well as the development and product candidates resulting from this are the cornerstones for Heidelberg Pharma's development and business activities. The Company endeavors to safeguard its proprietary platform as well as future products and the associated inventions, which may encompass treatment methods, manufacturing processes and applications, by submitting the appropriate IP applications, thereby strengthening the Company's patent position. Building up and securing Heidelberg Pharma's patent portfolio is therefore a top priority.

Patents for the ATAC technology held by Heidelberg Pharma Research GmbH

Heidelberg Pharma Research GmbH holds technology patents protecting its ATAC technology. The technology patents and patent applications on which this technology is based have been filed by Professor Heinz Faulstich and the German Cancer Research Centre (DKFZ), Heidelberg, and Heidelberg Pharma Research GmbH has been granted an exclusive license to use them in an ATAC technology context. Corresponding patents have been granted in the USA and Europe, among others. Heidelberg Pharma Research GmbH has systematically improved the technology and expanded its patent portfolio with several new filings. In the meantime, applications for more than 20 additional international patents have been filed, some of which have already been nationalized or regionalized in many countries. To date, three international patent applications for the development candidate HDP-101 have been submitted. Heidelberg Pharma also filed patent applications that protect specific methods for the modification and manufacture of antibodies. Patent protection for the improved toxin linker technology has been strengthened in recent years through the granting of intellectual property rights in Europe and the United States. Of particular relevance here are the intellectual property rights granted in Europe and the USA for the chemical synthetic building block dihydroxyisoleucine for the production of Amanitin, since this synthetic building block has no natural source, as well as property right applications in the USA and Europe, among others, covering the synthesis of (S)-hydroxytryptophan, which is another synthetic building block for Amanitin. These intellectual property rights and applications are key for producing Amanitin in GMP quality in clinical applications. New priority applications that cover certain synthesis processes and derivatives of Amanitin were filed in the past fiscal year again. In October 2023, the European Patent Office (EPO) granted a patent for site-specific ATAC conjugates. Site-specific ATAC conjugates comprise a genetically engineered antibody with a mutation crucial for coupling specific linker amatoxin conjugates, allowing for the coupling of Heidelberg Pharma's proprietary amatoxin payloads. Heidelberg Pharma Research GmbH currently assumes potential exclusivity for individual ATAC technology-based development candidates to run until 2045.

 Glossary

Patents held by Heidelberg Pharma AG

These patents refer to the clinical portfolio beyond the ATAC technology and were submitted by and granted to the Company under its former name WILEX AG. At the end of the 2023 fiscal year, Heidelberg Pharma AG held licensed intellectual property rights and owned more than 70 patents and patents pending worldwide. While most of these patents were developed by the Company itself, Heidelberg Pharma AG has expanded its intellectual property rights in targeted ways through strategic acquisitions of patent portfolios.

2 Economic environment in 2023

2.1 Macroeconomic environment

While the global economy continued to suffer from the after-effects of the COVID-19 pandemic, the war in Ukraine, widespread inflation and high interest rates in 2023, a slow recovery did set in. Inflation fell from an exceptional 8.8% in 2022² to a high level of 5.8% in 2024 and is expected to reach 4.4% in 2025.³ The International Monetary Fund (IMF) anticipates global economic growth of 3.1% for both 2023 and 2024.⁴ Growth in the eurozone plummeted from 3.1% in 2022⁵ to a predicted 0.5% in 2023,⁶ with a modest recovery of 0.9% then expected in 2024.⁷ Germany lagged far behind global growth levels at 1.8% in 2022, and is expected to record negative growth of -0.3% in 2023.⁸ Crises and war-related extraordinary factors led to supply shortages and soaring prices for energy and in upstream stages of production. Although Heidelberg Pharma's business operations are not directly affected by the weak economy, the Company is impacted by reduced availability of materials as well as interest rate and price increases for products and services.

2.2 Development of the pharmaceutical and biotechnology industry

A surge of innovation in 2023 contrasted with a gloomy year on the capital markets in which the majority of biotech companies faced a challenging financing environment that claimed quite a few victims.⁹ The sector impressively showcased its ability to develop groundbreaking therapies with significant social impact, including the world's first approved gene therapy to use CRISPR¹⁰ gene editing and anti-obesity drug semaglutide^{11,12}. As a result, 2023 proved to be a strong year overall for new drug approvals by the US Food and Drug Administration (FDA). After just 37 approvals in 2022, 2023 saw the second-largest number of new drugs

 Glossary

² <https://www.imf.org/en/Publications/WEO/Issues/2022/10/11/world-economic-outlook-october-2022>

³ <https://www.imf.org/en/Publications/WEO/Issues/2024/01/30/world-economic-outlook-update-january-2024>

⁴ <https://www.imf.org/en/Publications/WEO/Issues/2024/01/30/world-economic-outlook-update-january-2024>

⁵ <https://www.imf.org/en/Publications/WEO/Issues/2022/10/11/world-economic-outlook-october-2022>

⁶ <https://www.imf.org/en/Publications/WEO/Issues/2023/10/10/world-economic-outlook-october-2023>

⁷ <https://www.imf.org/en/Publications/WEO/Issues/2024/01/30/world-economic-outlook-update-january-2024>

⁸ <https://www.imf.org/en/Publications/WEO/Issues/2024/01/30/world-economic-outlook-update-january-2024>

⁹ BioCentury, 21 December 2023, Diamonds in a rough 2023, predictions for 2024:

<https://www.biocentury.com/article/650956/diamonds-in-a-rough-2023-predictions-for-2024>

¹⁰ Nature Biotechnology, 21 November 2023, The world's first CRISPR therapy is approved: who will receive it?

<https://www.nature.com/articles/d41587-023-00016-6>

¹¹ EMA: <https://www.ema.europa.eu/en/medicines/human/EPAR/wegovy>

¹² BioCentury, 21 December 2023, Diamonds in a rough 2023, predictions for 2024:

<https://www.biocentury.com/article/650956/diamonds-in-a-rough-2023-predictions-for-2024>

approved by the FDA's Center for Drug Evaluation (CDER) in the last 30 years, with 55.^{13, 14} Oncology drugs once again received the highest number of approvals by therapeutic area. In 2023, the CDER gave the green light to 13 new cancer therapies, followed by neurology with nine approvals.¹⁵ A high number of biological products were also approved by the Center for Biologics Evaluation and Research (CBER) in 2023, with a growing number of cell and gene therapies and new vaccines.^{16, 17, 18}

 Glossary

One possible explanation for the marked difference in approvals between 2022 and 2023 is the pandemic's impact on clinical and regulatory development steps, which caused delays to the FDA's approval process.¹⁹

By contrast, Germany recorded a sharp decline in new approvals to 30 in 2023 (2022: 49).²⁰ The 2022 German Financial Stabilization of the Statutory Health Insurance System Act (GKV-Finanzstabilisierungsgesetz) may have adversely affected new approvals in Germany, as several companies may have refrained from marketing individual drugs in Germany as a result of this intervention in the reimbursement system.²¹ As in previous years, drug approvals focused on oncology (12 new drugs), as well as three medications designed to provide protection against the RSV respiratory virus.²²

In spite of improved options for cancer treatment, there is still a high unmet need for new innovative therapies. According to the World Health Organization (WHO), nearly 10 million people died of cancer in 2020. The number of new cancer cases per year is expected to grow to over 30 million by 2040, with around 16 million deaths per year.²³ Cancer medicine spending came to USD 196 billion in 2022, and global oncology spending is expected to exceed USD 375 billion by 2027.²⁴ The high demand for cancer therapies is also reflected in the number of clinical trials. The number of new clinical trials in oncology remained at a historically high level in 2022, increasing by 22% compared to 2018.²⁵

¹³ FDA, 29 December 2023: <https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2023>

¹⁴ Nature reviews, 2 January 2024, 2023 FDA approvals: <https://www.nature.com/articles/d41573-024-00001-x>

¹⁵ Nature reviews, 2 January 2024, 2023 FDA approvals: <https://www.nature.com/articles/d41573-024-00001-x>

¹⁶ FDA, 21 December 2023: <https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/2023-biological-license-application-approvals>

¹⁷ Nature reviews, 2 January 2024, 2023 FDA approvals: <https://www.nature.com/articles/d41573-024-00001-x>

¹⁸ FiercePharma, 2 January 2024, 2023 drug approvals: After a down year, FDA signs off on a bounty of new meds, including 7 from Pfizer: <https://www.fiercepharma.com/special-reports/2023-drug-approvals-after-down-year-fda-signs-bounty-new-medicines>

¹⁹ FiercePharma, 2 January 2024, 2023 drug approvals: After a down year, FDA signs off on a bounty of new meds, including 7 from Pfizer: <https://www.fiercepharma.com/special-reports/2023-drug-approvals-after-down-year-fda-signs-bounty-new-medicines>

²⁰ vfa press release, 18 December 2023: <https://www.vfa.de/de/presse/pressemitteilungen/pm-040-2023-arzneimittelinnovation-2023-gesetz-bremst-medizinischen-fortschritt.html>

²¹ vfa press release, 18 December 2023: <https://www.vfa.de/de/presse/pressemitteilungen/pm-040-2023-arzneimittelinnovation-2023-gesetz-bremst-medizinischen-fortschritt.html>

²² vfa press release, 18 December 2023: <https://www.vfa.de/de/presse/pressemitteilungen/pm-040-2023-arzneimittelinnovation-2023-gesetz-bremst-medizinischen-fortschritt.html>

²³ World Health Organization: <https://gco.iarc.fr/tomorrow/en/dataviz/isotype> (as of 5 January 2024)

²⁴ IQVIA Global Oncology Trends 2023, 24 May 2023: <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/global-oncology-trends-2023>

²⁵ IQVIA Global Oncology Trends 2023, 24 May 2023: <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/global-oncology-trends-2023>

Therapies with antibody drug conjugates (ADCs)

The global ADC market had a volume of USD 4.75 billion in 2022 and is estimated to grow to almost USD 19 billion in 2030.²⁶ Most ADCs are developed as cancer therapies, with antibodies in particular used against antigens (targets) that are typically highly expressed on the surface of cancer cells. The most common indication is now breast cancer, closely followed by **lymphoma** and other hematologic cancers, but with a strong trend towards solid tumors.²⁷

According to BioCentury's BCIQ database, the number of ADC development programs is similar to the previous year. At the end of 2023, 15 (2022: 14) oncological ADCs were in 17 **Phase III** clinical trials, of which four have already received initial approval and are currently being tested in other indications. The database lists a further 33 (2022: 34) ADCs in **Phase II** trials and 133 (2022: 126) in Phase I trials. A total of 123 ADC candidates (2021: 120) are currently in preclinical studies²⁸, but very early preclinical development programs are unlikely to be fully recorded in the database and this number is probably actually higher.

No ADCs were newly approved by the FDA or **EMA** in 2023, leaving the number of FDA-approved ADCs unchanged at 12.²⁹

Despite some setbacks in clinical development, there were also progress to report in the ADC field. In Europe, AstraZeneca and Daiichi Sankyo's Enhertu (trastuzumab deruxtecan) received conditional approval for two additional indications. In January 2023, Enhertu was approved as the first HER2-directed therapy for patients with HER2-low metastatic breast cancer.³⁰ In October 2023, it received approval as the first HER2-directed therapy for patients with HER2-mutant advanced non-small cell lung cancer.³¹

²⁶ Vantage Market Research:

<https://www.vantagemarketresearch.com/industry-report/antibody-drug-conjugates-adcs-market-1280>

²⁷ BioCentury database BCIQ, as of 19 December 2023

²⁸ BioCentury database BCIQ, as of 19 December 2023

²⁹ Drug Development World, 1 June 2023, Three trends in the antibody-drug conjugate (ADC) market:

<https://www.ddw-online.com/three-trends-in-the-adc-market-23879-202306/>

³⁰ AstraZeneca press release, 26 January 2023:

<https://www.astrazeneca.com/media-centre/press-releases/2023/enhertu-approved-in-the-eu-as-the-first-her2-directed-therapy-for-patients-with-her2-low-metastatic-breast-cancer.html>

³¹ AstraZeneca press release, 23 October 2023:

<https://www.astrazeneca.com/media-centre/press-releases/2023/enhertu-approved-in-the-eu-as-the-first-her2-directed-therapy-for-patients-with-her2-mutant-advanced-non-small-cell-lung-cancer.html>

Selected other developments relating to the approval of ADCs are presented in the following table in chronological order:

Company	Product or candidate	Event	Description
Magenta Therapeutics	MGTA-117	Termination of trial	Magenta paused and later voluntarily terminated its Phase I/II trial of an ADC in preparation for stem cell transplantation following the death of a trial participant. ³²
Mersana Therapeutics	XMT-2056	Suspension of trial	The Phase I trial is placed on clinical hold by the FDA following a Grade 5 (fatal) serious adverse event. ³³
Byondis	[vic-] trastuzumab duocarmazine	Approval denied	The FDA denies approval of Byondis' BLA for an ADC for treating HER2-positive metastatic breast cancer. ³⁴
Mersana Therapeutics	upifitamab rilsodotin (UpRi)	Suspension of trial	FDA issues partial clinical hold on two clinical trials of UpRi after five Grade 5 bleeding events. ³⁵
GSK	Blenrep®	Negative CHMP opinion	The EMA CHMP recommends not renewing the conditional marketing authorization for Blenrep in Europe. ³⁶
Genmab A/S and Seagen Inc.	TIVDAK® (tisotumab vedotin-tftv)	Positive Phase III data	The results of the global trial show that TIVDAK significantly prolongs overall survival in patients with in recurrent or metastatic cervical cancer compared with chemotherapy. ³⁷
Sanofi	tusamitamab ravtansine	Suspension of trial	Sanofi announces the end of the program evaluating tusamitamab ravtansine after a NSCLC 2L Phase 3 trial failed to meet a primary endpoint. ³⁸

 Glossary

³² Magenta Therapeutics press release, 25 January 2023:

<https://www.globenewswire.com/news-release/2023/01/25/2595611/0/en/Magenta-Therapeutics-Voluntarily-Pauses-the-MGTA-117-Phase-1-2-Dose-Escalation-Clinical-Trial-to-Investigate-Drug-Safety.html>

³³ Mersana press release, 13 March 2023: <https://ir.mersana.com/news-releases/news-release-details/mersana-therapeutics-announces-clinical-hold-xmt-2056-phase-1>

³⁴ Byondis press release, 15 May 2023: <https://www.byondis.com/media/press-releases/us-food-and-drug-administration-issues-complete-response-letter-for-vic-trastuzumab-duocarmazine>

³⁵ Mersana press release, 15 June 2023:

<https://ir.mersana.com/news-releases/news-release-details/mersana-therapeutics-announces-partial-clinical-hold-next-and>

³⁶ EMA press release, 15 September 2023:

<https://www.ema.europa.eu/en/news/ema-recommends-non-renewal-authorisation-multiple-myeloma-medicine-blenrep>

³⁷ Genmab press release, 22 October 2023:

<https://ml-eu.globenewswire.com/Resource/Download/88f6013f-9b0b-4614-abb3-e25a27cbf3c4>

³⁸ Sanofi press release, 21 December 2023:

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

Interest in ADCs was notably high in 2023, with numerous deals of significant size continuing into early 2024 as well. ADCs are currently considered one of the most interesting areas for M&A in the biopharma industry – not just because of Pfizer’s billion-euro takeover of Seagen.^{39, 40} A chronological overview of selected financing transactions and license agreements in the ADC domain is shown in the following table:

Company	Partner	Event	Description
Synaffix	Amgen	Agreement	License agreement for up to 5 ADCs with a total volume of up to USD 2 billion. ⁴¹
Seagen	Pfizer	Takeover	Pfizer acquires Seagen for USD 43 billion. ⁴²
KYM Biosciences	Astra-Zeneca	Agreement	License agreement worth up to USD 1.1 billion for an ADC. ⁴³
Duality Biologics	BioNTech	Agreement	USD 1.5 billion global strategic partnership to accelerate ADC development. ⁴⁴
Tubulis	Bristol Myers Squibb (BMS)	Agreement	Tubulis grants BMS access to its ADC technology. The license agreement has a total volume of USD 1 billion. ⁴⁵
Bliss Bio-pharmaceutical	Eisai Co.	Agreement	Joint development and commercialization agreement for an ADC with a volume of USD 2 billion. ⁴⁶
Emergence Therapeutics	Eli Lilly	Takeover	Eli Lilly acquires European ADC company Emergence Therapeutics. ⁴⁷
Duality Biologics	BeiGene	Agreement	BeiGene acquires an option to a preclinical ADC for a total volume of up to USD 1.3 billion. ⁴⁸

³⁹ FiercePharma, 14 December 2023, Done deal: Pfizer completes \$43B acquisition of Seagen, doubling its oncology pipeline: <https://www.fiercepharma.com/pharma/done-deal-pfizer-completes-43b-acquisition-seagen-doubling-its-oncology-pipeline>

⁴⁰ Endpoints News, 20 December 2023, The 2023 winners and losers list: Who was up and who was down in biopharma: <https://endpts.com/biotech-and-pharma-2023-winners-and-losers-list/>

⁴¹ Sanofi press release, 21 December 2023: <https://www.sanofi.com/assets/dotcom/pressreleases/2023/2023-12-21-06-30-00-2799759-en.pdf>

⁴² Pfizer press release, 13 March 2023: <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-invests-43-billion-battle-cancer>

⁴³ AstraZeneca press release, 30 March 2023: <https://www.astrazeneca.com/media-centre/press-releases/2023/astrazeneca-completes-agreement-with-kym-for-cmg901.html>

⁴⁴ BioNTech press release, 3 April 2023: <https://investors.biontech.de/de/news-releases/news-release-details/biontech-und-dualitybio-schliessen-globale-strategische>

⁴⁵ Tubulis press release, 20 April 2023: <https://tubulis.com/tubulis-announces-strategic-license-agreement-with-bristol-myers-squibb-to-develop-next-generation-adcs-for-the-treatment-of-cancer-patients-2/>

⁴⁶ Eisai press release, 8 May 2023: <https://www.eisai.com/news/2023/news202330.html>

⁴⁷ BioPharma Dive, 29 June 2023, Lilly to acquire cancer antibody drug startup Emergence: <https://www.biopharmadive.com/news/lilly-acquire-emergence-adc-cancer-drugs/654326/>

⁴⁸ BeiGene press release, 10 July 2023: <https://www.businesswire.com/news/home/20230710061783/en/BeiGene-and-DualityBio-Announce-Partnership-to-Advance-Differentiated-Antibody-Drug-Conjugate-ADC-Therapy-for-Solid-Tumors>

Company	Partner	Event	Description
MediLink Therapeutics	BioNTech	Agreement	Agreement on the rights for a HER3 ADC with MediLink Therapeutics with a total volume of over USD 1 billion. ⁴⁹
Mablink Bioscience	Eli Lilly	Takeover	Eli Lilly acquires Mablink Bioscience. ⁵⁰
Daiichi Sankyo	Merck & Co.	Agreement	Agreement to jointly develop three Daiichi Sankyo ADCs valued at up to USD 22 billion, including USD 4 billion upfront. ⁵¹
ImmunoGen	AbbVie	Takeover	AbbVie acquires ImmunoGen – including its ADC ELAHERE – for USD 10.1 billion. ⁵²
SystImmune	Bristol Myers Squibb (BMS)	Agreement	Global license agreement for SystImmune’s EGFRxHER3 ADC with a total value of up to USD 8.4 billion. ⁵³
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. ⁵⁴
LegoChem Biosciences	Janssen Biotech, Inc.	Agreement	LegoChem Biosciences potentially receives up to USD 1.7 billion for LCB84, a Trop2-directed ADC. ⁵⁵
MediLink Therapeutics	Roche	Agreement	Worldwide license agreement to develop an ADC with a total volume of up to just under USD 1 billion. ⁵⁶
Ambrx	Johnson & Johnson	Takeover	Johnson & Johnson acquires Ambrx for USD 2 billion. ⁵⁷

⁴⁹ MediLink Therapeutics press release, 12 October 2023:

<https://www.prnewswire.com/news-releases/medilink-therapeutics-announces-strategic-collaboration-and-worldwide-license-agreement-with-biontech-to-develop-next-generation-anti-cancer-antibody-drug-conjugate-301954622.html>

⁵⁰ Mablink Bioscience press release, 18 October 2023: <https://www.globenewswire.com/news-release/2023/10/18/2762713/0/en/Mablink-Bioscience-Enters-an-Agreement-to-be-Acquired-by-Lilly.html>

⁵¹ Merck press release, 19 October 2023: <https://www.merck.com/news/daiichi-sankyo-and-merck-announce-global-development-and-commercialization-collaboration-for-three-daiichi-sankyo-dxd-adcs/>

⁵² ImmunoGen press release, 30 November 2023: <https://investor.immunogen.com/news-releases/news-release-details/abbvie-acquire-immunogen-including-its-flagship-cancer-therapy>

⁵³ 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>

⁵⁴ 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/>

⁵⁵ LegoChem Biosciences press release, 26 December 2023: https://www.legochembio.com/media/press_view.php?lang=e&sc_seq=594

⁵⁶ 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>

⁵⁷ 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>

Competitive environment for HDP-101

The B-cell maturation antigen (BCMA), a cell surface protein generally expressed by malign plasma cells, has proven to be an extremely selective antigen and is thus a target of novel treatments for multiple myeloma (MM), the second most common type of blood cancer, chronic lymphatic lymphoma (CLL) and diffuse large B-cell lymphoma (DLBCL).⁵⁸

The ATAC candidate HDP-101 will initially be developed with the MM indication and is now in a Phase I/IIa study. Around 50 companies are currently working on the BCMA antigen in this indication using different technologies (2022: 55). The number of development projects decreased slightly from 74 in the previous year to 70.⁵⁹ More than 80% of these projects are still in the preclinical stage or in Phase I of clinical development. A continuing focus is immune cell therapies (46 projects), followed by bispecific and multispecific antibodies (16).⁶⁰

Two new BCMA-targeting therapies were approved in 2023: ELREXFIO® (elranatamab), a BCMA and CD3-directed bispecific antibody by Pfizer, received conditional marketing authorization in Europe and accelerated approval in the United States.^{61, 62} This means that after Tecvayli (Teclistamab) by Ligand Pharmaceuticals and Johnson & Johnson, a second bispecific antibody for the treatment of multiple myeloma has now been approved.⁶³ In China, Fucaso (equecabtagene autoleucel), a BCMA-directed autologous CAR-T cell therapy by Innovent Biologics and IASO Biotechnology, received approval for the treatment of multiple myeloma.⁶⁴ Two cell therapies directed against the target antigen BCMA, Carvykti and Abecma, have been approved in the USA and Europe since 2022 and 2021, respectively.^{65, 66} In November 2023, the FDA announced an investigation into the potential link between CAR-T cell therapies and rare cases of malignant T-cell malignancies, without questioning the overall benefit of the therapies for patients.⁶⁷

⁵⁸ BioCentury, 14 December 2019: BCMA programs begin to find their niches

⁵⁹ BioCentury database BCIQ, as of 19 December 2023

⁶⁰ BioCentury database BCIQ, as of 19 December 2023

⁶¹ Pfizer press release, 8 December 2023: <https://www.pfizer.com/news/press-release/press-release-detail/european-commission-approves-pfizers-elrefxior-relapsed-and>

⁶² FDA, as of 14 August 2023: <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-elranatamab-bcmm-multiple-myeloma>

⁶³ FiercePharma, 25 October 2022, J&J's BCMA bispecific Tecvayli wins FDA approval in multiple myeloma – but as a late-line therapy: <https://www.fiercepharma.com/pharma/jjs-bcma-bispecific-tecvayli-wins-fda-approval-multiple-myeloma-again-late-line>

⁶⁴ Innovent Biologics press release, 2 July 2023: <https://www.prnewswire.com/news-releases/innovent-and-iaso-bio-announce-the-nmpa-approval-of-fucaso-the-first-fully-human-bcma-car-t-therapy-for-the-treatment-of-relapsed-or-refractory-multiple-myeloma-301868594.html>

⁶⁵ FDA, as of 30 August 2022: <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-disco-burst-edition-fda-approval-carvykti-ciltacabtagene-autoleucel-treatment-adult-patients>

⁶⁶ FDA, as of 27 March 2021: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-cell-based-gene-therapy-adult-patients-multiple-myeloma>

⁶⁷ STAT, 28 November 2023, FDA investigating whether CAR-T, a treatment for cancer, can also cause lymphoma: <https://www.statnews.com/2023/11/28/fda-investigation-t-cell-malignancy-car-t-cell-therapy/>

The first approved BCMA-directed therapy, ADC Blenrep (belantamab mafodotin; GlaxoSmithKline) failed to reach its primary endpoint in a Phase III confirmatory trial in 2022,⁶⁸ as a result of which the FDA withdrew its approval for the drug in late 2022. In December 2023, the EMA also confirmed that it would recommend not renewing the conditional approval for Blenrep, as the benefit for patients no longer outweighed the risks.⁶⁹ Shortly before this, GSK announced the results of another Phase III trial, which, according to the EMA, did not demonstrate that Blenrep significantly improved progression-free survival compared to standard second-line therapy.^{70, 71}

Overall, there are currently four BCMA-directed treatments for **relapsed/refractory** multiple myeloma approved in the USA, each as fifth-line therapy.^{72, 73, 74, 75} Blenrep is still approved in Europe as fifth-line treatment pending a binding decision by the European Commission on the non-renewal of conditional approval.⁷⁶ The four other BCMA-directed therapies are currently approved in Europe as fourth-line treatment.^{77, 78, 79, 80}

 Glossary

Besides HDP-101, two other BCMA-directed ADCs are in development for the treatment of multiple myeloma: JS115, an ADC by Shanghai Junshi Biosciences Co. Ltd. in preclinical development, and CC-99712, jointly developed by Sutro Biopharmaceuticals and Bristol Myers Squibb in a Phase I trial.⁸¹ The partnership between the two companies was terminated in October 2023.⁸²

⁶⁸ GSK press release, 7 November 2022:

<https://www.gsk.com/en-gb/media/press-releases/gsk-provides-update-on-dreamm-3-phase-iii-trial-for-blenrep/>

⁶⁹ EMA, 15 December 2023: <https://www.ema.europa.eu/en/news/ema-confirms-recommendation-non-renewal-authorisation-multiple-myeloma-medicine-blenrep>

⁷⁰ EMA, 15 December 2023: <https://www.ema.europa.eu/en/news/ema-confirms-recommendation-non-renewal-authorisation-multiple-myeloma-medicine-blenrep>

⁷¹ GSK press release, 27 November 2023: <https://www.gsk.com/en-gb/media/press-releases/gsk-announces-positive-results-from-dreamm-7-head-to-head-phase-iii-trial-for-blenrep/>

⁷² Abecma: <https://www.abecmahcp.com/>

⁷³ CARVYKTI: <https://www.carvykti.hcp.com/about-carvykti>

⁷⁴ TECVAYLI: <https://www.tecvayli.hcp.com/>

⁷⁵ ELREXFIO: <https://www.elrefxio.com/>

⁷⁶ EMA: <https://www.ema.europa.eu/en/medicines/human/EPAR/blenrep#authorisation-details-section>

⁷⁷ EMA: <https://www.ema.europa.eu/en/medicines/human/EPAR/abecma>

⁷⁸ EMA: <https://www.ema.europa.eu/en/medicines/human/EPAR/carvykti>

⁷⁹ EMA: <https://www.ema.europa.eu/en/medicines/human/EPAR/tecvayli>

⁸⁰ EMA: <https://www.ema.europa.eu/en/medicines/human/EPAR/elrefxio>

⁸¹ BioCentury database BC1Q, as of 19 December 2023

⁸² MarketScreener, 14 June 2023: <https://www.marketscreener.com/quote/stock/SUTRO-BIOPHARMA-INC-46353309/news/Sutro-Biopharma-Inc-Receives-a-Notice-of-Termination-from-Celgene-Corporation-44130319/>

Chemotherapy is still being used as standard therapy for multiple myeloma, including in combination with autologous hematopoietic stem cell transplantation or radiotherapy.⁸³ At present, the most commercially successful therapy in this indication is the immunomodulator REVLIMID® from Celgene (acquired by Bristol Myers Squibb in November 2019), although its global sales declined by approximately 40% to an expected USD 6.0 billion in 2023 after the approval of the first generics.⁸⁴

Other BCMA-independent therapeutic approaches for multiple myeloma are also currently in clinical development.

Competitive environment for HDP-102

HDP-102 is an ATAC candidate that targets CD37, a surface molecule expressed on B-cells but not found on normal stem cells or plasma cells. This makes it an excellent target for developing treatments for non-Hodgkin lymphoma (NHL).⁸⁵

Apart from Heidelberg Pharma, five companies (previous year: four) are currently working on development candidates for treating NHL with CD37 as the target.⁸⁶ Debiopharm developed naratuximab emtansine (Debio 1562, IMG529), an ADC that completed a Phase II trial for the treatment of relapsed/refractory (r/r) diffuse large B-cell lymphoma (DLBCL) and other NHL indications. This project is currently inactive. A next-generation ADC is being tested as Debio 1562M using Debiopharm's Multilink technology in preclinical development for Acute Myeloid Leukemia (AML).⁸⁷ Moreover, a radioactive conjugated antibody from Thor Medical (formerly Nordic Nanovector) is in Phase I/II and a bispecific antibody from Genmab A/S is in Phase I for the treatment of NHL.⁸⁸ Enterome is a new entry with EO2463, a mixture of four peptides directed at CD37, which is already in Phase II of clinical development.^{89, 90}

Competitive environment for HDP-103

Heidelberg Pharma is developing HDP-103, an anti-PSMA ATAC for the treatment of prostate cancer. Prostate specific membrane antigen (PSMA) is a surface protein that specifically appears on prostate cells and is overexpressed in prostate cancer, making it an attractive target for an ADC approach.⁹¹

Glossary

⁸³ ONKO Internet portal: <https://www.krebsgesellschaft.de/onko-internetportal/basis-informationen-krebs/krebsarten/multiples-myelom-plasmozytom-morbus-kahler/therapie.html>

⁸⁴ Bristol Myers Squibb press release 26 October 2023: <https://news.bms.com/news/corporate-financial/2023/Bristol-Myers-Squibb-Reports-Third-Quarter-Financial-Results-for-2023/default.aspx>

⁸⁵ Witkowska M, Smolewski P, Robak T. Investigational therapies targeting CD37 for the treatment of B-cell lymphoid malignancies. *Expert Opin Investig Drugs*. 2018 Feb;27(2):171-177. doi: 10.1080/13543784.2018.1427730. Epub 2018 Jan 15. PMID: 29323537

⁸⁶ BioCentury database BCIQ, as of 19 December 2023

⁸⁷ *Blood*, volume 142, Issue Supplement 1, November 2023: <https://ashpublications.org/blood/article/142/Supplement%201/1542/499677/Debio-1562M-a-Next-Generation-Antibody-Drug>

⁸⁸ BioCentury database BCIQ, as of 19 December 2023

⁸⁹ BioCentury database BCIQ, as of 19 December 2023

⁹⁰ Enterome: <https://www.enterome.com/pipeline/>

⁹¹ P. Bühler, P. Wolf, U. Elsässer-Beile: Targeting the prostate-specific membrane antigen for prostate cancer therapy. In: *Immunotherapy*. Volume 1, number 3 May 2009, p. 471–481, ISSN 1750-7448. doi:10.2217/imt.09.17. PMID 20635963

Besides Heidelberg Pharma, 45 other companies (previous year: 39) are working on developing a total of 64 different therapies for prostate cancer targeting PSMA.⁹² While most of these are antibody-based therapies, there are also cell therapies, some cell-based vaccines targeting cancer and small-molecule compounds. A total of five therapies are in Phase III of clinical development, including three radioactive conjugated antibodies from Telix (TLX591, ¹⁷⁷Lu-DOTA-Rosopatamab), Point Biopharma Inc. (¹⁷⁷Lu-PNT2002) and Curium Pharma (¹⁷⁷Lu-PSMA-I&T). A cell-based vaccine developed by Northwest Biotherapeutics (DCVax-Prostate) also received FDA approval for a Phase III trial, although the company has not published any further updates on the trial.⁹³ Apart from Heidelberg Pharma, three other companies are developing PSMA ADCs. The candidates developed by Lantheus and Ambrx are in Phase II and Phase I/II, respectively, and Dantari is developing a PSMA ADC in the preclinical phase.⁹⁴

3 Course of business in 2023

3.1 Research and development projects of Heidelberg Pharma Research GmbH

Amanitin as an innovative compound for cancer therapy

Heidelberg Pharma Research GmbH is developing the compound Amanitin for the first time as a new cancer therapy. Amanitin has a unique biological mode of action which could serve as the basis for developing highly effective, innovative drugs. Amanitin is a member of the amatoxin group of natural poisons, which occur in the death cap mushroom (*Amanita phalloides*), among others. It works by inhibiting **RNA polymerase II**, which results in programmed cell death, or **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.

 Glossary

To enable therapeutic use of this natural toxin, Heidelberg Pharma Research GmbH is utilizing already clinically proven ADC technology, which is being refined for use with Amanitin. The core of the ADC technology consists of using a chemical compound (linker) to crosslink a suitable antibody to a toxin. The role of the antibody is to transport the crosslinked toxin specifically to – and then into – the cancer cell. After binding to the tumor cell, the ADC is taken up by the cell and releases the toxin within the cell. The released toxin then destroys the tumor cell without affecting healthy tissue. Called Antibody Targeted Amanitin Conjugates, Amanitin-based ADCs are third generation ADCs that have shown improved efficacy in preclinical models, including in quiescent and therapy-resistant tumor cells.

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 more or less common in almost all cancers, especially in very advanced cancers. For example, in metastatic castration-resistant prostate cancer (**mCRPC**), the prevalence of 17p deletion is 60%.⁹⁵ Tumors with 17p deletion could be a particularly effective target for treatment with ATACs.

⁹² BioCentury database BCIQ, as of 19 December 2023

⁹³ Northwest Biotherapeutics: <https://nwbio.com/product-candidates/>

⁹⁴ BioCentury database BCIQ, as of 19 December 2023

⁹⁵ <https://www.nature.com/articles/s41467-018-06811-z>



Immunological effects of ATAC molecules

In addition to killing cells directly, ATACs could have an additional anti-tumor effect by stimulating the immune system.⁹⁶ Heidelberg Pharma's earlier work with PDX models (where tumor cells derived from patients are induced to grow in immunodeficient mice) indicated that treatment with ATAC molecules induces immune response. The working group headed up by Bob Orłowski from the MD Anderson Cancer Center, Houston, USA, (MD Anderson) presented data at the Annual ASH Meeting as early as the 2020, confirming previous findings with new preclinical data and providing new insights into the induction of a specific immune response against multiple myeloma cells by HDP-101. Using certain markers, it was demonstrated that in addition to the direct effect of HDP-101 on tumor cells, the immune system was induced to destroy cancer cells (known as immunogenic cell death). Therapy with HDP-101 was also shown to immunize the treated animals against renewed growth of cancer cells.⁹⁷

Exatecan – expansion of compound portfolio

Exatecan is a synthetic derivative of the naturally occurring toxin **camptothecin**. Camptothecin is a cytostatic agent that is obtained from the seeds, roots, bark, wood and (young) leaves of the Chinese "Happy Tree" (*Camptotheca acuminata*). Camptothecin is a type I topoisomerase inhibitor. A topoisomerase is an enzyme that is responsible for relaxing double-stranded DNA during processes such as DNA **replication** and transcription. The mode of action used by topoisomerase I inhibitors targets reversible cleavage complexes in the DNA strand. This inhibition of the enzyme results in irregular, irreversible DNA damage such as breaks and cross-linking, which can therefore impair cell growth and cell division, consequently leading to programmed cell death (apoptosis).

In recent years, this drug payload class has achieved positive results in clinical trials with ADCs. For example, the ADC trastuzumab-deruxtecan (Enhertu®), which uses the exatecan derivative Dxd as the payload, was approved by the FDA for HER2-positive metastatic mammary carcinoma in May 2022.⁹⁸

Heidelberg Pharma is able to have the compound manufactured without a license to develop proprietary ADCs.

Proprietary ATAC pipeline

Project HDP-101 (BCMA-ATAC)

HDP-101 consists of an anti-BCMA antibody, a specific linker and the Amanitin toxin. BCMA (B-cell maturation antigen) is a surface protein that is highly expressed in multiple myeloma cells and to which BCMA antibodies specifically bind. The candidate is being evaluated since February 2022 in a Phase I/IIa clinical trial for treatment of relapsed or refractory multiple myeloma. 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.

⁹⁶ https://heidelberg-pharma.com/images/managed/finanzberichte/629937ff75687_Postter_AACR_2022_1754.pdf

⁹⁷ <https://ash.confex.com/ash/2020/webprogram/Paper141615.html>

⁹⁸ AstraZeneca press release, 5 May 2022:

<https://www.astrazeneca.com/media-centre/press-releases/2022/enhertu-approved-in-us-for-2l-her2-positive-breast-cancer.html>

The first part of this trial is a Phase I dose escalation study involving up to 36 patients to determine a safe and optimal dosage of HDP-101 for the Phase IIa part of the study. First four patient cohorts and dose levels have been completed and proved to be safe and well tolerated.⁹⁹ Since September 2023, patients in the fifth cohort have been treated with a dose of 100 µg/kg HDP-101. After the initial administration of HDP-101, a temporary drop in thrombocyte count occurred in all patients. However, this normalized within a few days, with counts returning to clinically unremarkable levels. This effect was largely absent with subsequent doses of HDP-101. Encouragingly, biological activity was observed in three patients after the third dose. In three patients, an objective improvement in disease (partial response) was detectable.

A planned modification and optimization of the medication regimen aims to lessen the initial dose effect. The corresponding protocol adjustments were implemented and recruitment of the sixth cohort started.

Furthermore, one of the trial participants from the third cohort has been treated with HDP-101 as a monotherapy for more than a year and their clinical progression has now stabilized (stable disease). This male patient has received 17 doses by mid-February 2024; a single dose was 60 µg/kg until the end of the fourth cohort. After the confirmed completion of the fourth cohort, he was then offered this cohort's higher dose. Following his consent, he has since been treated with 80 µg/kg HDP-101.

In the Phase IIa dose expansion phase, at least 30 patients are to be treated with the recommended dose of HDP-101. The primary objective of the Phase IIa part of the trial is to assess the preliminary anti-tumor activity of HDP-101 along with further evaluation of the safety of the drug.

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). In preclinical trials, this development candidate has shown to have a comparatively broad therapeutic window.


Production of the clinical trial medication according to Good Manufacturing Practice (GMP) standards is proceeding according to plan and has largely been completed. Apart from conjugate production, the past months saw the completion of further preclinical and toxicology studies and the finalization of the data package required for submitting the first trial.

Planning of the Phase I clinical trial to investigate the tolerability and safety of HDP-102 is already well advanced. Preparatory work on the data package for submission of the study protocol to the authorities of several countries is currently underway, with completion planned for the first half of 2024. The aim is to start patient recruitment in the clinical study towards the end of 2024.

Back in 2021, a scientific paper on CD37 ATAC was introduced at the American Society of Hematology (ASH) annual meeting. This paper was a product of an earlier research collaboration with the University of Turin, Italy, where the indication of Richter's syndrome was established. The data from a xenograft model showed the high efficacy of CD37 ATAC on tumor cells, which lead to a highly significant regression of the tumor.¹⁰⁰ Richter's syndrome, a type of non-Hodgkin lymphoma, could be one of the indications of treatment with HDP-102.

⁹⁹ https://heidelberg-pharma.com/images/managed/HDP-101-01_ASH_2023_Final.pdf

¹⁰⁰ <https://ashpublications.org/blood/article/138/Supplement%201/791/480056>

 Glossary

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 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 Amanitin *sensitivity* of prostate cancer cells with a 17p deletion has already been preclinically validated.¹⁰¹ Since tumor cells with a 17p deletion are particularly sensitive to Amanitin, PSMA-ATACs might be particularly suitable for treating mCRPC.

Over the last few months, production of the compound HDP-103 under GMP conditions has been completed as planned. Preclinical and toxicological studies with HDP-103 are now also largely complete. A clinical trial to investigate tolerability and efficacy is currently being planned. At the Annual Meeting of the American Association for Cancer Research (AACR) in April 2023, Heidelberg Pharma presented various preclinical findings for its ATAC technology. For HDP-103, these data showed that subcutaneous administration results in an improved therapeutic window compared with intravenous delivery, i.e. an improved level of tolerability with no change in antitumor efficacy.

Project HDP-104 (GCC)

The target for another ATAC candidate, HDP-104, was revealed in the fall of 2022. HDP-104 is to be developed for treating gastrointestinal tumors. The target protein, to which the antibody used binds, is overexpressed in over 95% of colorectal cancers and around 65% of the esophageal, gastric and pancreatic tumors.

Further development of the candidate is currently not a priority at Heidelberg Pharma. The company is looking for a potential development partner, as funding of the project is not currently prioritized internally.

Amanitin production in accordance with Good Manufacturing Practice (GMP) – provision of material to partners (supply model)

Heidelberg Pharma ensures the supply of material for its own projects and those of its partners by providing Amanitin linker material in GMP quality as required.

ATAC research projects

Heidelberg Pharma is continuously working to identify further potential targets which, in combination with the properties of Amanitin, could represent new treatment options for diseases that are difficult to treat. Antibodies and ATACs will be produced for this and research conducted.

Predictive biomarker p53/RNA polymerase II project: The available preclinical data show that Amanitin has the potential to be particularly effective against aggressive tumors in connection with a 17p deletion. The name '17p' refers to the short arm of chromosome 17, whose DNA includes both the gene for the *tumor suppressor protein TP53* and the largest subunit for RNA polymerase II (*POLR2A*). 17p deletion in tumors results in TP53 being less effective in tumor cells, thus weakening the cells' natural defenses. Since POLR2A is also partially deleted at the same time, the tumor cell altered in this way has less RNA polymerase II, making it

¹⁰¹ <https://www.nature.com/articles/s41467-018-06811-z>

particularly sensitive to Amanitin. Results from the collaboration with different research groups regarding 17p deletion have already been published in previous years (including with the MD Anderson Cancer Center and the Indiana University School of Medicine).^{102, 103}

Heidelberg Pharma will examine the possibilities of using these results for clinical treatment and will evaluate the 17p status of the patients. Patients in the Phase II part of the clinical trial with HDP-101 will be stratified. Heidelberg Pharma holds an exclusive license to the patent rights for this diagnosis and treatment approach.

ATAC partnerships

The second key pillar in the business model of Heidelberg Pharma involves the granting of ATAC technology licenses and application on antibodies provided by customers. Integrated into license agreements, Amanitin linker variants are to be made available and cross-linked to antibodies developed by partners and tested biologically. These technology partnerships give licensees access to the ATAC technology and rapidly generate initial sales revenue for Heidelberg Pharma Research for providing support to partners and from licenses to access the technology. These license agreements are also intended to provide attractive potential for generating sales revenue and creating added value long-term. Such agreements provide for upfront payments, assumption of development costs, milestone payments and royalties.

Heidelberg Pharma Research collaborates with partners under exclusive research agreements. These partners are granted access to Heidelberg Pharma Research's ATAC platform technology for developing and testing specific ATACs using their own antibodies. Depending on the terms of the agreement, options can be exercised for exclusive licensing of the global development and commercialization rights to each of the product candidates resulting from this collaboration.

Partnership with Magenta: Heidelberg Pharma Research was involved in an exclusive multi-target research agreement with Magenta Therapeutics, Cambridge, MA, USA, (Magenta) since March 2018.

Magenta announced on 25 January 2023 that in the third dose level of the MGTA-117 clinical trial, a grade 5 serious adverse event occurred that deemed to be possibly related to MGTA-117. For safety reasons, Magenta subsequently paused dosing in the clinical trial until further notice and announced shortly thereafter, following an internal review, that further development of all programs including the ATACs would be halted. At the end of February 2023, the Amanitin linker supply contract was terminated by Magenta. In April 2023, Heidelberg Pharma signed a termination agreement with Magenta under which all licensed ATAC rights and some MGTA patents were taken over by Heidelberg Pharma. There was no indication that these side effects could be a class effect of all amanitin-based ADCs (see also chapter 6).

 Page 54

Partnership 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 for an Antibody Targeted Amanitin Conjugate, which triggered a payment to Heidelberg Pharma.

 Glossary

¹⁰² <https://ash.confex.com/ash/2020/webprogram/Paper141615.html>

¹⁰³ <https://www.science.org/doi/10.1126/scitranslmed.abc6894>

Extended ADC pipeline

Partnership with Binghamton University

In December 2022, Heidelberg Pharma Research entered into a research and exclusive option agreement with Binghamton University, State University of New York, Binghamton, NY, USA, related to a novel and proprietary immunostimulatory technology platform. The platform includes potent novel immunostimulatory compounds (TLR-7 agonists) and ADC technology for the specific delivery of these compounds to tumor tissue. The resulting immunostimulatory ADCs have the potential to harness the patient's own immune system by making the tumor visible to the immune system to thus attack and eliminate malignancies. These immunostimulatory agents could be synergistic with cytotoxic agents, including ADCs generated by Heidelberg Pharma's ATAC technology.

Project HDP-201

The new HDP-201 project was unveiled in fall 2023. 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. This is the first ADC candidate project to utilize Heidelberg Pharma's newly introduced drug payload, exatecan. The GCC antibody has already been produced for the ATAC HDP-104 in sufficient quantities to supply two ADC projects. Since the antibody was available at short notice, research was completed earlier than usual and Heidelberg Pharma was able to quickly start the development process of HDP-201. *In vitro/in vivo* tests and initial preclinical trials have now been completed. Results show tolerability and efficacy to be at least comparable with exatecan-based ADCs that already have approval. The scientific team is currently working to identify a lead candidate from various exatecan-based ADC candidates.

Funded projects

Together with several European universities, research institutions and companies, Heidelberg Pharma Research took part in four research projects – MAGICBULLET::Reloaded, INTEGRATA, pHionic and TACT – and received proportionate funding from the programs.

Following the successful conclusion of the ETN MAGICBULLET project, Heidelberg Pharma Research and several other applicants were successful in receiving funding for further projects as part of the EU's HORIZON 2020 program. The MAGICBULLET::Reloaded program will continue from 2019 to 2024 and involve total funding for all project partners amounting to up to €3.9 million (Heidelberg Pharma share: €0.25 million). The field of investigation is being expanded from small molecule-drug conjugates to include peptide-drug conjugates and is focusing on candidates that stimulate the immune response to tumors and can overcome resistance to immunotherapies. Heidelberg Pharma is also working on peptide-Amanitin conjugates in this context.

INTEGRATA funds research which assesses the potential of NAD enzymes as a novel therapy for cancer. The project received EU funding totaling €3.7 million for all project partners (Heidelberg Pharma share: €0.25 million) and ran until April 2023.

The pHionic program focused on research on pancreatic ductal adenocarcinoma. Heidelberg Pharma Research used this opportunity to assess new target structures for pancreatic cancer and their suitability for therapy with ATACs. The European Union intended to issue a total of approximately €4 million in funding for all the project partners (Heidelberg Pharma share: €0.25 million). The program ended in mid-2023.

TACT is another HORIZON 2020 research project. It involves the development of a new, more effective generation of protein-drug conjugates using site-specific bioconjugation methods, environment-specific cleavable linkers, more efficient protein-based targeting systems, and new analytical tools for protein characterization. The European Union issued a total of approximately €3 million in funding for the TACT program (Heidelberg Pharma share: €0.25 million), which was set to run until early 2024.

3.2 Customer-specific preclinical services business

The customer-specific preclinical service business will be continued with existing customers but is strategically less important than ATAC technology.

3.3 Clinical portfolio of Heidelberg Pharma AG – partnering

TLX250-CDx (girentuximab) – diagnostic antibody/Zircaix™

TLX250-CDx (Zircaix™) is a radiolabeled form of the antibody girentuximab, which binds to the tumor-specific antigen carbonic anhydrase IX (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 improve therapy planning for renal cancer patients and potentially avoid unnecessary surgery. The diagnostic agent may also prove suitable for monitoring response to treatment, detecting metastases and diagnosing other kinds of tumors.

 Glossary

The antibody was developed up to an initial, completed Phase III trial at Heidelberg Pharma AG and licensed in 2017 to the Australian firm Telix Pharmaceuticals Limited, Melbourne, Australia, (Telix). The license agreement also covers the development of a therapeutic radioimmunoconjugate program.

In the third quarter of 2022, Telix completed its Phase III ZIRCON trial of TLX250-CDx positron emission tomography (PET) imaging of kidney cancer, which began in August 2019 and involved 300 patients.¹⁰⁴

Top line positive data was reported in November 2022.¹⁰⁵ The study results delivered 86% sensitivity and 87% specificity, exceeding the pre-determined threshold required to demonstrate the ability of Zircaix™ to reliably detect the clear cell phenotype.

The study also met the key secondary endpoint, achieving 85% sensitivity and 89% specificity in detecting ccRCC in tumors <4 cm (“T1a” classification), currently a significant clinical challenge in the diagnosis of ccRCC.

¹⁰⁴ Telix press release, 11 July 2022:

<https://telixpharma.com/news-views/zircon-phase-iii-kidney-cancer-imaging-study-completes-enrolment-2/>

¹⁰⁵ Telix press release, 7 November 2022:

<https://telixpharma.com/news-views/zircon-phase-iii-top-line-data-study-meets-primary-objectives/>

 Glossary

Telix submitted a Biologics License Application (BLA) with the FDA for TLX250-CDx as a diagnostic imaging agent in ccRCC in December 2023.¹⁰⁶ Under the Breakthrough Therapy designation, Zircaix™ has been granted a rolling review process, which enables a progressive submission and review of required modules in a timetable pre-agreed with the FDA. With the BLA submission, Telix also requested **Priority Review**. Also in December 2023, Telix initiated a global early access program (**EAP**) to provide patients with continued access to Zircaix™ for detecting ccRCC whilst regulatory submissions are progressed. The first patients have already been enrolled in the programs in the Netherlands¹⁰⁷ and the USA¹⁰⁸.

Telix is also conducting further clinical trials with TLX250-CDx to potentially expand the indication beyond kidney cancer. In early December 2023, Telix presented positive data from the Phase II OPALESCENCE trial. The study, conducted at the Institut de Cancérologie de l'Ouest (ICO) in St. Herblain, France, evaluated 12 triple-negative metastatic breast cancer (TNBC) patients with TLX250-CDx. TLX250-CDx was able to detect 100% of lesions in the breast, skin, adrenal gland and brain. CAIX expression in nodes and bones was also detected at 88.0% – 91.9%.¹⁰⁹ The results support the potential of **TLX250** therapy in the TNBC indication, too.

In June 2023, Telix announced that the first patient in the Phase II STARBURST study had been dosed with TLX250-CDx. STARBURST is a prospective, open-label Phase II “basket” study designed to investigate CAIX expression in patients across a broad range of solid tumors for potential diagnostic and therapeutic applications. Tumor types being studied include breast, cervix, colorectal, gastric and esophageal cancers.¹¹⁰

TLX250 (girentuximab) – therapeutic antibody

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

TLX250 is being evaluated in two Phase II combination studies (STARLITE-1 and 2) with immunotherapies. The STARLITE-2 trial is conducted at the Memorial Sloan Kettering Cancer Center in New York with TLX250 in combination with Opdivo® anti-PD-1 immunotherapy. The STARLITE-1 study is testing TLX250 in combination with Cabometyx® and Opdivo® in the treatment of advanced renal cancer. Both studies are actively recruiting patients and investigate the response rate of combination therapy compared to the current standard treatment for solid tumors.

In collaboration with Merck KGaA, Telix is also evaluating TLX250 in an open-label, single-arm, multicenter Phase Ib dose escalation and dose expansion study in combination with the DNA protein kinase inhibitor peposertib, a DNA damage response inhibitor (DDRi). The first patient in this STARSTRUCK study was dosed in July 2023.

¹⁰⁶ Telix press release, 19 December 2023: <https://telixpharma.com/news-views/telix-submits-biologics-license-application-bla-for-tlx250-cdx-zircaix-for-imaging-of-kidney-cancer/>

¹⁰⁷ Telix press release, 4 December 2023: <https://telixpharma.com/news-views/first-patient-dosed-in-european-named-patient-early-access-program-for-tlx250-cdx-telixs-kidney-cancer-imaging-agent/>

¹⁰⁸ Telix press release, 11 December 2023: <https://telixpharma.com/news-views/first-patient-dosed-in-u-s-expanded-access-program-for-tlx250-cdx-telixs-breakthrough-kidney-cancer-imaging-agent/>

¹⁰⁹ Telix press release, 7 December 2023: <https://telixpharma.com/news-views/positive-topline-results-from-phase-ii-opalescence-study-of-tlx250-cdx-in-triple-negative-breast-cancer-presented-at-sabcs/>

¹¹⁰ Telix Pharmaceutical press release, 19 June 2023: <https://telixpharma.com/news-views/first-patient-dosed-in-phase-ii-starburst-study-of-tlx250-cdx-exploring-indication-expansion/>

upamostat – oral serine protease inhibitor

Developed by Heidelberg Pharma AG up to Phase II until 2014, **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 inhibit tumor growth and **metastasis**.

 Glossary

Since 2014, license agreements have been in place for the development and potential commercialization of upamostat with Link Health Co., Guangzhou, China, (Link Health), and RedHill Biopharma Ltd. (NASDAQ: RDHL), Tel Aviv, Israel, (RedHill).

Link Health informed Heidelberg Pharma that it will no longer continue development. Accordingly, Heidelberg Pharma does not expect any further progress from the collaboration with Link Health.

Heidelberg Pharma's partner RedHill is developing upamostat (referred to as **RHB-107** by RedHill) for treating COVID-19. RHB-107 has shown both antiviral and potential tissue-protective activity, with RHB-107 strongly inhibiting SARS-CoV-2 replication in a preclinical human bronchial tissue study. The drug candidate targets human serine proteases that are involved in the virus's entry into target cells.

Last year a report on the Phase II clinical study in COVID-19 outpatients, that demonstrated preliminary evidence of efficacy with an excellent safety profile, and a review on properties of upamostat and potential indications in a variety of diseases were published.

In May 2023, RedHill announced that it will focus the company's resources on the development of RHB-107.¹¹¹ After the end of the reporting period, the company announced in December 2023 that non-dilutive external funding had been committed for the RHB-107 arm of a platform trial.¹¹² In addition, the 300-patient Phase II RHB-107 arm of the PROTECT study received FDA clearance to start.¹¹³ The study is being conducted in the US, Thailand, Ivory Coast, South Africa and Uganda, with the first patient expected to be enrolled in the coming weeks.¹¹⁴

RHB-107 is also being tested in development programs against several viral diseases, including Ebola.¹¹⁵ After the end of the reporting period, 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.¹¹⁶

¹¹¹ RedHill R&D Update, 22 May 2023:

<https://www.redhillbio.com/news/news-details/2023/RedHill-Provides-RD-Update/default.aspx>

¹¹² 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>

¹¹³ 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>

¹¹⁴ 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>

¹¹⁵ RedHill 9-month financial report 2022, 29 November 2022: <https://www.redhillbio.com/news/news-details/2022/RedHill-Biopharma-Announces-Q322-Results-and-Operational-Highlights/default.aspx>

¹¹⁶ 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>

3.4 Other key events in fiscal year 2023

New Chief Financial Officer appointed

Walter Miller was appointed to the Executive Management Board as Chief Financial Officer with effect from 1 May 2023. At the same time, he took on the role of Managing Director of the subsidiary Heidelberg Pharma Research GmbH. Dr. Jan Schmidt-Brand, who served in a dual function since 2014, handed over his duties as CFO to him.

Walter Miller holds a degree in business administration and has many years of experience in corporate finance, M&A, strategic controlling as well as accounting and corporate development. He was most recently CFO of Optimapharm Group, headquartered in Zagreb, Croatia, a clinical research organization (CRO), where he was responsible for finance, M&A and administration. Prior to that, Walter Miller served as CFO at Mologen AG, Berlin, and as CFO at Nuvisan Group, headquartered in Neu-Ulm, Germany, and held senior finance positions at Santhera Pharmaceuticals AG, Pratteln, Switzerland, for more than ten years.

Minority interest in Emergence sold

In summer 2023, Heidelberg Pharma sold its minority interest in Emergence Therapeutics AG, Duisburg, (Emergence). The pharma company Eli Lilly and Company, Indianapolis, Indiana, USA, acquired all outstanding shares in Emergence.

The preliminary total sale price is broken down as follows:

- In the reporting year, the Group received an inflow of cash of €6.8 million as a result of the sale. Cash was mainly used for a loan repayment of €5.0 million to the shareholder loan granted by the main shareholder dievini BioTech holding GmbH & Co. KG, Walldorf.
- In addition, a purchase price receivable of €1.2 million was recognized as at the reporting date, which is divided into a current of €0.2 million and a non-current receivable of €1.0 million.
- Further, there are two contingent purchase price claims totaling USD 4.0 million. The conditions for the accrual of the other claims are based on the achievement of contractually defined, long-term, non-financial targets at Emergence.

For further details, please refer to section 5 of this Group management report and section 23 of the notes to the consolidated financial statements.

Change on the Executive Management Board announced

In late November 2023, the Company announced that Dr. Jan Schmidt-Brand, Chief Executive Officer (CEO) of Heidelberg Pharma AG and Managing Director of the subsidiary Heidelberg Pharma Research GmbH, will step down from his positions effective 31 January 2024 upon reaching retirement age. The Supervisory Board appointed Professor Andreas Pahl as CEO effective 1 February 2024. Mr. Pahl will also assume the role of Managing Director of the subsidiary and continue to be in charge of research and development.

4 Non-financial performance indicators

Employees

The Heidelberg Pharma Group employed 105 (30 November 2022: 110) people (including members of the Executive Management Board) at the end of the fiscal year. This represented an decline of 5%.

Several individual departments were transferred to other business areas during the year. Due to the dwindling significance of the service business, these resources were allocated to research and development to cover the far greater need for resources in this area. A distinction was also made between administrative tasks and strategic central and capital market functions.

The employees are distributed as follows among business areas as of the end of year:

Employees ¹	30 Nov. 2023	30 Nov. 2022 ²
Research and development	70	79
Business development	3	4
Central functions (corporate)	13	10
Administration	19	17
Total	105	110

¹ Without postdocs, staff on extended sick leave and interns

² Figures were not reported in the 2022 Annual Report; these figures are shown for reasons of transparency.

For better comparability, the trend in employee figures according to last year's allocation is shown below.

Employees	30 Nov. 2023	30 Nov. 2022
Research and development	55	62
Manufacturing, service and distribution	18	22
Administration	32	26
Total	105	110

5 Results of operations, financial position and net assets of the Group

The 2023 fiscal year concerns the period from 1 December 2022 to 30 November 2023. Due to rounding, it is possible that individual figures in this combined management report may not add up exactly to the totals and that percentages given may not precisely reflect the absolute figures to which they relate. The results of operations, financial position and net assets according to the German Commercial Code (HGB) of Heidelberg Pharma AG as an independent company are explained separately in chapter 11.

The basis of consolidation comprises Heidelberg Pharma AG and Heidelberg Pharma Research GmbH.

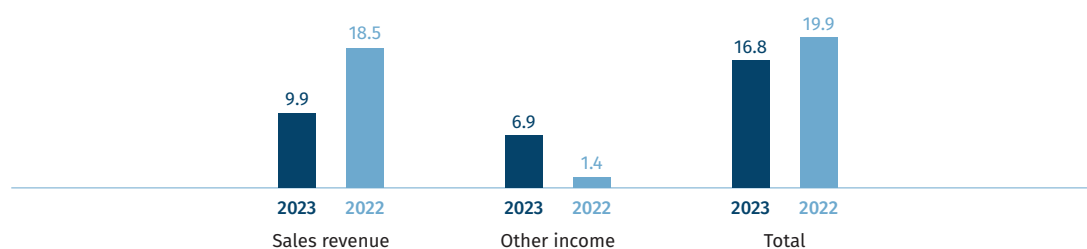
Heidelberg Pharma does not have business units that differ materially in their risk/reward profiles and would therefore require segment reporting.

5.1 Sales revenue and other income

The Heidelberg Pharma Group generated sales revenue and other income totaling €16.8 million in fiscal year 2023 (2022: €19.9 million).

Sales revenue totaling €9.9 million (previous year: €18.5 million) comprised revenue from collaboration agreements for the ATAC technology (€9.8 million; previous year: €17.5 million) and the service business (€0.1 million; previous year: €0.5 million). The previous year was notably defined by the out-licensing of HDP-101 and HDP-103 to Huadong Medicine Co., Ltd., Hangzhou, China, (Huadong), with HDP-101 having been fully recognized in profit or loss.

Income in € million¹



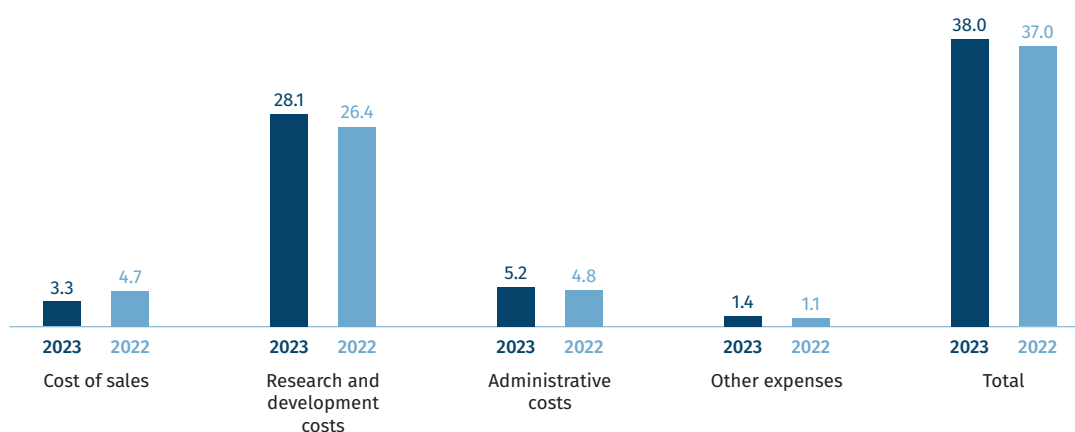
¹ rounded

Other income amounted to €6.9 million (previous year: €1.4 million) and was primarily attributable to the unscheduled disposal of Emergence shares (€5.9 million), while 2022 saw considerable foreign exchange gains (€1.0 million). The total amount of income also includes government grants to support projects by Heidelberg Pharma Research (€0.1 million, previous year: €0.1 million), income from the reversal of unused accrued liabilities (€0.6 million; previous year: €0.1 million) and other items (€0.3 million; previous year: €0.2 million).

5.2 Operating expenses

Operating expenses including depreciation and amortization increased slightly to €38.0 million in 2023 compared to the previous year (€37.0 million).

Operating expenses in € million¹



¹ rounded

The cost of sales concerns the Group's costs directly related to sales revenue. These costs were mainly related to expenses for customer-specific research and for the supply of Amanitin linkers to licensing partners. At €3.3 million, they were down on the prior year (€4.7 million) and accounted for 8% of operating expenses.

Research and development costs were slightly higher year-over-year at €28.1 million (previous year: €26.4 million). This increase is due in particular to the cost-intensive production of antibodies for successor candidates. At 74% of operating expenses, R&D remained the largest cost item.

Administrative costs were €5.2 million, an increase on the prior year (€4.8 million), and accounted for 14% of operating expenses. These include staff costs of €3.0 million (previous year: €2.6 million), of which €0.3 million (previous year: €0.2 million) concerned expenses from stock options in the reporting period. This line item also includes legal and operating consulting costs in the amount of €0.8 million (previous year: €1.1 million) and expenses related to the Annual General Meeting, Supervisory Board remuneration and the stock market listing (€0.7 million; previous year: €0.6 million). Other items amounted to €0.7 million (previous year: €0.5 million).

Other expenses for business development, marketing and commercial market supply activities, which mainly comprise staff and travel costs, increased to €1.4 million year-over-year (previous year: €1.1 million) and made up 4% of operating expenses.

5.3 Earnings

The Heidelberg Pharma Group recognized a net loss for the year of €–20.4 million (previous year: €–19.7 million) in fiscal year 2023. Basic earnings per share improved from €–0.53 in the previous year to €–0.44.

5.4 Financing and liquidity

The Group had cash of €43.4 million at the close of the fiscal year (30 November 2022: €81.3 million).

According to the assessment of the Executive Management Board and based on the current budget, the funds available as of the 30 November 2023 reporting date would be sufficient to finance the business activities of Heidelberg Pharma AG and its subsidiary until probably mid-2025.

In the fiscal year now ended, exceptionally high finance income of €1.6 million (previous year: €235 thousand) was generated on bank balances after years of zero or negative interest rates. Heidelberg Pharma exclusively used short-term deposits for investing its liquid funds (e.g., overnight money); at no time were investments made in stock or share-based financial instruments. Finance costs amounted to €762 thousand (previous year: €840 thousand), comprising mainly interest expense for the dievini shareholder loan. In line with the higher finance income, the financial result improved substantially to € 863 thousand (previous year: €–605 thousand).

5.5 Cash flow statement

Net cash outflow from operating activities during the reporting period was €33.7 million (previous year: €8.9 million). The significant increase is mainly due to lower inflows from income.

Total cash inflow from investing activities came to €5.8 million (previous year: €–0.6 million) and was mainly due to the unscheduled sale of the shares in Emergence.

The net change in cash flows from financing activities amounts to €–10.1 million (previous year: €84.0 million) and is attributable to the partial repayment of the shareholder loan to dievini in the amount of €10 million, which reduced the outstanding loan amount from €15 million at the beginning of the fiscal year to €5 million at the reporting date. The previous year was dominated by cash inflows from Huadong Medicine as part of the capital increase.

In addition, a currency loss of €14 thousand (previous year: €649 thousand currency gain) was recognized.

The total change in cash in fiscal year 2023 came to €–37.9 million (previous year: €75.2 million). This corresponded to an average outflow of cash of €3.2 million per month (previous year: inflow of €6.3 million). Adjusted for the effect of the financing activities, i.e. the partial repayment of the shareholder loan, the average cash outflow per month was €2.3 million in fiscal year 2023 and €0.7 million in fiscal year 2022, not including the capital increase with Huadong.

Cashflow	2023 € million	2022 € million
Cash as of 1 December	81.3	6.1
Net change in cash from operating activities	(33.7)	(8.9)
Net change in cash from investing activities	5.8	(0.6)
Net change in cash from financing activities	(10.1)	84.0
Exchange rate effect	(0.01)	0.6
Cash as of 30 November	43.4	81.3

5.6 Assets

The Company has prepared its financial statements on a going-concern basis.

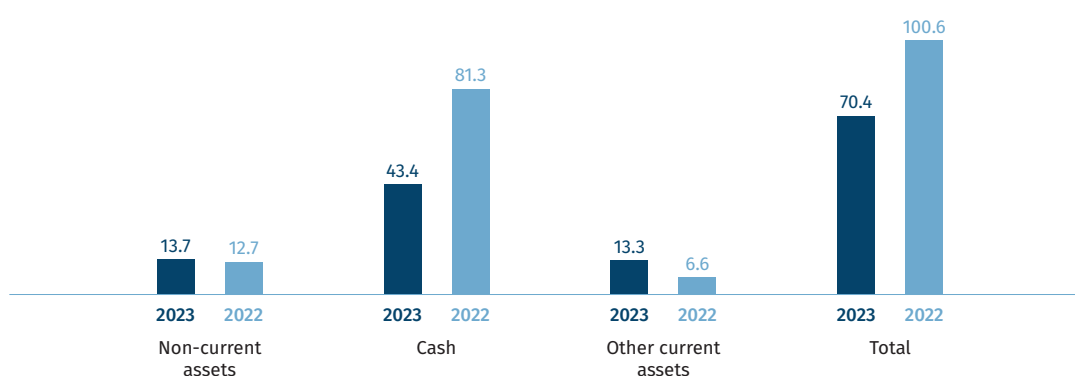
Non-current assets at €13.7 million as of 30 November 2023 were up on the prior-year figure of €12.7 million. As in the previous year, they mainly included the goodwill of Heidelberg Pharma Research (€6.1 million) as well as the recognition of the not yet ready for use intangible assets “In Process Research & Development” (IP R&D) of €2.5 million identified in connection with the purchase price allocation.

 Glossary

Property, plant and equipment increased from €3.7 million to €3.9 million as of 30 November 2023 as a result of higher investments in laboratory equipment in particular. Intangible assets excluding goodwill and IP R&D remained stable at €0.3 million. By contrast, the Emergence share sale caused non-current assets to rise from €35 thousand in the previous year to €1.0 million due to the recognition of a receivable.

Current development expenses for Heidelberg Pharma’s product and development candidates were not capitalized because they were not deemed to fully meet the requirements of IAS 38 for capitalization. They were expensed in full as current research and development costs.

Balance sheet – assets in € million¹



¹ rounded

Current assets decreased from €87.9 million in the previous year to €56.6 million. Cash included in this item amounted to €43.4 million and were down on the prior-year figure of €81.3 million due to outflows triggered by the business and the loan repayments.

Other current assets increased to €13.3 million (previous year: €6.6 million). The inventories included in this figure rose from €4.6 million to €10.5 million, while other receivables grew from €0.4 million to €1.3 million. Both trade receivables at €1.0 million (previous year: €1.1 million) and prepayments of €0.5 million (previous year: €0.5 million) remained virtually unchanged.

Total assets at the end of the fiscal year amounted to €70.4 million (previous year: €100.6 million). This decrease was mainly due to the outflow of cash and the increase in inventories.

5.7 Liabilities

Lease liabilities, which due to the application of IFRS 16 Leases have to be disclosed separately as non-current or current lease liabilities (> 12 or < 12 months), totaled €0.2 million, unchanged from the previous year (of which €0.1 million each non-current and current), and concern leases in connection with office and building rent as well as company cars. Non-current contract liabilities declined from €5.9 million in the previous year to €1.2 million. This reduction resulted from the pro-rata reversal of accrued license income from Huadong.

Non-current liabilities therefore totaled €1.2 million (2022: €6.0 million).

Current liabilities fell to €19.8 million at the close of the reporting period (previous year: €28.0 million).

Current lease liabilities totaled €0.1 million, unchanged from the preceding fiscal year.

Current contract liabilities remained unchanged year-over-year at €5.0 million and, as in 2022, exclusively concerned research collaborations.

Trade payables (€7.9 million; previous year: €5.8 million) increased versus 2022 as a result of an expansion of business activity. By contrast, other current liabilities (€1.2 million; previous year: €1.3 million) fell slightly.

In the reporting year, there was a retrospective change in the accounting method, which led to an increase in trade payables of €4.2 million (previous year: €2.7 million) and a corresponding reduction in other current liabilities.

Financial liabilities at the end of the reporting period amounted to €5.6 million. The decrease from €15.8 million was attributable to two loan repayments of €5 million each on the shareholder loan granted by dievini to Heidelberg Pharma.

5.8 Equity

Equity of the Heidelberg Pharma Group at the end of the reporting period was €49.3 million (30 November 2022: €66.6 million).

The exercise of 20,520 shares stock options lifted the total number of Heidelberg Pharma shares issued as of the reporting date from 46,584,457 to 46,604,977.

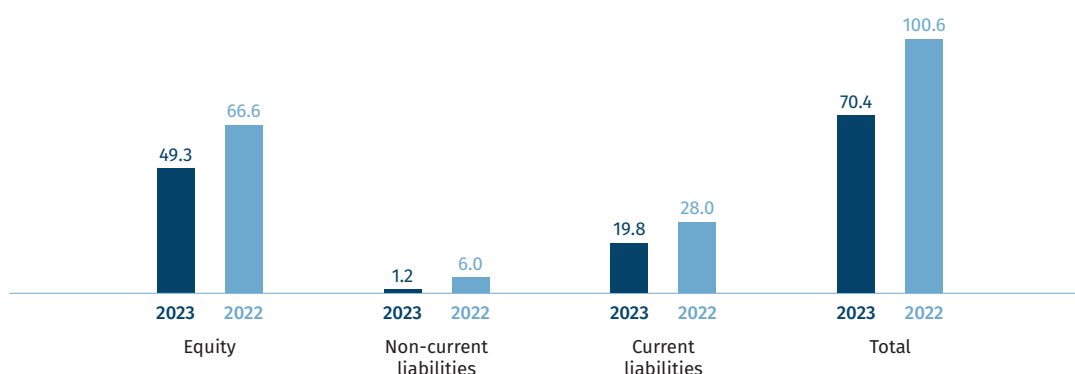
Taking into account the measurement of stock options issued, the capital reserve increased by a net €1.0 million to €312.5 million as of the 2023 reporting date (30 November 2022: €311.5 million).

In addition, other reserves amounting to €2.0 million were recognized in the current fiscal year in connection with the sale of the Emergence investment. This results from the sale of the financial instrument classified as FVtOCI according to IFRS 9 in the fiscal year (see section 23 of the Group management report).

Page 143

The losses accumulated since the foundation of the Heidelberg Pharma Group totaled €311.7 million (30 November 2022: €291.4 million). The equity ratio was 70.1% (30 November 2022: 66.3%).

Balance sheet – equity and liabilities in € million¹



¹ rounded

6 Overall assessment of the course of business and position of the Group by the Executive Management Board

During the past fiscal year, Heidelberg Pharma focused on further clinical development of its first ATAC candidate, HDP-101, and on continued development of the corporate strategy that began with the Huadong partnership in 2022. Together with its strategic partner, the Company plans to expand its proprietary ADC pipeline, a process that is expected to start with a joint Phase I trial of HDP-101 in China. The scientific teams maintained an active dialog with their colleagues last year and developed their first steps. The plan is for Huadong to sponsor the trial and implement operational measures. Developing and expanding the ADC portfolio should allow the Company to evolve from a research company to an ADC development company.

At the start of the fiscal year, the clinical team presented positive initial safety data from the Phase I clinical trial of HDP-101. At the same time, then-ATAC technology partner Magenta unveiled positive preliminary safety data and initial efficacy data from its ATAC project MGTA-117. Shortly after publishing this data, one patient in the Magenta trial experienced serious respiratory side effects that led to the cessation of all development activities and ultimately the termination of its license agreement with Heidelberg Pharma.

The events at Magenta also required Heidelberg Pharma to review its trial process and planning. In the interests of patient safety, the Company, together with the Safety Review Committee and based on available data, decided to take additional steps on safety as a precautionary measure, particularly with regard to the identification and exclusion of patients who might be prone to respiratory events. Additional investigations were carried out accordingly to rule out similar events or detect them at an early stage. The study protocol was modified and implemented for the fourth cohort onwards after approval from the authorities.

The modifications made in spring 2023 delayed the recruitment of additional patients by approximately three months. Heidelberg Pharma opened additional trial centers, primarily in Poland and Hungary, to offset this delay and speed up recruitment. As a result of these efforts, the fourth patient cohort was launched in June 2023. An evaluation of patient data did not show any dose-limiting toxicity. The first four dose levels proved to be safe and well tolerated. As a result, initial dosing of the fifth cohort took place in September at 100 µg/kg. While there was good biological efficacy accompanied by a temporary reduction in the number of thrombocytes after the first dose, there was little evidence of this from the second treatment onwards. To utilize this tolerance, further improve efficacy and evaluate alternative dosing regimens during treatment in more patients, the clinical team revised the clinical trial protocol with regard to the dosing regimen for HDP-101. The corresponding protocol adjustments were implemented and recruitment of the sixth cohort started.

The successor candidate, HDP-102, was prepared for clinical development. We gathered the documents needed to file an application with the authorities to conduct an early clinical trial over the last few months, and this process is nearly complete.

The Company's technology partner Takeda began a toxicology study with an ATAC that triggered a milestone payment to Heidelberg Pharma. The research and exclusive option agreement with Binghamton University, which consists of an innovative and proprietary immunostimulatory technology platform, is proceeding according to plan. Together with research staff at Heidelberg Pharma, the first proprietary ADCs are being conjugated with immunostimulants to combine proprietary ATAC technology with the benefits of immunotherapy.

One major step in our journey towards becoming a diversified ADC development company is using the compound exatecan, a topoisomerase inhibitor, in connection with new linker technology. The new platform and its first project, HDP-201, uses the compound Amanitin instead of this compound. Exatecan is a proven compound for cancer therapy that is also being used in an already approved ADC. Numerous *in vitro* and *in vivo* studies and intensive work has been carried out in recent months to identify a possible lead candidate.

Beyond the ADC technology portfolio, the Zircaix™ (TLX250-CDx) project from the legacy portfolio made very encouraging progress. Telix, our partner for the out-licensed CAIX antibody, filed an application with the FDA for approval of TLX250-CDx as a PET/CT imaging agent for use in the characterization of indeterminate renal masses based on positive results from the Phase III ZIRCON study. In the event of market approval, Heidelberg Pharma would receive revenue from royalties in the low double-digit percentage range in the short to medium term.

The Executive Management Board was strengthened with the addition of new Chief Financial Officer Walter Miller in the middle of the year. At the end of the reporting period, the Company announced that its long-serving Chief Executive Officer, Dr. Jan Schmidt-Brand, would resign from his post effective 31 January 2024. The Supervisory Board appointed experienced Chief Scientific Officer Professor Andreas Pahl as his successor.

Heidelberg Pharma has made important progress despite the major challenges posed by events at Magenta. First and foremost, it was ensured that the clinical trial of HDP-101 can continue under the highest safety standards for patients. Five patient cohorts were treated at doses up to 100 µg/kg by the end of the fiscal year. The safety and biological efficacy profile is promising and may be utilized further by expanding the trial protocol. At the same time, scientific teams carried out preclinical and clinical work on further candidates and prepared the data package for successor candidate HDP-102. Another significant step in our strategic expansion was the development of a new linker platform that enables us to implement new and already clinically validated payloads.

Heidelberg Pharma essentially met the guidance it issued in March 2023. The Company significantly increased other income as a result of the Emergence transaction, which meant that the operating result exceeded annual planning. Operating expenses were within the planned range. Funding requirements were slightly above planned levels on a nominal basis due to the loan repayment of €10 million to dievini, which exceeded inflows from the disposal of Emergence shares.

Financials	Guidance 03/2023 € million	Actual 2023 € million
Sales revenue and other income	7.0 – 10.0	16.8
Operating expenses	37.0 – 41.0	(38.0)
Operating result	(28.5) – (32.5)	(21.2)
Total funding requirement ¹	32.5 – 36.5 ¹	37.9
Funds required per month ¹	2.7 – 3.1 ¹	3.2

¹ Not including any corporate actions

Based on the existing financial planning, the cash reach for the Group and its consolidated companies will extend until mid-2025 if business proceeds as planned. Additional financing options are constantly being reviewed.

7 Corporate governance

7.1 Statement on Corporate Governance pursuant to Sections 289f, 315d German Commercial Code for the 2023 fiscal year

The Statement on Corporate Governance pursuant to Sections 289f and 315d of the German Commercial Code contains the Declaration of Conformity of the Executive Management Board and the Supervisory Board with the German Corporate Governance Code (GCGC) pursuant to Section 161 of the German Stock Corporation Act (Aktiengesetz, AktG). Both corporate bodies had an in-depth discussion regarding compliance with the requirements of the GCGC as amended on 28 April 2022.

In addition, the Statement addresses the principles of proper corporate governance and makes relevant disclosures about the Company's actual corporate governance practices above and beyond statutory requirements. It also describes the procedures of the Executive Management Board and the Supervisory Board as well as the composition and procedures of their committees.

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Heidelberg Pharma's Statement on Corporate Governance was posted on the Company's website under "Press & Investors > Corporate Governance" on 1 February 2024. The Statement on Corporate Governance was updated to reflect new targets for the proportion of women on the Executive Management Board and published as amended on 19 March 2024. Pursuant to Section 317 (2) sentence 6 of the German Commercial Code, the content of the statement on corporate governance in accordance with Sections 289f and 315d of the German Commercial Code is not part of the audit of the financial statements. The audit of the disclosures pursuant to Section 289f (2) and (5) and Section 315d shall be limited to whether the disclosures have been made.

The remuneration report on the last fiscal year and the auditor's report as well as the applicable remuneration system and the last resolution on remuneration are available in the public domain at www.heidelberg-pharma.com in the "Press & Investor > Corporate Governance" section.

7.2 Disclosures under Section 289a (1) and 315a (1) of the German Commercial Code as well as explanatory report

Summary of subscribed capital

As a result of the exercise of 20,520 stock options during the reporting period, the Company's subscribed capital increased from €46,584,457 to €46,604,977 compared with the end of the previous year.

The share capital is composed of 46,604,977 no par value bearer shares. The Company does not hold any treasury shares.

Restrictions on voting rights or on the transfer of shares

The rights and duties related to the shares arise, in particular, from Sections 12, 53a ff, 118 ff and 186 of the German Stock Corporation Act and the Company's Articles of Association. There are no restrictions on voting rights or on the transfer of shares. No shareholder or shareholder group has special rights. Each share entitles the holder to one vote at the Annual General Meeting and determines the proportion of the Company's profits the shareholder will receive.

No shareholder was prohibited from selling, pledging or otherwise disposing of the Company's securities (shares and options) as of 30 November 2023.

Equity interests exceeding 10% of voting rights

Section 315a (1) number 3 of the German Commercial Code requires any interest in a company's capital in excess of ten percent of the voting rights to be disclosed.

Entity with disclosure requirement	Voting interest as of the reporting date
Dietmar Hopp, Walldorf, parties related to him and companies controlled by them ^{1,2}	45.7%
Huadong Medicine Co., Ltd.	35.0%

¹ Shares of dievini Hopp BioTech holding GmbH & Co. KG, DH-Holding Verwaltungs GmbH, Walldorf, and DH-LT-Investments GmbH (as of 30 November 2023)

² The former managing directors of dievini Hopp BioTech holding GmbH & Co. KG, Prof. 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.

Shares with special rights conferring powers of control

None of the shareholders have shares with special rights conferring powers of control. In particular, no individual may claim a right to be appointed to the Supervisory Board pursuant to Section 101 (2) of the German Stock Corporation Act.

Nature of voting control where employees have an equity interest and do not directly exercise their control rights

Any employees of Heidelberg Pharma AG who hold an equity interest in the Company exercise their voting rights directly.

Legal regulations and provisions of the Articles of Association on the appointment and dismissal of members of the Executive Management Board and on amendments to the Articles of Association

The members of the Executive Management Board are appointed for a maximum of five years by the Supervisory Board in accordance with Section 84 German Stock Corporation Act and Articles 7 to 9 of the Articles of Association. The appointment of members of the Executive Management Board may be renewed, or the term of office extended, provided that the term of each such renewal or extension does not exceed five years. The Supervisory Board may revoke appointments to the Executive Management Board for good cause as defined by Section 84 (3) of the German Stock Corporation Act.

If the Executive Management Board does not have the required number of members, a court shall make the necessary appointment in urgent cases in accordance with Section 85 of the German Stock Corporation Act.

Pursuant to Section 179 (1) of the German Stock Corporation Act, any amendment to the Articles of Association requires a resolution by the Annual General Meeting be passed with a majority of at least three-quarters of the share capital represented at the adoption of the resolution. This does not apply to changes which only affect the wording and which may be made by the Supervisory Board in accordance with the Articles of Association.

Authority of the Executive Management Board to issue and buy back shares

Authorized capital:

Authorized capital currently amounts to €20,992,228, divided into 20,992,228 new no-par value bearer shares (Authorized Capital 2022/I). The Executive Management Board is thus authorized pursuant to Article 5 (5) of the Articles of Association to increase the Company's share capital, with the approval of the Supervisory Board, by up to €20,992,228 by issuing up to 20,992,228 new no par value bearer shares in return for cash contributions and/or contributions in kind on one or several occasions up to and including 27 June 2027 (Authorized Capital 2022/I).

Further authorized capital amounts to €2,300,000, divided into 2,300,000 new no-par value bearer shares (Authorized Capital 2022/II). The Executive Management Board is authorized pursuant to Article 5 (10) of the Articles of Association to increase the Company's share capital, with the approval of the Supervisory Board, by up to a total of €2,300,000, divided into 2,300,000 new no par value bearer shares, on one or several occasions up to (and including) 27 June 2027 (Authorized Capital 2022/II), which opens up additional opportunities for employee participation.

Contingent capital:

The Company's share capital was contingently increased by a total of up to €17,291,355 (previous year: €15,223,027) as of the 30 November 2023 reporting date. The various underlying contingent capitals after stock options and convertible bonds are summarized in the following table:

Contingent capital	As of 30 Nov. 2022 €	New issue €	Reduction €	As of 30 Nov. 2023 €	Purpose of use: to satisfy
2011/I	366,172	0	5,500	360,672	2011 Stock Option Plan
2017/I	661,200	0	72,945	588,255	2017 Stock Option Plan
2018/I	1,490,622	0	474,262	1,016,360	2018 Stock Option Plan
2023/I	0	2,621,035	0	2,621,035	2023 Stock Option Plan
2020/I	12,705,033	0	0	12,705,033	Convertible bonds
Total	15,223,027	2,621,035	552,707	17,291,355	

The Executive Management Board, with the approval of the Supervisory Board, and – to the extent that members of Executive Management Board are affected – the Supervisory Board are authorized to determine any other details concerning the contingent capital increase and its implementation in connection with all contingent capital. The Supervisory Board is authorized to change the wording of the Articles of Association to reflect the scope of the respective capital increase from Contingent Capital.

Acquisition of own shares

The Company is not authorized at present to acquire own shares pursuant to Section 71 (1) No. 8 of the German Stock Corporation Act.

Compensation agreements for members of the Executive Management Board or employees in the event of a takeover bid

Heidelberg Pharma AG has not entered into any compensation agreements that provide for remuneration to members of the Executive Management Board or employees in the event of a takeover bid.

Key agreements entered into by the parent company providing for a change of control following a takeover bid

There are no key agreements entered into by Heidelberg Pharma AG providing for a change of control following a takeover bid.

7.3 Closing statement from the dependent company report

In fiscal year 2023, Heidelberg Pharma AG was a dependent company within the meaning of Section 17 (1) of the German Stock Corporation Act because a majority of its shares are held Mr. Dietmar Hopp, parties related to him and companies controlled by them such as by dievini Hopp BioTech holding GmbH & Co. KG. Despite a share of voting rights of less than 50%, the Company expects to maintain a stable majority presence at Annual General Meetings in the future.

Pursuant to Section 312 (1) of the German Stock Corporation Act, the Executive Management Board of Heidelberg Pharma AG therefore prepared a dependent company report that includes the following closing statement:

“In accordance with Section 312 (3) of the German Stock Corporation Act, the Executive Management Board of Heidelberg Pharma AG hereby declares that, with respect to the legal transactions listed in this dependent company report in the 2023 fiscal year during the period from 1 December 2022 to 30 November 2023, and according to the circumstances that were known to the Executive Management Board when those legal transactions were performed, the Company received appropriate consideration for each legal transaction and was not placed at a disadvantage.”

8 Risk report

8.1 Risk management and control

Heidelberg Pharma's business risks predominantly relate to the development of compounds, protection of intellectual property, collaboration with partners, capital recovery and sustainable financing of the Group in the medium to long term. At Heidelberg Pharma, risk management and control is a key function managed by the Executive Management Board that involves those responsible for the various divisions as well as all of our employees. Potential risks are recorded, assessed as risks using specific criteria, and closely monitored on a regular basis, taking into account the requirements of our established risk management system. This system is an important part of corporate control and monitoring.

Based on a process defined in our risk management policy, Risk Officers from the various divisions appointed by the Executive Management Board identify and analyze individual threats and assess the resulting risks according to the criteria of probability of occurrence, potential amount of loss, and existing and planned countermeasures. The Risk Officers periodically – once a month – brief the Risk Management Officer, who updates the Executive Management Board and Executive Management Team (EMT) on the status of the risks. In the interests of the entire company, each employee must report any existing or emerging threats and risks without delay. There are various ways to report these threats and risks, including anonymously if necessary/ desired. Summaries of the regular reports are a set item on the agenda of meetings of Heidelberg Pharma's EMT, which uses them to develop approaches for action for the internal management of the Company. This ensures that existing risks are monitored and managed.

In accordance with the corresponding guidelines, risk management is designed to detect threats and resulting risks as early as possible, use suitable measures to avert risks and resulting financial losses and keep these to a minimum, and avert going-concern risks. Heidelberg Pharma uses this risk management system to monitor risks and manage the measures designed to minimize them. Comprehensive risk assessments are carried out on a quarterly basis as part of a systematic process that includes and assesses all material risks related to the different departments and the subsidiary in a standardized way in accordance with predetermined criteria.

All material risks are addressed in a risk report that is made available to the Executive Management Board at least once a quarter in order to record the risk situation. The risk situation is regularly discussed with the Supervisory Board with regard to material or going-concern risks.

Use of the risk management system, which comprises the basis of consolidation of the consolidated financial statements and lists risks but not opportunities, is described in detail in internal operating procedures (company policies). These documents are regularly updated (most recently in 2023) and made available to all employees. Employees also undergo regular training on using the risk management system, both when necessary as well as on a case-by-case basis ("on-the-job training"). The risk early warning system is reviewed by the Company's auditor once a year in order to ensure that it meets the requirements of Section 91 (2) of the German Stock Corporation Act.

The identified risks are subjected to a risk assessment, taking into account their potential impact on the Company’s business activity, and are categorized according to their potential amount of loss and probability of occurrence. All risks relate to a short-term period (i.e. one year) or medium-term period (i.e. two, less frequently up to five years). The first step entails assessing the risks without taking planned countermeasures into account (gross assessment). The next step is to assess them after countermeasures have been implemented (net assessment). The assessment categories for probability of occurrence and amount of loss are as follows for the Company:

Probability of occurrence in %					
81% to ≤100% Very high					
61% to ≤80% High					
41% to ≤60% Medium					
21% to ≤40% Low					
0% to ≤20% Very low					
Amount of loss in € thousand	0 to ≤100 Very low	101 to ≤250 Low	251 to ≤500 Medium	501 to ≤2.000 High	>2.000 Very high

to be tracked
 to be monitored
 material

The risk categories and subcategories are set out in the following table. Risks are listed in descending order of net expected loss (EL). The EL results from multiplying the probability of occurrence and the net loss amount of the risk.

Heidelberg Pharma has defined seven risk categories with a total of 30 risk subcategories. A total of 58 individual risks were recorded at the end of fiscal year 2022/23, with no material individual risks identified.

Two subcategories recorded an aggregate total risk of > €2,000 thousand (“material”) each, while six subcategories recorded an aggregated total risk of between €500 thousand and €2,000 thousand each (“to be monitored”).

Of these eight risk subcategories, five were attributable to “operational risks”, two were “financial risks” and one was a “strategic risk”. The two risks aggregated as “material” related to the “Ladenburg site” subcategory of “operational risks” and the “liquidity” subcategory of “financial risks”.

Classification	Category	Subcategory	# Individual risks	Amount of loss	Total net EL €'000	Ø Probability of occurrence	Change year-over-year
Material	Operational	Ladenburg site	10	10,025	3,519	25%	—
	Financial	Liquidity	5	9,225	3,363	31%	—
Monitor	Operational	Research and development portfolio	2	3,050	995	22%	—
	Operational	Selecting and collaborating with service providers	2	2,500	825	33%	—
	Financial	Capital market	2	1,625	813	50%	—
	Operational	Collaborating with business partners	2	1,625	749	42%	—
	Operational	Clinical trials – Management studies	2	1,425	748	60%	—
	Strategic	Market, predicting trends, competitive situation	1	1,250	625	50%	—
	Track	Legal	General risk	4	1,300	429	33%
Operational		License agreements	1	1,250	413	33%	—
Legal		Patent protection	3	1,125	371	33%	—
Compliance		IT security	3	1,800	307	25%	—
Going-concern		Going-concern	1	3,000	300	10%	—
General		Business model	2	425	268	40%	▼
Operational		Fluctuation and shortage of skilled workers	2	775	256	33%	▲
Legal		Disputes with business partners	1	375	188	50%	—
Compliance		General risk	2	1,425	183	22%	▼
Operational		Clinical trials – patient recruitment	2	350	175	50%	▼
Operational		Employee health and safety	2	425	129	22%	▼
Legal		Third-party rights	1	375	124	33%	—
Operational		Complexity of research and development	1	375	124	33%	—
Strategic		Regulatory and scientific environment	1	175	88	50%	—

Classifi- cation	Category	Subcategory	# Indi- vidual risks	Amount of loss	Total net EL €'000	Ø Proba- bility of occurrence	Change year- over- year
	Strategic	Shareholder structure	1	175	58	33%	—
	Compliance	Stock corporations and shareholder protection	1	375	38	10%	—
	Operational	Clinical trials – manufacturing, packaging, labeling, delivery	1	50	5	10%	▼
	Legal	Pharmaceutical law – patient safety	1	375	38	10%	—
	Compliance	Research and development quality standard	1	375	38	10%	—
	Financial	Impairment of assets	1	175	18	10%	—
	Financial	Tax loss carryforwards	1	50	5	10%	—
	Strategic	Health economics environment	0	—	—	—	—

Only the risks classified as “material” and “to be monitored” in the subcategories relevant for the Company are described in detail below. Material individual risks are defined as risks that are classified as involving a high or very high amount of loss.

8.2 Internal control system for financial reporting

Pursuant to Section 91 and 93 of the German Stock Corporation Act, the Executive Management Board is responsible for ensuring compliance with an effective internal control system designed to ensure reliable financial reporting. Section 289 (4) and 315 (6) of the German Commercial Code requires the Executive Management Board to prepare a report on this. The Company’s internal control system (ICS) is an integral part of its risk management system and serves primarily to ensure that its financial statements comply with all rules and regulations. It comprises all principles, methods and actions aimed at ensuring the effectiveness, economy and propriety of the Company’s accounting system as well as ensuring compliance with material legal requirements. The Company’s auditor assesses whether the Executive Management Board has set up a functional risk early warning system in accordance with Section 91 (2) of the German Stock Corporation Act (AktG) as part of their audit and in accordance with Section 317 (4) of the German Commercial Code (HGB). This assessment is carried out in accordance with IDW AuS 340, new version (Audit of the risk early recognition system), in particular.

Financial control in the Group is divided into planning, monitoring and reporting. Based on its strategic business plan, Heidelberg Pharma prepares annual budgets for internal management and control purposes that are applicable not only to the Group but also to the parent company and subsidiary. Based on these plans, a monthly as well as a more comprehensive quarterly variance analysis is prepared for all financial and non-financial key performance indicators and reported to the Executive Management Board with the support of the relevant departments. This control tool enables the Finance Department and the Executive Management Board to identify opportunities and risks at an early stage.

The corporate bodies of Heidelberg Pharma AG receive a report on the effectiveness of the internal control system based on this audit. In particular, reports on this system are submitted to the Audit Committee of the Supervisory Board, which generally discusses the audit results.

To ensure reliable financial reporting, Heidelberg Pharma AG observes the International Financial Reporting Standards (IFRSs) and the provisions of the German Commercial Code (HGB). The ICS follows the framework "Internal Control – Integrated Framework" of the Committee of Sponsoring Organizations of the Treadway Commission (COSO Framework). In keeping with the COSO Framework, the ICS has the following components:

- Control environment
- Risk assessment
- Control activities
- Information and communication
- Monitoring the internal control system

Using IT-based solutions, among others, the ICS is intended to ensure compliance with applicable accounting principles required for reliable financial reporting. The system comprises actions that are managed automatically and manually. Preventive and downstream risk controls are carried out, and care is taken to maintain both the division of responsibilities in the Finance Department and compliance with corporate guidelines (e.g., dual-control principle when approving expenditures).

If necessary, the Company also includes external experts in the process, such as for questions related to the measurement of stock option grants, the preparation of securities prospectuses and purchase price allocations.

With Heidelberg Pharma's organizational, control and monitoring structures, the ICS makes it possible to record, process and measure all transactions pertaining to the Company and to present them appropriately through the accounting of the Group companies and the Group. However, personal discretion, defective controls, criminal acts or other circumstances cannot be precluded and, as a result, may limit the effectiveness and reliability of the ICS such that even group-wide application of the systems utilized cannot guarantee with absolute certainty complete, accurate and timely recording of transactions as part of the financial reporting process. The risk management system is adjusted, as necessary and in a timely manner, to account for changes in the risk environment.

8.3 Going-concern risks

As a rule, all of the risks in each risk category also have the potential to endanger the Company's position as a going concern if they have a sufficiently significant and serious impact on the Company's results of operations, financial position and net assets.

Based on the assessment of the Executive Management Board and the budget, the cash available to the Company as of the 30 November 2023 reporting date are sufficient to ensure its ability to continue as a going concern beyond at least the next 12 months. Specifically, there are sufficient funds to ensure the continued existence of the Company as a going concern until mid-2025.

If the corporate strategy based on research and development targets is not implemented as planned beyond this period and/or there is no option to obtain additional funding, this would jeopardize the ability of the Group and/or its consolidated companies to continue as a going concern. As a result, it cannot be ruled out that the companies of the Heidelberg Pharma Group could be unable to satisfy their payment obligations from mid-2025 and/or that they could become overindebted due to loss allowances resulting from a failure to meet targets, for example. This would jeopardize the Group's and/or consolidated entities' existence as a going concern and shareholders could lose some or all of their invested capital. This means that the Company may not be able to realize its assets and settle its liabilities in the regular course of business. This would jeopardize the existence of the Heidelberg Pharma Group or individual affected companies.

The IFRS consolidated financial statements and the HGB annual financial statements are prepared on a going-concern basis in accordance with IAS 1.25 and Section 252 (1) No. 2 German Commercial Code (HGB), as the Executive Management Board expects the Group's operations to continue beyond mid-2021.

Circumstances could also arise that, while not connected with the corporate strategy, could have an existential impact on the Company's business activities, its ability to achieve key corporate goals and/or obtain funding and could thus affect the results of operations, financial position and net assets of the Company.

One fundamental risk is the full or partial non-usability of company buildings due to cases of force majeure such as fire or flooding. The consequences are highly dependent on the scale of destruction; in addition to temporary restrictions on productivity, there is also the possibility of various significant financial expenses associated with the refurbishment of the buildings, partial or full relocation, all the way to the total closure of the Company.

8.4 Risks classified as MATERIAL

8.4.1 Operational risks – Ladenburg site (EL: €3,519 thousand)

Building fabric

Heidelberg Pharma's business premises at its headquarters in Ladenburg are situated in a building that was constructed in the early 1960s. The fabric and infrastructure of the building are only of limited suitability for operating laboratories with up-to-date equipment. The premises no longer meet requirements in terms of energy supply (electricity, heating), network technology, occupational safety, building security, burglary and vandalism protection or fire safety. Potentially more stringent legal requirements (in the areas of environmental protection and fire safety, for example) will require significant financial outlay if these requirements are to be implemented to the extent necessary to maintain operations.

Termination of the lease for business premises in Ladenburg

The lease for the business premises in Ladenburg can be terminated by both parties in writing with notice of twelve months. If the other party were to terminate the lease and if the Company were unable to lease new business premises during this time, the Company's business activities may be halted temporarily.

Sustainability

As tenant of the business premises at its Ladenburg site, Heidelberg Pharma is responsible for the functionality of the facility. The site's energy supply is derived from both fossil and non-fossil fuels. The Company has limited options for moving away from fossil fuels for its heating supply. This risk is defined by volatile energy prices or a temporary energy supply failure. Although Heidelberg Pharma is responsible for choosing its electricity provider and relies on alternative energy suppliers, any nationwide disruption to the energy supply could result in power being obtained from fossil fuel sources.

Global climate change may have an impact on the measurement of assets and liabilities, e.g. on the value and useful life of assets, expected credit risks and other factors affecting business development such as changing regulatory requirements for research and development or a change in the behavior of collaboration partners.

The dominant risks here primarily relate to the buildings and their maintenance and use (net risk classification "to be monitored" residual risk: >€500 thousand: building sustainability, tenancy, building fabric/ infrastructure). Seven additional individual risks with residual risk figures of between €125 thousand and €5 thousand are also recorded in this subcategory.

Countermeasures: Operational risks – Ladenburg site

Heidelberg Pharma is aware of its public responsibility and is actively committed to saving fossil fuels, promoting e-mobility as a company, and focusing on the railway when it comes to travel management.

All internal planning (user requirements) for relocating by 2028 has been completed and the next phases (investors, developers, fitters) are underway. The focus here is to take all regulatory and technical aspects into account to ensure the new building and the business activities as a whole have an optimal ecological footprint.

8.4.2 Financial risks (EL: €3,363 thousand)

Funding of business activities

The Company's research and development activities as well as ensuring business continuity require sufficient regular cash inflows for at least the next fiscal year and beyond. Cash inflows from sales revenue or royalties are not yet sufficient to sustain the Company's operations.

Based on current planning, the cash available at the reporting date will be sufficient to finance the planned business activities of Heidelberg Pharma Research GmbH and Heidelberg Pharma AG until mid-2025.

The financial planning provides for an increase in research and development expenses in the future as the Group builds a proprietary ATAC pipeline, with spending to focus on the planned preclinical and clinical activities for the ATAC successor candidates, the expansion of the portfolio with additional ADC candidates, and the clinical trial of HDP-101. These growing financial requirements will need to be met through sufficient cash inflows as the corporate strategy continues to be successfully implemented and/or through additional borrowings if business develops according to plan, probably from mid-2025 onwards.

Willingness to invest

The key risk here is willingness on the part of investors to invest sufficient funds in Heidelberg Pharma, particularly when successes in developing clinical candidates are not achieved as planned, there is uncertainty on the capital markets (e.g. war in Ukraine, high inflation), and/or there is fundamentally less capital available in the market for investments in biotech companies.

If the Company is unable to obtain funding, there is a risk (see section 8.3 "Going-concern risks") that the cash flow to be generated at Heidelberg Pharma will not be sufficient to ensure financing of the planned business activities beyond mid-2025 or fulfill its payment obligations thereunder.

 Page 65

In addition to the risk of not being able to attract investors to Heidelberg Pharma, there is an additional risk that planned sales revenue could fail to materialize. To ensure that the Company is able to meet its financial obligations beyond the defined period, sales revenue at the subsidiary and parent company level, which consists of licensing or milestone payments, royalties and other sales revenue, will need to be increased or additional financing measures will need to be reviewed and implemented in the short to medium term.

The continuation of the Company's business activities cannot be guaranteed if its funding requirements are not sufficiently covered. This would jeopardize the Group's existence as a going concern and shareholders could lose some or all of their invested capital.

Countermeasures: Financial risks

Heidelberg Pharma is working hard to conclude partnerships, expand existing investor contacts and attract potential new investors. Careful liquidity planning and budgeting are as important as cost-cutting measures and restructuring considerations.

8.5 Risks classified as TO BE MONITORED

8.5.1 Operational risks – Research and development portfolio (EL: €995 thousand)

Risks of product development and of a lack of market maturity of the proprietary ATAC technology

Heidelberg Pharma is currently involved in early-stage research and preclinical and early-stage clinical development and to date has only collected early-stage clinical data. There is a risk that the ATAC technology and the use of Amanitin for cancer therapy may be unable to demonstrate a sufficiently broad therapeutic window (ratio of efficacy to intolerable side effects) in patients in clinical trials.

It can also not be ruled out that the data obtained to date in animal model testing of promising ATACs is not sufficiently transferable to human patients. Therefore, no assurance may be given that the ATAC technology will be feasible for therapeutic use in humans.

Should the risks described here materialize, it may be impossible to successfully implement the current business model of Heidelberg Pharma or portions thereof, because contractual partners terminate the technology cooperation agreements for various reasons. This could jeopardize the continued existence of Heidelberg Pharma AG and the Heidelberg Pharma Group as a going concern.

Countermeasures: Operational risks – Research and development portfolio

Heidelberg Pharma takes great care in selecting and supporting projects in terms of its technology and product development. Additional research candidates with different modes of action have been established with the aim of broadening the Company's platform technology. Where possible, the aim is to expand the technology base to include complementary technologies that do not have an identical risk structure.

8.5.2 Operational risks – Selecting and collaborating with service providers (EL: €825 thousand)

Selecting and collaborating with service providers for production

Antibodies, the toxin and the conjugates for the planned trials are manufactured by service providers (contract development manufacturing organizations – CDMOs). Heidelberg Pharma Research is also responsible for supplying licensees with GMP-quality Amanitin linkers, using third-party manufacturers as subcontractors.

Any deviations from timetables, quality standards or budgets may result in the provision of an inadequate service, delays, loss of investment, loss of funding and/or quality issues with the services provided. This could also mean that trials have to be repeated or terminated. Heidelberg Pharma may be liable to its licensees for the manufacturing defects of the CDMO. All of this could have a negative impact on the assets, liabilities and financial position of Heidelberg Pharma.

Although recourse to the CDMO is contractually agreed, full coverage cannot always be guaranteed. As a sponsor, Heidelberg Pharma is also liable for damages to third parties, especially patients participating in clinical trials, for losses that could arise from faulty production by subcontractors of clinical trial materials. This could result in claims against Heidelberg Pharma. For such cases, the Company takes out the corresponding insurance for its clinical trials. Corresponding insurance has already been taken out to cover liability for previous clinical trials.

Should the risks described here materialize, clinical studies could become more expensive or be delayed. Liability risks could impair the available financial resources.

Selecting and collaborating with service providers to conduct clinical trials

Heidelberg Pharma does not conduct clinical trials independently but instead engages external service providers (contract research organizations, or CROs) to conduct them. Although due care is taken when selecting service providers, the possibility cannot be ruled out that stringent quality, communication, process management and project management requirements for conducting clinical trials will not be met.

Any deviations from timetables, quality standards or budgets may result in the provision of an inadequate service, delays, loss of investment, loss of funding and/or quality issues with the services provided. This could also mean that trials have to be repeated or terminated.

Trials may be delayed or become more costly if a change of CRO is required.

Countermeasures: Operational risks – Selecting and collaborating with service providers

Requests for proposals should be conducted based on a standardized protocol or proposal grid to ensure comparability of the proposals submitted. It is essential to define the service provider's responsibilities precisely, qualify relevant service providers in a timely manner and set up and calibrate instrumentation and/or systems with each other to ensure that contractually agreed services are managed, controlled, coordinated, monitored and geared towards their objectives (e.g. by using trackers, protocols, etc.). Other measures include providing those involved with extensive training, introducing corrective measures that take various scenarios into account, and stipulating suitable and timely warning signals.

8.5.3 Financial risks – Capital markets (EL: €813 thousand)

Low share price

A persistently low share price undermines existing and potential investors' confidence in both Heidelberg Pharma AG in general and the Company's plans/forecasts, and can also prompt shareholders to sell off their shares, pushing down the share price even further. It also reflects poorly on the Company's view of its total and/or technology value (market value or capitalization = share price x number of issued shares).

A low valuation also increases the risk of a (potentially hostile) takeover, as the shares are "cheap" to procure via the capital markets. In addition, a low share price disadvantages the Company when implementing any corporate actions involving the issuance of new shares. A low share price also means there is a lack of incentive when issuing stock options for employees and Executive Management Board members, as it means the options cannot be exercised or will only generate a small profit.

Countermeasures: Financial risks – Capital markets

The aim is to adjust the Company's business model to reduce investor influence by increasing the number of licensing and collaboration partners to give Heidelberg Pharma greater financial independence and enable it to use its own funds to finance its business activities in the medium term.

The priority is to develop and strengthen ties with banks as well as new and existing investors. Another appropriate measure is to ensure the Company is always ready to refinance at short notice, e.g. when conditions are favorable or whenever refinancing is possible.

8.5.4 Operational risks – Collaborating with business partners (EL: €849 thousand)

Collaborating with business partners

Heidelberg Pharma maintains various licensing, collaboration and other agreements with business partners across the pharmaceutical industry and academia for the technologies and product candidates developed by the Company.

There is a risk that the contractual partners will breach the provisions of the agreement in place or fail to meet their mutual contractual obligations. Conflicts with partners over responsibilities, quality standards, compliance with timelines or the general provision of services may result in the loss of specific rights, termination of the relevant collaboration or agreement, loss of investment, or contractual penalties. Such conflicts may also delay R&D activities, increase their costs, and delay or prevent the generation of revenue.

In the case of partnerships concluded for strategic investment purposes, it cannot be assumed that partners will be willing to make follow-up investments. In operating terms, the partner could feel that the services provided by Heidelberg Pharma are insufficient and turn away from joint projects or withdraw from the collaboration for internal strategic reasons.

Such fundamental decisions would affect Heidelberg Pharma's assets, liabilities and financial position.

Countermeasures: Operational risks – Collaborating with business partners

To minimize the risks associated with collaborating with business partners and facilitate negotiations or renegotiations, the Company should use checklists for agreements or separate documents (e.g. legal opinions) to help it conclude risk-balanced agreements with appropriate milestones that take all affected functional areas into account.

Heidelberg Pharma considers it important to have or gain influence over strategic and operational decisions about its out-licensed assets or those in-licensed by business partners.

It is also very important to integrate residual risk into risk documentation, establish risk management and mitigation processes, and foster an understanding of the agreements in question. Risks should be mitigated by diversifying R&D projects and collaboration partners. When conflicts arise, it is advisable to involve mediators, arbitrators or lawyers in the process from an early stage.

8.5.5 Operational risks – Clinical trials – Management studies (EL: €748 thousand)

Drug development is subject to risks typical for the industry, including setbacks in clinical development and/or the associated discontinuation of clinical development of the respective product candidates.

Clinical trials are expensive and time-consuming, and can only be carried out after approval is given by regulatory authorities in the country in question. The trials themselves may be delayed or not reach completion. Successful results generated in preclinical and early clinical trials do not offer any certainty regarding a compound's safety and efficacy in later-stage trials. New treatment methods such as new drugs are used for the first time in clinical trials in the same way as planned for the eventual approved product. As a result, there may be occasions where previously unknown side effects arise, despite all the precautionary measures taken.

Conduct of these trials is scrupulously monitored by the relevant authorities and specially trained staff who respond swiftly if dose-limiting toxicity is observed. The trial could be paused, extended or canceled. Even if the candidate shows a positive side effect and safety profile, there is still the risk that the endpoints set out in the clinical trial protocol will not be reached and development of the candidate will be terminated.

Even after a successful registration trial, the approval of a drug candidate might be delayed or rejected, for instance if the execution or the results of the trial do not satisfy regulatory requirements. New therapeutic approaches in the indications examined could further increase the number of trials and make patient recruitment more difficult than currently expected. This could have a significant impact on the cost and timing of clinical trials.

Countermeasures: Operational risks – Clinical trials – Management studies

It is essential to carefully select and assess service providers who are able to render the necessary services fully, cost-efficiently, promptly and to the highest quality.

It is also vital to critically assess the clinical sites during the selection process. In addition, it is necessary to have an appropriate, comprehensive and risk-balanced agreement in place that includes regular audits/ co-monitoring of CROs and the implementation of CAPAs, the immediate discussion of defects with the relevant authorities, and training for doctors and hospital staff.

 Glossary

8.5.6 Strategic risks – Market, predicting trends, competitive situation (expected loss: €625 thousand)

The business area of oncology, in which Heidelberg Pharma is active, is extremely competitive, dynamic and characterized by rapid technological and scientific innovation due to the high unmet medical need and enormous market potential. Various companies operate in areas similar to those in which Heidelberg Pharma is active. There is the risk that competitor products might produce better efficacy data, reach the market earlier or be more commercially successful. Competitors also could be faster and more successful at out-licensing.

Competitors with larger financial and human resources could achieve their development targets sooner and obtain market approval before Heidelberg Pharma.

Even in cases where regulatory approval is obtained, no assurance can be given that patients, physicians or other decision-makers in the healthcare system will accept the product candidates to the extent required for commercial success.

Market evaluation is also limited, as no product candidates with a comparable mode of action have so far reached the market. As a result, our strategy and operational planning is based on assumptions and market comparisons whose quantification using forecast figures is also beset with uncertainty.

Should the risks described here materialize, the commercial prospects of these product candidates could be impaired or evaporate completely.

Countermeasures: Strategic risks – Market, predicting trends, competitive situation

As these risks are also general business risks, it is almost impossible to take specific countermeasures. As a rule, we focus on business development and maintaining a competitive advantage by agreeing fast and flexible deals. Every deviation from previous forecasts should be assessed; likewise, the Company should plan conservatively and maintain a flexible structure.

8.6 Overall assessment of the risk situation

Page 60

The aforementioned risks are those classified as “material” and “to be monitored” (see 8.1) that have the potential to jeopardize the Company’s position as a going concern. The Executive Management Board endeavors to reduce the Company’s risk profile by leveraging opportunities, minimizing risks and deploying countermeasures.

Financing risks are expected to increase due to the planned utilization of funds until mid-2025 and beyond. However, in the view of the Executive Management Board, the increasing maturity of the technology should produce better marketing opportunities for the ATAC technology, and therefore enhance the revenue potential of Heidelberg Pharma. In addition, the portfolio has been expanded to include additional toxins since 2023. The Executive Management Board of Heidelberg Pharma AG believes that successful entry into the clinical phase, positive safety and efficacy data, and progress on projects by our partners will significantly reduce the risks to which the Company is exposed.

8.7 Risk-bearing capacity

The Company’s total net expected loss – excluding dependencies – is approximately €15 million. The potential risk offset that could be applied to cover these risks is around €22 million (cash as of 30 November 2023, less all liabilities). This means Heidelberg Pharma has sufficient risk-bearing capacity to cope with the current level of risk and thus ensure the continued existence of the Company as a going concern.

9 Report on post-balance sheet date events

After the end of the fiscal year, the following significant events impacting the financial position, net assets and results of operations of Heidelberg Pharma occurred:

- Heidelberg Pharma Announces Royalty Financing Agreement with HealthCare Royalty

Page 165

Detailed information on the event is provided in section 35 “Events after the reporting period” in the notes to the consolidated financial statements.

10 Heidelberg Pharma – Report on expected developments and on opportunities 2023

The following paragraphs contain forecasts and expectations regarding future developments. These forward-looking statements are neither promises nor guarantees and are contingent on many factors and uncertainties, some of which are beyond management's control and could have a significant impact on the statements made herewith.

10.1 Economic environment

According to International Monetary Fund (IMF) forecasts, global growth will reach 3.1% in 2024 (2023: 3.1%), an increase of 0.2% percentage points compared to the figure predicted in October 2023.¹¹⁷ The eurozone will expand significantly less than the world economy, with experts anticipating growth of 0.9% in the region (2023: 0.5%); by comparison, the USA is set to see significantly higher growth of 2.1% (2023: 2.5%). The German economy is predicted to deliver very weak performance of 0.5% (2023: -0.3%).

Central banks raised their key interest rates several times over the past year, which had a positive impact on the exceptionally high inflation rates seen in the last two years. Inflation is likely to fall faster than expected to 5.8% in 2024 and 4.4% in 2025.¹¹⁸ The turnaround in interest rates made more conservative forms of investments more attractive again, while high-risk investments in instruments such as Heidelberg Pharma shares are less in demand in this environment. The Heidelberg Pharma Group is not directly affected by the current macroeconomic and political turmoil and does not see any risks with regard to either its research and development activities or supply chains at the present time. However, it does need to factor in interest rate and price increases.

10.2 Market opportunities in the biotechnology industry

After a weaker year of approvals in 2022 (37 approvals), the FDA approved 55 new products in 2023.¹¹⁹ As in previous years, the highest number of approvals were in the area of oncology (13).¹²⁰ There was also a high number of biological products and a growing number of cell and gene therapies and new vaccines in 2023.^{121, 122, 123}

¹¹⁷ <https://www.imf.org/en/Publications/WEO/Issues/2024/01/30/world-economic-outlook-update-january-2024>

¹¹⁸ <https://www.imf.org/en/Publications/WEO/Issues/2024/01/30/world-economic-outlook-update-january-2024>

¹¹⁹ Nature reviews, 2 January 2024, 2023 FDA approvals: <https://www.nature.com/articles/d41573-024-00001-x>

¹²⁰ Nature reviews, 2 January 2024, 2023 FDA approvals: <https://www.nature.com/articles/d41573-024-00001-x>

¹²¹ FDA, 21 December 2023: <https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/2022-biological-license-application-approvals>

¹²² Nature reviews, 2 January 2024, 2023 FDA approvals: <https://www.nature.com/articles/d41573-024-00001-x>

¹²³ FiercePharma, 2 January 2024, 2023 drug approvals: After a down year, FDA signs off on a bounty of new meds, including 7 from Pfizer: <https://www.fiercepharma.com/special-reports/2023-drug-approvals-after-down-year-fda-signs-bounty-new-medicines>

By contrast, Germany recorded a sharp decline in new approvals to 30 in 2023 (2022: 49).¹²⁴ As in previous years, drug approvals focused on oncology (12 new drugs), though three medications designed to provide protection against the RSV respiratory virus were also approved.¹²⁵

In spite of improved options for cancer treatment, there is still a high unmet need for new innovative therapies. According to the World Health Organization (WHO), nearly 10 million people died of cancer in 2020. The number of new cancer cases per year is expected to grow to over 30 million by 2040, with around 16 million deaths per year.¹²⁶

According to the sector report published by global research firm IQVIA, cancer medicine spending came to USD 196 billion in 2022, and global oncology spending is expected to exceed USD 375 billion by 2027.¹²⁷ The high demand for cancer therapies is also reflected in the number of clinical trials. The number of new clinical trials in oncology remained at a historically high level in 2022, increasing by 22% compared to 2018.¹²⁸

Biotechs completed 46 IPOs in 2023 (2022: 53), including 17 in the USA and just one in the EU, still lagging well behind the weak previous year.¹²⁹ The IPO market is expected to gradually pick up in 2024, particularly for biotech companies able to present initial clinical data.¹³⁰

The 2023 trading year was a turbulent one for biotech stocks, with geopolitical crises, high inflation and rising interest rates all adversely affecting stock market performance. Although the NASDAQ Biotechnology Index ended the year up 3%, it still fell well short of its performance in previous years.

Despite all this uncertainty, the biotechnology sector remains a fast-growing market. IQVIA estimates that biotechnology spending will reach USD 522 billion in 2024 and USD 569 billion in 2025.¹³¹ Expenditure in this sector has increased by around 10% per annum in recent years.¹³²

The global ADC market had a volume of USD 4.75 billion in 2022 and is estimated to grow to almost USD 19 billion in 2030.¹³³ Most ADCs are developed as cancer therapies, with antibodies in particular used against antigens (targets) that are typically highly expressed on the surface of cancer cells. The most common indication is now breast cancer, closely followed by lymphomas and other hematologic cancers, but with a strong trend towards solid tumors.¹³⁴

¹²⁴ vfa press release, 18 December 2023: <https://www.vfa.de/de/presse/pressemitteilungen/pm-040-2023-arzneimittelinnovation-2023-gesetz-bremst-medizinischen-fortschritt.html>

¹²⁵ vfa press release, 18 December 2023: <https://www.vfa.de/de/presse/pressemitteilungen/pm-040-2023-arzneimittelinnovation-2023-gesetz-bremst-medizinischen-fortschritt.html>

¹²⁶ World Health Organization: <https://gco.iarc.fr/tomorrow/en/dataviz/isotype> (as of 5 January 2024)

¹²⁷ IQVIA Global Oncology Trends 2023, 24 May 2023: <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/global-oncology-trends-2023>

¹²⁸ IQVIA Global Oncology Trends 2023, 24 May 2023: <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/global-oncology-trends-2023>

¹²⁹ BCIQ database, 30 January 2024

¹³⁰ BioCentury, 21 December 2023: Diamonds in a rough 2023, predictions for 2024

¹³¹ <https://de.statista.com/statistik/daten/studie/1368790/umfrage/weltweite-ausgaben-fuer-biotech/>

¹³² <https://de.statista.com/statistik/daten/studie/1368790/umfrage/weltweite-ausgaben-fuer-biotech/>

¹³³ Vantage Market Research: <https://www.vantagemarketresearch.com/industry-report/antibody-drug-conjugates-adcs-market-1280>

¹³⁴ BioCentury database BCIQ, as of 19 December 2023

No ADCs were newly approved by the FDA or EMA in 2023, leaving the number of FDA-approved ADCs unchanged at 12.¹³⁵ At the end of 2023, 15 (2022: 14) oncological ADCs were in 17 Phase III clinical trials, of which four have already received initial approval and are currently being tested in other indications. A further 33 (2022: 34) ADCs are in Phase II trials and 133 ADCs (2022: 126) are in Phase I trials. A total of 123 ADC candidates (2021: 120) are currently in preclinical studies¹³⁶, but very early preclinical development programs are unlikely to be fully recorded in the database and this number is probably actually higher.

10.3 Opportunities

ADC technology

Heidelberg Pharma's ATACs occupy a special position due to the Amanitin toxin used and its unique mode of action. Preclinical models demonstrated that ADCs based on ATAC technology have shown improved efficacy in quiescent and therapy-resistant tumor cells. The toxin Amanitin 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. 17p deletion mainly appears in very aggressive cancers with a poor prognosis. Patients in the Phase I/IIa clinical trial of HDP-101 will be stratified based on their 17p deletion biomarker to obtain information on whether these patient groups could derive a particular benefit from therapy with HDP-101. If the assumption proves true, Amanitin-based therapies could be particularly suitable for the treatment of advanced cancers.

Alongside its ATAC technology with the toxin amanitin, Heidelberg Pharma supplemented its development activities to include a linker platform for other compounds. The aim here is to broaden its scope as an ADC development company, both expanding its own portfolio with other candidates while enlarging the range of options offered to potential partners.

The Company also continues to pursue the goal of further improving its ATAC technology platform and achieving progress with its successor candidates. For HDP-102, the preclinical data package for the submission of the first clinical trial is being completed.

The scientific teams are currently working to identify a lead candidate for the new HDP-201 project. The candidate is the first pipeline project to utilize both a new drug payload and a new linker technology.

The partnership with Chinese company Huadong entered into in 2022 was an important validation of Heidelberg Pharma's proprietary projects and data. It supports the Company's strategy of becoming a global ADC player. Huadong's strong development and commercialization expertise and knowledge of the Asian markets could both shorten time to market and maximize commercial opportunities for development projects in this key region. Not only that, but Huadong's strategic investment strengthened the Company's financial position, which will enable product development to be accelerated and the product pipeline to be continuously expanded.

The current and future ADC partnerships will expand the range of applications for the technology to additional oncological applications as well as including possible applications outside oncology and will underpin validation of the technology. Furthermore, the conclusion of further partnership agreements whereby the granting of exclusive license rights for the testing, development and marketing of each individual ADC will

¹³⁵ Drug Development World, 1 June 2023, Three trends in the antibody-drug conjugate (ADC) market: <https://www.ddw-online.com/three-trends-in-the-adc-market-23879-202306/>

¹³⁶ BioCentury database BCIC, as of 19 December 2023

be generating increasingly significant and growing revenues as projects mature, in the form of customary upfront payments, co-funding of development, milestone payments and royalties. Early-stage research collaborations (material transfer agreements, MTAs) are still in place and negotiations are held with additional companies on continuing and expanding such collaborations under license agreements.

Opportunities provided by the partner programs beyond ATAC technology

TLX250-CDx and TLX250 (girentuximab)

Telix is performing the clinical development of the antibody girentuximab licensed by Heidelberg Pharma AG with different forms of radioactive labeling. This entails a diagnostic project (TLX250-CDx labeled with zirconium; Zircaix™) and a therapeutic project (TLX250 labeled with lutetium in Phase II).

With Zircaix™, the Phase III ZIRCON study on the diagnostic imaging of renal cancer using positron emission tomography (PET) was completed. Study results exceeded the required target levels for sensitivity and specificity, and were therefore able to provide evidence for the non-invasive detection of clear cell renal cell carcinoma. Furthermore, the most important secondary endpoint was also achieved: the detection of small (<4 cm) tumors – which currently constitutes a major clinical challenge.

Telix submitted a Biologics License Application (BLA) for Zircaix™ as a diagnostic imaging agent for detecting ccRCC with the FDA in December 2023.¹³⁷ Under the Breakthrough Therapy designation, Zircaix™ has been granted a rolling review process, which enables a progressive submission and review of required modules in a timetable pre-agreed with the FDA. With the BLA submission, Telix also requested Priority Review. Benefits of the diagnostic agent could include active surveillance, surgical staging and treatment response monitoring for renal cancer. As a preparatory step, Telix opened an Expanded Access Program (EAP) to provide patients with pre-approval access to Zircaix™ for detecting ccRCC. This application significantly increases the likelihood of market approval. In the event of a positive decision, Heidelberg Pharma would be eligible to receive milestone payments and royalties reaching double digit percentages.

In the therapeutic project, the Lutetium-177-labeled antibody girentuximab (¹⁷⁷Lu-DOTA-girentuximab, TLX250) is to be evaluated in two Phase II combination studies (STARLITE-1 and 2) with immunotherapies.

upamostat

Heidelberg Pharma's partner RedHill is developing upamostat (referred to as RHB-107 by RedHill) for treating COVID-19. RHB-107 has shown both antiviral and potential tissue-protective activity, with RHB-107 strongly inhibiting SARS-CoV-2 replication in a preclinical human bronchial tissue study. The drug candidate targets human serine proteases that are involved in the virus's entry into target cells.

Last year a report on the Phase II clinical study in COVID-19 outpatients, that demonstrated preliminary evidence of efficacy with an excellent safety profile, and a review on properties of upamostat and potential indications in a variety of diseases were published.

The company announced that non-dilutive external funding had been committed for the RHB-107 arm of a platform trial.¹³⁸ In addition, the 300-patient Phase II RHB-107 arm of the PROTECT study received FDA clearance to start.

¹³⁷ Telix press release, 19 December 2023: <https://telixpharma.com/news-views/telix-submits-biologics-license-application-bla-for-tlx250-cdx-zircaix-for-imaging-of-kidney-cancer/>

¹³⁸ 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>

RHB-107 is also being tested in development programs against several viral diseases, including Ebola.¹³⁹ RedHill showed 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.¹⁴⁰

Heidelberg Pharma AG is eligible to receive royalties in the double-digit percentage range if RHB-107 is approved.

10.4 Strategy and forecast for ADC technology

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.

Own pipeline

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. Initial study findings are also to be used as input to design the Phase I part of the trial to provide the highest-quality data possible. 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. 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 further evaluation of the safety of the drug.

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. As this was rarely observed after further doses of HDP-101, modification of the dosing regimen is therefore expected to avoid this effect.

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.

¹³⁹ RedHill 9-month financial report 2022, 29 November 2022: <https://www.redhillbio.com/news/news-details/2022/RedHill-Biopharma-Announces-Q322-Results-and-Operational-Highlights/default.aspx>

¹⁴⁰ 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>

Partner programs

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.

10.5 Financial forecast and non-financial forecast

Expected results of operations

With regard to the financial forecast, it should be noted that the effects of the financing agreement entered into with HealthCare Royalty, Delaware, USA, (HCRx) for the sale of future royalties well after the reporting date (see section 35 "Events after the balance sheet date" in the notes to the consolidated financial statements) cannot yet be taken into account in this context. However, the Company expects that this development will be reflected in the expected results of operations and in the expected financial position and net assets.

The Executive Management Board expects the Heidelberg Pharma Group to generate between €11.0 million and €15.0 million in sales revenue and other income (2023: €16.8 million) in the 2024 fiscal year. Sales revenue generated by Heidelberg Pharma Research GmbH (especially from ATAC technology) is expected to account for slightly more than half of this figure, with deferred revenue and potential milestone payments to Heidelberg Pharma AG contributing a slightly smaller amount. Sales revenue from a potential license agreement from the proprietary ATAC development projects was not included in this planning. Sales revenue should then increase noticeably given the licensing agreement with HCRx.

Other income will mainly comprise government grants and the passing on of patent costs in the context of out-licensing.

Based on current planning, operating expenses are expected to be in the range between €36.0 million and €40.0 million, more or less level with the reporting year (€38.0 million).

Earnings before interest and taxes (EBIT) in the 2024 fiscal year are expected to be between €-23.5 million and €-27.5 million (2023: €-21.2 million). Preliminarily including the agreement with HCRx, Heidelberg Pharma expects to post a significantly improved operating result.

The results of operations in the next few years will generally depend to a large extent on whether Heidelberg Pharma Research will be able to enter into additional agreements for ATAC partnerships and license agreements with various pharmaceutical partners.

Heidelberg Pharma assumes that over the next few years expenses will exceed income.

Expected financial position and net assets

If income and expenses develop as anticipated, financing requirements in the 2024 fiscal year for Heidelberg Pharma AG's business operations are expected to decrease compared to 2023 (€37.9 million including the €10 million repayment made on the dievini shareholder loan). Funds used will be in the range of €28.0 million to €32.0 million. This corresponds to an average monthly use of cash of €2.3 million to €2.7 million (2023: €3.2 million). Given the financing agreement with HCRx, it can be assumed that the funding requirement will also be noticeably reduced compared with the 2023 reporting year.

This planning takes into account additional potential cash inflows from new licensing activities in the context of the ATAC technology at Heidelberg Pharma Research. The Group's financing is secured until mid-2025 based on current planning.

Consolidated equity (30 November 2023: €49.3 million) would decline despite any corporate actions given the anticipated loss for the 2024 fiscal year.

All measures being discussed to improve the Company's financial situation are described in detail in sections 8.3 "Going-concern risks" and 8.4.2 "Financial risks" of chapter 8 "Risk report."

 Pages 60, 65 and 67

Financial outlook	Actual 2023 € million	Plan 2024 € million
Sales revenue and other income	16.8	11.0 – 15.0
Operating expenses	38.0	36.0 – 40.0
Operating result	(21.2)	(23.5) – (27.5)
Total funding requirement	37.9	28.0 – 32.0 ¹
Funds required per month	3.2	2.3 – 2.7 ¹

¹ Not including any corporate actions

Non-financial forecast

The Company believes it is currently well positioned in terms of staffing and has no plans to recruit additional employees. The number of employees is expected to remain stable in 2024.

11 Disclosures on Heidelberg Pharma AG (HGB)

The management report of Heidelberg Pharma AG and the Group management report for the 2023 fiscal year have been combined in accordance with Section 315 (5) in conjunction with Section 298 (2) of the German Commercial Code (HGB). The annual financial statements of Heidelberg Pharma AG prepared in accordance with the German Commercial Code and the combined management report are published in the Company Register.

Domiciled in Ladenburg, Germany, Heidelberg Pharma AG is the parent company of the Heidelberg Pharma Group. Heidelberg Pharma AG wholly owns the company Heidelberg Pharma Research GmbH, Ladenburg, Germany (formerly: Heidelberg Pharma GmbH, Ladenburg, Germany).

The business activities, economic environment, financial and non-financial key performance indicators, including important contracts, and the risks and opportunities for Heidelberg Pharma AG have been described in detail in the relevant sections or do not differ materially from the situation of the Group.

11.1 Results of operations, financial position and net assets of Heidelberg Pharma AG

Heidelberg Pharma AG reported an operating result of €-17.1 million (previous year: €-21.6 million) in the 2023 fiscal year (1 December 2022 to 30 November 2023) according to German commercial law. The net loss for the year came to €16.5 million (previous year: €20.7 million).

In this context, the allocation of functions within the Heidelberg Pharma Group, which took effect at the beginning of fiscal year 2020, needs to be mentioned. The parent company Heidelberg Pharma AG takes over the development of Group-internal projects. Heidelberg Pharma Research GmbH has been commissioned with operational development of these projects and remains responsible for research on new projects, the availability of materials and marketing the technology. At the beginning of the 2020 fiscal year, Heidelberg Pharma AG and Heidelberg Pharma Research GmbH also signed a profit and loss transfer agreement with a minimum term of five years. Under this agreement, the subsidiary has an obligation to transfer any profit to the parent company after the close of the fiscal year. Conversely, the parent company has an obligation to absorb losses in accordance with Section 302 of the German Stock Corporation Act. This led to expenses from loss absorption in the amount of €3.2 million in 2023 (previous year: income from profit transfer of €0.5 million, with expenses from correcting the previous year's profit transfer having an offsetting effect in 2023).

Both sales revenue and operating income decreased significantly year-on-year (combined €5.0 million; previous year combined: €10.7 million), as did operating expenses at €22.1 million (2022: €32.3 million).

Heidelberg Pharma thus met the previous year's expected target range for income (€4.5 million to €6.5 million). The Company performed better than expected with regard to operating expenses (expected target range of €27.0 million to €31.0 million) and operating result (expected target range of €-21.5 million to €-25.5 million). This is due to significantly lower expenses.

Sales revenue and other operating income

Sales revenue of €4,671 thousand (previous year: €8,816 thousand) was generated within the framework of the strategic partnership with Huadong.

Other operating income of €305 thousand (previous year: €1,882 thousand) in the previous year included significant income from foreign currency measurement. In 2023, these amounted to €13 thousand (previous year: €1,751 thousand) and mainly stemmed from the foreign currency translation of US dollar holdings.

There was also prior-period income from the reversal of other provisions (€228 thousand; previous year: €11 thousand). An amount of €13 thousand (previous year: €42 thousand) was generated by charging on patent costs in the context of out-licensing; reimbursement under the Expenditure Compensation Act (Aufwendungsausgleichsgesetz, AAG) accounted for €49 thousand (previous year: €49 thousand). Income of €25 thousand was recognized from non-monetary benefits (previous year: €29 thousand).

Operating expenses

Cost of materials resulting from development activities totaled €14,609 thousand (previous year: €24,054 thousand). Expenses for raw materials, consumables and supplies and for purchased goods were incurred in the amount of €942 thousand (previous year: €1,304 thousand). Expenses for purchased services disaggregate into third-party services (€9,028 thousand; previous year: €10,040 thousand), third-party services charged on (€1,771; previous year: €1,935 thousand) and intragroup cost allocations (€2,849 thousand, previous year: €4,771 thousand). Royalties paid to the subsidiary were incurred as an expense in the context of the strategic partnership with Huadong (€19 thousand; previous year: €6,004 thousand).

Personnel expenses were increased significantly on the 2022 figure (€2,823 thousand) to €3,716 thousand in the past fiscal year. Besides the rise in headcount, periodic salary increases also had an impact. Personnel expenses comprise salaries (€3,348 thousand; previous year: €2,526 thousand), social security contributions (€345 thousand; previous year: €280 thousand) and pension expenses of €23 thousand (previous year: €17 thousand).

The amortization of intangible fixed assets and depreciation of tangible fixed assets item totaling €26 thousand (previous year: €28 thousand) consists of depreciation of tangible fixed assets of €19 thousand (previous year: €5 thousand) and amortization of intangible fixed assets of €7 thousand (previous year: €23 thousand).

Other operating expenses of €3,745 thousand (previous year: €5,433 thousand) consisted primarily of legal and consulting costs (€1,480 thousand), which fell compared to 2022 (€1,536 thousand), however. This expense item contains both expenses for conventional legal advice and consulting costs for business development, business strategy and business financing as well as for industrial property rights and patents.

Expenses were also incurred for the stock market listing in the broader sense (€453 thousand; previous year: €454 thousand), the preparation and audit of the annual financial statements (€186 thousand; previous year: €143 thousand), travel costs and conventions (€247 thousand; previous year: €204 thousand), Supervisory Board remuneration (€199 thousand; previous year: €190 thousand), insurance and contributions (€94 thousand; previous year: €67 thousand), office costs (€33 thousand; previous year: €29 thousand), other ancillary personnel expenses (€106 thousand; previous year: €106 thousand) and IT costs (€158 thousand; previous year: €125 thousand). There were also expenses from foreign currency measurement (€494 thousand; previous year: €1,507 thousand) and last year's costs for the capital increase (€766 thousand). Expenses for other operating costs make up €295 thousand (previous year: €306 thousand).

All of the aforementioned items gave rise to an operating result of €-17,120 thousand (previous year: €-21,639 thousand).

The expenses from loss absorption required to be reported as a result of the profit and loss transfer agreement with the subsidiary Heidelberg Pharma Research GmbH came to €3,239 thousand (previous year: income from profit transfer of €514 thousand, with expenses from correcting the previous year's profit transfer having an offsetting effect in 2023).

Interest

Other interest and similar income of €5,083 thousand (previous year: €3,219 thousand) consisted of interest income from the loan to affiliated company Heidelberg Pharma Research GmbH (€3,458 thousand; previous year: €2,984 thousand) and traditional interest income on monetary assets (€1,625 thousands; previous year: €235 thousand).

Interest and similar expenses (€756 thousand; previous year: €837) were incurred for the shareholder loan extended by dievini (€748 thousand; previous year: €836 thousand), and for overdraft interest and custodian fees (€8 thousand; previous year: €1 thousand). As a result, net interest income totaled €4,328 thousand (previous year: €2,382 thousand).

Taxes

There were no taxes on income in the past fiscal year (2022: €1,916 thousand). The loss after taxes on income was therefore €16,545 thousand (previous year: €20,659 thousand). Other taxes were insignificant.

Earnings

All of the aforementioned items resulted in a net loss for the past fiscal year of €16,545 thousand (previous year: €20,660 thousand). Together with the accumulated losses brought forward from the previous fiscal year in the amount of €248,979 thousand (previous year: €228,319 thousand), net accumulated losses came to €265,523 thousand (previous year: €248,979 thousand).

Financing and liquidity

Heidelberg Pharma AG had sufficient funds throughout fiscal year 2023 to ensure the financing of its business operations.

Heidelberg Pharma AG showed cash of €43,358 thousand at the close of the fiscal year (30 November 2022: €81,271 thousand).

If the current financial planning is implemented successfully, the available cash are expected to secure the Heidelberg Pharma Group's cash reach until mid-2025 (see section 8.3).

Page 65

Capital expenditures

In 2023, additions of €22 thousand were made to tangible fixed assets (€78 thousand), but none to intangible fixed assets (€12 thousand). Additions in 2022 amounted to €104 thousand and solely related to tangible fixed assets.

Net assets and financial position

Total assets in the past fiscal year fell by around €28.2 million to €122.9 million compared to €151.1 million in the previous year. This is mainly due to a reduction in cash in the context of the operating losses incurred.

The corresponding decrease in total equity and liabilities was mainly attributable to the lower level of equity triggered by the losses and the considerable reduction in liabilities.

Fixed assets were mainly unchanged compared to the previous year at €13.4 million at the end of 2023, with the carrying amount of the equity investment in Heidelberg Pharma Research GmbH recognized under financial assets accounting for the main portion of non-current assets.

The impairment test for the carrying amount of the equity investment requires the determination of the value in use based on the expected future cash flows of Heidelberg Pharma Research GmbH and the appropriate discount rate.

Impairment testing, and therefore the calculation of the lower fair value of the equity investment, is based on a model that makes assumptions in respect of company planning and uses the present value of the cash flow calculated in this way to determine the enterprise value.

The mid-term planning for the ADC business used for the impairment test comprises detailed planning over a three-year period from 2024 to 2026 (clinical phases I and II). This is followed by a second, longer-term 19-year planning phase from 2027 to 2045 (clinical Phase III, approval and market launch) that is based on model assumptions and continues the first planning phase.

Allowing for the risks and opportunities arising from the business activities, the weighted average cost of capital (after tax) used for the impairment test was 9.1% (previous year: 8.3%). Furthermore, an effective tax rate of 28.43% was used for the calculation.

Further model parameters:

- Derivation of potential sales revenue based on comparison data of approved cancer drugs
- Significant license income from 2026 onwards with sustained positive cash flows in the market phase from 2030
- Maximum exploitation period for license income until 2045 through patents granted
- Discounts for the success rates of individual clinical phases based on scientific literature

The carrying amount of the equity investment in Heidelberg Pharma Research GmbH was €13.3 million for the past fiscal year, which was the same as the previous year. Despite losses incurred by Heidelberg Pharma Research GmbH, Heidelberg Pharma AG firmly believes that, based on revenue potential and expected cash flows, there is no need to write down the investment.

Within inventories, the antibody inventory was reported as raw materials, consumables and supplies in the amount of €3,408 thousand (2022: €26 thousand). In the previous year, there were also prepayments of €219 thousand, which no longer existed in 2023.

There were no trade receivables required to be shown at the end of the 2023 reporting period (previous year: €16 thousand). These were due within less than one year.

Receivables from affiliated companies include loan and interest receivables from Heidelberg Pharma Research GmbH under a fixed-rate, uncollateralized and indefinite loan (overdraft or credit line) granted to Heidelberg Pharma Research GmbH to secure its financing. Overall, the receivable (including interest) due from Heidelberg Pharma Research GmbH increased from €55,597 thousand to €61,757 thousand in the past fiscal year. This loan will allow the subsidiary to finance most of its research and development expenses and will be continuously built up as the cash required is drawn down. The recoverability of the loan will depend on the progress of the research and development activities of Heidelberg Pharma Research GmbH and thus on its ability to repay the loan at a future date. Failure to meet targets would directly compromise recoverability. Based on the rise in the entity value of Heidelberg Pharma Research GmbH as research and development activities progress on schedule, Heidelberg Pharma AG firmly believes that the receivable is recoverable.

Other assets of €920 thousand (previous year: €293 thousand) comprise several items including VAT receivables of €240 thousand (previous year: €218 thousand) and security deposits/other items amounting to €244 thousand (previous year: €75 thousand). For the first time in 2023, receivables from the tax authorities for the reimbursement of import VAT (€28 thousand) and withholding tax on capital gains (including solidarity surcharge) amounting to €408 thousand had to be recognized.

Bank balances decreased to €43,358 thousand as of the balance sheet date (previous year: €81,271 thousand) as a result of the cash outflows from operating activities and the financing of the subsidiary Heidelberg Pharma Research GmbH.

For more information on the Company's financial position and a possible threat to its continuation as a going concern, refer to sections 8.3 "Going-concern risks" and 8.5.3 "Financial risks – Capital markets (EL: €813 thousand)."

Prepaid expenses (€126 thousand; previous year: €301 thousand) were attributable to advance payments to service providers (€106 thousand; previous year: €142 thousand) and project services for clinical development (€20 thousand; previous year: €159 thousand).

As of 30 November 2023 and after the exercise of 20,520 stock options during the year, subscribed capital consisted of 46,604,977 no par value bearer shares with a notional value of €1.00 per share (previous year: 46,584,457 no par value shares). As of the reporting date, the capital reserves amounted to €320,678 thousand (previous year: €320,640 thousand). The losses accumulated since the start of the Company's business activities in 1997 totaled €265,523 thousand as of the end of the fiscal year, of which €248,979 thousand was brought forward to new account from the previous fiscal year and €16,545 thousand was attributable to the net loss for the year. The equity of Heidelberg Pharma AG therefore decreased from €118,245 thousand in the previous year to €101,760 thousand as of the 2023 reporting date.

Other provisions (€2,909 thousand; previous year: €2,276 thousand) were recognized for staff costs and services. The latter were incurred in the context of clinical development (€1,614 thousand; previous year: €1,244 thousand), other services (€537 thousand; previous year: €385 thousand) and costs of preparing and auditing financial statements (€105 thousand; previous year: €151 thousand). As in the previous year, roughly 20% of the total amount had to be recognized as provisions for the Executive Management Board and employee bonus program (€418 thousand; previous year: €333 thousand) and for vacation entitlements (€235 thousand; previous year: €163 thousand).

Trade payables (€1,526 thousand; previous year: €1,433 thousand) consist of compensation for services and suppliers. As in the previous year, all liabilities have a residual term of up to one year.

Liabilities to affiliated companies of €5,042 thousand related to the consolidated VAT tax group and the intra-Group business relationships that exist with the subsidiary, the obligation to absorb the loss of the subsidiary and the intragroup business relations with the subsidiary. In the previous year, €2,715 thousand had to be recognized for this item.

The figure also includes the shareholder loan provided to Heidelberg Pharma AG by its main shareholder under the loan agreement dated 21 December 2020, together with the interest payable (€5,648 thousand; previous year: €15,786 thousand). The reduction is due to two repayments of €5 million each made during the year. The unsecured loan is not limited in time and has carried annual interest of 8% p.a. since the beginning of the fiscal year (previously: 6% p.a.). Any loan repayment claim of dievini is subordinate in rank to the receivables of any Heidelberg Pharma AG creditor.

The item other liabilities (€198 thousand; previous year: €117 thousand) mainly comprised wage and church tax liabilities (€81 thousand; previous year: €64 thousand). Liabilities of €20 thousand for a social insurance body were also recognized (2022: €12 thousand). In addition, miscellaneous other liabilities of €97 thousand and €41 thousand were recognized in the two comparative fiscal years. As in the previous year, all such liabilities are due for payment within one year.

The deferred income to be recognized is attributable to the Huadong out-licensing of HDP-103 for parts of Asia. Of the USD 15 million received for this, the equivalent of €5,839 thousand was deferred as of the reporting date (previous year: €10,510 thousand) and the difference between the two amounts was recognized as sales revenue.

11.2 Other disclosures

Heidelberg Pharma AG employed an average of 19 people (salaried employees) during the year, nine of them in R&D, four in administration, two in business development and four in central functions. The Company had also appointed three Executive Management Board members as of the balance sheet date of 30 November 2023.

11.3 Financial outlook for the parent company, Heidelberg Pharma AG

Expected results of operations

With regard to the financial outlook for the 2023/2024 fiscal year, it should be noted that the financing agreement entered into with HCRx will not have any direct impact on Heidelberg Pharma AG, as it is not a contractual partner of HCRx (see section 10.5 of this Group management report and note 35 of the notes to the consolidated financial statements).

Pages 78 and 165

The Executive Management Board expects the Company to generate between €7.0 million and €9.5 million in sales revenue and other operating income in the 2024 fiscal year (2023: €5.0 million). The earnings target for 2024 does not include potential sales revenue from a potential additional license agreement.

Total operating expenses in 2024 are expected to be in the range of €20.0 million to €24.0 million if business proceeds as planned, thus remaining at a level similar to the 2023 reporting period (€22.1 million). The Company also assumes that expenses will continue to exceed income in the next few years.

The operating result in the 2024 financial year is expected to come in between €-12.0 million and €-16.0 million (2023: €-17.1 million). Furthermore, positive interest income of €3.5 million to €4.5 million (2023: €4.3 million) and expenses from loss compensation of €13.5 million to €16.5 million (2023: €3.2 million) are expected in 2024.

Heidelberg Pharma AG therefore expects to post a net loss of between €23.0 million and €27.0 million for 2024 (2023: €16.5 million).

Expected financial position and net assets

If income and expenses develop as anticipated, financing requirements in the 2024 fiscal year for Heidelberg Pharma AG's business operations are expected to decrease compared to 2023 (€37.9 million including the €10 million repayment made on the dievini shareholder loan). Funds used will be in the range of €28.0 million to €32.0 million. This corresponds to an average monthly use of cash of €2.3 million to €2.7 million (2023: €3.2 million).

Equity as defined by German commercial law (30 November 2023: €101,760 thousand) would decrease regardless of any corporate actions given the anticipated loss for the 2024 fiscal year.

All measures being discussed to improve the Company's financial situation are described in detail in sections 8.3 "Going-concern risks" and 8.4.2 "Financial risks" of chapter 8 "Risk report."

Pages 65, 67 and 60

Ladenburg, 21 March 2024

The Executive Management Board of Heidelberg Pharma AG



Professor Andreas Pahl
Chief Executive Officer



Walter Miller
Chief Financial Officer

CONSOLIDATED FINANCIAL STATEMENTS

for the fiscal year 2023



88	Consolidated statement of comprehensive income
89	Consolidated balance sheet
90	Consolidated cash flow statement
92	Consolidated statement of changes in equity

Notes to the consolidated financial statements

93	Business and the Company
94	Application of new and revised standards
96	Key accounting policies
116	Segment reporting in accordance with IFRS 8
116	Financial risk management
119	Going concern risk
119	Critical estimates and discretionary decisions
121	Impairment testing pursuant to IAS 36
124	Property, plant and equipment
126	Intangible assets
128	Other non-current financial assets
128	Inventories
129	Prepayments
129	Trade receivables and contract assets
130	Other receivables
131	Cash
131	Equity
133	Non-current liabilities
133	Current liabilities
135	Other disclosures on financial instruments
140	Sales revenue
142	Other income
143	Sale of shares in Emergence Therapeutics AG
144	Types of expenses
147	Staff costs
152	Currency gains/losses
152	Financial result
153	Income taxes
156	Earnings per share
158	Leases, guarantees and obligations
159	Corporate bodies and remuneration
163	Related party transactions
164	Expenses for the auditors
165	Declaration of Conformity with the German Corporate Governance Code in accordance with Section 161 German Stock Corporation Act
165	Events after the reporting period

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME (IFRS)

for the fiscal year from 1 December 2022 to 30 November 2023

	Note	2023 €	2022 €
Sales revenue	21	9,858,912	18,513,920
Other income	22	6,942,310	1,346,342
Income		16,801,221	19,860,262
Cost of sales	24	(3,252,828)	(4,679,340)
Research and development costs	24	(28,074,846)	(26,376,595)
Administrative costs	24	(5,248,170)	(4,816,228)
Other expenses	24	(1,435,176)	(1,169,588)
Operating expenses		(38,011,020)	(37,041,751)
Operating result		(21,209,799)	(17,181,489)
Finance income	27	1,624,913	235,214
Finance costs	27	(761,600)	(839,883)
Financial result		863,313	(604,669)
Earnings before tax		(20,346,486)	(17,786,158)
Income taxes	28	0	(1,915,938)
Net loss for the year		(20,346,486)	(19,702,097)
Net gain/loss from investments in equity instruments designated at fair value through other comprehensive income	17	2,022,021	0
Other comprehensive Income		2,022,021	0
Comprehensive income		(18,324,465)	(19,702,097)
Earnings per share	29		
Earnings per share (basic)		(0.44)	(0.53)
Earnings per share (diluted)		(0.31)	(0.44)

Rounding of exact figures may result in differences.

CONSOLIDATED BALANCE SHEET (IFRS)

for the fiscal year ended 30 November 2023

Assets	Note	30 Nov. 2023 €	30 Nov. 2022 €
Property, plant and equipment and right-of-use assets	9	3,847,160	3,717,915
Intangible assets	10	2,786,188	2,837,776
Goodwill	10	6,111,166	6,111,166
Other non-current financial assets	11	974,818	34,900
Non-current assets		13,719,332	12,701,758
Inventories	12	10,487,792	4,585,024
Prepayments	13	382,700	513,337
Trade receivables and contract assets	14	978,836	1,098,902
Other receivables	15	1,345,451	353,468
Cash	16	43,438,922	81,329,482
Current assets		56,633,700	87,880,213
Total assets		70,353,032	100,581,970

Equity and liabilities	Note	30 Nov. 2023 €	30 Nov. 2022 €
Subscribed capital	17	46,604,977	46,584,457
Capital reserve	17	312,453,759	311,454,427
Other reserves	17	2,022,021	0
Accumulated losses	17	(311,740,961)	(291,394,475)
Equity		49,339,797	66,644,409
Lease liabilities (non-current)	18	70,407	100,382
Contract liabilities (non-current)	18	1,167,725	5,903,032
Non-current liabilities		1,238,132	6,003,414
Trade payables	19	7,875,241	5,751,441
Lease liabilities (current)	19	113,193	94,439
Contract liabilities (current)	19	4,965,325	5,017,266
Financial liabilities	19	5,647,778	15,785,833
Other current liabilities	19	1,173,566	1,285,168
Current liabilities		19,775,103	27,934,147
Total equity and liabilities		70,353,032	100,581,970

Rounding of exact figures may result in differences.

CONSOLIDATED CASH FLOW STATEMENT (IFRS)

for the fiscal year from 1 December 2022 to 30 November 2023

	Note	2023 €	2022 €
Net loss for the year		(20,346,486)	(19,702,097)
Adjustment for items in the statement of comprehensive income			
Stock options	25	960,645	553,836
Depreciation and amortization	24	878,509	756,583
Cash gain/loss from the sale of an investment	23	(4,754,427)	0
Losses (+) / gains (-) on disposal of other non-current assets	9	73,360	(14,077)
Exchange rate effects	26	462,429	(648,599)
Finance income	27	(1,624,913)	(235,214)
Finance costs	27	761,600	839,883
		(3,242,798)	1,252,412
Changes in balance sheet items			
Inventories	12	(5,902,768)	(3,839,105)
Prepayments	13	130,637	162,948
Trade receivables	14	120,067	(79,151)
Other receivables	15	(991,983)	76,091
Other non-current assets	11	(939,918)	0
Trade payables	19	2,123,800	2,147,518
Contract liabilities	18/19	(4,787,248)	10,405,985
Other liabilities	19	(111,601)	1,001,664
		(10,359,015)	9,875,950
Cash flow from operating activities		(33,948,298)	(8,573,736)
Finance costs paid	27	(907,419)	(525,421)
Finance income received	27	1,183,919	235,214
Net cash flow from operating activities		(33,671,799)	(8,863,943)

	Note	2023 €	2022 €
Cash flow from investing activities			
Proceeds from disposal of property, plant and equipment	9	31,343	15,367
Payments to acquire property, plant and equipment	9	(939,617)	(584,347)
Payments to acquire intangible assets	10	(20,237)	(28,585)
Proceeds from disposal of an investment	23	6,776,448	0
Net cash flow from investing activities		5,847,938	(597,565)
Cash flow from financing activities			
Change in shareholder loan	19	(10,000,000)	5,000,000
Proceeds from the capital increases	17	0	79,911,693
Capital procurement costs of capital increases	17	0	(817,753)
Income from creating shares for stock options exercised	17	59,208	0
Principal portion of lease payments	9/10	(112,076)	(93,000)
Net cash flow from financing activities		(10,052,869)	84,000,940
Exchange rate and other effects on cash	26	(13,830)	648,599
Net change in cash		(37,890,560)	75,188,031
Cash			
at beginning of period	16	81,329,482	6,141,451
at end of period	16	43,438,922	81,329,482

Rounding of exact figures may result in differences.

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY (IFRS)

for the fiscal year from 1 December 2022 to 30 November 2023

	Note	Shares	Subscribed capital €	Corporate actions/ premium €	Stock options €	Capital reserve €	Other reserves €	Accumulated losses €	Total €
				238,054,927	6,160,373				
As of 1 December 2021		34,175,809	34,175,809	244,215,300		0	(271,692,378)		6,698,731
Measurement of stock options	25				553,836				553,836
Comprehensive income							(19,702,097)		(19,702,097)
Capital increase after accounting for capital procurement costs	17	12,408,648	12,408,648	66,685,292					79,093,940
Net change in equity									59,945,679
				304,740,219	6,714,208				
As of 30 November 2022	17	46,584,457	46,584,457	311,454,427		0	(291,394,475)		66,644,409
				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	25				960,645				960,645
Comprehensive income							(20,346,486)		(20,346,486)
Creation of shares for stock options exercised	17	20,520	20,520	38,688					59,208
Equity instruments through other comprehensive income	17						2,022,021		2,022,021
Net change in equity									(17,304,612)
				304,778,906	7,674,853				
As of 30 November 2023	17	46,604,977	46,604,977	312,453,759		2,022,021	(311,740,961)		49,339,797

Rounding of exact figures may result in differences.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

of Heidelberg Pharma AG, Ladenburg, in accordance with IFRSs
for the 2022/2023 fiscal year
from 1 December 2022 to 30 November 2023

1 Business and the Company

Heidelberg Pharma AG was founded in 1997 as WILEX GmbH by a team of physicians and cancer research specialists from the Technische Universität München (TUM). The Company was converted into a stock corporation (Aktiengesellschaft) under German law in 2001 and Willex AG was recorded in the Commercial Register in the same year. In November 2006, the Company was listed on the Regulated Market (Prime Standard) of the Frankfurt Stock Exchange, where it is listed under ISIN DE000A11QVV0/securities identification number A11QVV/symbol HPHA. On 29 September 2017, the Company moved its registered office to Gregor-Mendel-Straße 22, 68526 Ladenburg, near Heidelberg, Germany. Since its entry in the Mannheim Commercial Register on 18 October 2017 under registration number HRB 728735, the former Willex AG has been doing business as Heidelberg Pharma AG. As of 30 November 2023, the Company's Executive Management Board consisted of Dr. Jan Schmidt-Brand, who resigned from his post as of 31 January 2024; Professor Andreas Pahl, who will act as the new Chief Executive Officer with effect from 1 February 2024; and Walter Miller, who was appointed Chief Financial Officer as of 1 May 2023.

"Heidelberg Pharma" will be used as a synonym for the Group hereinafter. Each entity's full corporate name is stated whenever facts specific to Heidelberg Pharma AG as the parent company or Heidelberg Pharma Research GmbH as the subsidiary are reported.

Heidelberg Pharma AG is responsible for the development phase of the Group's own projects, which the Company took over on completion of the research phase performed by the subsidiary under a license agreement for further preclinical and clinical development and production of the clinical material.

As a result of an internal reorganization of tasks, since 1 December 2019 the Company has also been tasked with taking over internal Group projects after completion of the research phase and implementing the development phase. The Heidelberg Pharma AG team also performs functions relating to Group and research strategy, finance, investor and public relations, business development, clinical development and project management, regulatory matters and contract management. Other areas covered are alliance and data management, as well as intellectual property rights.

The subsidiary Heidelberg Pharma Research GmbH conducts research in the field of therapeutic antibody drug conjugates (ADCs). To the best of the Company's knowledge, Heidelberg Pharma Research is the first company to develop the compound Amanitin for cancer therapies. It uses the mushroom toxin's biological mode of action as a new therapeutic principle, employing its proprietary ATAC technology platform for the purpose of producing, researching and developing selected proprietary Antibody Targeted Amanitin Conjugates as well as new ATAC candidates in collaborations with external partners. Heidelberg Pharma Research also supplies its partners with good manufacturing practice (GMP)-quality compound linker material for their development projects as required.

1.1 Consolidated company

Heidelberg Pharma Research GmbH

The subsidiary Heidelberg Pharma Research GmbH (formerly Heidelberg Pharma GmbH until it was renamed) has been part of the Heidelberg Pharma Group since March 2011. Its Managing Directors are Walter Miller (since 1 May 2023) and Professor Andreas Pahl (since 1 February 2024). As of the reporting date, Dr. Jan Schmidt-Brand also served as managing director; he also resigned from this position on 31 January 2024. The registered office of Heidelberg Pharma Research GmbH is also at Gregor-Mendel-Straße 22, 68526 Ladenburg, Germany.

Heidelberg Pharma Research GmbH is making use of the exemption options in accordance with Section 264 III HGB in the annual financial statements for fiscal year 2022/2023.

2 Application of new and revised standards

2.1 New and revised standards and interpretations

The following International Financial Reporting Standards (IFRSs) newly issued or amended by the International Accounting Standards Board (IASB) which must be applied to the consolidated financial statements as of 30 November 2023 had the following effects on Heidelberg Pharma AG's financial statements:

Standard/interpretation		Effective for fiscal years beginning on or after	Adopted by the European Union	Effects on Heidelberg Pharma
Annual Improvements to IFRS Standards 2018–2020 Cycles and Amendments to IFRS 3/IAS 16/IAS 37	Amendments to various IFRSs	1 Jan. 2021	Yes	No material effects
IAS 12 (Amendments)	International Tax Reform – Pillar 2 Model Rules	Immediately and 1 Jan. 2023 ¹	Yes	No material effects

¹ The accounting exemption must be applied immediately after announcement of the amendment. The amendments affecting these consolidated notes must be applied for annual periods beginning on or after 1 January 2023.

2.2 New and revised standards and interpretations whose application in the consolidated financial statements was voluntary or who were not yet applicable

The following new and amended standards issued by the IASB or interpretations by the International Financial Reporting Interpretations Committee (IFRIC) which were not yet required to be applied in the reporting period or have not yet been adopted by the European Union will not be applied prior to the effective date. Effects on the consolidated financial statements by standards marked “Yes” are considered likely and are currently being reviewed. Only material effects are described in greater detail below. Standards marked “None” or “No material effects” are expected to have the corresponding effects on the consolidated financial statements.

Standard/interpretation		Effective for fiscal years beginning on or after	Adopted by the European Union	Effects on Heidelberg Pharma
IAS 1 (Amendments)	Disclosure of Accounting Policies	1 Jan. 2023	Yes	No material effects
IAS 8 (Amendments)	Changes in Accounting Policies and Estimates	1 Jan. 2023	Yes	No material effects
IFRS 17	Insurance Contracts	1 Jan. 2023	Yes	None
IFRS 17 (Amendments)	First-time application of IFRS 17 and IFRS 9 – Comparative Information	1 Jan. 2023	Yes	None
IAS 12 (Amendments)	Deferred Tax related to Assets and Liabilities arising from a Single Transaction	1 Jan. 2023	Yes	No material effects
IAS 1 (Amendments)	Classification of Liabilities as Current or Non-current – Deferral of Effective Date; Non-current Liabilities with Covenants	1 Jan. 2024	Yes	No material effects
IFRS 16 (Amendments)	Lease Liability in a Sale and Leaseback Transaction	1 Jan. 2024	Yes	None
IAS 7 / IFRS 7 (Amendments)	Qualitative and Quantitative Information about Supplier Finance Arrangements	1 Jan. 2024	No	No material effects
IAS 21 (Amendments)	Determination of the Exchange Rate When there is a Long-term Lack of Exchangeability	1 Jan. 2025	No	No material effects
IFRS 10 and IAS 28 (Amendments)	Sale or Contribution of Assets between an Investor and its Associate or Joint Venture	Delayed for an indefinite period	No	None

3 Key accounting policies

The significant accounting policies applied are explained below.

3.1 Statement of conformity

These consolidated financial statements were prepared in accordance with the International Financial Reporting Standards (IFRSs) and the Interpretations of the International Financial Reporting Standards Interpretations Committee (IFRS IC) as applicable in the European Union (EU). Moreover, the supplementary provisions of Section 315e German Commercial Code (HGB) were applied.

3.2 Basis for preparation of the consolidated financial statements

- The reporting period begins on 1 December 2022 and ends on 30 November 2023. It is also referred to hereafter as the “2023 fiscal year/fiscal year 2023” (“2022 fiscal year/fiscal year 2022” for the previous period).
- Based on Group-wide financial and liquidity planning, the cash available trigger a cash reach until mid-2025 and therefore support the preparation of the IFRS consolidated financial statements on a going concern basis in accordance with IAS 1.25 a, at the time the financial statements were being prepared, it could be assumed that the Company would continue to operate as a going concern beyond the next twelve months.
- In accordance with Section 325 (3) German Commercial Code, Heidelberg Pharma transmits these IFRS consolidated financial statements to the Company Register. These IFRS consolidated financial statements as referred to in Section 315e (1) German Commercial Code exempt the Company from preparing consolidated financial statements in accordance with the German Commercial Code.
- These consolidated financial statements were prepared by the Executive Management Board on 21 March 2024 and released for publication in accordance with IAS 10. The consolidated financial statements are to be approved by the Supervisory Board on 21 March 2024. The Supervisory Board can decline to approve the consolidated financial statements and Group management report released by the Executive Management Board, in which case the Annual General Meeting would have to decide on the approval of the consolidated financial statements.
- Due to commercial rounding up or down of exact figures, it is possible that individual figures in these consolidated financial statements may not add up exactly to the totals and that percentages given may not precisely reflect the absolute figures to which they relate.

3.3 Foreign currencies

The consolidated financial statements are prepared in euros (€), the Group’s functional currency.

At the end of each reporting period the following steps are taken within the Group in accordance with IAS 21.23

- monetary amounts in a foreign currency are translated at the closing rate;
- non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rate at the date of the transaction;
- non-monetary items that are measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was measured.

Heidelberg Pharma carries out business processes in US dollars (USD), Swiss francs (CHF), British pound (GBP) and, to a smaller extent, in other foreign currencies. In fiscal year 2023, a portion of both sales revenue and expenses were recognized in foreign currencies.

The translation of USD, CHF and GBP amounts within the Group was based on the following euro exchange rates: For reasons of materiality, no exchange rates of other currencies are shown.

US dollar:

- Closing rate 30 November 2023: €1 = USD 1.0931 (previous year: €1 = USD 1.0342)
- Average exchange rate in fiscal year 2023: €1 = USD 1.0791 (previous year: €1 = USD 1.0592)

Swiss francs:

- Closing rate 30 November 2023: €1 = CHF 0.9562 (previous year: €1 = CHF 0.9870)
- Average exchange rate in fiscal year 2023: €1 = CHF 0.9751 (previous year: €1 = CHF 1.0092)

British pound:

- Closing rate 30 November 2023: €1 = GBP 0.8637 (previous year: €1 = GBP 0.8647)
- Average exchange rate in fiscal year 2023: €1 = GBP 0.8703 (previous year: €1 = GBP 0.8510)

Differences may result from commercial rounding of exact figures.

3.4 Basis of consolidation

The consolidated financial statements comprise the financial statements of the parent company and the companies controlled by it, including structured companies (its subsidiaries). The Company has control where it:

- Has power over the investee,
- is exposed to variable returns from its involvement with the investee and
- has the ability to affect those returns through its power over the investee.

The Company reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control listed above.

When the Company has less than a majority of the voting rights of an investee, it has power over the investee when the voting rights are sufficient to give it the practical ability to direct the relevant activities of the investee unilaterally. The Company considers all relevant facts and circumstances in assessing whether or not the Company's voting rights in an investee are sufficient to give it power, including:

- The size of the Company's holding of voting rights relative to the size and dispersion of holdings of the other vote holders;
- Potential voting rights held by the Company, other vote holders or other parties;
- Rights arising from other contractual arrangements; and
- Any additional facts and circumstances that indicate that the Company has, or does not have, the current ability to direct the relevant activities at the time that decisions need to be made, including voting patterns at previous shareholders' meetings.

Subsidiaries are fully consolidated from the date on which the Company obtains control over the subsidiary and deconsolidated when the Company loses control of the subsidiary. Specifically, income and expenses of a subsidiary acquired or disposed of during the year are included in the consolidated income statement and the Group's other comprehensive income from the date the Company gains control until the date when the Company ceases to control the subsidiary.

Profit or loss and each component of other comprehensive income are attributed to the owners of the parent company. This applies even where this results in the non-controlling interests having a deficit balance.

The annual financial statements of the subsidiaries are adjusted, if necessary, to bring their accounting policies in line with those used by the Group.

All intra-group assets, liabilities, equity, income, expenses and cash flows associated with transactions between Group companies are eliminated in full during consolidation.

In the past fiscal year, the voting interest held in the Group's existing subsidiary did not change, and nor was any new company acquired.

3.5 Revised accounting policies

Based on its current accounting policy, Heidelberg Pharma recognizes trade payables where it has a present outside obligation arising from the supply of goods and services received.

If the amount and timing of the outflow of resources with economic benefits are not fully certain as of the reporting date due to a lack of received invoices, for example, the present obligation has so far been recognized as an accrued liability under other current liabilities.

They are recognized in this way because of difficulties estimating the expected outflow of resources and timing of this outflow. For these reasons, and to provide more reliable and relevant information, such items have so far been recognized as other liabilities and not as trade payables. This underscores the qualitative difference between a fully certain trade payable and an accrued liability.

Heidelberg Pharma investigated the recognition of accrued liabilities during the year under review. The increased amount of historical and empirical data available in the course of the Group's business activities alleviates the difficulties encountered in estimating the amount of these items.

The conclusion reached about the proper recognition of accrued liabilities is that recognizing these items under trade payables is appropriate for providing more reliable and relevant information.

This change to accounting policies is being retrospectively applied to the year under review by restating the comparative period. The effects of this change on the comparative period are shown below and affect the presentation of these balance sheet items:

Consolidated balance sheet – Equity and liabilities	30 Nov. 2022 reported €	Restated €	30 Nov. 2022 restated retrospectively €
Trade payables	3,050,532	+2,700,910	5,751,441
Other current liabilities	3,986,078	-2,700,910	1,285,168
Total	7,036,609	0	7,036,609

3.6 Property, plant and equipment and right-of-use assets

Heidelberg Pharma does not own plots of land or buildings. All office and laboratory premises used at present are rented. Property, plant and equipment consists of buildings on third-party land, technical equipment and machinery, other equipment, operating and office equipment, and right-of-use assets.

Property, plant and equipment is recognized at historical cost less accumulated depreciation and, if applicable, impairment losses. Right-of-use assets are subject to the provisions of IFRS 16 (Leases). The cost less net carrying amount is depreciated on a straight-line basis over the useful life of the asset. The expected useful lives, net carrying amounts and depreciation methods are reviewed at every reporting date and all necessary changes to estimates are applied prospectively. In addition, write-downs are recognized immediately if assets are impaired as defined by IAS 36.

Depreciation of property, plant and equipment is based on the following useful lives:

- Buildings on third-party land 3 to 10 years
- Technical equipment and machinery 3 to 14 years
- Other equipment, operating and office equipment 3 to 14 years
- Right-of-use assets (based on the term of the contract) 2 to 5 years

Expenses for the repair and maintenance and for the replacement of subordinate items are recognized in income at the time they arise. Extensive replacements and new fixtures and fittings are capitalized where they create a future economic benefit. Replacements are depreciated over their expected useful life. In the event of disposal, the cost and associated accumulated depreciation are derecognized. Any gains or losses resulting from such disposal are recognized in profit or loss in the fiscal year.

Write-downs are recognized if the recoverable amount of property, plant and equipment is lower than the net carrying amount.

Heidelberg Pharma has not pledged any property, plant or equipment as collateral for liabilities including contingent liabilities.

3.7 Intangible assets

3.7.1 Separately acquired intangible assets

Intangible assets with a determinable useful life are carried at cost less accumulated amortization and impairment losses. Amortization is on a straight-line basis over the expected useful life of the asset and is recognized as an expense. The expected useful life and the amortization method are reviewed at every reporting date and all necessary changes to estimates are applied prospectively. Separately acquired intangible assets with an indefinite useful life are carried at cost less accumulated impairment losses.

In addition, write-downs are recognized if assets are impaired as defined by IAS 38.111 in conjunction with IAS 36. This did not apply in 2023, however.

The following useful lives are assumed for intangible assets, which comprise capitalized patents and software:

- Patent rights 20 years
- Software 3 to 7 years

3.7.2 Intangible assets acquired from a business combination

Intangible assets acquired from a business combination, as well as the not yet ready for use intangible assets (In Process Research & Development, or IP R&D) resulting from the takeover of Heidelberg Pharma Research GmbH, are recognized separately from goodwill and measured at fair value, i.e. cost, as of the date of acquisition.

The intangible assets not yet ready for use (IP R&D) are not yet being amortized. The development of the ADC technology and other IP components is ongoing, and no antibody-specific [product license agreement](#) (PLA) that would specify the current use and marketability of this technology asset in the form of a therapeutic development candidate has been signed to date. Hence this asset has not yet been classified as ready for use in accordance with IFRSs. Amortization of this asset will begin once the development work has been completed. In accordance with IAS 36.10 (a), the acquired customer base is subject to an annual impairment test.

Goodwill and IP & R&D are also not amortized. Instead, they are also tested for impairment annually (see notes 3.9 and 8).

3.7.3 Research and development costs

Costs for research activities are recognized as expenses in the periods in which they are incurred.

Internally generated intangible assets resulting from development activities are recognized if and only if the following has been demonstrated:

- The technical feasibility of completing the intangible asset so that it will be available for use or sale.
- The Group's intention to complete production of the intangible asset and use or sell it.
- The Group's ability to use or sell the intangible asset.

- How the intangible asset will generate probable future economic benefits. Among other things, the entity can demonstrate the existence of a market for the output from the use of the intangible asset or the intangible asset itself or, if it is to be used internally, the usefulness of the intangible asset.
- The availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset.
- The Group's ability to measure reliably the expenditure attributable to the intangible asset during its development.

Since these requirements have not been met, no intangible assets could be recognized in the development phase.

At present, all research and development costs are therefore recognized in the income statement for the fiscal year in which they arise.

3.8 Impairment of property, plant and equipment, right-of-use assets and intangible assets with the exception of goodwill

The Company reviews the carrying amounts of property, plant and equipment and intangible assets at every reporting date to determine whether there is reason to believe that these assets are impaired. If there is indication of impairment, the recoverable amount of the asset is determined to identify the scope of a possible impairment loss. If the recoverable amount of the individual asset cannot be determined, then the recoverable amount of the cash-generating unit to which the asset belongs is estimated. A cash-generating unit is the smallest identifiable group of assets that generates cash inflows that are largely independent of the cash inflows from other assets or groups of assets (IAS 36.6).

In the case of intangible assets with an indefinite useful life and those not yet available for use, an impairment test is performed at least once a year and in all cases where there is indication of impairment.

The recoverable amount is the higher of the asset's fair value less costs to sell and its value in use. The estimated future cash flows are discounted using a pre-tax rate when determining the value in use. On the one hand, this pre-tax rate takes into account the current market estimate of the present value of the funds. On the other hand, it reflects the risks inherent in the asset to the extent that these have not already been incorporated into the cash flow estimate.

If the estimated recoverable amount of an asset or a cash-generating unit falls below the carrying amount, then the relevant carrying amount is decreased to the recoverable amount. The impairment is recognized immediately in profit or loss.

If there is a subsequent reversal of the impairment loss, the carrying amount of the asset or the cash-generating unit is increased to the new estimate of the recoverable amount. The increase in carrying amount is limited to the amount that would have resulted if no impairment losses had been recognized in previous years. An impairment reversal is recognized immediately in profit or loss.

3.9 Goodwill

The goodwill resulting from a business combination is recognized at cost less impairment losses, as required, and is reported separately in the consolidated balance sheet. Goodwill is the difference between the purchase price of a company, and the difference between the assets and liabilities of that company, provided that this difference is positive.

For purposes of impairment testing, the goodwill must be allocated to the cash-generating unit of the Group (Heidelberg Pharma Research GmbH) that is expected to derive benefit from the synergies generated by the business combination.

Cash-generating units to which the goodwill is allocated must be tested for impairment at least annually. This involves determining and considering a value in use. As soon as there is some indication of impairment, the cash-generating unit must be tested for impairment immediately. If the recoverable amount of a cash-generating unit is less than the carrying amount of the unit, then the impairment loss must be initially allocated to the carrying amount of the allocated goodwill and subsequently pro rata to the other assets based on the carrying amounts of each asset within the cash-generating unit. Any impairment loss on goodwill is recognized directly in profit or loss in the consolidated statement of comprehensive income. An impairment loss recognized on goodwill may not be reversed in future periods.

3.10 Other non-current financial assets

When leases for buildings and laboratory equipment and motor vehicles are signed, rent security or security for leased equipment may have to be paid to the landlord or lessor. Depending on the duration of the lease, this item is allocated to non-current or current assets as of the reporting date; please also see section 3.14.

3.11 Inventories

Inventories comprise raw materials, consumables and supplies and work in progress.

Inventories are measured at the lower of cost and net realizable value based on the FIFO method. The cost of sales for internally generated inventories contains all directly attributable costs as well as a reasonable percentage of the general overhead costs. Borrowing costs are not included in the cost of inventories because the performance period is shorter than 12 months.

3.12 Prepayments

The other assets and prepayments, e.g. to service providers or insurers, are either recognized in income in accordance with progress on the relevant order or offset against the final supplier invoice.

3.13 Trade receivables

Trade receivables belong to the category of financial instruments measured at amortized cost (see note 3.15). They are therefore recognized at the initial invoice amount net of any allowances for doubtful accounts. Such allowances are based on an assessment by management of the recoverability and aging structure of specific receivables.

Page 103

3.14 Other receivables

Receivables are initially recognized at fair value and subsequently at amortized cost, less any impairment losses. An impairment of other receivables is recognized if there is an objective, substantial indication that not all of the amounts due according to the original contractual terms and conditions are recoverable or discounting that is adequate for the maturity and risk-adjusted seems reasonable. The impairment is recognized in profit or loss.

3.15 Financial instruments

A financial instrument is any contract that gives rise to a financial asset of one entity and a financial liability or an equity instrument of another entity (IAS 32.11).

The trade and settlement dates generally do not coincide in regular cash purchases or sales of financial assets. There is the option to use either trade date accounting or settlement date accounting in connection with such regular cash purchases or sales. The Heidelberg Pharma Group uses trade day accounting in connection with regular cash purchases and sales of financial assets at the time of both initial measurement and disposal.

Financial assets

As of their initial measurement, financial assets are classified for the purpose of their subsequent measurement as measured either at amortized cost, at fair value through other comprehensive income or at fair value through profit or loss.

The classification of financial assets as of their initial recognition depends on the characteristics of the contractual cash flows of the financial assets and on the business model of Heidelberg Pharma for management of its financial assets.

Trade and other receivables are measured at amortized cost. Equity instruments are measured at fair value through other comprehensive income and structured financial instruments are measured at fair value through profit or loss.

In order that a financial asset can be classified as measured at amortized cost or at fair value through other comprehensive income and measured accordingly, the cash flows may solely consist of payments of principal and interest (SPPI) on the outstanding capital amount. This assessment is known as the SPPI test and is implemented at the level of the individual financial instrument.

The Group's business model for management of its financial assets reflects how a company manages its financial assets in order to generate cash flows. Depending on the nature of the business model, the cash flows will arise either through the collection of contractual cash flows, the sale of financial assets or both.

Purchases or sales of financial assets which envisage the delivery of these assets within a period of time which is determined according to rules or conventions on the market in question (normal market purchases) will be recognized on the trade date, i.e. the date on which the Group entered into the obligation to purchase or sell the asset.

For the purpose of subsequent measurement, financial assets will be classified in terms of the following four categories:

- 1) Financial assets measured at amortized cost (debt instruments)
- 2) Financial assets measured at fair value through other comprehensive income with reclassification of cumulative profit and loss (debt instruments)
- 3) Financial assets measured at fair value through other comprehensive income without reclassification of cumulative profit and loss upon derecognition (equity instruments)
- 4) Financial assets measured at fair value through profit or loss

Re. 1) Financial assets measured at amortized cost (debt instruments) – AC category

The Group measures financial assets at amortized cost where the following two conditions are met:

- a) the financial asset is held within the scope of a business model whose purpose is to hold financial assets in order to collect the contractual cash flows and
- b) the contractual terms of the financial asset give rise on specified dates to cash flows which solely consist of payments of principal and interest on the outstanding capital amount.

Financial assets measured at amortized cost will be measured in subsequent periods using the effective interest method and must be tested for impairment. Gains and losses will be recognized through profit or loss upon derecognition, modification or impairment of the asset.

The Group's financial assets measured at amortized cost comprise trade receivables, other receivables, other non-current financial assets as well as cash.

Re. 2) Financial assets measured at fair value through other comprehensive income (debt instruments) – FVtOCI category

The Group measures debt instruments at fair value through other comprehensive income where the following two conditions are met:

- a) the financial asset is held within the scope of a business model whose purpose is the collection of the contractual cash flows as well as the sale of financial assets and
- b) the contractual terms of the financial asset give rise on specified dates to cash flows which solely consist of payments of principal and interest on the outstanding capital amount.

In case of debt instruments which are measured at fair value through other comprehensive income, interest income, remeasurements of currency translation gains and losses and well as impairment losses and impairment reversals are recognized in the income statement and calculated in the same way as financial assets measured at amortized cost. The remaining fair value changes are recognized through other comprehensive income. Upon derecognition, the cumulative gain or loss resulting from fair value changes which is recognized through other comprehensive income will be reclassified to the income statement.

No such assets were recognized in the period under review.

Re. 3) Financial assets measured at fair value through other comprehensive income (equity instruments) – FVtOCI category

As of initial measurement, the Group may irrevocably opt to classify its equity instruments as equity instruments measured at fair value through other comprehensive income if they fulfill the definition of equity according to IAS 32 “Financial Instruments: Presentation” and are not held for trading purposes.

The classification will be made individually for each instrument. Gains and losses from these financial assets will never be reclassified to the income statement. Dividends will be recognized in the income statement as other income in case of a legal right to payment, unless a portion of the cost of the financial asset is recovered through the dividends. In this case, the gains will be recognized through other comprehensive income. Equity instruments measured at fair value through other comprehensive income are not tested for impairment.

The Group has exercised the option to measure equity instruments at fair value through other comprehensive income.

Re. 4) Financial assets measured at fair value through profit or loss – FVtPL category

The group of financial assets measured at fair value through profit or loss consists of the financial assets held for trading purposes, which are classified as measured at fair value through profit or loss upon initial recognition and financial assets which must be measured at fair value. Financial assets will be classified as held for trading purposes if they are purchased in order to be sold or repurchased in the near future. Derivatives, including separately recognized embedded derivatives, will likewise be classified as held for trading purposes, with the exception of derivatives which have been designated as hedging instruments and are effective as such. Independently of the business model, financial assets with cash flows which are not solely payments of principal and interest are classified at fair value through profit of loss and measured accordingly. Irrespective of the criteria outlined above for classification of debt instruments in terms of the categories “measured at amortized cost” or “measured at fair value through other comprehensive income,” upon initial recognition debt instruments may be classified as measured at fair value through profit or loss if this would eliminate or at least significantly reduce an accounting anomaly.

Financial assets measured at fair value through profit or loss are recognized at fair value in the balance sheet, while the fair value changes are recognized on a net basis in the income statement.

Allowance for financial assets

Heidelberg Pharma recognizes an allowance for expected credit losses (ECL) on all debt instruments which are not measured at fair value through profit or loss. Expected credit losses are based on the difference between the contractual cash flows which are contractually payable and the total cash flows which the Group expects to receive, discounted by an approximation of the original effective interest rate. The expected cash flows include the inflows from the sale of collateral held or other credit enhancements which are integral to the contractual terms.

In case of trade receivables and contract assets without a significant financing component, the Company applies a simplified method for calculation of the expected credit losses. Instead of monitoring changes in the credit risk, it recognizes risk provisioning at each reporting date on the basis of the ECL for the overall term. Heidelberg Pharma has produced an analysis of its experience to date of credit losses, which it has adjusted in line with future factors which are specific to the borrowers and the economic outline conditions.

In case of a financial asset, the Company will not necessarily assume a default if contractual payments are 90 days past due. However, in certain cases the Group may assume a default in case of a financial asset if internal or external information indicates that it is unlikely that the Group will receive the outstanding contractual amounts in full before all of the credit enhancements which it holds have been taken into consideration. A financial asset will be written down where there is no legitimate expectation that the contractual cash flows will be realized.

Derecognition of financial assets

The Company derecognizes financial assets when either the payment claims arising from these instruments have expired or all of the material risks and opportunities associated with this instrument have been transferred.

Financial liabilities

All financial liabilities are initially measured at fair value, in case of loans and liabilities less the directly attributable transaction costs.

The subsequent measurement of financial liabilities will depend on their classification as follows:

Financial liabilities measured at fair value through profit or loss

Financial liabilities measured at fair value through profit or loss consist of the financial liabilities held for trading purposes as well as other financial liabilities classified as measured at fair value through profit or loss upon initial recognition.

Financial liabilities will be classified as held for trading purposes if they have been entered into in order to be repurchased in the near future. Gains or losses from financial liabilities held for trading purposes are recognized through profit or loss. Financial liabilities are classified as measured at fair value through profit or loss as of the date of their initial recognition, subject to fulfillment of the criteria stipulated in IFRS 9. The Group has not classified any financial liabilities as measured at fair value through profit or loss.

Financial liabilities measured at amortized cost

Financial liabilities which do not represent any contingent consideration of an acquirer within the scope of a business combination, are not held for trading purposes and have not been designated as measured at fair value through profit or loss are measured at amortized cost in accordance with the effective interest method.

All financial liabilities of Heidelberg Pharma shall subsequently be measured at amortized cost using the effective interest method.

These financial liabilities are classified on initial recognition. Heidelberg Pharma reviews the carrying amounts of these financial liabilities at regular intervals or at least at every reporting date as to whether there is an active market for the respective assets and whether there are indications of impairment (for example, because the debtor is having substantial financial difficulties).

The net profit always contains all other expenses and income associated with the financial instruments in the given measurement category. Besides interest income and dividends, in particular this includes the results of both the initial and the subsequent measurement.

Carrying amounts and fair values are identical in all cases due to their short maturities.

In addition, financial instruments are divided into current or non-current liabilities as of the balance sheet date depending on their remaining life. Financial instruments with a remaining life of more than one year at the reporting date are recognized as non-current financial instruments while those with a remaining life of up to one year are recognized as current assets or liabilities.

A class of financial instruments encompasses financial instruments that are grouped in accordance with the disclosures required under IFRS 7 and the features of the financial instruments an entity uses.

Hedges

Heidelberg Pharma does not utilize hedge accounting for hedging currency risks. Potential currency risks concern the US dollar, the Swiss franc and the British pound in particular. A portion of cash is held in US dollars and British pound to minimize risk.

Derecognition

A financial liability will be derecognized if the underlying obligation has been fulfilled, has been cancelled or has expired. Where an existing financial liability is replaced by another financial liability of the same lender subject to substantially different contract terms or where the terms of an existing liability are subject to substantial change, this replacement or change will be treated as derecognition of the original liability and recognition of a new liability. The difference between the respective carrying amounts will be recognized in profit or loss.

Offsetting of financial instruments

Financial assets and financial liabilities are offset and the net amount is reported in the consolidated balance sheet if there is a currently enforceable legal right to offset the recognized amounts and there is an intention to settle on a net basis.

3.16 Capital management

3.16.1 Composition of equity

The Group's equity consists of the subscribed capital, which is denominated in common bearer shares with a notional value of €1.00 each. Additional costs directly attributable to the issue of new shares and a capital measure are recognized under equity as a deduction from equity (e.g. from capital reserves).

The Company's capital comprises its equity including subscribed capital, capital reserves, other reserves and accumulated deficits. Equity as of the end of the reporting period was €49.3 million (30 November 2022: €66.6 million).

As a result of the exercise of stock options, the total number of Heidelberg Pharma shares issued increased from 46,584,457 shares as of the prior-year reporting date by 20,520 new shares to 46,604,977 shares as of 30 November 2023.

3.16.2 Capital management

The capital management program of Heidelberg Pharma serves to safeguard the currently solid capital base in a sustainable manner so as to be able to continue to assume the going-concern premise and to operate under this premise.

Given the losses the Company has incurred since its founding, it focuses mainly on using cash to fund the ongoing development of its technology and product pipeline and, not least, to maintain the confidence and trust of investors and business partners alike in the Company. In the past fiscal year, a shareholder loan from dievini Hopp BioTech holding GmbH & Co. KG, Walldorf, (dievini) was utilized in this context, but no capital was borrowed from banks.

Management regularly monitors the liquidity and equity ratios and the sum of the items recognized in equity. There were no changes during the reporting year in the Company's strategy or objectives as they relate to its capital management program.

	30 Nov. 2023 €'000	30 Nov. 2022 €'000
Liquidity	43,439	81,329
In % of total capital	61.7	80.9
In % of current liabilities (cash ratio)	219.7	291.1
Equity	49,340	66,644
In % of total capital	70.1	66.3
Liabilities	21,013	33,938
In % of total capital	29.9	33.7
Total capital	70,353	100,582

The liquidity ratios (ratio of available cash to either total capital or current liabilities) were impacted in particular by the cash outflows from operating activities and loan repayments, and decreased year-over-year.

The ratio of liquidity to total capital fell from 80.9% to 61.7%. Similarly, the cash ratio, defined as cash divided by current liabilities, fell from 291.1% to 219.7%.

The equity ratio was 70.1% as of 30 November 2023. This is higher than in the previous year (66.3%), mainly due to the significant reduction in liabilities in the past fiscal year. Liabilities fell by around €12.9 million, particularly as a result of lower deferred revenue and partial repayments of the shareholder loan.

In relation to total capital, they decreased accordingly to 29.9% as of the 2023 reporting date, down from 33.7% in the previous year.

Preventing the share capital from being reduced by more than half by losses in the annual financial statements prepared under German commercial law is the main quantitative control variable of equity management.

3.17 Liabilities and provisions

Liabilities are recognized if a legal or constructive obligation exists towards third parties. With the exception of any financial liabilities, liabilities are carried at their settlement amount. In contrast, any financial liabilities are initially measured at their fair value. They are subsequently measured at amortized cost. All liabilities that fall due within at least one year are recognized as non-current liabilities; they are discounted to their present value.

Provisions are recognized if the Group has a present obligation from a past event, it is probable that the Group will have to meet this obligation and its amount can be estimated reliably. The provision amount recognized is the best estimated amount as of the reporting date for the expenditure required to fulfill the present obligation, taking into account the risks and uncertainties inherent in the obligation. If it is expected that the amount required to settle the provision will be reimbursed by a third party in whole or in part, this claim is recognized accordingly under other receivables.

3.18 Income taxes

Income tax expense is composed of the current tax expense and deferred taxes. Due to the significant loss carryforwards, no considerable tax expenses were incurred except for the previous year's income taxes in connection with the strategic partnership with Huadong Medicine Co. Ltd., Hangzhou, China, (Huadong).

Deferred income taxes are recognized by applying the balance sheet liability method for temporary differences which arise between the tax base of the assets and liabilities and their carrying amounts in the financial statements according to IFRS. Deferred income taxes are to be measured in accordance with the tax rates (and tax regulations) that are applicable as of the reporting date or that have essentially been passed as law and are expected to be applicable during the period in which an asset is realized or a debt is settled. Deferred tax assets and deferred tax liabilities are not recognized when the temporary differences arise from the initial recognition of goodwill or from the initial recognition of other assets and liabilities in transactions which are not business combinations and affect neither accounting profit nor taxable profit (tax loss).

Deferred tax assets are recognized to the extent it is probable that a taxable profit will be available against which the temporary differences can be applied. Deferred tax assets for tax loss carryforwards are recognized to the extent it is probable that the benefit arising will be realized in future.

If relevant, current or deferred taxes are recognized in profit or loss, unless they are related to items that are either recognized in other comprehensive income or directly in equity. In this case, the current or deferred tax must also be recognized in other comprehensive income or directly in equity.

3.19 Earnings per share

Undiluted earnings per share are calculated as that proportion of net profit or loss for the year available to common shareholders, divided by the weighted average number of common shares outstanding during the period under review. The Treasury Stock Method is usually applied to calculate the effect of subscription rights (stock options). It is assumed that the options are converted in full in the reporting period. The number of shares issued to the option holder as consideration for the proceeds generated, assuming exercise at the exercise price, is compared with the number of shares that would have been issued as consideration for the proceeds generated assuming the average market value of the shares. The difference is equal to the dilutive effect resulting from the potential shares and corresponds to the number of shares issued to the option holder compared to another market participant receiving no consideration. The proceeds assumed from the issue of potential common shares with dilutive effect must be calculated as if they had been used to repurchase common shares at fair value. The difference between the number of common shares issued and the number of common shares which would have been issued at fair value must be treated as an issue of common shares for no consideration and is reflected in the denominator when calculating diluted earnings per share. The profit or loss is not adjusted for the effects of stock subscription rights. The conditional increase of the share capital to grant stock option rights to employees and members of the Executive Management Board (see note 3.20) could potentially dilute the diluted earnings per share in future.

 Page 110

3.20 Employee and Executive Management Board member benefits

3.20.1 Share-based payment

Equity-settled share-based payment provided to employees in the form of stock options is recognized at the fair value of the relevant option prevailing on the respective grant date. Additional information on calculation of the fair value of share-based payment is presented in note 25.

 Page 147

The fair value calculated upon equity-settled share-based payment is recognized as an expense over the period until vesting with a corresponding increase in equity and is based on the Company's expectations with regard to the equity instruments which are likely to vest. At each reporting date, the Group must review its estimates regarding the number of equity instruments vesting. The effects of changes to the original estimates, if any, must be recognized as in profit or loss in such a way that the cumulative expense reflects the change in the estimate and results in a corresponding adjustment in the reserve for equity-settled share-based payments to employees.

3.20.2 Profit-sharing scheme

Heidelberg Pharma recognizes both a liability and an expense for bonus entitlements of both Executive Management Board members and employees. A liability is recognized if there is a contractual obligation or if an obligation is assumed to have arisen as a result of past business practice.

Bonus entitlements and variable remuneration are contingent on the achievement of personal targets and the Heidelberg Pharma's performance targets. The performance-based remuneration of the members of the Executive Management Board and non-executive personnel is based for one on corporate goals and for another on performance targets that are fixed on an individual basis. These goals and targets comprise and essentially refer to the achievement of defined milestones in research and development, the securing of the Company's further funding and the future performance of Heidelberg Pharma's shares.

Since some of the profit-sharing payments are made subsequently as of the reporting date and there is uncertainty in terms of their amount as a result, the Company recognizes a corresponding accrued liability that is measured using estimates and judgments based on previous payments.

3.20.3 Pension costs

Payments for defined-contribution pension plans for current and former Executive Management Board members and managing directors are recognized as expenses when the beneficiaries have performed the work that entitles them to the contributions. Currently there is a defined-contribution pension plan at Heidelberg Pharma Research into which contributions are still being paid.

The payments, which were pledged in exchange for the work performed by the beneficiaries, are expensed in the fiscal year in question.

3.20.4 Employer's contributions to the statutory pension insurance scheme

In the 2023 fiscal year, Heidelberg Pharma paid €587 thousand in employer contributions to the statutory pension insurance scheme; this expense is allocated to staff costs (previous year: €521 thousand).

3.21 Recognition of revenue and earnings

3.21.1 Sales revenue from contracts with customers

Revenue from contracts with customers will be recognized where the power of disposal over these goods or services is transferred to the customer. Revenue is recognized in line with the value of the consideration which the entity is expected to receive in exchange for these goods or services. The payment terms typically require a payment within a period of 30 to 90 days of receipt of an invoice.

Heidelberg Pharma's business activities are aimed at generating revenue from cooperation agreements and/or license agreements (depending on the design of the given contract in the form of upfront payments, milestone payments, material supplies, cost reimbursements and royalties).

Up-front payments are usually due as prepayments at the start of a given agreement.

Milestone payments are contingent upon achievement of targets previously stipulated in the cooperation or license agreement. Earlier realization under IFRS 15 entails a high risk of revenue correction. This option has therefore not been exercised.

Thanks to the technology transfer of Amanitin production to an industrial scale, the Group is now able to ensure the supply of material not only for its own projects but also to provide its license partners with the necessary GMP-quality Amanitin linker material.

The cooperation agreements also normally generate sales revenues in the form of cost reimbursements for ongoing project development with the respective partner that are billed as the costs are incurred and reported as sales.

Revenue from royalties can become payable after the successful marketing of technologies or programs, for example when licensees generate sales revenue from these. This is recognized in the period in which the sales revenue report or the payment is received. Payment may occur together with the sales revenue report or subsequently. Royalties typically involve contract components with variable consideration which, in line with the above comments, is only recognized as revenue where it is highly probable that this will be received.

3.21.2 Sales revenue from granting licenses

Heidelberg Pharma provides research services and grants research licenses as defined in IFRS 15 B52ff. for a large number of customers and through various sets of agreements. A distinction must be made between a right of access to licenses, which represent performance obligations that are fulfilled over time, and a right to use licenses, which represent performance obligations that are fulfilled at a specific point in time.

Where these agreements relate to separate performance obligations which are distinct in the context of the agreement, the Group will allocate the transaction price to these individual service components on the basis of the stand-alone selling prices of the separate services. However, particularly in service agreements for research services which involve the provision of a large number of individual services which are remunerated by means of a fee which is paid in advance, either in whole or in part, and whose general purpose is to produce new research findings, Heidelberg Pharma has identified agreements where the services are in some cases strongly dependent on one another in the context of the agreement and has defined these as an individual performance obligation.

3.21.3 Evaluation of sales revenue

In accordance with IFRS 15 Revenue from Contracts with Customers, license agreements are evaluated according to the five-step framework model. Moreover, according to IFRS 15.B34 for each specific, i. e. distinct service or provision of goods that has been promised to the customer an assessment must be made of whether the entity is acting as an agent or principal. The latter applies due to the power of control over the service and material, which also suggests itself in view of the licensor or rights holder status.

Step 1 – Identification of contracts with customers

A contract with a customer falls within the scope of IFRS 15 if the following conditions pursuant to IFRS 15.9 are met:

- the contract has been approved by the parties to the contract,
- each party's rights in relation to the goods or services to be transferred can be identified,
- the payment terms for the goods or services to be transferred can be identified,
- the contract has commercial substance and
- it is probable that the consideration to which the entity is entitled to in exchange for the goods or services will be collected.

Step 2 – Identification of a separate performance obligation

At the start of the contract, Heidelberg Pharma is required to assess the goods or service that has been promised to the customer in accordance with IFRS 15.22 and must identify it as a performance obligation. A performance obligation is a promise to transfer distinct goods or services to the customer.

Step 3 – Identification of the transaction price

The transaction price is the amount of consideration to which an entity expects to be entitled in exchange for the transfer of the promised goods and services.

When making this determination, pursuant to IFRS 15.47 past customary business practices must be taken into consideration. Where a contract contains elements of variable consideration, the amount of variable consideration to which Heidelberg Pharma expects to be entitled under the contract will be estimated (IFRS 15.50). Variable consideration is also present if the Group's right to consideration is contingent on the occurrence of a future event (IFRS 15.51). According to IFRS 15.B63, revenue arising from sales or usage-based royalty revenue arising from licenses of intellectual property will be recognized only when and after the underlying sales or usage occur.

If the consideration is to be paid upfront or afterwards, the entity shall consider whether the contract contains a significant financing arrangement. If this is the case, the transaction price must be adjusted for the time value of money (IFRS 15.60). A practical expedient exists for cases where the period between performance and payment by the customer is likely to be less than twelve months (IFRS 15.63). However, Heidelberg Pharma did not use this practical expedient.

Step 4 – Allocation of the transaction price

According to IFRS 15.73, the transaction price is to be allocated to the individual performance obligations. If a contract consists of multiple performance obligations, the transaction price is to be allocated to the performance obligations in the contract on the basis of the stand-alone selling prices (IFRS 15.74). If a stand-alone selling price is not directly observable, this must be estimated.

Step 5 – Revenue recognition

According to IFRS 15.31, revenue will be recognized as control is passed, i.e. the ability to direct the use of and obtain substantially all of the remaining benefits from the asset. This may occur either over time or at a point in time.

IFRS 15.35 prescribes recognition of revenue over time if

- the customer continuously receives all of the benefits provided by the entity as the entity performs or
- an asset that the customer controls as the asset is created or enhanced
- the entity's performance creates an asset with no alternative use to the entity and the entity has an enforceable right to payment for performance completed to date.

If an entity does not satisfy its performance obligation over time, it satisfies it at a point in time. Revenue will therefore be recognized when control is passed at a certain point in time. According to IFRS 15.38, factors that may indicate the point in time at which control passes include, but are not limited to:

- the entity is currently entitled to receive payment for the asset or
- the customer has legal title to the asset or
- the entity has transferred physical possession of the asset or
- the customer has the significant risks and rewards related to the ownership of the asset or
- the customer has accepted the asset.

Heidelberg Pharma also generates sales revenue from the provision of preclinical services as part of a customer specific service business.

Heidelberg Pharma measures the progress of satisfaction, depending on the respective performance obligation, on the one hand on the basis of output methods, such as measuring the services already provided in relation to the contractually agreed services. On the other hand, input methods, such as the expense incurred in relation to the total expense at project level, are also used for revenue recognition. Changes to the progress estimates may therefore result in a restatement of revenue in the current period or future periods.

3.21.4 Contract balances

A contract asset is an entity's right to consideration in exchange for goods or services that the entity has transferred to a customer, other than receivables. The costs to obtain a contract must be recognized as an asset if the entity expects to recover those costs in the future and would not have incurred those costs if the contract had not been obtained.

Payments for performances not yet provided (e.g. as a prepayment) will be recognized as a contract liability. A contract liability corresponds to the liability of the company to transfer goods or services to a customer from whom it has received (or is yet to receive) consideration for these goods or services. If the customer pays consideration before the Group transfers goods or services to it, a contract liability will be recognized once the payment is made or falls due (whichever occurs first). Contract liabilities will be recognized as revenue once the Group meets its contractual liabilities.

3.21.5 Other income

In addition to the reversal of unused provisions from prior periods through profit or loss, other income relates to positive effects from exchange rate differences. In addition, income was generated from costs passed on to third parties to maintain patents in the context of out-licensing and from the sale of equity interests.

Government grants, such as those from the Federal Ministry of Education and Research (BMBF), are also included in other income. These government grants are used to support certain projects by reimbursing (portions of) research expenses from public funds. Reimbursement is based on the project costs incurred and non-refundable. However, it is usually linked to conditions such as remuneration for the work of scientific staff. The cash amounts received in advance are recognized over the underlying service period according to the research project's stage-of-completion.

3.22 Cost of sales

All costs directly related to generating sales revenue are reported as cost of sales. Cost of sales thus comprise staff costs, material costs and other costs directly attributable to manufacturing in reference to the respective goods and services sold.

3.23 Research and development

Research and development activities comprise all associated costs not related to the generation of sales revenue, including staff costs, consulting costs, depreciation, amortization and impairment losses, material and cost of sales, third party services, laboratory costs and fees for legal advice. They are recognized as expenses in the period in which they are incurred.

3.24 Administrative expenses

This expense item essentially comprises staff costs, operating costs, consumables, depreciation and amortization, and costs for external services and the stock listing.

Under IFRSs, the costs of a capital increase are closely related conceptually to the inflow of funds. Costs necessarily incurred as a result of and directly attributable to the capital increase are therefore not recognized as an expense in profit or loss, but taken to the capital reserves and offset directly against the capital received (IAS 32.37).

Administrative expenses therefore do not include expenses for capital increases.

3.25 Other expenses

Other expenses are incurred for business development, marketing and commercial market supply activities, and also include expenses arising from exchange rate differences.

3.26 Interest income

Any interest income is recognized in the statement of comprehensive income at the time it is generated, taking into account the effective yield on the asset.

3.27 Interest expense

Any interest expense generally comprises interest expense on non-current and current liabilities including the utilized shareholder loan and, since the initial application of IFRS 16, interest expenses on lease liabilities. Since the Group does not own qualifying assets, borrowing costs are recognized as an expense in the period in which they are incurred.

4 Segment reporting in accordance with IFRS 8

According to IFRS 8, operating segments are to be defined on the basis of the internal segment reporting, which is regularly reviewed by the Company's chief operating decision maker with respect to decisions on the allocation of resources to these segments and the assessment of their profitability. For the purpose of monitoring segment performance and allocating resources to segments, the Group's chief operating decision maker monitors the tangible, intangible and financial assets attributable to the individual segments.

Applying IFRS 8 Operating Segments, Heidelberg Pharma reported on three segments in up to and including the 2014 fiscal year: Customer Specific Research (Cx), Diagnostics (Dx) and Therapeutics (Rx). However, no business activities are currently conducted within the Group that differ materially in their risk/reward profiles. Furthermore, internal reporting is not broken down by operating segment. This means that Heidelberg Pharma no longer has any reportable business segments for internal management purposes. The Executive Management Board is currently in charge of all control variables and decisions of the Group as a whole. R&D activities focus on ATAC technology.

5 Financial risk management

5.1 Financial risk factors

Given its business activities, Heidelberg Pharma is exposed to certain risks, in particular market risk (including currency risks, interest and price risks), liquidity risk and default risk. Heidelberg Pharma's risk management focuses on the unpredictability of the financial markets and aims to minimize any potential adverse effects on the Group's ability to finance its business activities. However, Heidelberg Pharma does not use embedded derivatives or other derivative financial instruments to hedge against risks.

Responsibility for Groupwide risk management rests with the full Executive Management Board. It has implemented a Groupwide risk management system throughout the entire Heidelberg Pharma Group and monitors compliance with the risk management principles approved by the Supervisory Board with the help of the respective individuals responsible for the individual fields of risk identified as well as in cooperation with Controlling. The Executive Management Board specifies written principles for all risk management aspects. The Risk Officer identifies, assesses and communicates financial and corporate risks in close cooperation with the Executive Management Board. Moreover, all potential risks, particularly financial risks with substantial ramifications and a reasonable probability of occurring are closely monitored and discussed by the Company's Executive Management and Supervisory Boards at every quarterly reporting date.

The Groupwide risk management system serves to identify and analyze risks to which Heidelberg Pharma is exposed, making it possible to take appropriate countermeasures as necessary. The principles underlying the risk management system are reviewed and adjusted in a regular and ongoing process in order to ensure that any changes in and requirements of Heidelberg Pharma's business environment are covered. Internal policies and training ensure that every employee is aware of their tasks and duties in connection with the risk management system.

5.1.1 Market risk

5.1.1.1 Currency risk

Currency risks arise when future business transactions, or recognized financial assets or liabilities are denominated in a currency other than the Group's functional currency. Heidelberg Pharma operates internationally and cooperates with different customers and service providers worldwide and is therefore exposed to currency risks in connection with currency positions, mainly in US dollars, British pound, Swiss francs and, to a lesser extent, in other foreign currencies. This risk includes the relative decrease or increase of the euro vis-à-vis the other currencies during the period until payment of the liability or receivable.

As the currency risk is limited overall, Heidelberg Pharma has not concluded any hedging transactions but is attempting to achieve financial hedging by matching cash inflows and outflows in the same currency.

5.1.1.2 Price risk

Heidelberg Pharma is not exposed to risks from share price fluctuations related to equity securities, nor to risks from changes in the price of commodities, as these are not purchased.

5.1.1.3 Interest rate risk

Fluctuations in market interest rates affect the cash flows of floating-rate assets or liabilities or their fair values.

The shareholder loan is a liability to dievini, which since the beginning of the past year bears a fixed interest rate of 8.00% p.a. (previously 6.00%). Since Heidelberg Pharma does not hold any floating-rate or fixed-rate financial instruments as assets as of the reporting date other than bank balances, the Company is not exposed to any interest rate risks in this context. As interest rates on bank balances are rising again, Heidelberg Pharma is no longer subject to negative interest rate risks as in previous years. Given a lack of materiality, no interest rate sensitivity analysis was carried out.

5.1.2 Liquidity risk

Heidelberg Pharma has a detailed cash planning system, which is updated regularly, at least once a month. It serves to ensure that Heidelberg Pharma is aware of the available cash and the due dates of its liabilities at all times in order to be able to pay liabilities as they fall due. With regard to any long-term liquidity risks, please see note 6 "Going concern risks".

 Page 119

5.1.3 Default risk

The default risk is the risk of a business partner failing to meet its obligations within the scope of a financial instrument or customer framework agreement and this resulting in a financial loss. Within the scope of its operating business, the Group is exposed to default risks (particularly in case of trade receivables) as well as risks associated with financing activities, including those resulting from deposits with banks and financial institutions, foreign exchange business and other financial instruments. This conservative investment approach ensures that there is no nonpayment risk (see note 3.16).

 Page 108

The maximum default risk in connection with trade receivables is €979 thousand (previous year: €1,099 thousand) and corresponds to the trade receivables balance sheet item. The maximum default risk from other receivables is €1,345 thousand (previous year: €353 thousand). The default risk regarding the drawdown of cash is considered to be very low.

5.1.4 Cash flow and fair value interest rate risk from financial instruments

Heidelberg Pharma invests cash only in bank accounts or short-term fixed deposits. Market interest rate fluctuations may therefore affect the Company's ability to generate interest income from these financial instruments or avoid interest expenses in the form of deposit fees. Due to the improving interest rate situation for capital investors, the Company was able to generate interest cash flow in 2023.

Furthermore, Heidelberg Pharma maintains domestic credit balances only with major banks that belong to the German Deposit Insurance Fund and/or the German Savings Banks Organization's deposit assurance fund. The default risk in connection with these credit balances is therefore minimal.

5.2 Determination and measurement of fair value

The rules in IFRS 13 Fair Value Measurement must always be applied if fair value measurement is stipulated or permitted by another IAS or IFRS, or if disclosures about fair value measurement are required. The fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price). The fair value of a liability therefore reflects the default risk (i. e. own credit risk). Measurement at fair value assumes that the asset is being sold or the liability is being transferred in the principal market or – if such is unavailable – in the most favorable market. The principal market is the market with the largest volume and the greatest activity to which the entity has access.

Fair value is determined using the same assumptions and taking into account the same characteristics of an asset or a liability on which independent market participants would base their assessment. Fair value is a market-based, not entity-specific measurement. For non-financial assets, the fair value is determined based on the best possible use of the asset by a market participant.

Heidelberg Pharma uses the following hierarchy to determine and disclose the fair value of financial instruments (see note 20):

Level 1: Quoted (unadjusted) prices in an active market for identical assets and liabilities that the entity can access. The fair value of financial instruments traded on an active market is based on the quoted market price at the reporting date.

Level 2: Inputs, other than quoted prices in Level 1, that are observable for the asset or liability either directly (such as prices) or indirectly (derived from prices). The fair value of financial instruments not traded on an active market can be determined using a valuation technique. In this case, fair value is estimated on the basis of the results of a valuation technique that makes maximum use of market inputs, and relies as little as possible on entity-specific inputs. If all of the inputs required to determine fair value are observable, the instrument is classified in Level 2.

Level 3: Inputs for the asset or liability that are not observable. If important inputs are not based on observable market data, the instrument is classified in Level 3.

The carrying amounts of financial assets and liabilities such as cash, marketable securities as well as trade receivables and payables are equal to their fair value on account of the short maturities.

6 Going concern risk

As the Group's financing is expected to be ensured until mid-2025 based on the budget available from the executive directors, and the executive directors also expect the Group's operations to continue as planned beyond this date, the IFRS consolidated financial statements have also been prepared on a going-concern basis. These financial statements were therefore prepared on a going-concern basis in accordance with IAS 1.25.

If the executive directors are unable to implement the corporate strategy focused on the ATAC technology as planned and/or there is no option to obtain additional funding externally, this would jeopardize the ability of the Group and/or its consolidated companies to continue as a going concern. As a result, it cannot be ruled out that the companies of the Heidelberg Pharma Group could be unable to satisfy their payment obligations from mid-2025 and/or that they could become overindebted due to loss allowances resulting from a failure to meet targets, for example. This would jeopardize the Group's and/or consolidated entities' existence as a going concern and shareholders could lose some or all of their invested capital. This means that the Company may not be able to realize its assets and settle its liabilities in the regular course of business. As a result, there is currently significant uncertainty about the Group's and/or both Group companies' ability to continue as a going concern.

For information on the most important events and conditions that cast significant doubt on our company's ability to continue as a going concern, as well as on our plans and measures to deal with these events and conditions, please refer to our explanations in sections 8.3 "Going-concern risks" and 8.4.2 "Financial risks" of the Group's combined management report.

 Pages 65 and 67

7 Critical estimates and discretionary decisions

Application of the accounting policies described under note 3 requires management to assess facts, perform estimates and make assumptions with respect to the carrying amounts of assets and liabilities that cannot be readily determined from other sources.

 Page 96

Estimates and judgments are continually evaluated and are based on historical data and experience and other factors, including expectations of future events that are believed to be reasonable and realistic under the circumstances. The Company makes estimates and assumptions concerning the future. By their nature, the resulting estimates rarely reflect the exact subsequent circumstances. The estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next fiscal year are discussed below.

The assumptions underlying the estimates are regularly reviewed. Changes in the estimates that concern only a specific period are considered solely in that period; if the changes concerns both the current and subsequent reporting periods, then they are considered in all relevant periods.

Assumptions underlying the recognition of sales revenue (€9.9 million; previous year: €18.5 million) and other income (€6.9 million; previous year: €1.3 million) are in some cases based on estimates by the Executive Management Board.

Determining the expense in the reporting year from the measurement of stock options granted and the parameters underlying the impairment test for goodwill and IP R&D materially concern assumptions and judgments that are made by management and regularly reviewed.

It is generally possible that Heidelberg Pharma could deviate in the future from the assumptions made to date, which could necessitate a material adjustment of the carrying amounts of the assets or liabilities in question.

7.1 Expense from the granting of stock options

Page 147

Heidelberg Pharma recognizes expenses in the amount of €961 thousand (previous year: €554 thousand) under staff costs from the granting of stock options (see note 25). For this purpose, future assumptions need to be made regarding the different calculation parameters, such as the expected volatility of the share price, the expected dividend payment, the risk-free interest rate during option terms and staff and Executive Management Board turnover. Should these assumptions change, Heidelberg Pharma would need to change the relevant parameters and adjust its calculations and staff costs accordingly.

7.2 Impairment testing pursuant to IAS 36

Page 121

The impairment tests of both goodwill (see note 8) in the amount of €6,111 thousand (previous year: €6,111 thousand) and the IP R&D technology asset – which is not yet ready for use – in the amount of €2,493 thousand (previous year: €2,493 thousand) require estimating either the fair value less costs to sell or, alternatively, the recoverable amount as the value in use, determined on the basis of the cash-generating unit's expected future cash flows and a reasonable discount rate.

Factors such as revenue that is lower than expected and the resulting decrease in net cash flows as well as changes in the WACC could have a material effect on the determination of the value in use and/or the fair value less costs to sell and, in the final analysis, on the impairment of the goodwill or the IP R&D technology asset acquired.

7.3 Revenue recognition according to IFRS 15

7.3.1 Identification of performance obligations, allocation of the transaction price and determination of progress in discharge of performance obligations in service agreements

Heidelberg Pharma provides research services for a large number of customers and through various sets of agreements. Where these agreements relate to separate performance obligations which are distinct in the context of the agreement, the Group will allocate the transaction price to these individual service components on the basis of the stand-alone selling prices of the separate services. However, particularly in service agreements for research services which involve the provision of a large number of individual services which are remunerated by means of a fee which is paid in advance, either in whole or in part, and whose general purpose is to produce new research findings, Heidelberg Pharma has identified agreements where the services are in some cases strongly dependent on one another in the context of the agreement and has defined these as an individual performance obligation. Where further distinct performance obligations are included in this type of agreement, Heidelberg Pharma likewise allocates the transaction price on the basis of the stand-alone selling prices of the separate services. Heidelberg Pharma typically measures progress in the discharge of performance obligations on the basis of input methods, such as the ratio of the number of hours worked on research projects to the total number of hours estimated to be necessary for provision of the service in full. Changes to the progress estimates may therefore result in a restatement of revenue in the current period or future periods.

7.3.2 Determination of the method for the estimation of variable consideration and assessment of a limitation

Customer agreements frequently include additional remuneration which is associated with the achievement of research findings as well as other potential payments which are dependent on future events. Since this generally involves a small number of concrete events, which are partially dependent on research services, the Group estimates the variable consideration by determining the most probable amount which will be received on account of this. Heidelberg Pharma also reviews whether this variable consideration is subject to a limitation which would prevent recognition of revenue. Due to past experience and the inherent uncertainty associated with research activities, Heidelberg Pharma has concluded that potential remuneration as variable consideration will not be included in the determination of the transaction price at the start of the contract and that revenue can instead only be recognized upon fulfillment or when fulfillment is highly probable.

8 Impairment testing pursuant to IAS 36

The following is a description of the updated impairment testing carried out on the 30 November 2023 measurement date and in January 2024 (previous year: January 2023) of the acquired goodwill and the intangible and not yet ready to use (and therefore not yet amortized) technology asset (IP R&D) acquired in the course of the 2011 business combination with Heidelberg Pharma Research GmbH. This testing, which includes expected milestone payments and royalties, was modified in 2023 to include HDP-102 and HDP-201 in addition to the primary development programs HDP-101 and HDP-103.

For purposes of annual impairment testing, goodwill and the IP R&D technology asset are assigned to Heidelberg Pharma's lowest and only identifiable cash-generating unit (Heidelberg Pharma Research GmbH), which is monitored by the Executive Management Board as a cash-generating unit based on the management approach.

The impairment test described below is performed for the intangible asset (IP R&D technology asset) first and then for the acquired goodwill as a second step. The conditions covering the assumptions and underlying measurement parameters used for impairment testing in the measurement model are the same due to the fact that there is one consistent business purpose.

When measuring goodwill, the intangible asset is included in the underlying cash-generating unit for the purposes of comparing the carrying amount and recoverable amount.

Heidelberg Pharma AG acquired Heidelberg Pharma Research GmbH in March 2011. This acquisition generated goodwill of €6,111 thousand. Furthermore, an IP R&D asset consisting of the ADC technology with a net carrying amount of €2,493 thousand was identified as a not-yet-ready-for-use technology asset in the course of the purchase price allocation performed at the time. The carrying amounts as of 30 November 2023 correspond to the value at acquisition in each case. Despite the progress made in development, management believes that the general conditions under which Heidelberg Pharma Research GmbH operates have not changed significantly since 2011.

Impairment testing, and therefore the calculation of the recoverable amount as the value in use, is based on a model in which assumptions in respect of company planning are included and in which the present value of the cash flows forecast in this way are calculated to determine the value in use. The expected future cash flows from Heidelberg Pharma Research GmbH were discounted applying a company-specific risk-adjusted interest rate.

Planning as regards the service business of Heidelberg Pharma Research GmbH is based on annual sales revenue of €0.15 million in the period from 2024 to 2045, which represents an extrapolation of sales revenue generated in the past fiscal year. For the period after 2045, a terminal value of €1.0 million and a growth rate of 0% was taken into account for the service business. As in the previous year, this is calculated using €50 thousand in sales revenue per year over a twenty-year term.

The ADC technology platform is a cornerstone of Heidelberg Pharma Research GmbH's business model. It is expected to be used to optimize antibodies for specific customers and manufacture corresponding antibody-drug conjugates to improve cancer treatments in the future. Heidelberg Pharma Research intends to market the ADC technology to third parties and plans to generate sales revenue in the form of milestone payments and royalties. Particularly in the final phase of an ADC agreement (product license agreement), these payments are essential to the business model. They come due as soon as the contractual partner pursues development of a drug candidate and completes the approval process. The development phase comprises the execution of several clinical trials and can therefore take several years, which necessitates a second long-term planning phase for purposes of the impairment test.

The mid-term planning for the ADC/ATAC business used for the impairment test comprises detailed planning over a three-year period from 2024 to 2026 (clinical phases I and II). This is followed by a second, longer-term 19-year planning phase from 2027 to 2045 (clinical phase III, approval and market launch) that is based on model assumptions and continues the first planning phase.

Medium-term planning is based on the following assumptions in the model:

- Derivation of potential sales revenue based on comparison data of approved cancer drugs
- significant license income from 2026 onwards with sustained positive cash flows starting in the market phase
- maximum exploitation period for license income until 2045 through patents granted and new patent applications
- Discounts for the success rates of individual clinical phases based on scientific literature

In the first two years of the three-year period from 2024 to 2026, negative cash flows (discounted) are expected due in particular to the budgeted clinical phase I expenses for HDP-101. Provided all goes to plan, positive cash flows (discounted and adjusted for tax effects) are forecast as for 2026 due to the material royalties expected. Overall, a sustained positive cash flow is expected from 2030 onwards.

In the phase from 2024 to 2026, the model projects cumulative discounted cash flows (adjusted for tax effects) of €0.4 million in total, while for the phase starting in 2027 it assumes cumulative discounted cash flows (adjusted for tax effects) of €88.6 million (including terminal value). These assumptions are based on market studies conducted by an external service provider.

The carrying amount of the cash-generating unit analyzed was €19.1 million as of the reporting date (previous year: €17.5 million), which corresponds to the sum total of assets of Heidelberg Pharma Research GmbH. Allowing for the risks and opportunities arising from the business activities, the discount rate (WACC – Weighted Average Cost of Capital) used for the impairment test was 12.1% before taxes, as in the previous year, and 9.1% after taxes (2022: 8.3%).

These weighted average costs of capital are calculated using a risk-free interest rate (base rate) plus a market risk premium multiplied by the Company's beta factor. Individual risk premiums were not used because deductions for risk had already been factored into the planning.

If the discount rate were to increase by one percentage point, the value in use would decrease by €14.4 million.

The impairment test showed that there was no need to recognize impairment losses on goodwill or the IP R&D technology as of 30 November 2023.

The income tax rate underlying the cash flows in the model is 28.43%, as in the previous year.

Indications necessitating impairment testing of goodwill and of the IP R&D technology in certain situations in accordance with IAS 36.12 (g)/IAS 36.14 (b) did not arise during the past fiscal year.

The calculation of fair value and the cash flow forecast is based on unobservable inputs (Level 3), that of WACC on Level 2 (see note 5.2).

The cash flows included in the calculation are not influenced by internal transfer prices. There is an active market for the products and services of the cash-generating unit measured.

9 Property, plant and equipment

As of 30 November 2022 and 30 November 2023, property, plant and equipment comprised the following (see section 3.6):

Page 99

	Buildings on third-party land, technical equipment and machinery, other equipment €'000	Right-of-use assets			Total €'000
		Buildings €'000	Office equipment €'000	Operating and office equipment €'000	
2022 fiscal year					
Opening carrying amount	3,019	151	11	492	3,673
Additions	249	68	56	347	720
Disposals	(37)	0	(14)	(3)	(54)
Impairment	28	0	14	3	44
Reclassification	0	0	0	0	0
Depreciation	(410)	(77)	(16)	(163)	(666)
Net carrying amount as of 30 Nov. 2022	2,848	143	51	677	3,718
As of 30 Nov. 2022					
Cost	7,357	360	117	2,140	9,975
Accumulated depreciation	(4,509)	(218)	(66)	(1,464)	(6,257)
Net carrying amount as of 30 Nov. 2022	2,848	143	51	677	3,718

	Buildings on third-party land, technical equipment and machinery, other equipment €'000	Right-of-use assets			Total €'000
		Buildings €'000	Office equipment €'000	Operating and office equipment €'000	
2023 fiscal year					
Opening carrying amount	2,848	143	51	677	3,718
Additions	685	60	39	257	1,041
Disposals	(449)	(3)	(14)	(12)	(477)
Impairment	346	3	14	10	373
Reclassification	162	0	0	(162)	0
Depreciation	(463)	(86)	(27)	(231)	(807)
Net carrying amount as of 30 Nov. 2023	3,129	117	63	538	3,847
As of 30 Nov. 2023					
Cost	8,102	420	156	2,233	10,911
Accumulated depreciation	(4,973)	(303)	(93)	(1,695)	(7,064)
Net carrying amount as of 30 Nov. 2023	3,129	117	63	538	3,847

Unless allocable to cost of sales, depreciation totaling €807 thousand (previous year: €666 thousand) was recognized in profit or loss as R&D costs and as general and administrative expenses. Loss allowances (or write-downs) of €373 thousand and €44 thousand were recognized on the value in use in fiscal years 2023 and 2022, respectively. This is essentially a valuation allowance for the historical costs of a laboratory instrument in the run-up to further marketing. Unless allocable to cost of sales, these were also recognized in profit or loss as R&D costs and as general and administrative expenses. Heidelberg Pharma has not pledged any property, plant or equipment as collateral for liabilities. There are no contractual obligations for the acquisition of property, plant and equipment.

An amount of €112 thousand in depreciation and €12 thousand in interest expense was recognized for right-of-use assets in the fiscal year ended (previous year: €93 thousand and €9 thousand, respectively).

No expense relating to short-term leases pursuant to IFRS 16.53 (c) was recognized in 2022 and 2023. As in the previous year, the expense relating to leases of low-value assets according to IFRS 16.53 (d) was €1 thousand.

Total cash outflows for leases in 2023 amounted to €124 thousand and €102 thousand in the previous year (IFRS 16.53 (g)). In the cash flow statement, these outflows were split up into interest paid and a principal of lease liabilities. While the interest paid (€12 thousand) will continue to be allocated to the net change in cash from operating activities, the principal portions will be included in financing activities (€112 thousand) (previous year: €9 thousand and €93 thousand, respectively). Payments made within the scope of short-term and/or low-value leases are allocated to operating cash flow, in accordance with 16.50(c).

10 Intangible assets

As of 30 November 2022 and 30 November 2023, intangible assets comprised the following:

	Software €'000	Licenses €'000	Patents €'000	Other intangible assets €'000	Intangible assets not yet ready for use €'000	Goodwill €'000	Total €'000
2022 fiscal year							
Opening carrying amount	169	0	238	0	2,493	6,111	9,011
Additions	15	0	13	0	0	0	29
Disposals	0	0	0	0	0	0	0
Impairment	0	0	0	0	0	0	0
Reclassification	0	0	0	0	0	0	0
Amortization	(75)	0	(16)	0	0	0	(91)
Net carrying amount as of 30 Nov. 2022	110	0	235	0	2,493	6,111	8,949
As of 30 Nov. 2022							
Cost	976	1	1,604	320	2,493	6,111	11,505
Accumulated amortization	(866)	(1)	(1,369)	(320)	0	0	(2,556)
Net carrying amount as of 30 Nov. 2022	110	0	235	0	2,493	6,111	8,949
2023 fiscal year							
Opening carrying amount	110	0	235	0	2,493	6,111	8,949
Additions	15	0	5	0	0	0	20
Disposals	0	0	0	0	0	0	0
Impairment	0	0	0	0	0	0	0
Reclassification	0	0	0	0	0	0	0
Amortization	(54)	0	(18)	0	0	0	(72)
Net carrying amount as of 30 Nov. 2023	71	0	222	0	2,493	6,111	8,897
As of 30 Nov. 2023							
Cost	991	1	1,609	320	2,493	6,111	11,525
Accumulated amortization	(920)	(1)	(1,386)	(320)	0	0	(2,628)
Net carrying amount as of 30 Nov. 2023	71	0	222	0	2,493	6,111	8,897

All of the additions stem from separate acquisitions. Unless allocable to cost of sales, €72 thousand (previous year: €91 thousand) in amortization were recognized in profit or loss as research and development costs and as general and administrative expenses. No loss allowances (or write-downs) were recognized in fiscal years 2023 and 2022.

As a rule, software and patents and licenses as part of intangible assets have a finite useful life.

There were no currency effects from the translation of foreign currencies into the reporting currency for any group of intangible assets. Heidelberg Pharma has not pledged any intangible assets as collateral for liabilities. The Company has no contractual obligations for the acquisition of intangible assets.

10.1 Goodwill

The goodwill recognized arises from the business combination of Heidelberg Pharma AG with Heidelberg Pharma Research GmbH completed in 2011. The assets and liabilities acquired as well as the deferred tax assets and liabilities are recognized separately as of the acquisition date.

Using the acquisition method, goodwill of €6,111 thousand was identified in connection with the acquisition of Heidelberg Pharma and the subsequent purchase price allocation; it will be tested for impairment annually in accordance with IAS 36 (see note 8).

 Page 121

10.2 Intangible assets not yet ready for use

In the purchase price allocation carried out in 2011 in connection with the acquisition of Heidelberg Pharma Research GmbH, the novel ADC technology still under development and not yet ready for use was defined as IP R&D and identified as an intangible asset. The carrying amount is €2,493 thousand, as in the previous year.

The Company believes that the ADC technology has the potential to improve the efficacy of many antibody-based compounds, including those marketed.

This technology will not be amortized until its development has been successfully completed and the technology can thus be deemed ready for use, i.e. a therapeutic agent can be marketed. Subsequent costs are recognized through profit and loss as research and development expenses. They are not capitalized pursuant to IAS 38 in keeping with the treatment of other development costs and given Heidelberg Pharma's industry-related specificities. It is typical for the biotechnology industry that particularly the technical feasibility pursuant to IAS 38.57(a) as well as any future economic benefits pursuant to IAS 38.57(c) are uncertain, even in projects where the research has largely been completed. This IP R&D technology asset was tested for impairment as of 30 November 2023 during the impairment test carried out in January 2024. Heidelberg Pharma has not found any indication of impairment of this intangible asset.

10.3 Patents and licenses

There was no need to write down the patents and licenses of the Heidelberg Pharma Group in the fiscal year.

10.4 Software

Software includes various capitalized office and laboratory software items written down over their useful lives.

11 Other non-current financial assets

The other non-current financial assets in the amount of €975 thousand (previous year: €35 thousand) mainly include receivables in connection with the sale of shares in Emergence Therapeutics AG, Duisburg, (Emergence) (€940 thousand) and security for leased equipment and property in the amount of €30 thousand (previous year: €30 thousand). The latter are each deposited in bank accounts. As in 2022, other items accounted for €5 thousand.

Heidelberg Pharma expects no non-current financial assets to be realized within the next 12 months.

12 Inventories

The inventories and work in progress recognized at cost (2023: €10,488 thousand; previous year: €4,585 thousand) mainly concern work in progress and raw materials, consumables and supplies, which increased in the course of the supply of Amanitin to the cooperation partners (supply model) and the build-up of own inventories.

	30 Nov. 2023 €'000	30 Nov. 2022 €'000
Raw materials, consumables, and supplies	3,351	2,094
Work in progress	6,606	6
Prepayments made	531	2,485
Inventories	10,488	4,585

No inventories were pledged as collateral for liabilities. Heidelberg Pharma projects that all inventories will be used up within the next 12 months and work in progress/unfinished goods will be completed/realized.

13 Prepayments

Prepayments in the sense of prepaid expenses are comprised as follows:

	30 Nov. 2023 €'000	30 Nov. 2022 €'000
Prepayments related to clinical development	20	159
Prepayments to other service providers	363	354
Prepayments	383	513

All prepayments made are of a current nature (< 12 months).

14 Trade receivables and contract assets

The trade receivables and the contract assets arising in the past year amounting to €979 thousand (previous year: €1,099 thousand) mainly result from collaborations including related material supplies and services invoiced by Heidelberg Pharma Research GmbH. Unlike in the previous year, no contract assets were to be recognized as of the 2023 reporting date.

	30 Nov. 2023 €'000	30 Nov. 2022 €'000
Trade receivables	979	973
Contract assets	0	126
Total	979	1,099

The aging structure of trade receivables only (not including contract assets) as of the reporting date was as follows:

	30 Nov. 2023 €'000	30 Nov. 2022 €'000
0–30 days	965	231
30–90 days	14	742
More than 90 days	0	0
Total	979	973

As of the balance sheet date, trade receivables of €14 thousand were past due and remained unpaid after more than 30 days (previous year: €742 thousand). Heidelberg Pharma expects all trade receivables and contract assets to be realized within the next 12 months. Due to the manageable debtor structure, no general valuation allowance was recognized for reasons of materiality.

15 Other receivables

Other receivables are comprised as follows:

	30 Nov. 2023 €'000	30 Nov. 2022 €'000
VAT claim	240	218
Other tax receivables	607	0
Other items	498	135
Other receivables	1,345	353

Heidelberg Pharma expects all other receivables to be realized within the next 12 months.

16 Cash

	30 Nov. 2023 €'000	30 Nov. 2022 €'000
Cash	43,439	81,329
Total	43,439	81,329

Cash consists exclusively of bank balances and due to the cash outflows from operating activities was down considerably on the prior-year figure, which had been extraordinarily high as a result of the capital increase implemented with Huadong.

The following table shows the change in the Group's liabilities from financing activities, including cash changes during fiscal year 2023:

	1 Dec. 2023 €'000	New loans (+) or repayment (-) of loans from affiliated companies €'000	Principal portion of lease payments €'000	Liabilities from new leases €'000	30 Nov. 2023 €'000
Loans from affiliated companies	15,000	-10,000	-	-	5,000
Lease liabilities	195	-	(112)	101	184

17 Equity

As of 30 November 2023, the share capital (or subscribed capital) consisted of 46,604,977 (30 November 2022: 46,584,457) no par value bearer shares with a notional value of €1.00 per share (fully paid-up).

The increase of 20,520 shares is due to the exercise of stock options during the fiscal year 2023.

With regard to contingent and authorized capital, please refer to our disclosures in section 7.2 "Disclosures under Section 289a (1) and 315a (1) of the German Commercial Code as well as explanatory report" of the combined management report of the Group.

The following shares were issued or created by way of exercising stock options in the reporting period or in the previous year:

Issue date	Entry in the Commercial Register	Number of shares	€
On 30 Nov. 2021		34,175,809	34,175,809
30 Aug. 2022	2 Sep. 2022	12,408,648	46,584,457
On 30 Nov. 2022		46,584,457	46,584,457
Exercise of stock options in fiscal year 2023	28 Dec. 2023	20,520	20,520
On 30 Nov. 2023		46,604,977	46,604,977

The arithmetical nominal amount and any premium on the issue of shares are reported under “subscribed capital” and “capital reserves” respectively. For the most part, the capital reserve includes the premiums exceeding the par value from the issue of new shares from capital increases as well as the share-based payment granted as consideration to employees in the form of stock options. The premium on all stock options exercised during the year amounted to €39 thousand.

In accordance with IFRS 2, equity-settled share-based payments to employees are recognized in the capital reserve in the amount of the share earned as an offsetting item to the staff costs incurred. A total of €961 thousand (previous year: €554 thousand) was recognized in this context in the period under review (see note 25).

Page 147

In the context of the sale of shares in Emergence, an amount of €2,022 thousand had to be recognized under other reserves in accordance with IFRS 9 as an equity instrument measured at fair value through other comprehensive income (FVtOCI). Please refer to note 23 for further details.

Page 143

As of the reporting date of 30 November 2023, the capital reserves thus amounted to €312,454 thousand (previous year: €311,454 thousand) and other reserves came to €2,022 thousand. There were no other reserves to be recognized in the previous fiscal year.

Taking into account the cumulative losses of €311,741 thousand accumulated from the date of the Company's establishment through to the reporting date (previous year: €291,394 thousand), the equity of Heidelberg Pharma amounted to €49,340 thousand (previous year: €66,644 thousand).

18 Non-current liabilities

18.1 Lease liabilities (non-current)

Non-current lease liabilities – which must be reported separately – total €70 thousand (previous year: €100 thousand) and consist of liabilities for office, laboratory and archive space as well as vehicles.

18.2 Contract liabilities (non-current)

There were non-current contract liabilities at the end of the 2023 reporting period amounting to €1,168 thousand (previous year: €5,903 thousand). These arose as a result of the upfront payment of USD 20 million from Huadong for exclusive development and commercialization rights to the ATAC candidates HDP-101 (BCMA ATAC) and HDP-103 (PSMA ATAC) for parts of Asia; they decreased due to the passing of time and the smaller non-current portion resulting from this.

19 Current liabilities

19.1 Trade payables

	30 Nov. 2023 €'000	30 Nov. 2022 restated retrospectively €'000	30 Nov. 2022 reported €'000
Trade payables – Equity and liabilities			
Current trade payables	3,641	3,051	3,051
Current accrued trade payables	4,234	2,701	0
Trade payables	7,875	5,751	3,051

Current trade payables increased as of the reporting date from €3,051 thousand in fiscal year 2022 to €3,641 thousand at the end of the 2023 reporting period.

The amount of accrued current trade payables recognized for the first time on an ongoing basis under trade payables is €4,234 thousand.

Heidelberg Pharma recognizes accrued current trade payables for goods and services where it has a present obligation arising from the supply of goods and services received. Accruals were recognized in the amount of the payment outflow required to fulfill the current obligation. Most obligations in this category relate to research and development costs of service providers.

The retrospective restatement of the comparative period made during the year under review amounts to €2,701 thousand. The reported trade payables figure for the previous year is €3,051 thousand. As a result, the restated trade payables figure for the previous year is €5,751 thousand.

For more information, see sections 3.5 and 19.5.

19.2 Lease liabilities (current)

Current lease liabilities totaled €113 thousand (previous year: €94 thousand) and consist of liabilities for office, laboratory and archive space as well as vehicles.

19.3 Contract liabilities (current)

Current contract liabilities decreased from €5,017 thousand in the previous year to €4,965 thousand, mainly due to the advance payment from Huadong.

19.4 Financial liabilities

Financial liabilities in the amount of €5,648 thousand (previous year: €15,786 thousand) are attributable to the dievini shareholder loan, which since the start of fiscal year 2023 has been carrying 8.00% interest (previously 6.00%). An amount of €10,000 was repaid on this loan during the year. The financial liability as of the respective balance sheet date therefore consists of a loan amount of €5,000 thousand and €648 thousand in interest liabilities (2022: €15,000 thousand/€786 thousand).

19.5 Other current liabilities

Other current liabilities included the following:

	30 Nov. 2023 €'000	30 Nov. 2022 restated retrospectively €'000	30 Nov. 2022 reported €'000
Obligation for holidays not taken	396	406	406
Social security and other taxes	225	294	294
Employee bonuses and profit-sharing bonuses	418	332	332
Costs of preparing the financial statements and tax advisory costs	134	253	253
Accrued trade payables	0	0	2,701
Other current liabilities	1,173	1,285	3,986

Heidelberg Pharma retrospectively changed its accounting policies relating to the recognition of accrued liabilities during the year under review. As shown in the table, this resulted in a reclassification of €2,701 thousand in accrued liabilities from the comparative period to the balance sheet item "Trade payables". These changes are explained in detail in sections 3.5 and 19.1.

Employee bonuses are granted depending on the performance of the Company and of individual employees or members of the Executive Management Board, and, once determined, are due for payment. They are recognized as an expense when the remunerated service is provided by the employee. The portion of the expense in excess of the payments already made is presented as an accrued liability as of the reporting date. The amount is attributable to the assumption that slightly lower bonuses will be paid than in the past fiscal year.

20 Other disclosures on financial instruments

In summary, Heidelberg Pharma applied the following classification to financial assets:

20.1 Fair values

Carrying amounts and fair values follow from the table below. In addition, the financial instruments were broken down into categories pursuant IFRS 9 (see note 3.15):

Page 103

30 November 2023	IFRS 9 measure- ment category	Carrying amount €'000	Fair value €'000	Fair value by level			Total
				Level 1	Level 2	Level 3	
Assets							
Trade receivables	AC	979	979				
Other receivables	AC	1,345	1,345				
Cash	AC	43,439	43,439				
Contingent purchase price receivables	FVtPL	0	0			0	0
Liabilities							
Trade payables	AC	(7,875)	(7,875)				
Lease liabilities (current/non-current)	AC	(184)	-				
Financial liabilities	AC	(5,648)	(5,648)				

Trade receivables all have remaining maturities of less than one year. No default risks are discernible in connection with the assets.

The remaining purchase price receivables from the sale of the equity interest in Emergence are presented as other receivables (current/non-current).

The contingent purchase price receivables comprise non-current receivables subject to conditions precedent from the sale of the equity interest in Emergence.

For full details on the sale of the shares in Emergence, please refer to note 23.

Page 143

The carrying amounts of liabilities such as cash and trade payables correspond to their fair values on account of their current nature.

Interest expense of €648 thousand arose from financial liabilities carried at amortized cost (previous year: €786 thousand).

As of 30 November 2022, the figures were as follows:

30 November 2022	IFRS 9 measure- ment category	Carrying amount €'000	Fair value €'000	Fair value by level			
				Level 1	Level 2	Level 3	Total
Assets							
Trade receivables	AC	1,099	1,099				
Other receivables	AC	353	353				
Equity investment in Emergence	FVtOCI	0	0			0	0
Convertible bond, Emergence	FVtPL	0	0			0	0
Cash	AC	81,329	81,329				
Liabilities							
Trade payables	AC	(5,751)	(5,751)				
Lease liabilities (current/non-current)	AC	(195)	-				
Financial liabilities	AC	(15,786)	(15,786)				

20.2 Fair value hierarchy levels

In accordance with IFRS 13.76 ff., hierarchy levels are to be used to determine and disclose the fair value of financial instruments (see note 5.2).

 Page 118

Fair value is determined using the same assumptions and taking into account the same characteristics of an asset or a liability on which independent market participants would base their assessment.

As of the balance sheet date, the Company held no underlying financial instruments measured at fair value. In 2023 and 2022, there were no reclassifications of items between fair value hierarchy levels.

For assets that the Group holds and liabilities that the Group reports, the carrying amounts are generally used as approximate fair values. The fair value of financial liabilities was determined using cash flows discounted at the risk-adjusted market interest rate; it is a fair value of hierarchy level 2.

20.3 Risks from financial instruments

In respect of risks from financial instruments, see for example the section on the management of financial risks (see note 5).

 Page 116

Financial instruments with an inherent default and liquidity risk mainly comprise cash, financial assets as well as other receivables. The carrying amounts of the financial assets generally reflect the maximum default risk.

Liquidity risk

Most of the cash (€43,439 thousand; previous year: €81,329 thousand) are denominated in euros, with a smaller amount denominated in US dollars and British pounds, and have been invested essentially with banks belonging to the German Deposit Insurance Fund and/or the deposit assurance fund of the German Savings Banks Organization. But Heidelberg Pharma monitors the positions held and the respective bank's credit rating on an ongoing basis nonetheless. No such risks were identifiable at the reporting date.

Since the Company's cash as of the reporting date were invested exclusively in demand deposits and current accounts, the Company believes there is no interest rate risk and cash would not react sensitively to interest rate changes.

The Company is exposed to a liquidity risk given both its business model and the still insufficient cash flows from the marketing of its own products and services. Heidelberg Pharma employs a rolling, monthly cash flow planning and age analysis in order to be able to recognize liquidity risks in due time. Heidelberg Pharma was able to meet its payment obligations at all times in the fiscal year just ended.

The Group's financial liabilities have the following maturities. The disclosures are based on contractual, undiscounted payments.

30 November 2023	Due on demand €'000	Up to 3 months €'000	3 to 12 months €'000	1 to 5 years €'000	More than 5 years €'000	Total €'000
Trade payables	69	7,806				7,875
Other liabilities	226	777	171	–	–	1,174
Financial liabilities	0	5,648	0	0	0	5,648

30 November 2022	Due on demand €'000	Up to 3 months €'000	3 to 12 months €'000	1 to 5 years €'000	More than 5 years €'000	Total €'000
Trade payables	146	5,587	18	0	0	5,751
Other liabilities	43	1,142	100	0	0	1,285
Financial liabilities	0	15,786	0	0	0	15,786

Page 158

With regard to the maturity analysis for lease liabilities, please see note 30.

Default risk

The company in question controls the default risk arising from receivables due from customers in line with the Group's policies, procedures and controls for the management of the default risk for customers. However, the customer's credit quality is not checked.

The trade receivables (€979 thousand; previous year: €973 thousand) at the close of the fiscal year were attributable to business customers; they were mainly invoiced as of the 30 November 2023 reporting date or immediately preceding it. Trade receivables in the amount of €14 thousand were past due as of the reporting date (see note 14). However, no bad debt allowances are necessary in the Executive Management Board's view because Heidelberg Pharma does not expect any default risks to arise.

Page 129

Market risk

Heidelberg Pharma is also exposed to a market risk, e. g. from changes in interest rates, and a currency risk from the euro's exchange rate vis-à-vis other currencies. This exchange rate risk includes the relative decrease or increase of the euro vis-à-vis the other currencies during the period until payment of the liability or receivable. Heidelberg Pharma reviews the need for foreign currency hedges on an ongoing basis during the year but does not engage in any hedging. Instead, the Company aims to pay liabilities in foreign currencies using existing bank balances in the respective currency in order to keep the risk of exchange rate fluctuations as low as possible.

As of 30 November 2023, there were foreign currency risks concerning trade payables in the amount equivalent to €46.6 thousand in US dollars (USD), €20.9 thousand in Swiss francs (CHF) and €90.4 thousand in British pounds (GBP). Any increase or decrease in the euro by 10% compared to the given foreign currency would have had the following effect on earnings and equity in the fiscal year ended:

	Liabilities in €'000	10% increase in €'000	10% decrease in €'000
Euro vs. US dollar	46.6	4.2	(5.2)
Euro vs. Swiss franc (CHF)	20.9	1.9	(2.3)
Euro vs. British pound (GBP)	90.4	8.2	(10.0)

In 2023 and 2022, a significant portion of the sales revenue was affected by the respective USD/euro exchange rate (see note 21). These were one-off cash transactions that were translated at the transaction date exchange rate, and recognized as revenue or accrued. The Company generated sales revenue equivalent to €5.1 million in USD in the 2023 fiscal year (previous year: €13.9 million).

Page 140

An increase of 10% in the average USD exchange rate in fiscal year 2023 as part of a sensitivity analysis (i.e. the USD appreciates against the euro) would have lifted sales revenue by €1,095 thousand (previous year: €1,543 thousand). A decrease of 10% in the average USD exchange rate (i.e. the USD depreciates against the euro) would have depressed sales revenue by €896 thousand (previous year: €1,263 thousand). Sales revenue in foreign currencies other than the US dollar was not generated in 2022 or 2023.

Heidelberg Pharma's cash held in foreign currencies (USD and GBP) are exposed to foreign currency risks. Heidelberg Pharma monitors the USD exchange rate throughout the year in order to intervene as necessary by selling or buying foreign currencies without however hedging such transactions by means of derivative financial instruments.

Cash in USD as of the 30 November 2023 reporting date were equivalent to €881 thousand (30 November 2022: €8,774 thousand). The amount held in British pounds was equivalent to €492 thousand (30 November 2022: €2,104 thousand).

Non-derivative financial liabilities in the form of trade payables must be classified as current. As a rule, trade payables are due within one month.

Heidelberg Pharma for the first time generated a significant net income from financial instruments in fiscal year 2023 through the gain on the sale of the investment in Emergence.

21 Sales revenue

Sales revenue (or revenue from contracts with customers) of the Heidelberg Pharma Group in the fiscal year just ended totaled €9,859 thousand (previous year: €18,514 thousand).

	2023 €'000	2022 €'000
ATAC technology sales revenue	9,745	17,477
Sales revenue from portfolio out-licensing	0	498
Service business sales revenue	114	539
Sales revenue	9,859	18,514

At €4.6 million, almost half of the increase in sales revenue stems from granting the development and commercialization rights to HDP-103 for parts of Asia to Huadong (previous year: €8.2 million).

There was also sales revenue of €5.1 million from the ATAC business and €0.1 million from the service business (previous year: €9.3 million and €0.5 million, respectively).

Unlike in 2023, a milestone payment of €0.5 million became due in 2022 for an earlier out-licensing.

The sales revenue realized from ATAC technology was recognized either at a point in time or over time, depending on the respective contractual arrangements. Sales revenue from out-licensing was recognized at a point in time, sales revenue from service business was recognized over time.

Sales revenue which was exclusively allocated to the current contract liabilities as of 1 December 2023 was fully realized in the amount of €5.0 million in fiscal year 2022 (previous year: €0.5 million).

The transaction price allocated to the (unfulfilled or partially unfulfilled) remaining performance obligations results from expected sales revenue from the ATAC technology in the amount of €6,133 thousand (previous year: €10,920 thousand).

Heidelberg Pharma estimates that €4,965 thousand of the total transaction price of €10,920 thousand, which was recognized as a contract liability as of 30 November 2022, will be realized in the 2023 fiscal year.

Regional distribution

The following table shows the regional distribution of 2023 sales revenue in terms of a customer's or collaboration partner's domicile:

Region	2023		2022	
	€'000	%	€'000	%
Germany	60	1%	549	3%
Europe	145	1%	52	0%
of which CH	145	–	52	–
USA	4,672	47%	8,982	49%
Rest of the world	4,982	51%	8,931	48%
of which China	4,740	–	8,204	–
Total	9,859	100%	18,514	100%

All sales revenue was generated in euros (€4.8 million) and US dollar (€5.1 million) in 2023.

More than 10% of sales revenue (€4.7 million) was generated in each case with two US companies in 2023 under a research and license agreement. In addition, more than 10% of sales revenue was generated with a Chinese company as part of a strategic partnership (also €4.7 million).

In the previous fiscal year, more than 10% of sales revenue (total of €17.1 million) was generated in each case with two US companies under a research and license agreement and with a Chinese company.

	30 Nov. 2023 €'000	30 Nov. 2022 €'000
Contract balances		
Trade receivables	978	973
Contract assets	0	126
Contract liabilities	6,133	10,920

Trade receivables are not interest-bearing and, as a rule, they are due within a period of between 30 and 90 days. No loss allowances were recognized in 2023 and 2022. As a result, the closing balance of the allowances on trade receivables remained at €0 thousand.

The contract liabilities usually comprise current and non-current prepayments for cooperation agreements and public funding schemes.

22 Other income

Other income (€6,942 thousand; previous year: €1,346 thousand) comprises the following items:

Other income	2023 €'000	2022 €'000
Income from investments	5,923	0
Income from exchange rate gains	6	963
Income from grants	55	124
Accrued liabilities not utilized to date	634	69
Proceeds from non-monetary benefits	46	47
Income from passing on patent costs	13	42
Income from sales of fixed assets	31	15
Reimbursement under the Expenditure Compensation Act	75	69
Other items	159	17
Total	6,942	1,346

As a result, other income was up significantly year-over-year. After being affected by exchange rate gains in the previous year, other income was significantly impacted by the sale of Emergence shares in 2023, which raised €5.9 million. Please refer to note 23 for further details.

Largely stable exchange rates for relevant currencies meant that these gains were considerably lower at €6 thousand compared to the previous year (€963 thousand).

There were also German and European grants to support Heidelberg Pharma Research GmbH projects in the amount of €55 thousand (previous year: €124 thousand).

Furthermore, income of €634 thousand was recognized from the reversal of unused accrued liabilities (2022: €69 thousand).

All other items such as proceeds from non-monetary benefits, income from passing on patent costs, from sales of fixed assets, from the Expenditure Compensation Act (Aufwendungsausgleichsgesetz, AAG) and from all other items amounted to €0.3 million (previous year: €0.2 million).

23 Sale of shares in Emergence Therapeutics AG

In November 2019, the Company had acquired an equity interest in Emergence Therapeutics AG through its subsidiary Heidelberg Pharma Research GmbH together with French and German investors. This equity interest was initially measured at cost, which amounted to the original capital contribution of €13 thousand for 25% of the ordinary shares of Emergence. No undisclosed reserves or liabilities were identified as of the date of acquisition. In addition, no goodwill arose.

After the Group ceased to have a supervisory board appointment and therefore significant influence (and Emergence abandoned a key technology provided by Heidelberg Pharma), Heidelberg Pharma Research GmbH still held a 1.49% interest as of the prior-year reporting date, 30 November 2022. This equity interest was classified as FVtOCI in the previous year (see information on the classification of financial assets, section 3.15). This classification was made due to considerations based on Heidelberg Pharma's business model. The equity interest was measured at a fair value of €0 as of the prior-year reporting date, 30 November 2022.

 Page 103

Heidelberg Pharma disposed of its minority interest in Emergence in August of the 2023 reporting year. The pharma company Eli Lilly and Company, Indianapolis, Indiana, USA, acquired all outstanding shares in Emergence. At the time of sale, approximately 25% of the 2.05% stake sold consisted of the original equity investment, while 75% was attributable to a convertible bond converted in connection with the sale (see below). The purchase price agreed for the sale, for which there are various payment arrangements, totaled up to USD 12.3 million for Heidelberg Pharma (approx. €11.4 million).

The provisional total selling price breaks down as follows:

- In the reporting period, the Group received a cash inflow of €6.8 million from the sale. The cash was mainly used for a loan repayment of €5.0 million on the shareholder loan extended by dievini.
- A purchase price receivable of €1.2 million was also recognized based on its cost/nominal amount as of the reporting date. This was classified as a financial instrument at amortized cost (AC). The receivable breaks down into a non-current component of €1.0 million and a current component of €0.2 million. Due to standard legal warranties agreed in the contract of sale, there are risks associated with the receivable. The executive directors of Heidelberg Pharma consider the probability of a subsequent reduction in the purchase price under these provisions to be low.
- There are also two purchase price claims totaling USD 4.1 million, which are subject to conditions precedent. The conditions under which these additional claims may arise are based on the achievement of contractually stipulated long-term, non-financial targets by Emergence. Each of the receivables is classified as a contingent purchase price receivable at FVtPL and measured at fair value through profit or loss. As of the end of the reporting period, the fair value of each of the contingent purchase price receivables was €0.

As a result of this purchase price obtained (excluding two contingent purchase price claims measured at a fair value of €0 each), an amount of €2.0 million was recognized in other comprehensive income when the fair value of the equity interest classified as at FVtOCI was remeasured in the course of the sale. The purchase price achieved therefore functions as a Level 3 input as set out in IFRS 13.

In addition to its equity interest in Emergence, Heidelberg Pharma also held a convertible bond issued by Emergence. This debt instrument classified as at FVtPL was measured at a fair value of €0 as of the prior-year reporting date of 30 November 2022.

Due to the indicative purchase price, the convertible bond was measured at a pro-rated fair value of €5.9 million in August 2023. The change in value arising from fair value measurement was recognized in profit or loss as other operating income. The purchase price achieved for the entire equity investment therefore functions as a Level 3 input as set out in IFRS 13.

According to the bond conditions, the convertible bond was converted into an equity instrument by Heidelberg Pharma as part of the acquisition and change of control at Emergence, with a 1:1 conversion ratio. No premium was required to acquire the new equity instrument in accordance with the bond conditions. The entire equity interest, including the converted bond, was then sold.

The newly added equity instrument was classified as a separate tranche at FVOCI based on Heidelberg Pharma's business model in accordance with IFRS 9 and recognized at a fair value of €5.9 million.

Following the bond's conversion, as shown above, and before derecognizing all ownership interests in Emergence, Heidelberg Pharma held a 2.05% share. The disproportionately low increase in Heidelberg Pharma's ownership interest after exercising the conversion rights associated with the convertible bond is due to the dilution of its equity interest in Emergence, as third-party bondholders also exercised their conversion rights in the course of Eli Lilly's acquisition.

The carrying amount of the equity instruments sold and derecognized in accordance with the rules in IFRS 9 was €8.0 million at the date of the sale.

24 Types of expenses

The statement of comprehensive income breaks down operating expenses into the following categories:

- Cost of sales
- Research and development costs
- Administrative costs
- Other expenses

Operating expenses including depreciation and amortization rose marginally to €38.0 million compared to 2022 (€37.0 million).

Operating expenses	2023 € million	2022 € million
Cost of sales	3.3	4.7
Research and development costs	28.1	26.4
Administrative costs	5.2	4.8
Other expenses	1.4	1.1
Total	38.0	37.0

The cost of sales concerns the Group's costs directly related to sales revenue. These costs were mainly related to expenses for customer-specific research and for the supply of Amanitin linkers to licensing partners. At €3.3 million, they were down on the prior year (€4.7 million) and accounted for 8% of operating expenses.

Research and development costs were slightly higher year-over-year at €28.1 million (previous year: €26.4 million). This increase is due in particular to the cost-intensive production of antibodies for successor candidates. At 74% of operating expenses, R&D remained the largest cost item.

Administrative costs were €5.2 million, an increase on the prior year (€4.8 million), and accounted for 14% of operating expenses.

These include staff costs of €3.0 million (previous year: €2.6 million), of which €0.3 million (previous year: €0.2 million) concerned expenses from stock options in the reporting period. This line item also includes legal and operating consulting costs in the amount of €0.8 million (previous year: €1.1 million) and expenses related to the Annual General Meeting, Supervisory Board remuneration and the stock market listing (€0.7 million; previous year: €0.6 million). Other items amounted to €0.7 million (previous year: €0.5 million).

Other expenses for business development, marketing and commercial market supply activities, which mainly comprise staff and travel costs, increased to €1.4 million year-over-year (previous year: €1.1 million) and made up 4% of operating expenses.

The following expenses are recognized in the statement of comprehensive income:

	2023 €'000	2022 €'000
Staff costs	11,381	9,938
Travel costs (incl. conference fees)	494	379
Office costs (incl. utilities and maintenance)	764	543
Other internal costs	506	543
External research and development costs/laboratory	18,770	19,694
Legal and consulting costs (incl. patent costs)	3,261	3,349
Depreciation and amortization	879	757
Stock market listing	655	647
IT/licenses	804	352
Expenses from exchange rate differences	462	364
Other expenses	35	476
Total	38,011	37,042

The rise in staff costs in the past fiscal year is mainly attributable to the recruitment of experts and general salary increases. Expenses from the granting of stock options under IFRS 2 Share-based Payments also rose considerably (see note 25).

Travel costs rose due to a higher level of attendance at trade conferences and an increase in external employees.

Occupancy costs increased as a result of major renovation work at the Ladenburg site. In accordance with IFRS 16, the actual rental expense is not recognized as occupancy costs, but as depreciation in the respective amount of €86 thousand (previous year: €77 thousand).

Despite the expansion of business activities, other internal costs, and legal and consulting costs decreased. The latter result from numerous projects related to business development, funding, strategy as well as the considerable expansion of R&D activities including the patent portfolio. This expense item contains the cost of conventional legal representation as well as operating consulting costs.

External research, development and laboratory costs mainly comprise the cost of purchased services. These decreased compared to the previous year despite the cost-intensive implementation of a clinical trial.

Depreciation and amortization rose as a result of higher investment in depreciable assets in the reporting periods.

The costs of listing on the stock exchange include, among other things, expenses for the Annual General Meeting, the remuneration of the Supervisory Board and other investor relations expenses directly attributable to this matter.

IT and license expenses once again rose year-over-year as a result of increasing digitalization.

Since 2022, the expense from exchange rate differences in accordance with IAS 1.35 needs to be presented separately; it came to €462 thousand (previous year: €364 thousand).

25 Staff costs

In the comparative periods, Heidelberg Pharma employed the following number of staff on average (headcount):

Employees ¹	2023	2022 ²
Research and development	75	73
Business development	3	3
Central functions (corporate)	12	9
Administration	18	17
Total	108	102

¹ Without postdocs, staff on extended sick leave and interns

² Figures were not reported in the 2022 Annual Report; these figures are shown for reasons of transparency.

Staff costs for this purpose are comprised as follows:

	2023 €'000	2022 €'000
Wages and salaries	8,075	6,833
Social security costs	1,333	1,126
Costs of pensions	148	137
Expenses from accrued vacation entitlements	0	95
Bonuses	528	560
Expenses from share-based payment	961	554
Continuing professional development	72	83
Recruitment	93	111
Occupational safety and employer's liability insurance association	66	82
Other staff costs	105	357
Total staff costs	11,381	9,938

The wages and salaries and social security costs items rose year-over-year due to the elevated salary structure.

The granting of stock options in accordance with IFRS 2 Share-based Payments resulted in significantly higher staff costs of €961 thousand in 2023 (previous year: €554 thousand), because new stock options were issued under the 2023 Option Plan in the reporting period.

The following is a breakdown of the stock option plans in place during the reporting period, all of which were classified and measured as equity-settled share-based payments. There were no changes to or cancellations of plans in either the past fiscal year or the prior period.

2011 Stock Option Plan (2011 SOP)

The Annual General Meeting on 18 May 2011 voted to authorize Heidelberg Pharma AG to issue a total of 1,156,412 stock options as part of the 2011 Stock Option Plan to members of the Executive Management Board and employees of Heidelberg Pharma AG as well as beneficiaries of affiliates.

The first time the stock options can be exercised is after a lock-up period of four years from the respective issuing date. The stock options can only be exercised if Heidelberg Pharma AG's share price during the ten trading days preceding the start of the relevant exercise period ("reference price") exceeds the exercise price by at least 20% (absolute performance target). Furthermore, it must be noted that the options can only be exercised as long as the reference price exceeds the exercise price at least by the ratio by which the TecDAX on the last trading day prior to the relevant exercise period exceeds the TecDAX on the issuing date (relative performance target).

If the Heidelberg Pharma share price increases by more than 50% within the last three months prior to the respective exercise period and the percentage increase in the TecDAX (price index) in the same period is not equal to at least two thirds of the increase in the Heidelberg Pharma share price, the value of the new Heidelberg Pharma shares issued to a beneficiary in an exercise period is limited ("cap"). The cap corresponds to three times the annual gross remuneration (including all benefits subject to income tax, such as company cars, etc.) that the beneficiary received from the Company or its affiliates in the twelve months preceding the exercise date.

The authorization to grant stock options from the 2011 Stock Option Plan expired in 2016. No new options can therefore be granted under this plan. Tranche 1 from the 2011 Stock Option Plan (issued in 2012) expired without replacement after a ten-year term; tranche 2 (issued in 2016) can still be exercised. As in the previous year, Heidelberg Pharma no longer incurred any staff costs in 2023 under the 2011 Stock Option Plan.

2017 Stock Option Plan (2017 SOP)

The Annual General Meeting on 20 July 2017 voted to authorize Heidelberg Pharma AG to issue a total of 661,200 stock options as part of the 2017 Stock Option Plan to members of the Executive Management Board and employees of Heidelberg Pharma AG as well as beneficiaries of affiliates.

The first time the stock options can be exercised is after a lock-up period of four years from the respective issuing date. The stock options can only be exercised if Heidelberg Pharma AG's share price during the ten trading days preceding the start of the relevant exercise period ("reference price") exceeds the exercise price by at least 20% (absolute performance target). Furthermore, it must be noted that the options can only be exercised as long as the reference price exceeds the exercise price at least by the ratio by which the TecDAX on the last trading day prior to the relevant exercise period exceeds the TecDAX on the issuing date (relative performance target). If the Heidelberg Pharma share price increases by more than 50% within the last three months prior to the respective exercise period and the percentage increase in the TecDAX (price index) in the same period is not equal to at least two thirds of the increase in the Heidelberg Pharma share price, the value of the new Heidelberg Pharma shares issued to a beneficiary in an exercise period is limited ("cap"). The cap corresponds to twice the annual gross remuneration (including all benefits subject to income tax, such as company cars, etc.) that the beneficiary received from the Company or its affiliates in the twelve months preceding the exercise date.

The authorization to grant stock options from the 2017 Stock Option Plan expired in 2022. No new options can therefore be granted under this plan.

Heidelberg Pharma no longer incurred any staff costs in 2023 under the 2017 Stock Option Plan (previous year: €3 thousand).

2018 Stock Option Plan (2018 SOP)

The Annual General Meeting on 26 June 2018 voted to authorize Heidelberg Pharma AG to issue a total of 1,490,622 stock options as part of the 2018 Stock Option Plan to members of the Executive Management Board and employees of Heidelberg Pharma AG as well as beneficiaries of affiliates. The first time the stock options can be exercised is after a lock-up period of four years from the respective issuing date. The stock options can only be exercised if Heidelberg Pharma AG's share price during the ten trading days preceding the start of the relevant exercise period ("reference price") exceeds the exercise price by at least 20% (absolute performance target). Furthermore, it must be noted that the options can only be exercised as long as the reference price exceeds the exercise price at least by the ratio by which the TecDAX on the last trading day prior to the relevant exercise period exceeds the TecDAX on the issuing date (relative performance target). If the Heidelberg Pharma share price increases by more than 50% within the last three months prior to the respective exercise period and the percentage increase in the TecDAX (price index) in the same period is not equal to at least two thirds of the increase in the Heidelberg Pharma share price, the value of the new Heidelberg Pharma shares issued to a beneficiary in an exercise period is limited ("cap"). The cap corresponds to twice the annual gross remuneration (including all benefits subject to income tax, such as company cars, etc.) that the beneficiary received from the Company or its affiliates in the twelve months preceding the exercise date.

Heidelberg Pharma incurred staff costs of €252 thousand under the 2018 Stock Option Plan in 2023 (previous year: €551 thousand).

2023 Stock Option Plan (2023 SOP)

The Annual General Meeting on 25 May 2023 voted to authorize Heidelberg Pharma AG to issue a total of 2,621,035 stock options as part of the 2023 Stock Option Plan to members of the Executive Management Board and employees of Heidelberg Pharma AG as well as beneficiaries of affiliates. The first time the stock options can be exercised is after a lock-up period of four years from the respective issuing date. The stock options can only be exercised if Heidelberg Pharma AG's share price during the ten trading days preceding the start of the relevant exercise period ("reference price") exceeds the exercise price by at least 20% (absolute performance target). Furthermore, it must be noted that the options can only be exercised as long as the reference price exceeds the exercise price at least by the ratio by which the TecDAX on the last trading day prior to the relevant exercise period exceeds the TecDAX on the issuing date (relative performance target). If the Heidelberg Pharma share price increases by more than 50% within the last three months prior to the respective exercise period and the percentage increase in the TecDAX (price index) in the same period is not equal to at least two thirds of the increase in the Heidelberg Pharma share price, the value of the new Heidelberg Pharma shares issued to a beneficiary in an exercise period is limited ("cap"). The cap corresponds to twice the annual gross remuneration (including all benefits subject to income tax, such as company cars, etc.) that the beneficiary received from the Company or its affiliates in the twelve months preceding the exercise date.

Heidelberg Pharma for the first time incurred staff costs of €709 thousand under the 2023 Stock Option Plan in 2023.

The following table shows a summary of the Company's stock option plans/stock options with respect to their measurement:

Stock option plan	2011 ¹	2017	2018	2023	
Issue	Tranche 2	Tranche 1	Tranche 1	Tranche 2	Tranche 1
Measurement date	2 June 2016	23 April 2018	19 June 2019	5 August 2021	31 July 2023
Measurement method	Monte Carlo model in each case				
Fair value per option	€1.41	€1.07	€1.12	€3.07	€1.75
Exercise price (uniform and therefore also average) ¹	€1.89	€3.41	€2.79	€7.28	€3.57
Price of the Heidelberg Pharma share as of the measurement date	€1.83	€2.82	€2.83	€6.90	€3.56
Maximum term	10 years	10 years	10 years	10 years	10 years
Expected vesting period until the measurement date	3.95 years	4.00 years	3.96 years	3.96 years	3.96 years
Expected volatility of the Heidelberg Pharma share ²	89.42 %	54.96 %	48.59 %	60.33 %	61.20 %
Expected dividend yield of the Heidelberg Pharma share	0.00 %	0.00 %	0.00 %	0.00 %	0.00 %
Risk-free interest rate	-0.47 %	-0.19 %	-0.70 %	-0.82 %	2.60 %
Remaining term as of 30 Nov. 2023	2.50 years	4.39 years	5.51 years	7.68 years	9.67 years

¹ Tranche 1 of the AOP 2011 expired without replacement in fiscal year 2022 after a ten-year term

² Determined on the basis of the historical volatility of Heidelberg Pharma shares

The following table shows a summary of the Company's stock option plans/stock options under the 2011, 2017, 2018 and 2023 plans with respect to their issue:

All information provided in no. of options	2011 Plan	2017 Plan	2018 Plan	2023 Plan	Total
Max. number of stock options to be issued acc. to plan terms	1,156,412	661,200	1,490,622	2,621,035	5,929,269
of which Exec. Management Board	346,924	201,200	298,100	786,311	1,632,535
of which employees	809,488	460,000	1,192,522	1,834,724	4,296,734
Stock options actually issued	685,726	653,430	1,116,140	952,500	3,407,796
of which Exec. Management Board ¹	364,000	201,200	223,050	180,000	968,250
of which employees	321,726	452,230	893,090	772,500	2,439,546
Max. number of stock options still available for issue	0	0	0	1,668,535	1,668,535
of which Exec. Management Board	0	0	0	606,311	606,311
of which employees	0	0	0	1,062,224	1,062,224
Exercise of stock options by beneficiaries	44,100	11,140	3,880	0	59,120
of which Exec. Management Board	0	0	0	0	0
of which employees	44,100	11,140	3,880	0	59,120
of which Executive Management Board 2023	0	0	0	0	0
of which employees 2023	5,500	11,140	3,880	0	20,520
Return of stock options by beneficiaries leaving the Company	97,743	54,035	95,900	6,000	253,678
of which Exec. Management Board	26,500	0	0	0	26,500
of which employees	71,243	54,035	95,900	6,000	227,178
of which Executive Management Board 2023	0	0	0	0	0
of which employees 2023	0	8,630	42,973	6,000	57,603
Expiry of stock options without replacement after ten-year term	183,211	0	0	0	183,211
of which Exec. Management Board	85,500	0	0	0	85,500
of which employees	97,711	0	0	0	97,711
of which Executive Management Board 2023	0	0	0	0	0
of which employees 2023	0	0	0	0	0

All information provided in no. of options	2011 Plan	2017 Plan	2018 Plan	2023 Plan	Total
Stock options outstanding	360,672	588,255	1,016,360	946,500	2,911,787
of which Exec. Management Board	252,000	201,200	223,050	180,000	856,250
of which employees	108,672	387,055	793,310	766,500	2,055,537
Vested stock options (outstanding)	360,672	588,255	870,636	118,750	1,938,313
of which Exec. Management Board	252,000	201,200	195,300	22,500	671,000
of which employees	108,672	387,055	675,336	96,250	1,267,313
of which have vested in 2022	0	0	156,627	118,750	275,377
of which Exec. Management Board	0	0	37,131	22,500	59,631
of which employees	0	0	119,496	96,250	215,746
Non-vested stock options (outstanding)	0	0	145,725	827,750	973,475
of which Exec. Management Board	0	0	27,750	157,500	185,250
of which employees	0	0	117,975	670,250	788,225
Exercisable stock options (outstanding)	360,672	588,255	602,181	0	1,551,108
of which Exec. Management Board	252,000	201,200	149,050	0	602,250
of which employees	108,672	387,055	453,131	0	948,858

26 Currency gains/losses

Heidelberg Pharma incurred an unrealized currency loss of €462 thousand in fiscal year 2023 (previous year: unrealized currency gain of €649 thousand), which was allocated to other expenses (2023) and other income (2022).

27 Financial result

In the fiscal year now ended, finance income of €1,625 thousand (previous year: €235 thousand) was generated. Heidelberg Pharma exclusively used short-term deposits for investing its liquid funds (e.g. overnight money); at no time were investments made in stock or share-based financial instruments.

Finance costs triggered by the dievini shareholder loan amounted to €748 thousand (previous year: €836 thousand). These will be paid out in the first fiscal quarter of the following year. The interest portion of leases (€12 thousand; previous year: €2 thousand) and other interest expense (€2 thousand in each of the two comparative periods) were also added to finance costs.

This gives a financial result of €863 thousand (previous year: €-605 thousand).

	2023 €'000	2022 €'000
Interest income from bank accounts/Other	1,625	235
Finance income	1,625	235
Interest expense from shareholder loans	(748)	(836)
Interest expense from leasing agreements	(12)	(2)
Interest expense from other items	(2)	(2)
Finance costs	(762)	(840)
Financial result	863	(605)

28 Income taxes

Due to operating losses in previous periods, income tax was incurred only in 2022. The strategic partnership with Huadong and the out-licensing of HDP-101 and HDP-103 led to foreign withholding tax of €1.9 million being charged. Neither expenses nor income from deferred taxes were included in tax expenses in 2022 and 2023.

Deferred tax assets or liabilities were determined using the tax rates in effect in each case. A composite tax rate of 28.43% (previous year: 28.43%) is applied to Heidelberg Pharma AG, which is comprised of a corporation tax rate of 15% (previous year: 15%), solidarity surcharge of 5.5% (previous year: 5.5%) and trade tax of 12.60% (previous year: 12.60%).

A tax rate of 28.43% (unchanged from the previous year) was also applied to the subsidiary Heidelberg Pharma Research GmbH.

The reported current tax expense deviates from the expected tax income. The nominal tax rate of 28.43% (previous year: 28.43%) must be applied to income in accordance with IFRSs. Reconciliation of the differences is shown in the following table.

	2023 €'000	2022 €'000
Earnings before tax	(20,346)	(17,786)
Tax rate	28.43%	28.43%
Expected tax income (earnings x tax rate)	5,783	5,056
Deferred taxes on losses for the period not qualifying for recognition	(4,702)	(2,451)
Change in non-recognized temporary differences	(22)	(40)
Non-deductible operating expenses/Other	(1,060)	(649)
Reported tax expense	0	1,916

The existing deferred tax assets and deferred tax liabilities as of 30 November are attributable as follows:

	2023 €'000	2022 €'000
Deferred tax assets		
Other non-current assets	278	265
Different carrying amount of the equity investment	94	94
Loss carryforwards taken into account	669	687
Other liabilities	56	33
	1,097	1,079
Deferred tax liabilities		
Intangible assets	709	709
Other liabilities	388	370
	1,097	1,079
Deferred income taxes, net	0	0

As in the previous year, a portion of €94 thousand of the deferred tax assets resulted from outside basis differences in respect of different measurements of the equity investment.

Applying IAS 12.74, deferred tax assets and liabilities have been offset, since they exist vis-à-vis the same taxation authority, arise in the same periods and entail corresponding rights. Deferred tax assets on loss carryforwards are recognized only in an amount that is equal to the existing deferred tax liabilities.

As further losses can be expected over the next years, no deferred tax assets were recognized regarding the following matters:

	2023 €'000	2022 €'000
Loss carryforwards		
for corporation tax	321,376	304,960
for trade tax	316,516	300,348
Deductible temporary differences	0	0

The tax loss carryforwards shown in the table above based on tax notices issued and current tax calculations are mainly attributable to Heidelberg Pharma AG (corporation tax loss carryforward of €254,252 thousand; trade tax loss carryforward of €250,966 thousand) and may be carried forward indefinitely. Further loss carryforwards concern the subsidiary Heidelberg Pharma Research GmbH, which based on the tax notices issued by the tax office and its current tax calculations shows €67,124 thousand and €65,550 thousand in losses carried forward for corporation tax and trade tax purposes, respectively. Deferred tax assets (amounting to €669 thousand) were recognized in the fiscal year just ended for €2,353 thousand in tax loss carryforwards and offset against correspondingly high deferred tax liabilities (€2,416 thousand and €687 thousand, respectively).

Note the following in regards to the tax loss carryforwards available to Heidelberg Pharma AG and Heidelberg Pharma Research GmbH: The deduction of existing losses carried forward is excluded if the company carrying forward these losses loses its tax identity. In accordance with Section 8 (4) German Corporation Tax Act (version applicable until the end of 2007), a company is deemed to have lost its tax identity if the two following criteria are met cumulatively: (i) more than 50% of the shares in the company have been transferred and (ii) the company continues or relaunches its operations mainly with new assets. The legal limit on deductibility of operating losses applies to corporation tax and trade tax.

In fiscal year 2022, Heidelberg Pharma AG was subject to a tax audit for the period from 2017 to 2019. Since the audit did not result in any changes in the tax base, the final determination was made that the loss carryforwards accrued by 31 December 2019 amounted to €175.0 million (corporation tax) and €171.9 million (trade tax).

According to the amendment of Section 8c German Corporation Tax Act pursuant to the 2018 Annual Tax Act (Jahressteuergesetz, JStG), the amended Section 8c now only provides for a single set of circumstances, i.e. the full extinguishment of loss carryforwards in the event of the transfer of more than 50% of the shares in a corporation within five years. As a result, the loss carryforwards are no longer extinguished proportionately, if more than 25% and up to 50% of the shares are transferred within five years. The group clause and the hidden reserve clause in Section 8c of the KStG and the loss carryforward subject to continuation of the business ("fortführungsgebundener Verlustvortrag") in Section 8d of the KStG were preserved unchanged.

Because capital increases also cause shifts in shareholdings and thus adverse acquisitions of equity as defined in Section 8c of the KStG, the capital increases implemented after 2019 and the changed identity of the Company as a result of the restructuring measures might possibly have led to the elimination of the tax loss carryforwards.

In 2011, Heidelberg Pharma AG acquired 100% of the shares in Heidelberg Pharma Research GmbH, which had recognized accumulated tax loss carryforwards of €40,286 thousand up to the acquisition date. The only thing not in doubt was that the tax loss carryforwards corresponding to the undisclosed reserves transferred may be retained. The undisclosed reserves result from the difference between the transaction price under German tax law and the equity of Heidelberg Pharma Research under German tax law; they amounted to €12,808 thousand. Pursuant to tax notices issued in the meantime, a portion of the accumulated loss carryforwards of Heidelberg Pharma Research were not recognized by the tax authorities.

A purchase price allocation carried out in connection with this transaction resulted in the identification of intangible assets and goodwill. The deferred tax liabilities determined in connection with the valuation amounted to €800 thousand; they were offset at the time in the same amount by deferred tax assets from tax loss carryforwards taken over. As of 30 November 2022, deferred tax liabilities on these intangible assets amounted to €709 thousand, as in the previous year. The Company continues to make use of the option to offset them against deferred tax assets in accordance with IAS 12.74.

29 Earnings per share

29.1 Basic

Basic earnings per share are calculated by dividing the net profit for the year available to shareholders by the weighted average number of shares issued during the fiscal year.

As a result of the exercise of 20,520 stock options during the year, the total number of Heidelberg Pharma shares issued as of the reporting date increased to 46,604,977.

		2023	2022
Net loss for the year attributable to equity providers	€'000	(20,346)	(19,702)
Level of capital and corporate actions in the fiscal year			
Number of issued shares at the beginning of the fiscal year	in thousand	46,584	34,176
Number of shares newly issued during the fiscal year	in thousand	–	12,408
Number of new shares created by converting stock options	in thousand	21	–
Average number of shares issued during the fiscal year	in thousand	46,596	37,235
Basic earnings per share based on the weighted average number shares issued in the reporting period	in € per share	(0.44)	(0.53)

Basic earnings per share in 2023

In fiscal year 2023, basic earnings per share amounted to €–0.44 based on the weighted average number of shares issued in the reporting period (46,595,741 shares and earnings attributable to equity providers of €–20,346 thousand).

Basic earnings per share in 2022

In fiscal year 2022, basic earnings per share amounted to €–0.53 based on the weighted average number of shares issued in the reporting period (37,235,476 shares and earnings attributable to equity providers of €–19,702 thousand).

29.2 Diluted

The Company's Annual General Meetings in 2011, 2017, 2018 and 2023 each adopted resolutions to contingently increase the share capital of the Company for the purpose of satisfying subscription rights. The associated granting or possibility of granting stock option rights to employees and members of the Executive Management Board could potentially dilute the basic earnings per share in the future beyond the stock options exercised in 2023.

Since in the past fiscal year at €5.02 the average market price of Heidelberg Pharma's shares exceeded the exercise price payable to the Company for the exercisable stock options (€1.89/€3.41/€2.79), diluted earnings per share need to be reported. The following parameters are to be used for diluted earnings per share in 2023 (see note 24):

 Page 144

- Number of stock options exercisable as of 30 November 2022:
 - 360,672 options at €1.89 each
 - 588,255 options at €3.41 each
 - 602,181 options at €2.79 each
 - Total: 1,551,108 options
- Average number of shares: 46,596 thousand + 1,551 thousand = 48,147 thousand shares
- Effect on earnings if fully exercised:
 - €1.89 x 360,672 options = €681,670
 - €3.41 x 588,255 options = €2,005,950
 - €2.79 x 602,181 options = €1,680,085
 - Total €4,367,705
- Attributable profit/loss for the year: €-20,346 thousand + €4,368 thousand = €-15,978 thousand
- €-15,978 thousand / 48,147 thousand shares = €-0.31

This gives diluted earnings per share of €-0.31 for 2023.

30 Leases, guarantees and obligations

As of the reporting date, a total of €30 thousand in security were made available for right-of-use assets (buildings and vehicles) (previous year: €30 thousand).

Heidelberg Pharma has leased office equipment and vehicles under operating leases, which will expire at different times until 2027. All of the office premises used at present are rented under indefinite leases that can be terminated by giving three or twelve months notice as of the end of a month.

In accordance with IFRS 16, the cost of office and laboratory equipment as well as office and laboratory premises under the operating leases are reported as depreciation in the statement of comprehensive income, together with the obligations under lease agreements for company cars:

Expense/depreciation of right-of-use assets	€'000
2023	112
of which from tenancy agreements (property)	86
of which from other leases (cars)	26
2022	102
of which from tenancy agreements (property)	85
of which from other leases (cars)	17

Heidelberg Pharma has not provided a deposit for landlords, nor are there any other guarantees.

The future minimum annual payments under tenancy agreements and leases are comprised as follows:

Obligations as of 30 Nov. 2023	Up to 1 year €'000	1–5 years €'000	More than 5 years €'000	Total €'000
Rental obligations for laboratory and office premises ¹	87	33	0	120
Obligations under other leases (laboratory and other office equipment, vehicles)	26	38	0	64
	113	71	0	184

¹ Due to short notice periods (three, six and twelve months) assuming that the leases for the offices have been terminated effective at the end of 2024 at the latest.

Below are previous year's figures:

Obligations as of 30 Nov. 2022	Up to 1 year €'000	1–5 years €'000	More than 5 years €'000	Total €'000
Rental obligations for laboratory and office premises ¹	83	0	0	83
Obligations under other leases (laboratory and other office equipment, vehicles)	19	19	0	38
	102	19	0	121

¹ Due to short notice periods (three, six and twelve months) assuming that the leases for the offices have been terminated effective at the end of 2023 at the latest.

These leases do not stipulate contingent lease payments, nor do they impose restrictions in respect of dividends, additional liabilities or other leases. No price adjustment clauses were stipulated, and there is no obligation to purchase the leased equipment once the given lease expires.

31 Corporate bodies and remuneration

31.1 Executive Management Board

The Executive Management Board members of Heidelberg Pharma AG in the reporting period were:

Dr. Jan Schmidt-Brand, Chief Executive Officer for the entire year and Chief Financial Officer until 30 April 2023 (appointed until 31 August 2024). Dr. Schmidt-Brand stepped down as a member of the Executive Management Board on 31 January 2024 as part of the retirement-related succession plan.

Professor Andreas Pahl, Chief Scientific Officer (appointed until 31 December 2025). Since 1 February 2024, Professor Pahl has been Chief Executive Officer.

Walter Miller, Chief Financial Officer (since 1 May 2023, appointment until 30 April 2025).

In parallel to their work as members of the Executive Management Board, Dr. Jan Schmidt-Brand and Walter Miller acted as the Managing Director of Heidelberg Pharma Research GmbH, a position they assumed in 2004 and 2023, respectively. In the interests of transparency, the remuneration of Dr. Schmidt-Brand is presented in full, which means that the amounts that he has earned as Managing Director of the subsidiary are also listed below. Mr. Miller does not receive any separate remuneration for his work as Managing Director of the subsidiary.

Dr. Schmidt-Brand also resigned from his position as Managing Director of Heidelberg Pharma Research GmbH effective 31 January 2024. Since 1 February 2024, Professor Pahl has also been Managing Director of the subsidiary, together with Mr. Miller.

31.2 Supervisory Board

The Supervisory Board of Heidelberg Pharma AG as of 30 November 2023 comprised the seven members:

Professor Christof Hettich (Chairman of the Supervisory Board of Heidelberg Pharma AG)

- Lawyer and partner at RITTERSHAUS Rechtsanwälte Steuerberater PartmbB, Mannheim/Frankfurt am Main/Munich, Germany
- Chairman of the Management Board of SRH Holding SdbR, Heidelberg, Germany

Dr. Georg F. Baur (Deputy Chairman of the Supervisory Board of Heidelberg Pharma AG)

- Managing partner of an agricultural business

Dr. Mathias Hothum (Vice Chairman of the Supervisory Board of Heidelberg Pharma AG)

- Managing Director of dievini Verwaltungs GmbH, the general partner of dievini Hopp BioTech holding GmbH & Co. KG, Walldorf, Germany

Dr. Friedrich von Bohlen und Halbach

- Managing Director of Molecular Health GmbH, Heidelberg, Germany

Dr. Birgit Kudlek

- Self-employed pharmaceutical manager

Dr. Dongzhou Jeffery Liu, PhD

- Chief Scientific Officer (CSO) and President of Huadong Global Development, Huadong Medicine Co., Ltd., Hangzhou, China

Dr. Yan Xia, MD, PhD (since 25 May 2023)

- Director of ADC Research Center, Huadong Medicine Co. Ltd., Hangzhou, China

Dr. Brady Xumin Zhao, MD, PhD (member until 31 March 2023) stepped down during the year.

- Vice President, China Grand Enterprise, Inc., Beijing, PRC, the parent company of Huadong Medicine Co., Ltd., Hangzhou, China

31.2.1 Supervisory Board committees

For reasons of efficiency, a joint Compensation and Nomination Committee was established, which covers both areas separately in its meetings. The Compensation Committee deals with employment issues and with the remuneration of the members of the Executive Management Board. The tasks of the Nomination Committee include proposing suitable candidates for the Supervisory Board to the Annual General Meeting and the appointment of new members of the Executive Management Board.

The Supervisory Board also established an Audit Committee, whose tasks include the discussion and preparatory examination of the IFRS consolidated financial statements, the HGB single-entity financial statements, the consolidated half-yearly report, the consolidated interim management statements, and the preselection of the auditor of the financial statements and the monitoring of its independence.

Below is an overview of the composition of the Supervisory Board applicable until the end of the Annual General Meeting in May 2025:

Supervisory Board member	First appointed	End of term	Audit Committee	Compensation and Nomination Committee
Prof. Dr. Christof Hettich	2010	2025		C
Dr. Georg F. Baur (IAE)	2000	2025	C	M
Dr. Mathias Hothum (IFRE)	2015	2025	M	
Dr. Friedrich v. Bohlen u. Halbach	2005	2025		
Dr. Birgit Kudlek	2012	2025	M	
Dr. Dongzhou Jeffery Liu	2022	2025		M
Dr. Yan Xia	2023	2025		

C = Chair, M = Member, IAE = Independent auditing expert, IFRE = Independent financial reporting expert

31.2.2 Other appointments of the Supervisory Board members

In addition to being a member of the Supervisory Board of Heidelberg Pharma AG, Professor Christof Hettich is also the Chairman or a member of the following bodies:

Company	Position
• LTS Lohmann Therapie-Systeme AG, Andernach, Germany	Chairman of the Supervisory Board
• Companies of the Vetter Group: Vetter Pharma-Fertigung GmbH & Co. KG, Vetter Pharma-Fertigung Verwaltungs-GmbH, Arzneimittelgesellschaft mbH Apotheker Vetter & Co., Vetter Injekt System GmbH & Co. KG, Vetter Injekt System Verwaltungs-GmbH, Ravensburg, Germany	Member of the Advisory Boards
• Molecular Health GmbH, Heidelberg, Germany	Chairman of the Supervisory Board
• SRH Gesundheit GmbH, Heidelberg, Germany	Chairman of the Supervisory Board
• EPPLE Holding GmbH, Heidelberg, Germany	Member of the Advisory Board

In addition to being a member of the Supervisory Board of Heidelberg Pharma AG, Dr. Mathias Hothum is also the Chairman or a member of the following bodies:

Company	Position
• Apogenix AG, Heidelberg, Germany	Member of the Supervisory Board
• CureVac AG, Tübingen, Germany	Member of the Supervisory Board
• Joimax GmbH, Karlsruhe, Germany	Chairman of the Advisory Board
• Novaliq GmbH, Heidelberg, Germany	Member of the Supervisory Board
• Molecular Health GmbH, Heidelberg, Germany	Member of the Supervisory Board
• Geuder AG, Heidelberg, Germany	Chairman of the Supervisory Board
• Immatics N.V., Tübingen, Germany	Member of the Supervisory Board

In addition to being a member of the Supervisory Board of Heidelberg Pharma AG, Dr. Friedrich von Bohlen und Halbach is also the Chairman or a member of the following bodies:

Company	Position
• Apogenix AG, Heidelberg, Germany	Chairman of the Supervisory Board
• InnoSource Ventures AG, Zurich, Switzerland	Chairman of the Board of Directors

In addition to being a member of the Supervisory Board of Heidelberg Pharma AG, Dr. Birgit Kudlek is also a member of the following bodies:

Company	Position
• Pharmanovia Pharma Limited, London, United Kingdom	Member of the Advisory Committee
• Cidron Atrium SE (Alloheim Group), Düsseldorf, Germany	Member of the Advisory Board
• Rottendorf Pharma GmbH, Ennigerloh, Germany	Member of the Supervisory Board
• Remedica Ltd., Limassol, Cyprus	Member of the Advisory Committee
• Lohmann GmbH & Co. KG, Neuwied, Germany	Member of the Advisory Board

The Supervisory Board members Dr. Georg F. Baur, Dr. Dongzhou Jeffery Liu and Dr. Yan Xia do not hold any such positions in control bodies.

The members of the Company's Supervisory Board were not active in any other control bodies at the reporting date above and beyond the activities described in the foregoing.

31.3 Remuneration of corporate bodies

In fiscal year 2023, the members of the Executive Management Board were paid total remuneration of €1,268 thousand (previous year: €717 thousand). The strong year-over-year increase is mainly due to the measurement of the stock option issue and the temporary expansion of the Executive Management Board to three members.

According to IAS 24.17, the total remuneration of the Executive Management Board is comprised as follows:

Item	2023 Remuneration in €'000	2022 Remuneration in €'000
a) Short-term employee benefits	953	717
b) Post-employment benefits	0	0
c) Other long-term benefits	0	0
d) Termination benefits	0	0
e) Share-based payment	315	0
Total	1,268	717

The members of the Supervisory Board were paid remuneration of €197 thousand (previous year: €190 thousand), plus reimbursement of travel expenses.

32 Related party transactions

Details concerning transactions between the Group and other related parties are listed below.

32.1 Other transactions

- Heidelberg Pharma Research GmbH granted Dr. Jan Schmidt-Brand a defined contribution pension commitment in 2012 in his capacity as Managing Director of the company for which matching reinsurance was arranged. A total of €13 thousand was paid into Heidelberg Pharma Research GmbH's defined contribution pension plan in the reporting period (previous year: €13 thousand) and included in the staff costs for the fiscal year. There is also a defined-contribution pension commitment in respect of an employee who has since retired and in respect of Dr. Jan Schmidt-Brand, in relation to which reinsurance was arranged for the respective commitment amounts.
- In December 2020, Heidelberg Pharma entered into a subordinated shareholder loan for €15 million with dievini. The loan does not have an expiration date, is unsecured, includes a mutual right of termination and, since the start of the past fiscal year, has an interest rate of 8% per annum (previously 6%). Heidelberg Pharma AG was entitled to access the loan when needed. Two tranches of €5 million each were drawn down in fiscal year 2021, and a further €5 million tranche in February 2022. Two tranches of €5 million each were repaid in fiscal year 2023, as a result of which the loan amounts to €5 million as of the reporting date.
- Under the 2011, 2017, 2018 and 2023 stock option plans, Heidelberg Pharma AG issued a total of 916,250 subscription rights were issued to current members of the Executive Management Board, of which 856,250 are still outstanding as 60,000 options have expired without replacement. As of the end of the reporting period, 671,000 of these options are vested, of which 59,631 options vested in 2023. In the past fiscal year, no options held by the current Executive Management Board expired without replacement or were forfeited due to a member's departure from the Board. No options have yet been exercised by current or former members of the Executive Management Board.
- In fiscal year 2023, transactions took place between payment recipient Heidelberg Pharma Research GmbH and service recipient Huadong, and between Heidelberg Pharma Research GmbH and entities controlled by dievini or its affiliated companies, namely service recipient Apogenix AG, Heidelberg. These transactions amounted to €39 thousand and €20 thousand, respectively. No collateral or guarantees were agreed. Moreover, no provision was required as the outstanding balance as of the reporting date was in each case cleared and no obligations exist. All transactions took place without any influence or action on the part of dievini or its affiliated companies and strictly at arm's length.

No other relationships to related parties exist in addition to the relations and financing services listed. Furthermore, no transactions that were not at arm's length within the meaning of IAS 24.23 were entered into.

32.2 Disclosures regarding the majority shareholder

The main shareholder in Heidelberg Pharma AG is dievini Hopp BioTech holding GmbH & Co. KG, Walldorf, (dievini). This entity also prepares the largest group of consolidated financial statements. The Executive Management Board of Heidelberg Pharma AG is not aware whether dievini as the parent prepares consolidated financial statements for the largest and smallest group of consolidated companies. Together with all entities attributable to or affiliated with it at that time, such as DH-Holding Verwaltungs GmbH and Curacyte GmbH, and the shares in Heidelberg Pharma AG held personally by Mr. Dietmar Hopp, dievini held approximately 51.7% of the 9,305,608 Heidelberg Pharma shares as of 13 April 2015 following the capital increase at Heidelberg Pharma that became effective upon its entry in the Commercial Register on 10 April 2015. An interest of over 50% in Heidelberg Pharma was therefore attributable to dievini and its affiliated companies for the first time in the 2015 fiscal year.

Following various changes in the meantime, this interest decreased to 45.67% as a result of a capital increase completed in September 2022 where a subsidiary of strategic partner Huadong Medicine acquired a 35.00% equity interest in Heidelberg Pharma AG (including dievini shares directly acquired off market). The interest held by dievini changed only insignificantly as a result of stock options exercised in fiscal year 2023 and is still 45.7%.

The shareholdings of Dietmar Hopp, parties related to him, and the companies they control, therefore no longer exceed the 50% threshold. This group of persons remains the majority shareholder and can still exercise control of or has power over Heidelberg Pharma AG as a stable majority can be assumed at general meetings.

33 Expenses for the auditors

Deloitte GmbH Wirtschaftsprüfungsgesellschaft, Munich, Frankfurt am Main branch office (Deloitte) was appointed the auditor of the Company's annual and consolidated financial statements at its Annual General Meeting on 25 May 2023. The Supervisory Board commissioned Deloitte with the audit.

The total fee billed by the auditor of the consolidated and annual financial statements of Heidelberg Pharma AG in fiscal year 2022/2023 was €206 thousand. Of this total, €16 thousand was attributable to the previous fiscal year, €165 thousand related to the audit of the consolidated and annual financial statements of the parent company, and €25 thousand was for the audit of the annual financial statements of the subsidiary as of 30 November 2022.

All of these services were rendered exclusively for audits of financial statements.

This fee totaled €318 thousand in the previous, of which €186 thousand was for audits of financial statements and €132 thousand was for other assurance services.

34 Declaration of Conformity with the German Corporate Governance Code in accordance with Section 161 German Stock Corporation Act

The Declaration of Conformity to be submitted annually in accordance with Section 161 of the German Stock Corporation Act was submitted by the Executive Management Board and the Supervisory Board in February 2024. It has been made permanently available to all shareholders and interested parties on the Company's website.

www.heidelberg-pharma.com

35 Events after the reporting period

Heidelberg Pharma reaches financing agreement with HealthCare Royalty

On 4 March 2024, Heidelberg Pharma announced that it had signed a royalty financing agreement with HealthCare Royalty, Delaware, USA, (HCRx). The Company is eligible to receive up to USD 115 million for the sale of its future royalties from worldwide sales of Zircaix™ (TLX250-CDx). More information about the candidate can be found in the management report under 3. Course of business in 2023 – 3.3 Clinical portfolio of Heidelberg Pharma AG – TLX250-CDx (girentuximab) – diagnostic antibody/Zircaix™.

Page 43

Heidelberg Pharma AG set up a wholly-owned subsidiary, HDP G250 AG & Co. KG, to implement its financing agreement with HCRx. This subsidiary is the contracting partner to HCRx and, as a result, is also the recipient of the payment claims arising from the agreement.

As part of the agreement, HCRx was first subject to a payment claim of USD 25 million upon closing. Claims for payment will then arise totalling USD 75 million following FDA approval of Zircaix™ as well as a further USD 15 million if calendar year 2025 worldwide net product sales of Zircaix™ exceed a certain level. Following the receipt by HCRx of a maximum cumulative amount, royalty payments will revert to Heidelberg Pharma and HCRx will receive a low single digit royalty percentage.

Ladenburg, 21 March 2024

The Executive Management Board of Heidelberg Pharma AG



Professor Andreas Pahl
Chief Executive Officer



Walter Miller
Chief Financial Officer

RESPONSIBILITY STATEMENT OF THE EXECUTIVE MANAGEMENT BOARD

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

Ladenburg, 21 March 2024

The Executive Management Board of Heidelberg Pharma AG



Professor Andreas Pahl
Chief Executive Officer



Walter Miller
Chief Financial Officer

INDEPENDENT AUDITOR'S REPORT

The English translation of the auditor's report is provided for convenience only. The German original is definitive.

To Heidelberg Pharma AG, Ladenburg

Report on the audit of the consolidated financial statements and of the combined management report

Audit opinions

We have audited the consolidated financial statements of Heidelberg Pharma AG, Ladenburg, Germany, and its subsidiary (the Group), which comprise the balance sheet as of 30 November 2023, the consolidated statement of comprehensive income, the consolidated statement of changes in equity and the consolidated cash flow statement for the fiscal year from 1 December 2022 to 30 November 2023, and the notes to the consolidated financial statements, including a summary of significant accounting policies. In addition, we have audited the Group management report of Heidelberg Pharma, Ladenburg, Germany, which is combined with the Company's management report, for the fiscal year from 1 December 2022 to 30 November 2023. In accordance with the German legal requirements, we have not audited the content of the statement on corporate governance pursuant to Sections 289f, 315d German Commercial Code (HGB), which is referred to in section 7.1 of the combined management report.

 Page 56

In our opinion, on the basis of the knowledge obtained in the audit,

- the accompanying consolidated financial statements comply, in all material respects, with the IFRSs as adopted by the EU, and the additional requirements of German commercial law pursuant to Section 315e (1) German Commercial Code (HGB) and, in compliance with these requirements, give a true and fair view of the assets, liabilities, and financial position of the Group as of 30 November 2023, and of its financial performance for the fiscal year from 1 December 2022 to 30 November 2023, and
- the accompanying combined management report as a whole provides an appropriate view of the Group's position. In all material respects, this combined management report is consistent with the consolidated financial statements, complies with German legal requirements and appropriately presents the opportunities and risks of future development. Our audit opinion on the combined management report does not cover the content of the statement on corporate governance mentioned above.

Pursuant to Section 322 (3) Sentence 1 German Commercial Code (HGB), we declare that our audit has not led to any reservations relating to propriety of the consolidated financial statements and of the combined management report.

Basis for the audit opinions

We conducted our audit of the consolidated financial statements and of the combined management report in accordance with Section 317 German Commercial Code (HGB) and the EU Audit Regulation (No. 537/2014; referred to subsequently as "EU Audit Regulation") and in compliance with German Generally Accepted Standards for Financial Statement Audits promulgated by the Institut der Wirtschaftsprüfer (IDW). Our responsibilities under those requirements and principles are further described in the "Auditor's responsibilities for the audit of the consolidated financial statements and of the combined management report" section of our auditor's report. We are independent of the Group entities in accordance with the requirements of

European law and German commercial law and rules of professional conduct and we have fulfilled our other ethical responsibilities applicable in Germany in accordance with these requirements. In addition, in accordance with Article 10 (2) (f) of the EU Audit Regulation, we declare that we have not provided non-audit services prohibited under Article 5 (1) of the EU Audit Regulation. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinions on the consolidated financial statements and on the combined management report.

Material uncertainty in connection with the Company's ability to continue as a going concern

We refer to sections 8.3 "Going-concern risks" and 8.4 "Risks classified as MATERIAL" of the combined management report as well as to chapter 6 "Going-concern risk" of the notes to the consolidated financial statements. In these sections, the executive directors state that based on their planning at that time the cash and cash equivalents available to the Company as of the 30 November 2023 reporting date are sufficient to guarantee the Company's ability to continue as a going concern for at least the next twelve months and until mid-2025, provided that no exceptional developments change the situation or there is no possibility to raise additional funds.

However, cash inflows from sales revenue or royalties are not yet sufficient to sustain the Group's operations. Building a proprietary ATAC pipeline will result in an increase in research and development expenses. Accordingly, additional revenues from marketing the ADC technology or further external cash inflows must be generated to sustain business operations beyond mid-2025.

As outlined in the above-mentioned sections and chapters of the combined management report and the notes to the consolidated financial statements, these events and circumstances indicate the existence of a material uncertainty that may cast significant doubt on the ability of the Group to continue as a going concern and constitute a risk that jeopardizes the existence of the Group as a going concern within the meaning of Section 322 (2) Sentence 3 German Commercial Code (HGB).

In accordance with Article 10 (2) (c) (ii) of the EU Audit Regulation, we summarize our audit response to this risk as follows: In our audit, we examined whether the preparation of the consolidated financial statements on a going-concern basis and the presentation of the Company's going-concern risks in the consolidated financial statements and in the combined management report are appropriate. In this context, we focused on assessing the current liquidity planning by examining the reliability of the data on which it is based and whether the assumptions made by the executive directors are sufficiently justified and evidenced.

Our audit opinions regarding the consolidated financial statements and the combined management report have not been modified with respect to this matter.

Key audit matters in the audit of the consolidated financial statements

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the consolidated financial statements for the fiscal year from 1 December 2022 to 30 November 2023. These matters were addressed in the context of our audit of the consolidated financial statements as a whole and in forming our audit opinion thereon; we do not provide a separate audit opinion on these matters.

In addition to the matter described in the section “Material uncertainty in connection with the Company’s ability to continue as a going concern”, we present the recoverability of goodwill as the key audit matter we have determined in the course of our audit.

Our presentation of these key audit matters have been structured as follows:

- a. Description (including reference to corresponding information in the consolidated financial statements)
- b. Auditor’s response


Recoverability of goodwill

- a) Goodwill of €6,111 thousand (approximately 8.7% of total assets) is shown in the consolidated financial statements of Heidelberg Pharma. The goodwill results from the acquisition of Heidelberg Pharma Research GmbH in 2011. The Company therefore allocated the goodwill to the Heidelberg Pharma Research GmbH cash-generating unit.

On this basis, the Company performs impairment testing once per year and whenever a triggering event occurs.

The basis for measurement is the present value of the future cash flows of the Heidelberg Pharma Research GmbH cash-generating unit to which the goodwill is allocated; this is determined using a discounted cash flow model. The expected future cash flows are derived from the current medium-term planning adopted by the executive directors, which is based on assumptions by the executive directors relating to the future development of the market and the Company. Discounting is based on the weighted average cost of capital rates of the cash-generating unit. The outcome of this valuation exercise is dependent to a large extent on the estimates made by the executive directors with respect to the future cash flows and the discount rate used, and is therefore fraught with considerable uncertainty. In the light of this, and owing to the underlying complexity of the valuation models, this issue was of particular importance within the framework of our audit.

The disclosures made by the executive directors about goodwill can be found in sections 3.8, 7.2, 8 and 10.1 of the notes to the consolidated financial statements.

 Pages 101, 120, 121 and 127

- b) as part of our audit, we first evaluated the method used to perform the impairment test and assessed the calculation of the weighted cost of capital rates and in this context assessed whether the approach can be influenced by subjectivity, complexity and other inherent risk factors.

In addition to our analysis of the planning, we satisfied ourselves of the appropriateness of the future cash inflows used in the measurement by comparing this data with the current projections from the medium-term planning adopted by the executive directors. With regard to the data and assumptions used in the valuation model relating to the future cash flows determined by the executive directors’ expert, we assessed the competence, skills and objectivity of the expert, gained an understanding of the expert’s work and evaluated the suitability of the expert’s work as audit evidence for the relevant statement, taking into account the significance of the expert’s work. We also considered general and industry-specific market expectations.

In the knowledge that even relatively small changes in the discount rate applied can have a material impact on the goodwill calculated using this method, we focused on examining the parameters used to determine the discount rate applied including the average cost of capital, and analyzed the method of calculation.

In the case of estimates within the scope of calculations, we have assessed the data used, methods applied and assumptions made.

Furthermore, due to the materiality of the goodwill for the Group's net assets, we also performed our own sensitivity analyses so as to be able to estimate a possible impairment risk in the event of a potential change in a key assumption for measurement. In addition, we examined the completeness and appropriateness of the disclosures in the notes to the consolidated financial statements required under IAS 36.

Other information

The executive directors and the Supervisory Board are responsible for the other information. The other information comprises

- the report of the Supervisory Board,
- the statement on corporate governance pursuant to Sections 289f, 315d HGB, which is referred to in section 7.1 of the combined management report,
- the executive directors' responsibility statement pursuant to Section 297 (2) sentence 4 and Section 315 (1) sentence 5 HGB, respectively, regarding the consolidated financial statements and the combined management report, and
- all remaining parts of the annual report,
- but not the consolidated financial statements, not the audited content of the combined management report, and not our auditor's report thereon.

The Supervisory Board is responsible for the report of the Supervisory Board included in the annual report. The executive directors and the Supervisory Board are responsible for the declaration pursuant to Section 161 German Stock Corporation Act (AktG) on the German Corporate Governance Code, which is part of the statement on corporate governance that is included as section 7.1 in the combined management report. In all other respects, the executive directors are responsible for the other information.

Our audit opinions on the consolidated financial statements and on the combined management report do not cover the other information, and consequently we do not express an audit opinion or any other form of assurance conclusion thereon.

In connection with our audit, our responsibility is to read the other information mentioned above and, in so doing, to consider whether the other information

- is materially inconsistent with the consolidated financial statements, the disclosures in the combined management report audited with regard to their content or our knowledge obtained in the audit, or
- otherwise appears to be materially misstated.

Responsibilities of the executive directors and the Supervisory Board for the consolidated financial statements and the combined management report

The executive directors are responsible for the preparation of the consolidated financial statements that comply, in all material respects, with IFRSs as adopted by the EU and the additional requirements of German commercial law pursuant to Section 315e (1) German Commercial Code (HGB) and that the consolidated financial statements, in compliance with these requirements, give a true and fair view of the assets, liabilities, financial position, and financial performance of the Group. In addition, the executive directors are responsible for such internal control as they have determined necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud (i.e. accounting fraud or error) or error.

In preparing the consolidated financial statements, the executive directors are responsible for assessing the Group's ability to continue as a going concern. They also have the responsibility for disclosing, as applicable, matters related to going concern. In addition, they are responsible for financial reporting based on the going concern basis of accounting unless there is an intention to liquidate the Group or to cease operations, or there is no realistic alternative but to do so.

Furthermore, the executive directors are responsible for the preparation of the combined management report that, as a whole, provides an appropriate view of the Group's position and is, in all material respects, consistent with the consolidated financial statements, complies with German legal requirements, and appropriately presents the opportunities and risks of future development. In addition, the executive directors are responsible for such arrangements and measures (systems) as they have considered necessary to enable the preparation of a combined management report that is in accordance with the applicable German legal requirements, and to be able to provide sufficient appropriate evidence for the assertions in the combined management report.

The Supervisory Board is responsible for overseeing the Group's financial reporting process for the preparation of the consolidated financial statements and of the combined management report.

Auditor's responsibilities for the audit of the consolidated financial statements and of the combined management report

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and whether the combined management report as a whole provides an appropriate view of the Group's position and, in all material respects, is consistent with the consolidated financial statements and the knowledge obtained in the audit, complies with the German legal requirements and appropriately presents the opportunities and risks of future development, as well as to issue an auditor's report that includes our audit opinions on the consolidated financial statements and on the combined management report.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with Section 317 German Commercial Code (HGB) and the EU Audit Regulation and in compliance with German Generally Accepted Standards for Financial Statement Audits promulgated by the Institut der Wirtschaftsprüfer (IDW) will always detect a material misstatement. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements and this combined management report.

We exercise professional judgment and maintain professional skepticism throughout the audit. We also

- identify and assess the risks of material misstatement of the consolidated financial statements and of the combined management report, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our audit opinions. The risk of not detecting a material misstatement resulting from fraud is higher than the risk of not detecting one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- obtain an understanding of internal control relevant to the audit of the consolidated financial statements and of arrangements and measures relevant to the audit of the combined management report in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an audit opinion on the effectiveness of these systems.
- evaluate the appropriateness of accounting policies used by the executive directors and the reasonableness of estimates and related disclosures made by the executive directors.
- conclude on the appropriateness of the executive directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in the auditor's report to the related disclosures in the consolidated financial statements and in the combined management report or, if such disclosures are inadequate, to modify our respective audit opinions. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Group to cease to be able to continue as a going concern.
- evaluate the presentation, structure and content of the consolidated financial statements as a whole, including the disclosures, and whether the consolidated financial statements present the underlying transactions and events in a manner that the consolidated financial statements give a true and fair view of the assets, liabilities, financial position and financial performance of the Group in compliance with IFRSs as adopted by the EU and with the additional requirements of German commercial law pursuant to Section 315e (1) German Commercial Code (HGB).
- obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express audit opinions on the consolidated financial statements and on the combined management report. We are responsible for the direction, supervision and performance of the Group audit. We remain solely responsible for our audit opinions.
- evaluate the consistency of the combined management report with the consolidated financial statements, its conformity with German law, and the view of the Group's position it provides.
- perform audit procedures on the prospective information presented by the executive directors in the combined management report. On the basis of sufficient appropriate audit evidence we evaluate, in particular, the significant assumptions used by the executive directors as a basis for the prospective information, and evaluate the proper derivation of the prospective information from these assumptions. We do not express a separate audit opinion on the prospective information and on the assumptions used as a basis. There is a substantial unavoidable risk that future events will differ materially from the prospective information.

We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide those charged with governance with a statement that we have complied with the relevant independence requirements, and communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, the actions taken or safeguards applied to address independence threats.

From the matters communicated with those charged with governance, we determine those matters that were of most significance in the audit of the consolidated financial statements of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter.

Other legal and regulatory requirements

Assurance report in accordance with Section 317 (3a) HGB on the electronic reproduction of the consolidated financial statements and the combined management report prepared for publication purposes

Conclusion

We have performed an assurance engagement in accordance with Section 317 (3a) HGB to obtain reasonable assurance about whether the reproduction of the consolidated financial statements and the combined management report (hereinafter the "ESEF documents") contained in the electronic file made available with the SHA-256-Wert 0573544b4c0d0cfbecefc1f6fdb9019c5981d53995228e31bb35d02d9e199b7 and prepared for publication purposes complies in all material respects with the requirements of Section 328 (1) HGB for the electronic reporting format ("ESEF format"). In accordance with German legal requirements, this assurance engagement only extends to the conversion of the information contained in the consolidated financial statements and the combined management report into the ESEF format and therefore relates neither to the information contained within this reproduction nor to any other information contained in the above-mentioned electronic file.

In our opinion, the reproduction of the consolidated financial statements and the combined management report contained in the above-mentioned electronic file and prepared for publication purposes complies in all material respects with the requirements of Section 328 (1) HGB for the electronic reporting format. We do not express any opinion on the information contained in this reproduction nor on any other information contained in the above-mentioned file beyond this reasonable assurance conclusion and our audit opinion on the accompanying consolidated financial statements and the accompanying combined management report for the fiscal year from 1 December 2022 to 30 November 2023 contained in the "Report on the audit of the consolidated financial statements and on the combined management report" above.

Basis for the opinion

We conducted our assurance engagement on the reproduction of the consolidated financial statements and the combined management report contained in the above-mentioned electronic file in accordance with Section 317 (3a) HGB and the IDW Assurance Standard: Assurance in Accordance with Section 317 (3a) HGB on the Electronic Reproduction of Financial Statements and Management Reports Prepared for Publication Purposes (IDW AuS 410 (06.2022)). Accordingly, our responsibilities are further described below in the “Group auditor’s responsibilities for the assurance engagement on the ESEF documents” section. Our audit firm has applied the Requirements of the IDW quality management standards.

Responsibilities of the executive directors and the Supervisory Board for the ESEF documents

The executive directors of the Company are responsible for the preparation of the ESEF documents including the electronic reproduction of the consolidated financial statements and the combined management report in accordance with Section 328 (1) sentence 4 no. 1 HGB and for the tagging of the consolidated financial statements in accordance with Section 328 (1) sentence 4 no. 2 HGB.

In addition, the executive directors of the Company are responsible for such internal control as they have considered necessary to enable the preparation of ESEF documents that are free from material non-compliance with the requirements of Section 328 (1) HGB for the electronic reporting format, whether due to fraud or error.

The Supervisory Board is responsible for overseeing the process of preparing the ESEF documents as part of the financial reporting process.

Group auditor’s responsibilities for the assurance engagement on the ESEF documents

Our objective is to obtain reasonable assurance about whether the ESEF documents are free from material non-compliance with the requirements of Section 328 (1) HGB, whether due to fraud or error. We exercise professional judgment and maintain professional skepticism throughout the audit. We also

- identify and assess the risks of material non-compliance with the requirements of Section 328 (1) HGB, whether due to fraud or error, design and perform assurance procedures responsive to those risks, and obtain assurance evidence that is sufficient and appropriate to provide a basis for our assurance conclusion.
- obtain an understanding of internal control relevant to the assurance engagement on the ESEF documents in order to design assurance procedures that are appropriate in the circumstances, but not for the purpose of expressing an assurance conclusion on the effectiveness of these controls.
- evaluate the technical validity of the ESEF documents, i.e., whether the electronic file made available containing the ESEF documents meets the requirements of the Delegated Regulation (EU) 2019/815 in the version applicable as at the balance sheet date on the technical specification for this electronic file.
- evaluate whether the ESEF documents enable an XHTML reproduction with content equivalent to the audited consolidated financial statements and the audited combined management report.
- evaluate whether the tagging of the ESEF documents with Inline XBRL technology (iXBRL) in accordance with the requirements of Articles 4 and 6 of the Delegated Regulation (EU) 2019/815, in the version applicable at the date of the consolidated financial statements, enables an appropriate and complete machine-readable XBRL copy of the XHTML rendering.

Further information pursuant to Article 10 of the EU Audit Regulation

We were elected as Group auditor by the Annual General Meeting on 25 May 2023. We were engaged by the Supervisory Board on 17/23 November 2023. We have been the Group auditor of Heidelberg Pharma AG, Ladenburg, Germany, without interruption since fiscal year 2011/12.

We confirm that the audit opinions expressed in this auditor's report are consistent with the additional report to the audit committee pursuant to Article 11 of the EU Audit Regulation (long-form audit report).

Other matter – use of the auditor's report

Our auditor's report must always be read together with the audited consolidated financial statements and the audited combined management report as well as the assured ESEF documents. The consolidated financial statements and the combined management report converted to the ESEF format – to be entered in the company register – are merely electronic renderings of the audited consolidated financial statements and the audited combined management report and do not take their place. In particular, the ESEF report and our assurance opinion contained therein are to be used solely together with the assured ESEF documents made available in electronic form.

German public auditor responsible for the engagement

The German Public Auditor responsible for the engagement is Steffen Schmidt.

Frankfurt am Main, 21 March 2024

Deloitte GmbH
Wirtschaftsprüfungsgesellschaft

signed Steffen Schmidt
Wirtschaftsprüfer
[German Public Auditor]

signed Marvin Nemeth
Wirtschaftsprüfer
[German Public Auditor]

GLOSSARY

17p-Deletion: “17p deletion” refers to the partial loss of genetic material located on the short arm of chromosome 17, whose DNA includes both the gene for tumor suppressor protein TP53 and the gene encoding the largest subunit of RNA polymerase II (POLR2A).

Amanitin: toxin that is a member of the amatoxin group of natural poisons occurring in the death cap (*Amanita phalloides*), among others.

Antibodies: Proteins which are produced by the immune system with the aim of identifying and destroying foreign substances that cause disease, such as viruses and bacteria.

Antibody Drug Conjugate (ADC) technology: Antibody drug conjugates are monoclonal antibodies attached to biologically active drugs by chemical linkers. Combining the specific targeting of antibodies with cancer-killing cytotoxic drugs enables ADCs to discriminate between healthy and tumor tissue and to bring the cytotoxin only to the cancer cells. This combination enhances the control of drug pharmacokinetics and significantly improves delivery to target tissue.

Antibody Targeted Amanitin Conjugate: Antibody drug conjugate using the amanitin toxic. ATACs are third-generation ADCs characterized by improved efficacy, also as regards quiescent tumor cells. Quiescent tumor cells are scarcely reached with existing standard therapies and contribute to tumor recurrence and resistance formation. These ATACs will also be used to treat therapy-resistant tumors that no longer respond to standard chemotherapy or anti-tumor antibodies.

Antigen: Structure onto which an antibody specifically binds.

Apoptosis: programmed cell death.

BCMA (B-cell maturation antigen): Surface protein that is highly expressed in multiple myeloma cells.

BLA (Biologics License Application): Application for drug approval of a biological product to the US Food and Drug Administration (FDA), which drug manufacturers must submit in order to obtain marketing approval.

CAIX: Antigen that binds to the antibody girentuximab.

Camptothecin: A cytostatic drug obtained from the seeds, roots, bark, wood and (young) leaves of the Chinese tree of happiness (*Camptotheca acuminata*).

CAPA (Corrective and Preventive Action): Any discrepancies/deviations/errors that occur are systematically investigated and corrective action and then preventive action are taken.

CBER: Center for Biologics Evaluation and Research.

CD37: Surface molecule expressed by B-cells.

CDER: Center for Drug Evaluation.

CDMO: Contract Development and Manufacturing Organization.

Chemotherapy: Use of cell toxins to destroy tumor cells in the body.

Cohort: A group of people selected according to certain criteria and examined over a certain period of time.

CRO (Clinical Research Organization): Contract research organization for conducting clinical trials.

Diagnostic agent: A tool, gene or protein that aids in the diagnosis of an illness.

EAP (Expanded Access Program): Extended access to unauthorized medicinal products for patients with particularly serious illnesses that cannot be treated satisfactorily with authorized medicinal products.

EMA (European Medicines Agency): Agency of the European Union that coordinates the evaluation and monitoring of all medicinal products for human and veterinary use.

EPO: European Patent Office.

Exatecan: The active ingredient exatecan is a synthetic derivative of the naturally occurring toxin camptothecin.

FDA: Food and Drug Administration – regulatory authority in the US.

GCC (guanylatecyclase): Surface protein on the luminal side of intestinal cells that is also present in various gastrointestinal tumors.

Girentuximab: International non-proprietary name (INN) for TLX250. TLX250 is the development name for the therapeutic antibody WX-G250, which is based on the chimeric antibody cG250. The radiolabeled antibody developed under the name TLX250-CDx has the INN Iodine (124I) girentuximab.

Good Laboratory Practice (GLP): International regulations governing the conduct of tests in laboratories.

Good Manufacturing Practice (GMP): International regulations governing the production of pharmaceutical products.

HPD-101: Development name for the proprietary ATAC candidate that is composed of a BCMA antibody, a linker and the Amanitin toxin.

HDP-102: Development name for the proprietary ATAC candidate, which consists of an antibody targeting the CD37 molecule, a linker and the toxin Amanitin.

HDP-103: Development name for the proprietary ATAC candidate HDP-103, which consists of an antibody targeting the prostate-specific membrane antigen (PSMA), a linker and the toxin Amanitin.

HDP-104: Development name for the proprietary ATAC candidate HDP-104, which is composed of an antibody against the target molecule GCC, a linker and the toxin Amanitin.

IMF: International Monetary Fund.

Immunostimulant: Enhancement of the body's natural immune response through active ingredients.

Inhibitor: Substance which reduces or inhibits specific biological activities.

In Process Research & Development (IP R&D): Not yet ready for use intangible assets.

In vitro: Refers to a procedure or reaction that takes place in a test tube.

In vivo: Refers to a procedure or reaction that takes place in the body.

Linker: Bridging molecule, used e. g. to connect a toxin to an antibody.

Lymphoma (malignant): Cancer of the lymphatic system. In lymphomas, white blood cells, known as lymphocytes, grow uncontrollably.

Metastases: The spread of malignant tumor cells in the body and the formation of secondary tumors.

MGTA-117: Development name for the ATAC candidate of our licensing partner, Magenta.

Molecule: A chemical structure composed of at least two particles (atoms).

Multiple myeloma (MM): MM is a cancer of the hematopoietic system. Its typical characteristic is the proliferation of antibody-producing cells, the plasma cells. Multiple myeloma is the most common malignant neoplasm of the bone marrow.

Non-Hodgkin lymphoma (NHL): All malignant cancers of the lymphatic system (malignant lymphomas), which are not Hodgkin lymphomas.

Oncology: Research field which focuses on cancer studies.

Oral: Administration via the mouth.

Overexpressed: Increased production of, for example, protein.

Partial response: objective improvement of the disease.

Phase I: Clinical trial of a substance carried out on a low number of healthy subjects or patients under strict supervision that serves to investigate toxicity, pharmacokinetics, form of administration and safe dosage of a substance.

Phase II: Clinical trial with a low number of patients with the aim of testing the efficacy of a substance for specific indications, identifying any side effects and safety risks and determining the tolerance and optimum dosage.

Phase III: Clinical trial with a large number of patients (several hundred to several thousand) to ascertain the safety, tolerance and efficacy as well as optimum dosage of a substance under real therapy condition. **Priority Review:** Expedited approval process for drug review by the FDA to make novel drugs for serious or life-threatening diseases available to patients more quickly.

POLR2A: Genes containing the information for RNA-polymerase II. RNA-polymerase II is a protein complex, which enables the synthesis of mRNA and thus the reading of DNA. This process is fundamental for protein synthesis in eukaryotic cells (in animals and humans).

Positron emission tomography (PET): A radio nuclide imaging procedure, which can visualize biochemical and physiological processes by means of radioactive materials.

Preclinical: The preclinical phase comprises all *in vitro* and *in vivo* test systems for examining the features of a substance prior to the start of the clinical phases.

Product license agreement (PLA): Agreement for the use of a product/technology based on a license that usually concerns a patent or protected, secret know-how.

Prostate cancer, metastatic castration-resistant (mCRPC): Malignant tumor disease of the prostate gland developing metastasis, which progresses despite hormone therapy. In the case of mCRPC the prostate specific antigen (PSA) value rises despite hormone therapy and low testosterone levels.

PSMA: Prostate-specific membrane antigen. PSMA is overexpressed in prostate cancer specifically and is a promising target for an ADC approach, as it shows very low expression in normal tissues.

R&D: Research and development.

Recurrent: The recurrence of a disease after it has already been successfully treated.

Refractory: The reappearance of a disease or the diminishing of its effect after an initial response to treatment or immediately after the end of treatment.

Replication: multiplication.

RHB-107: Development name for the orally-administered serine protease inhibitor, which treats different diseases [COVID-19, cancer, inflammatory lung diseases and diseases of the digestive tract (Partner RedHill)].

RNA-polymerase II: Enzyme complex that mainly catalyzes the synthesis of mRNA (messenger ribonucleic acids) in the transcription of DNA in eukaryotes.

Sensitivity: indicates how reliably a diagnostic procedure detects diseased patients.

Serine protease: A type of peptidase (i.e. enzymes which catalyze the split of proteins and peptides).

Stable disease: No visible progression of the disease.

Therapeutic agent: Drug applied for the treatment of illnesses.

Thrombin: Enzyme that enables blood to coagulate.

Thrombocytes: blood components that are responsible for blood clotting.

TLX250: Development name for the antibody-based platform with the antibody girentuximab for diagnosis (PET imaging with ⁸⁹Zr-girentuximab) and treatment (¹⁷⁷Lu-girentuximab) of different types of cancer (Partner Telix).

TLX250-CDx: Development name for the zirconium-89 (⁸⁹Zr) radiolabeled antibody girentuximab for PET diagnosis of kidney tumors (Partner Telix).

Topoisomerase: An enzyme responsible for the unwinding of DNA double strands during processes such as DNA replication and transcription.

Toxin: Poison.

Tumor suppressor gene TP53: Part of the genetic sequence of chromosome 17, where the p53 protein is located. P53 regulates and activates among others DNA repair mechanisms and programmed cell death TP53 is the tumor gene that mutates the most frequently.

uPA: Urokinase-type plasminogen activator.

upamostat: International non-proprietary name for the oral serine protease inhibitor RHB-107.

Zircaix™: Zircaix™ (TLX250-CDx) is a radiopharmaceutical imaging technique for the diagnosis and follow-up of clear cell renal cancer using PET.

FINANCIAL CALENDAR 2024

Date	Type of report/event
25 March 2024	Annual Report 2023
25 March 2024	Financial press conference and analysts' meeting
25 April 2024	Interim management statement on the first three months of 2024
20 June 2024	Annual General Meeting 2024
11 July 2024	Half-yearly Financial Report 2024
10 October 2024	Interim management statement on the first nine months of 2024

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Please see our website for the current list of conferences 2024.

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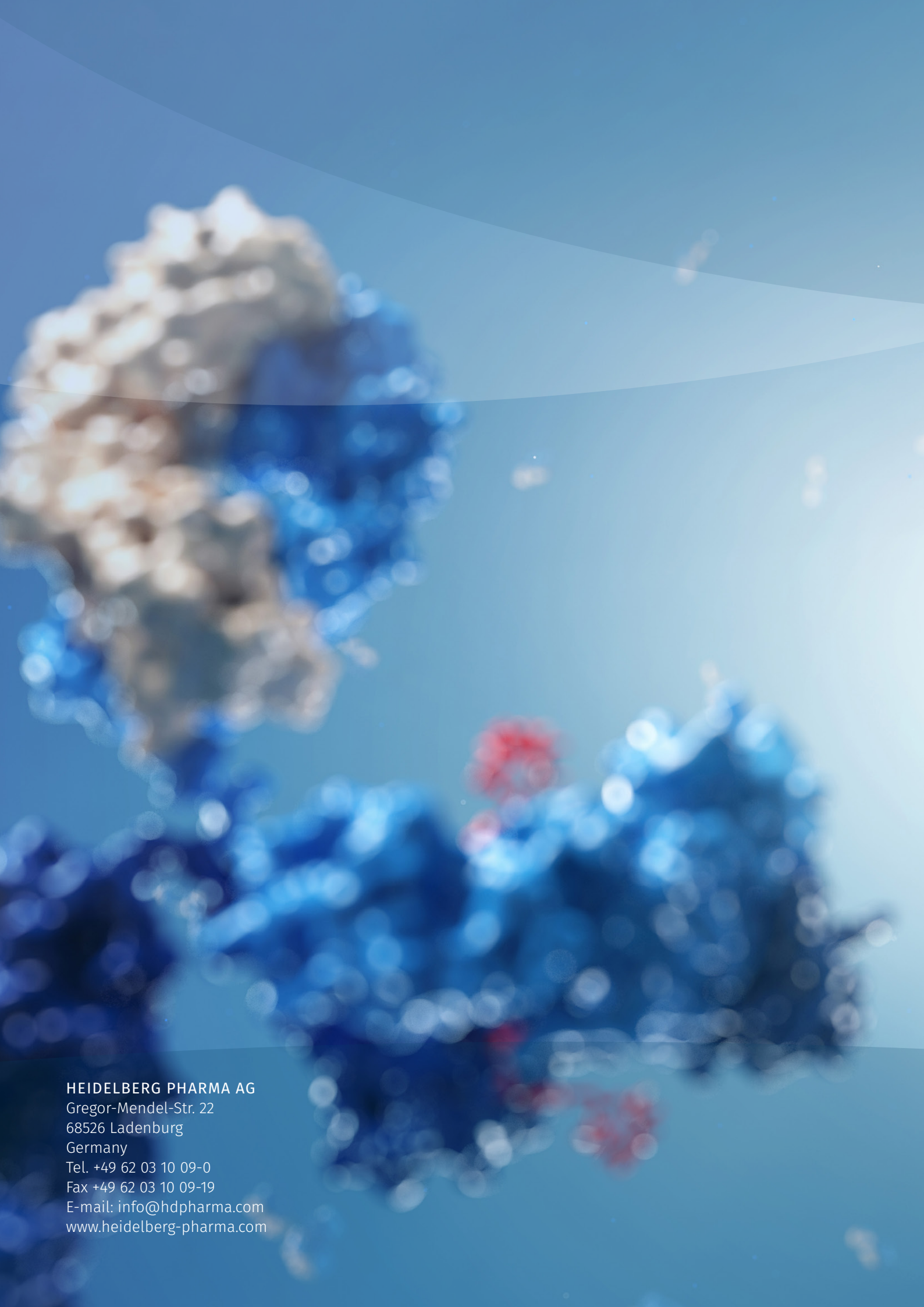
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The Annual Report is also published in German and is available for download from our website at www.heidelberg-pharma.com. The English translation of the Annual Report is provided for convenience only. The German original is definitive.

As of: 21 March 2024



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