

KEY FIGURES

	2022 ¹ €'000	2021 ¹ €'000
Earnings		
Sales revenue	18,514	1,750
Other income	1,346	564
Operating expenses	(37,042)	(27,945)
of which research and development costs	(26,377)	(18,750)
Operating result	(17,181)	(25,631)
Earnings before tax	(17,786)	(26,139)
Net loss for the period	(19,702)	(26,139)
Earnings per share in € (basic)	(0.53)	(0.80)
Balance sheet at end of period		
Total assets	100,582	21,732
Cash	81,329	6,141
Equity	66,644	6,699
Equity ratio ² in %	66.3	30.8
Cash flow statement		
Cash flow from operating activities	(8,864)	(26,613)
Cash flow from investing activities	(598)	(1,402)
Cash flow from financing activities	84,001	29,170
Employees (number)		
Employees as of the end of the period (headcount) ³	110	96
Employees as of the end of the period (full-time equivalents) ³	102	89

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

² Equity/total assets

³ Including members of the Executive Management Board

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

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 = Glossary (term marked in blue) or cross reference

 = Internet reference





Heidelberg Pharma's mission is to develop drugs for targeted, tailor-made and highly effective cancer treatments.

We are the first company to use the toxin Amanitin for the treatment of cancer, using the clinically proven ADC technology to transport the drug into affected cells. ADCs are antibody-drug conjugates that combine the high affinity and specificity of antibodies with the efficacy of small toxic molecules.

We research, develop and manufacture antibody-drug conjugates based on our patented and proprietary ATAC technology. ATACs are ADCs that use the active ingredient Amanitin. The particular mode of action of this toxin offers the opportunity to break through therapy resistance and also eliminate dormant tumor cells, which could lead to significant advances in cancer therapy.



PORTFOLIO

	Product	Target	Indication	Research	Preclinic	Phase			Partners
						I	II	III	
ATAC pipeline	HDP-101	BCMA	Multiple myeloma (DLBCL/CLL)	[Progress bar]	[Progress bar]	[Progress bar]			Huadong (Asia)
	HDP-102	CD37	Non-Hodgkin Lymphoma	[Progress bar]	[Progress bar]				Huadong (Asia, option)
	HDP-103	PSMA	Prostate cancer	[Progress bar]	[Progress bar]				Huadong (Asia)
	HDP-104	GCC	Gastro intestinal (e.g. CRC)	[Progress bar]	[Progress bar]				Huadong (Asia, option)
	HDP-XX	n/a	Solid and hematological tumors	[Progress bar]	[Progress bar]				Proprietary
ATAC partners	MGTA-ATACs	CD117, CD45	HSCs, conditioning programs for blood cancers and genetic diseases	[Progress bar]	[Progress bar]	[Progress bar]			Magenta
	TAK-ATAC	n/a	Oncology	[Progress bar]	[Progress bar]				Takeda
	CHIOME-ATAC	CDCP1	Oncology	[Progress bar]	[Progress bar]				Chiome
Legacy assets	TLX250-CDx	CA-IX	Renal and urothelial carcinoma, TNBC	[Progress bar]	[Progress bar]	[Progress bar]	[Progress bar]		Telix
	TLX250	CA-IX	Renal carcinoma	[Progress bar]	[Progress bar]	[Progress bar]			Telix
	RHB-107		Oncology/GI, COVID-19	[Progress bar]	[Progress bar]	[Progress bar]			RedHill
	LH011		Pancreatic cancer	[Progress bar]	[Progress bar]	[Progress bar]			Link Health



FOR CLINICAL TRIAL USE ONLY
Protocol: HDP-101-01

Re-test date / Datum der Nachtestung:
01-Oct-2021

Sponsor: Heidelberg Pharma AG, Gregor-Meyer-Str. 10
D-68526 Ladenburg, Phone number: +49 6204 49-100

FOR CLINICAL TRIAL USE ONLY
Protocol: HDP-101-01

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01-Oct-2021

Sponsor: Heidelberg Pharma AG, Gregor-Meyer-Str. 10
D-68526 Ladenburg, Phone number: +49 6204 49-100

HIGHLIGHTS IN 2022

February

Heidelberg Pharma treats first patient with HDP-101 in a phase I/IIa clinical trial in the indication Multiple Myeloma

Establishment of a strategic partnership with Huadong Medicine including license and option agreement as well as investment agreement

March

Milestone payment from partner Magenta for dosing the first patient with ATAC candidate MGTA-117

April

New preclinical data on ATAC Technology Platform to be presented at AACR Annual Meeting 2022

June

Virtual Annual General Meeting

July

Conclusion of an exclusive research and option agreement with Chiome Bioscience for the development of an ATAC

August

Rights issue carried out with proceeds of € 80 million, Huadong becomes second-largest shareholder

September

Conclusion of an exclusive license agreement with partner Takeda for the development of an ATAC

October

Adjustment of financial guidance due to higher sales and lower development expenses

November

Partner Telix reports positive data on its pivotal ZIRCON study with out-licensed imaging candidate TLX250-CDx

December

Presentation of initial safety data from clinical trial with candidate HDP-101 at the 2022 ASH Annual Meeting

LETTER TO THE SHAREHOLDERS

Dear Ladies and Gentlemen,
Dear Shareholders,

2022 was the most successful year since our realignment in 2017. We managed to reach important milestones with our ATAC technology, inked several deals, and successfully implemented a major financing measure.

Successful establishment of partnerships and financing

The strategic partnership with the Chinese company Huadong is pivotal for us. The licensing agreement for ATAC candidates HDP-101 and HDP-103 and the exclusive option agreement for HDP-102 and HDP-104 pave the way for clinical development and, if successful, commercialization of these candidates in the Asian region. The upfront payment we received improved our cash position.

The investment, which is part of an €80 million capital increase, along with the off-exchange acquisition of shares with a value of approximately €25 million from our main shareholder dievini underscores Huadong's strategic interest in our company and significantly strengthens Heidelberg Pharma's financial situation. After dievini, Huadong is now our second-largest shareholder with a 35% stake. As an investor with a long-term outlook, Huadong will support us in successfully refining our ATAC technology and becoming a global ADC player. The Chinese partner's extensive development and commercialization expertise as well as knowledge of the Asian markets will help to expand the product pipeline and accelerate development.

We are pleased with the deals made and the expansion of our ATAC technology partnerships with Chiome and Takeda over the past fiscal year.

Advances in the proprietary ATAC pipeline

One of the highlights was the start of the clinical development of our first proprietary ATAC candidate HDP-101 – something we had been working towards for years. The first patient was dosed with our development candidate HDP-101 at the beginning of February. We are pleased that an ATAC substance developed in our own labs has reached the clinical stage and that we are evolving from being a purely research-based company into a drug developer. To date, patients have been treated in three dose cohorts; HDP-101 has so far been shown to be safe and well tolerated.

Development of the successor candidates HDP-102 and HDP-103 also continued as planned. At a scientific convention in the fall of 2022, we presented our newest candidate from the ATAC portfolio: HDP-104 targeting the protein guanylyl cyclase-C, which is overexpressed in gastrointestinal tumors.

Successes in the clinical license portfolio

We received very promising news from Australia in November. Telix, our partner for the out-licensed antibody girentuximab, reported positive data and the reaching of all end points in its Phase III ZIRCON study with TLX250-CDx. Telix is preparing to submit applications with the FDA and other regulators around the world for approval of TLX250-CDx as a positron emission tomography/computed tomography (PET/CT) imaging agent for use in the characterization of indeterminate renal masses. The goal is to introduce the product candidate on the market in 2024, initially in the United States. In this case, Heidelberg Pharma will benefit from milestone payments and royalties.

Magenta suffers setbacks, with consequences for its business

After having started the clinical development with its ATAC candidate MGTA-117 in 2022, Magenta presented encouraging clinical data from two patient cohorts from its study for the targeted preparation, or conditioning, of patients for stem cell transplants, cell or gene therapy at the ASH Annual Meeting in December 2022.

Not long afterwards, it was reported that severe pulmonary side effects had appeared in Cohort 4, and in January 2023 it was reported that a participant dosed at the Cohort 3 level had experienced a Grade 5 Serious Adverse Event (SAE) resulting in death and possibly related to MGTA-117. Magenta decided to immediately pause the dosing in the clinical trial. The company announced at the beginning of February 2023 that all ongoing programs – including MGTA-117 – had been halted and that it would conduct a comprehensive review of strategic alternatives for the company. By the end of February, the company had cut its workforce by 84%.

Implications for Heidelberg Pharma

We take the findings of Magenta's clinical trial very seriously and are conducting a detailed analysis of how these could affect Heidelberg Pharma. At the end of February 2023, Magenta terminated the Amanitin linker supply agreement, which will lead to lost revenue for us in the low single-digit million range in 2023. Further consequences for the contract situation depend on the course of Magenta's strategic realignment and cannot be estimated at present. However, we assume that our partnership with Magenta will not be continued.

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

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

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

Financial position of Heidelberg Pharma

We are very pleased with our figures for the 2022 fiscal year, particularly sales revenue and the cash provided by the agreements with Huadong. The operating result improved and the funding requirements decreased significantly. Financials for 2022 are all within the last guidance.

We are confident to deliver a strong performance in 2023, though we do expect lower revenues compared to those of 2022 as a result of the strong prior-year effects of the Huadong partnership. Continued development of our pipeline will mean that our operating expenses will be higher than in the previous year. We have not included any income from major potential licensing agreements in our planning but will continue to work on the successful expansion of our partnerships.

Working together today on therapies for tomorrow

Our team is growing in line with our tasks. We aim to develop novel drugs that are safe to use in highly effective, tailor-made cancer therapies. We would like to warmly thank our staff for its enthusiasm and dedication. Our thanks also go to our business partners and shareholders for their trust and longstanding support.

Ladenburg, 22 March 2023

Yours sincerely,



Dr. Jan Schmidt-Brand
Chief Executive Officer and Chief Financial Officer



Professor Andreas Pahl
Chief Scientific Officer

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: cooperation with Huadong Medicine Co., Ltd, Hangzhou, China, (Huadong) development strategy for HDP-101, possible projects, licensing negotiations, technology partnerships, M&A opportunities and financing. 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 Executive Management Board. 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 2022 fiscal year

In the 2022 fiscal year (1 December 2021 to 30 November 2022), the Supervisory Board met for four regular meetings and several extraordinary meetings by telephone. Participation in the ordinary meetings took place either virtually or in person.

Attendance overview

Date	Hettich	Baur	Hothum	Von Bohlen und Halbach	Kudlek	Zhao	Liu
24/25 Feb. 2022 by phone	X	X	X	X	X	Not yet in office	Not yet in office
22 March 2022	–	X	X (in person)	–	X	Not yet in office	Not yet in office
28 June 2022	X (in person)	X	X (in person)	–	X (in person)	–	–
12/30 Aug. 2022 by phone	X	X	X	–	X	–	–
10 Oct. 2022	X (in person)	X (in person)	X (in person)	X (in person)	X (in person)	X (in person)	X (in person)
22 Nov. 2022	X	X	X (in person)	X (in person)	X (in person)	X	X

Main topics at the meetings of the Supervisory Board in the 2022 fiscal year

In the 2022 fiscal year, the Supervisory Board discussed and approved the following items requiring its approval:

- Approval of the 2021 annual and consolidated financial statements
- Evaluation of corporate objectives for the 2022 fiscal year and definition of corporate objectives for the 2023 fiscal year
- Budget for the 2023 fiscal year
- Agenda and proposed resolutions for the 2022 Annual General Meeting
- Preparations for the clinical development of HDP-101
- Start of production of the successor candidates HDP-102 and HDP-103
- Nomination of another successor HDP-104
- Establishment of cooperation agreement with Huadong
- Conclusion of a research and option agreement with Chiome
- Conclusion of a license agreement with Takeda
- Negotiation mandates for potential contractual partnerships
- Implementation of a capital measure based on a securities prospectus in August/September 2022
- Expansion of the Supervisory Board
- Renewal of the Supervisory Board's rules of procedure and preparation of a manual for the Supervisory Board
- Creation of a competency profile and conduct of an efficiency review for the Supervisory Board

- Expansion of the management level by senior positions as well as adoption of a virtual stock option program for consultants with executive functions
- Compensation system for the Executive Board and Supervisory Board
- Approval of a letter of intent for a new possible location

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 Supervisory Board was regularly informed about activities at Heidelberg Pharma AG's licensees for 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, which is focused on refining and marketing its technology platform for therapeutic antibody drug conjugates.

Virtual 2022 Annual General Meeting

The Annual General Meeting of Heidelberg Pharma AG was held on 28 June 2022 in a virtual format. All proposed resolutions were adopted by majorities ranging from 98,49% and 99,99%.

Corporate governance

The Supervisory Board together with the Executive Management Board decided on 30 January 2023 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".

 www.heidelberg-pharma.com

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 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 did not meet in fiscal year 2022.

The Audit Committee met two times in the year under review. The Audit Committee discussed the annual report for 2021 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 28 June 2022 and subsequently commissioned by the Supervisory Board to audit the 2022 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 2022 with the Executive Board prior to publication. The committee also dealt in detail with the Company's risk management system.

The Research and Development Committee of the Supervisory Board was dissolved as, in the view of the Supervisory Board, it was not necessary for the efficient functioning of the Supervisory Board.

There are no other committees.

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 2022, including the underlying accounting, and issued an unqualified auditor's report. The lead auditor of these consolidated financial statements was Mr. Jörg Wegner, who has held this position since the 2018 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 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 16 March 2023 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 22 March 2023:

"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 2022 fiscal year.

Ladenburg, 22 March 2023

For the Supervisory Board



Professor Christof Hettich
Chairman of the Supervisory Board

INVESTOR RELATIONS

Market development

The geopolitical crises in 2022 and monetary policy upheavals led to the stock markets delivering one of their worst performances in years.¹ All of the major indices lost ground, closing 2022 with losses. Nasdaq was down over 30% and the German benchmark index, the DAX, lost 13%; the TecDAX technology index finished the year down 25%.

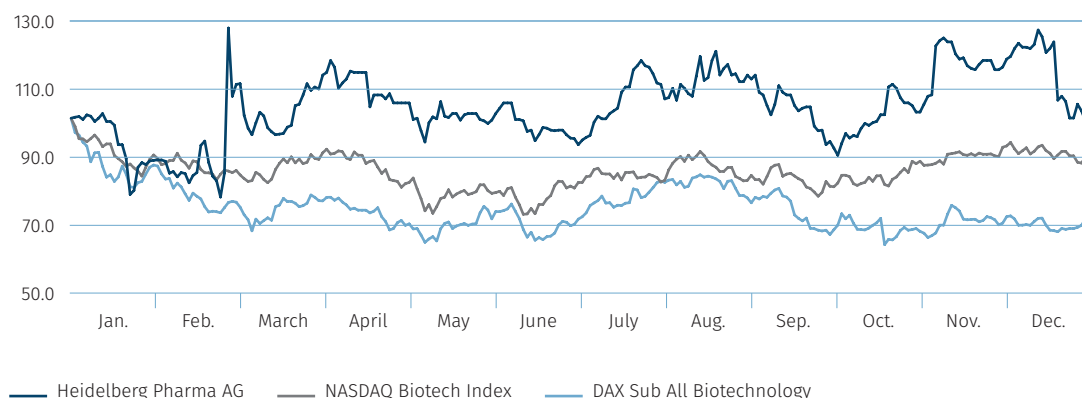
Biotechnology indices also presented a less than successful picture. The German DAX subsector Biotechnology Index recorded losses of over 30% on the prior-year figure. Following a rebound in the second half, the US NASDAQ Biotechnology Index ended the year down 12%, remaining far behind prior years.

Biotechs completed 53 IPOs in 2022 (2021: 208), with 19 in the USA and just two in the EU, falling significantly short of the previous year.² At least for the first half of 2023 a low number of IPOs is still expected.³

Share price performance of Heidelberg Pharma's shares in 2022

Heidelberg Pharma's shares started 2022 trading at €4.95, reaching their low for the year of €3.40 on 25 January 2022. The stock rallied briefly to €6.30 on the announcement of the strategic partnership with Huadong, but this was overshadowed by the outbreak of war in Ukraine. The shares held up well in the difficult market environment as the year went on, moving between €4.70 and €5.70, and reached their high for the year of €6.50 on 13 December 2022. Trading at €4.93 at year-end, Heidelberg Pharma's shares (Xetra) were down marginally by 0.4% and thus significantly outperformed the indices.

Heidelberg Pharma's share price performance, indexed as of 1 January 2022



1 Tagesschau, 31 December 2022, <https://www.tagesschau.de/wirtschaft/jahresueckblick-boerse-103.html>

2 BCIQ database, 31 January 2023

3 BioCentury, 13 January 2023: Surviving a year of the haves and have-nots

Trading and liquidity

The average daily trading volume of Heidelberg Pharma's shares across all German stock exchanges in 2022 (1 January to 31 December) was 6,874 shares (previous year: 17,735 shares). The Company's market capitalization at the end of December 2022 was €229.66 million (2021: €162.51 million).

Key share figures Period under review: 1 January to 31 December 2022 ¹	FY 2022	FY 2021
Market capitalization in € million	229.66	162.51
Number of shares issued	46,584,457	34,175,809
Closing price (XETRA) in €	4.93	4.75
High ² in €	6.50 (on 13 Dec. 2022)	9.70 (on 18 Feb. 2021)
Low ² in €	3.40 (on 25 Jan. 2022)	4.59 (on 1 Feb. 2021)
Volatility (260 days; XETRA) in %	61.23	69.22
Average daily trading volume ² in shares	6,874	17,735
Average daily trading volume ² in €	36,018	124,226

¹ As of the end of the reporting period

² All stock exchanges

Source: Bloomberg

Strategic partnership, corporate actions and financing

Heidelberg Pharma and Chinese company Huadong Medicine (SZ 000963; Huadong) signed an exclusive strategic partnership at the end of February comprised of a licensing agreement and an investment agreement. Huadong declared its readiness to invest a total of €105 million in Heidelberg Pharma, which means it will hold 35% of the available shares when the transaction is completed and consequently become the Company's second-biggest shareholder.

The transaction was essentially planned as a rights issue, which kicked off in August. Heidelberg Pharma offered all shareholders a total of 12,408,648 new shares for subscription at a price of €6.44 each. In accordance with the agreement dated 27 February 2022, the partner Huadong participated to a significant extent in the rights issue, acquiring 9,374,156 shares through pre-emption rights from the main shareholder dievini Hopp BioTech holding GmbH & Co. KG and its affiliated companies. Huadong also acquired 2,464,496 shares that were not subscribed by other shareholders, bringing its equity interest in Heidelberg Pharma to 25%. To reach the targeted 35% shareholding, Huadong bought 4,465,908 more shares from dievini at a price of €6.44 per share. Germany's federal financial supervisory authority BaFin exempted Huadong from making a takeover bid to all shareholders.

The corporate action generated total gross issue proceeds of approximately €80 million for Heidelberg Pharma, most of which will be used to carry out the ongoing Phase I trial of HDP-101 and to continue the development of the follow-on projects HDP-102 and HDP-103 as well as the proprietary ATAC technology.

After the implementation of the capital increase had been entered in the Commercial Register of Mannheim Local Court on 2 September 2022, the Company's share capital increased to 46,584,457 shares.

Annual General Meeting

The Annual General Meeting of Heidelberg Pharma AG took place in a virtual format on 28 June 2022. Of the Company's share capital at that time (34,175,809 no par value bearer shares), 28,111,713 shares, or 82.26%, 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:

- Increase in the number of Supervisory Board members and the corresponding amendment to the Articles of Association
- Elections to the Supervisory Board, specifically two representatives of Huadong
- Amendments to authorized and contingent capital and corresponding amendments to the Articles of Association
- Remuneration of the members of the Supervisory Board and the corresponding amendment to the Articles of Association
- Approval of the remuneration report

All proposed resolutions were adopted by a significant majority of between 98.49% and 99.99%.

Shareholder structure of Heidelberg Pharma AG¹

Dietmar Hopp, parties related to him and companies controlled by them ²	45.67%
Huadong Medicine Co., Ltd.	35.00%
Corporate bodies (held directly)	4.32%
Free float	15.01%

¹ As of 30 November 2022

² Includes dievini Hopp BioTech holding GmbH & Co. KG, DH-Holding Verwaltungs GmbH and DH-LT-Investments GmbH. All figures are assumptions by Heidelberg Pharma AG based on the most recent notifications in accordance with the German Securities Trading Act (Wertpapierhandelsgesetz - WpHG) and/or the voting rights reported at the most recent General Meeting.

General information¹

Listed:	Regulated Market (Prime Standard)
Stock exchange symbol:	HPHA
WKN/ISIN:	A11QVV/DE000A11QVV0
Share capital:	€ 46,584,457
Admitted capital:	46,584,457 bearer shares of common stock
Designated sponsors:	Pareto Securities AS, Stifel Europe Bank AG

¹ As of 30 November 2022

COMBINED MANAGEMENT REPORT

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COMBINED MANAGEMENT REPORT

for the Heidelberg Pharma Group and Heidelberg Pharma AG, Ladenburg

for the fiscal year from 1 December 2021 to 30 November 2022

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.

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. The Company's Executive Management Board consists of Dr. Jan Schmidt-Brand and Professor Andreas Pahl. Heidelberg Pharma (formerly WILEX AG) has been listed on the Regulated Market (Prime Standard, stock exchange symbol HPHA, ISIN DE000A11QVV0) 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. The subsidiary's Managing Director is Dr. Jan Schmidt-Brand. Heidelberg Pharma Research is also domiciled in Ladenburg, Germany. Since November 2019, the subsidiary has been 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 in the form of a supervisory board appointment, Emergence is now reported as an equity investment within the meaning of IFRS 9.

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 2022 fiscal year (1 December 2021 to 30 November 2022).

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52–71 and 52

1.2 Business activities

Heidelberg Pharma is active in biopharmaceutical drug development, specializing in [oncology](#). Its activities focus on an innovative [Antibody Targeted Amanitin Conjugate](#) technology that uses the biological mode of action of the toxin [Amanitin](#), which is known from the death cap mushroom, as a novel therapeutic principle in cancer medicine. This proprietary technology platform is being used to develop the Company's proprietary therapeutic antibody drug conjugates (ADCs) as well as in collaborations with external partners.

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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 further [preclinical](#) and clinical development and production of the clinical material under a license agreement. Heidelberg Pharma AG also performs functions relating to Group and research strategy, finance, investor and public relations, business development, project management, legal and regulatory matters and contract management. Other areas covered are alliance and data management, as well as intellectual property rights. Furthermore, the Company supports licensing partners for the legacy portfolio of diagnostic and therapeutic product candidates as well as the underlying intellectual property rights.

The subsidiary Heidelberg Pharma Research GmbH conducts research in the field of therapeutic antibody drug conjugates. To the best of the Company's knowledge, Heidelberg Pharma Research is the first company to develop the compound Amanitin for cancer therapies. It will be combined with tumor-specific [antibodies](#) designed to target the highly potent compound to the cancer cell. The goal is to develop a treatment that has fewer side effects and is more effective. The proprietary ATAC technology platform developed for this is employed for the purpose of producing, researching and developing selected proprietary Antibody Targeted Amanitin Conjugates as well as new ATAC candidates in collaborations with biopharmaceutical companies. Heidelberg Pharma Research also collaborates with production partners to supply its licensing partners with [good manufacturing practice \(GMP\)](#) quality Amanitin [linker](#) material for their development projects as required.

For detailed information regarding the projects and the current status of development, please see chapter 3, "Course of business in 2022."

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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 around 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 payload technologies.

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.

The first pillar of the business model involves producing proprietary ATAC [molecules](#) based on licensed or internally generated antibodies, testing these as [R&D](#) candidates and further refining them in the Company's own pipeline. At present, the most advanced of the Company's pipeline projects is [HDP-101](#), a drug conjugate 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.

The business model's second pillar involves working with partners in early-stage research collaborations to produce ATACs using the partners' antibodies. 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 ATAC alliances to continually generate sales revenue and license payments.

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 ATAC 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 ATAC technology, 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 external financing 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 exceed income and will 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. 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.

1.5 Intellectual property

The ATAC 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 protect its proprietary platform as well as future products and the associated inventions, which may encompass treatment methods, manufacturing processes and applications, and consequently strengthen 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. Some of these patents have already been granted, especially in the USA and Europe. Heidelberg Pharma Research GmbH has systematically improved the technology and expanded its patent portfolio with several new filings. In the meantime, applications for 20 more 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. Patent applications that protect specific methods for the modification and manufacture of antibodies have also been filed. 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 fiscal year ended again. The Company's patent strategy currently provides for potential exclusivity until 2045.

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 2022 fiscal year, Heidelberg Pharma AG held licensed intellectual property rights and owned more than 100 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 2022

2.1 Macroeconomic environment

Global economic activity experienced a sharper-than-expected slowdown in 2022, with inflation higher than seen in several decades. The International Monetary Fund (IMF) expects global growth of 3.4%¹ in 2022 (2021: 6.0%²). Projected growth for the eurozone economy is 3.1%, marginally below the global trend. European economic growth is proving to be more resilient than expected in the face of the large negative shock from the war in Ukraine. Germany, however, will fall significantly short of the global figure with growth of 1.9%.³ Crises and war-related extraordinary factors led to supply shortages and soaring prices for energy as well as in upstream stages of production. The average inflation rate in 2022 was 7.9% – significantly higher than in prior years.⁴

Both the war in Ukraine and the ongoing COVID-19 pandemic are weighing heavily on the global economy. However, the Heidelberg Pharma Group's activities have not been directly impacted by the war in Ukraine because we have no trial centers or suppliers in the affected regions. All the same, Heidelberg Pharma's activities are indirectly affected by the difficulties in procuring materials and higher prices for products and services.

2.2 Development of the pharmaceutical and biotechnology industry



FDA drug approvals fell sharply in 2022 compared with recent years, when many new drugs had been approved. After an average of 51⁵ new drug approvals per year since 2017, the FDA's Center for Drug Evaluation (CDER) logged only 37⁶ in 2022. The number of biological products approved by the Center for Biologics Evaluation and Research (CBER) likewise declined, from ten in 2021 to eight in 2022.⁷

The difficult overall economic situation and the effects of the pandemic on clinical and regulatory development steps may have contributed to the drop in drug approvals in the United States.⁸ The FDA also began to impose stricter requirements for accelerated approval. Particularly for oncology treatment, applications for accelerated approval are often made before a clinical confirmatory study begins.⁹ In the case of

1 <https://www.imf.org/en/Publications/WEO/Issues/2023/01/31/world-economic-outlook-update-january-2023>

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/2023/01/31/world-economic-outlook-update-january-2023>

4 <https://www.handelsblatt.com/finanzen/geldpolitik/inflation-die-inflationsrate-in-deutschland-von-2005-bis-2023/26252124.html>

5 <https://www.fiercepharma.com/special-reports/2022-drug-approvals-after-aduhelm-fiasco-fda-endorsements-were-harder-come>

6 <https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2022>

7 <https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/2022-biological-license-application-approvals>

<https://www.fiercepharma.com/special-reports/2022-drug-approvals-after-aduhelm-fiasco-fda-endorsements-were-harder-come>

Biocentury, 23 December 2022: FDA's 2022 approvals: oncology lulls while innovation rises

8 Biocentury, 23 December 2022: FDA's 2022 approvals: oncology lulls while innovation rises

9 Biocentury, 23 December 2022: FDA's 2022 approvals: oncology lulls while innovation rises

ADC Therapeutics SA, for example, the more stringent requirements led to postponement of the plans for a [BLA](#) filing for the ADC camidanlumab tesirine after the FDA recommended waiting until all patients had been recruited for a [Phase III](#) trial.¹⁰

 Glossary

By contrast, Germany saw 49 drug approvals in 2022, even more than in the previous year (2021: 46).¹¹ As in 2021, the focus was on compounds in the fields of infectious diseases and oncology (13 new compounds in each case), but four gene therapies were also approved.¹²

In spite of a rising number 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.¹³ Cancer medicine spending came to USD 185 billion in 2021, and global oncology spending is expected to exceed USD 300 billion by 2026.¹⁴ The high demand for cancer therapies is also reflected in the number of clinical trials. Cancer trial starts were up 56% in 2021 compared to 2016, reaching a record high.¹⁵

Therapies with antibody drug conjugates (ADCs)

The global ADC market had a volume of USD 4.2 billion in 2021 and is estimated to grow to over USD 13 billion in 2028.¹⁶ 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 two most common indications are lymphomas and hematologic cancers, followed by breast cancer and, increasingly, other solid tumors as well.¹⁷

The number of ADC programs has gone up compared with the previous year. At the end of 2022, 14 (2021: 12) oncological ADCs were in 16 Phase III clinical trials, of which four have already received approval and are being tested in other indications. A further 34 (2021: 25) ADCs are being studied in [Phase II](#) trials and 126 (2021: 100) in Phase I trials. A total of 120 ADC candidates (2021: 75) are currently in preclinical studies.¹⁸

10 ADC Therapeutics third quarter financial results 2022, 8 November 2022:

<https://ir.adctherapeutics.com/press-releases/press-release-details/2022/ADC-Therapeutics-Reports-Third-Quarter-2022-Financial-Results-and-Provides-Business-Updates/default.aspx>

11 <https://www.vfa.de/de/presse/press-releasen/pm-038-2022-innovationsbilanz-2022-grosse-bandbreite-neuer-medikamente.html>

12 <https://www.vfa.de/de/presse/press-releasen/pm-024-2021-bilanz-46-neue-medikamente-im-ausnahmjahr-2021.html>
<https://www.vfa.de/de/presse/press-releasen/pm-038-2022-innovationsbilanz-2022-grosse-bandbreite-neuer-medikamente.html>

13 <https://gco.iarc.fr/tomorrow/en/dataviz/isotype>

14 <https://www.iqvia.com/insights/the-iqvia-institute/reports/global-oncology-trends-2022>

15 <https://www.fiercebiotech.com/biotech/oncology-trial-starts-hit-record-levels-covid-disruptions-ease-report>

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

17 BioCentury data base BCIQ, as of 4 January 2023

18 BioCentury data base BCIQ, as of 4 January 2023

The FDA approved one new ADC in 2022 (two each in 2021 and 2020): ELAHERE (mirvetuximab soravtansine; ImmunoGen).¹⁹ The product may be used for the treatment of patients with folate receptor alpha (FR α)-positive, platinum-resistant ovarian cancer. This means that the number of ADCs approved by the FDA remains unchanged at twelve because approval of the ADC Blenrep (belantamab mafodotin; GlaxoSmith-Kline) was withdrawn in November 2022 after the primary endpoint in a Phase III confirmatory trial was not reached (see also “Competitive environment for HDP-101” in this section).²⁰

In addition to the new approval of ELAHERE, 2022 also saw new positive results for an already approved ADC, Enhertu (fam-trastuzumab deruxtecan-nxki; AstraZeneca and Daiichi Sankyo) in HR-positive breast cancer with low expression of the HER2 target. Here, an impressive doubling of progression-free survival was presented at the ASCO convention.²¹ The potential of ADCs in terms of improved tolerability and high efficacy was thus demonstrated once again.

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

Company	Product or candidate	Event	Description
Astellas and Seagen	PADCEV™	Approval	European Commission approves PADCEV™ as monotherapy for the treatment of adult patients with locally advanced or metastatic urothelial cancer. ²²
Daiichi Sankyo and AstraZeneca	Enhertu®	Expansion of indication Approval	FDA approves Enhertu for earlier use in metastatic breast cancer. ²³ Enhertu® is approved as the first therapy for the treatment of unresectable or metastatic HER2-low breast cancer. Approval comes just two months after the impressive results were presented at ASCO. ²⁴
		Accelerated approval	FDA approves Enhertu® as second-line treatment for HER2-mutant non-small cell lung cancer (NSCLC). ²⁵
Gilead Sciences	Trodely®	Expansion of indication	Sacituzumab govitecan (Trodely®) is approved in China for second-line metastatic triple-negative breast cancer. ²⁶

19 <https://www.bio-itworld.com/pressreleases/2022/11/28/fda-approved-adc-drugs-list-up-to-2022>

20 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/>

GSK press release, 22 November 2022:

<https://www.gsk.com/en-gb/media/press-releases/gsk-provides-update-on-blenrep-us-marketing-authorisation/>

21 BioCentury, 24 December 2022, Noisemakers and newsmakers of 2022, and hot takes for 2023

22 Astellas press release, 13 April 2022: <https://www.astellas.com/en/news/25711>

23 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>

24 AstraZeneca press release, 6 August 2022: <https://www.astrazeneca.com/media-centre/press-releases/2022/enhertu-approved-in-the-us-for-her2-low-abc.html>

25 AstraZeneca press release, 12 August 2022: <https://www.astrazeneca.com/media-centre/press-releases/2022/enhertu-approved-in-us-for-her2-mutant-nscl.html>

26 Everest Medicines press release, 9 June 2022: <https://www.prnewswire.com/news-releases/everest-medicines-announces-approval-of-trodely-in-china-for-second-line-metastatic-triple-negative-breast-cancer-301565539.html>

Company	Product or candidate	Event	Description
ImmunoGen	Elahere®	Accelerated approval	FDA approves mirvetuximab soravtansine-gynx for FRα+ platinum-resistant ovarian cancer. ²⁷
GSK	Blenrep®	Market withdrawal	GSK pulls Blenrep from the US market after failing to meet its primary endpoint in a Phase III confirmatory study. ²⁸

Interest in ADCs was very high in the period from January to December 2022, with license agreements significantly outpacing financing activity. Three ADC deals with a total value of over USD 11 billion were signed with major pharmaceutical companies in December alone.²⁹ Heidelberg Pharma's deal with Huadong Medicine Co, Ltd, Hangzhou, China, (Huadong) in February 2022, with a total value of close to USD 1 billion, also deserves mention. 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	Genmab	Agreement	Synaffix will receive up to USD 420 million for granting access to its ADC technologies. ³⁰
ADC Therapeutics	Mitsubishi Tanabe Pharma	Agreement	License agreement for USD 235 million plus royalties for the development and commercialization of ZYNLONTA in Japan. ³¹
Mersana Therapeutics	Janssen Biotech	Agreement	Partnership to develop ADCs for three targets for more than USD 1 billion. ³²
MacroGenics	Synaffix	Agreement	MacroGenics signs agreement for access to three ADCs from Synaffix worth up to USD 586 million. ³³
ImmunoGen	Eli Lilly	Agreement	ImmunoGen signs agreement with Eli Lilly for up to USD 1.7 billion for multiple targets. ³⁴

27 FDA, 14 November 2022: <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-mirvetuximab-soravtansine-gynx-fra-positive-platinum-resistant>

28 <https://www.fiercepharma.com/marketing/surprise-move-obedient-gsk-pulls-blenrep-accelerated-approval-days-after-confirmatory>

29 <https://www.fiercebiotech.com/biotech/amgen-merck-kgaa-add-budding-constellation-adc-deals-amid-modality-meteor-rise>

30 Genmab and Synaffix press release, 4 January 2022: <https://ir.genmab.com/news-releases/news-release-details/genmab-and-synaffix-enter-license-agreement-adc-technology>

31 ADC Therapeutics press release, 18 January 2022: <https://ir.adctherapeutics.com/press-releases/press-release-details/2022/ADC-Therapeutics-Announces-Exclusive-License-with-Mitsubishi-Tanabe-Pharma-Corporation-to-Develop-and-Commercialize-ZYNLONTA-loncastuximab-tesirine-lpyl-in-Japan/default.aspx>

32 Mersana press release, 3 February 2022: <https://ir.mersana.com/news-releases/news-release-details/mersana-therapeutics-announces-research-collaboration-and>

33 <https://www.fiercebiotech.com/biotech/synaffix-lines-up-586m-pact-macrogenics-en-route-to-one-stop-shop-for-adc-tech>

34 ImmunoGen press release, 15 February 2022: <https://www.businesswire.com/news/home/20220215005481/en/ImmunoGen-Announces-a-Global-Multi-Target-License-Agreement-of-its-Novel-Camptothecin-ADC-Platform-to-Lilly-for-Up-to-1.7-Billion/>

Company	Partner	Event	Description
RemeGen		IPO	RemeGen raises USD 410 million in Shanghai IPO for the development of antibody therapies and ADCs. ³⁵
Astellas Pharma Inc.	Sutro Biopharma	Agreement	Collaboration and licensing agreement for novel immunostimulatory ADCs for three targets valued at over USD 1.4 billion plus royalties. ³⁶
ADC Therapeutics	Swedish Orphan Biovitrum (Sobi®)	Agreement	Sobi licenses loncastuximab tesirine from ADC Therapeutics for up to USD 435 million plus royalties for hematologic and solid tumor indications in Europe. ³⁷
Kelun-Biotech	Merck/MSD	Agreement	Merck acquires the rights to an ADC for USD 35 million upfront and up to USD 901 million in milestone payments. ³⁸
Mersana Therapeutics	GSK	Agreement	GSK signs an agreement with Mersana for a preclinical ADC worth up to USD 1.5 billion. ³⁹
Emergence Therapeutics	Synaffix	Agreement	Emergence Therapeutics will pay Synaffix up to USD 360 million for using its Synaffix ADC technology. ⁴⁰
Kelun-Biotech	Merck KGaA	Agreement	Merck receives exclusive global licenses from Kelun-Biotech for several preclinical ADCs with an upfront payment of USD 175 million and up to USD 9.3 billion in milestones. ⁴¹
Mersana Therapeutics	Merck KGaA	Agreement	Merck signs collaboration agreement with Mersana for exclusive licenses for up to two immunostimulatory ADCs worth up to USD 830 million. ⁴²
LegoChem	Amgen	Agreement	LegoChem and Amgen sign multi-target collaboration and license agreement worth up to USD 1.25 billion. ⁴³

35 <https://seekingalpha.com/article/4499490-week-in-review-remegen-raises-410-million-in-shanghai-ipo-for-mabdrug-therapies>

36 Astellas press release, 27 Juni 2022: <https://www.prnewswire.com/news-releases/astellas-and-sutro-biopharma-announce-worldwide-strategic-collaboration-to-advance-novel-immunostimulatory-antibody-drug-conjugates-iadcs-301575555.html>

37 Sobi press release, 8. Juli 2022: <https://www.sobi.com/en/press-releases/sobi-license-loncastuximab-tesirine-adc-therapeutics-2035301>

38 <https://www.fiercebiotech.com/biotech/merck-strikes-second-adc-deal-kelun-biotech-paying-35m-rights-unnamed-asset>

39 Mersana press release, 8 August 2022: <https://ir.mersana.com/news-releases/news-release-details/mersana-therapeutics-announces-option-agreement-gsk-co>

40 Emergence press release, 6 September 2022: <https://www.prnewswire.com/news-releases/emergence-therapeutics-licenses-synaffix-adc-technology-platform-in-360m-deal-301617866.html>

41 Merck press release, 22 December 2022: <https://www.businesswire.com/news/home/20221222005122/en/Merck-and-Kelun-Biotech-Announce-Exclusive-License-and-Collaboration-Agreement-for-Seven-Investigational-Antibody-drug-Conjugate-Candidates-for-the-Treatment-of-Cancer>

42 Merck press release, 22 December 2022: <https://www.emdgroup.com/en/news/adcs-mersana-20-12-2022.html>

43 LegoChem press release, 23 December 2022: <https://www.businesswire.com/news/home/20221223005034/en/LegoChem-Biosciences-and-Amgen-Enter-into-a-Multi-Target-Research-Collaboration-and-License-Agreement-for-the-Development-of-Antibody-Drug-Conjugates>

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).⁴⁴

The ATAC candidate HDP-101 will initially be developed with the MM indication, where it is now in a Phase I/IIa study. Around 55 companies are currently working on the BCMA antigen in this indication (2021: 46). The number of development projects increased from 62 last year to 74.⁴⁵ 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 (52 projects), followed by bispecific and multispecific antibodies (19).⁴⁶

Two new BCMA-targeting therapies were approved last year. The second BCMA-targeted CAR T-cell therapy – Carvykti (Cilta-cel; CAR T-cell therapy) from Legend Biotech Corp. and Johnson & Johnson – was approved in February 2022 after Abecma (Idec-cel) from 2seventybio had received the green light in 2021.⁴⁷ In addition, the first bispecific antibodies for treating multiple myeloma – Tecvayli (teclistamab) from Ligand Pharmaceuticals and Johnson & Johnson – were approved.⁴⁸ The first approved BCMA-targeted therapy, ADC Blenrep (belantamab mafodotin; GlaxoSmithKline) failed to reach its primary endpoint in a Phase III confirmatory trial.⁴⁹ The FDA subsequently withdrew approval for the drug in November 2022 because the conditions for accelerated approval were therefore not met.⁵⁰ Results from two other Phase III trials with Blenrep are expected in the first half of 2023. This means that three BCMA-targeting therapies for relapsed/refractory multiple myeloma are currently approved in the United States, each as fifth-line therapy.⁵¹ In Europe, all four therapies have now been approved as fourth-line treatment.⁵²

Apart from Heidelberg Pharma's HDP-101, another BCMA-targeting ADC – CC-99712 from Bristol-Myers Squibb and Sutro Biopharma – is currently in Phase I of clinical development for the MM indication.⁵³ Shanghai Junshi Biosciences is likewise developing a BCMA-targeting ADC with JS115, which is still in the preclinical phase.⁵⁴

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

45 BioCentury data base BCIQ, as of 4 January 2023

46 BioCentury data base BCIQ, as of 4 January 2023

47 <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-disco-burst-edition-fda-approval-carvykti-ciltacabtagene-autoleucel-treatment-adult-patients>

<https://www.fda.gov/news-events/press-announcements/fda-approves-first-cell-based-gene-therapy-adult-patients-multiple-myeloma>

48 <https://www.fiercepharma.com/pharma/jjs-bcma-bispecific-tecvayli-wins-fda-approval-multiple-myeloma-again-late-line>

49 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/>

50 GSK press release, 22 November 2022:

<https://www.gsk.com/en-gb/media/press-releases/gsk-provides-update-on-blenrep-us-marketing-authorisation/>

51 <https://www.fiercepharma.com/pharma/jjs-bcma-bispecific-tecvayli-wins-fda-approval-multiple-myeloma-again-late-line>

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

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

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

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

53 <https://www.bms.com/researchers-and-partners/in-the-pipeline.html>

54 Junshi Interim Report 2022: <https://junshi-bioscience-v2-umb.azurewebsites.net/media/o0pjetr1/2022-interim-report-e.pdf>

Chemotherapy is still being used as standard therapies for MM, including in combination with autologous hematopoietic stem cell transplantation or radiotherapy.⁵⁵ At present, the most commercially successful therapy in this indication is the immunomodulator REVLIMID® from Celgene (acquired by Bristol-Myers Squibb in November 2019). Following approval of the first generic drugs, global sales of Revlimid fell for the first time to between USD 9.5 billion and USD 10 billion in 2022 from USD 12.9 billion in 2021.⁵⁶

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's lymphoma (NHL)**.⁵⁷

Apart from Heidelberg Pharma, four companies are currently working on development candidates for treating NHL with CD37 as the target.⁵⁸ Of these, the most advanced is an ADC from Debiopharm naratuximab emtansine (Debio 1562, IMGN529), which is in Phase II for the treatment of relapsed/refractory (r/r) diffuse large B-cell lymphoma (DLBCL). Moreover, a radioactive conjugated antibody from Nordic Nanovector is in Phase I/II and a bispecific antibody from Genmab A/S is in Phase I for the treatment of NHL.⁵⁹

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.⁶⁰

Besides Heidelberg Pharma, 39 other companies (previous year: 27) are working on developing a total of 52 different therapies for prostate cancer targeting PSMA.⁶¹ While most of these are antibody-based therapies, there are also cell therapies, some cell-based vaccines targeting cancer and small-molecule compounds. A first therapy was approved in 2022: Pluvicto, a radiopharmaceutical developed by Novartis that contains lutetium (¹⁷⁷Lu-PSMA-617) for targeting PSMA, received FDA approval in March 2022 and was also approved in Europe in December for treating castration-resistant prostate cancer in previously pretreated patients.⁶² A total of two therapies are in Phase III of clinical development, two radioactive conjugated anti-

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

56 <https://www.reuters.com/article/bristolmyers-sales-idUSL1N2TN2AP>

57 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

58 BioCentury data base BCIQ, as of 4 January 2023

59 BioCentury data base BCIQ, as of 4 January 2023

60 P. Bühler, P. Wolf, U. Elsässer-Beile: Targeting the prostate-specific membrane antigen for prostate cancer therapy. In: *Immunotherapy*. Volume 1, No. 3, May 2009, p. 471-481, ISSN 1750-7448. doi:10.2217/imt.09.17. PMID 20635963

61 BioCentury data base BCIQ, as of 4 January 2023

62 Novartis press release, 24 March 2022:

<https://www.novartis.com/us-en/news/media-releases/novartis-pluvictotm-approved-fda-first-targeted-radioligand-therapy-treatment-progressive-psma-positive-metastatic-castration-resistant-prostate-cancer>

<https://www.ema.europa.eu/en/medicines/human/EPAR/pluvicto>

bodies from Telix (TLX591, ¹⁷⁷Lu-DOTA-Rosopatamab) and Point Biopharma Inc. (¹⁷⁷Lu-PNT2002). A cell-based vaccine developed by Northwest Biotherapeutics (DCVax-Prostate) also received FDA approval for a Phase III trial. 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, respectively, and Dantari is developing a PSMA ADC in the preclinical phase.⁶³

Competitive environment for HDP-104

Heidelberg Pharma's newest ATAC development candidate, HDP-104, targets [guanylyl cyclase-C \(GCC\)](#), a receptor that is expressed on the surface of intestinal cells. In healthy cells, it occurs exclusively on the luminal side, where antibodies circulating in the blood cannot reach. GCC is also expressed on the surface of cancer cells in different gastrointestinal tumors, where it is then accessible for antibodies and is therefore a very suitable target for antibody-based therapeutic approaches.⁶⁴

 Glossary

Currently, six companies are working on anti-GCC therapies for tumors. The most advanced of these is a therapeutic vaccine being studied by Liminatus Pharma in a Phase II trial in different forms of gastrointestinal tumor disease. Pfizer is trialing a bispecific antibody targeting GCC and CD3 in Phase I. In addition, three CAR-T candidates are in preclinical trials and a further cell-based therapy candidate is in the early research phase.⁶⁵

3 Course of business in 2022

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.

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.

⁶³ BioCentury data base BCIQ, as of 4 January 2023

⁶⁴ Danaee, H., Kalebic, T., Wyant, T., Fassan, M., Mescoli, C., Gao, F., Trepicchio, W., & Rügge, M. (2017). Consistent expression of guanylyl cyclase-C in primary and metastatic gastrointestinal cancers. *PLoS One*, 12(12), e0189953.

⁶⁵ BioCentury data base BCIQ, as of 4 January 2023

Amanitin's mechanism 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. Tumors with 17p deletion could be a particularly effective target for treatment with ATACs.

Immunological effects of ATAC molecules

In addition to killing cells directly, ATACs could have an additional anti-tumor effect by stimulating the immune system.⁶⁶ 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 2020 Annual ASH Meeting, 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.⁶⁷

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 needed. HDP-101 also has potential in further hematologic indications.

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. The first three patient cohorts and dose levels were concluded and HDP-101 has so far been shown to be safe and well tolerated. Six trial centers are up and running in the United States and Germany, and further centers in Europe are about to initiate operations.⁶⁸

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.

66 https://heidelberg-pharma.com/images/managed/finanzberichte/629937ff75687_Posters_AACR_2022_1754.pdf

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

68 https://heidelberg-pharma.com/images/managed/63a18d1585d2c_Heidelberg_Pharma_Poster_ASH_3219.pdf

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).

Production of the material for GLP (Good Laboratory Practice) studies is going according to plan.

 Glossary

Apart from conjugate production, further preclinical and toxicology studies were carried out in the past months.

In early December 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.⁶⁹ Richter's syndrome, a type of non-Hodgkin lymphoma, could be one of the indications of treatment with HDP-102.

Project HDP-103 (PSMA-ATAC)

HDP-103 will be used to treat [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 sensitivity of prostate cancer cells with a 17p deletion has already been preclinically validated.⁷⁰ Since tumor cells with a 17p deletion are particularly sensitive to Amanitin, PSMA-ATACs might be particularly suitable for treating mCRPC.

Production of GMP material for HDP-103 has commenced at the contract manufacturers and is proceeding as planned. Preclinical and toxicological studies are also being carried out with HDP-103 and are expected to be concluded in the first half of 2023.

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.

The candidate is currently being prepared for preclinical development.

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

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

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 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).⁷¹

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 IIa part of the clinical trial with HDP-101 will be stratified based on their 17p deletion status. 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 Research 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 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.

⁷¹ <https://ash.confex.com/ash/2020/webprogram/Paper141615.html>
<https://www.science.org/doi/10.1126/scitranslmed.abc6894>

Partnership with Magenta: Heidelberg Pharma Research has been involved in an exclusive multi-target research agreement with Magenta Therapeutics, Cambridge, MA, USA, (Magenta) since March 2018. The collaboration will combine Magenta's stem cell platform for antibodies with Heidelberg Pharma's ATAC technology to develop up to four exclusive targets. Magenta has an option for an exclusive license for global development and commercialization rights to each of the product candidates resulting from the research collaboration. Under the exclusive license agreement, Heidelberg Pharma would be eligible to receive clinical development, regulatory and sales-related milestone payments, if Magenta were to exercise the option on one of the targets and reach all milestones.

The options for the CD117 and CD45 targets were exercised and ATAC development continued under exclusive licensing.

MGTA-117, the clinical candidate, is an ATAC consisting of a CD117 antibody and Amanitin as payload and has been in a clinical trial since March 2022.⁷² MGTA-117 is to be the first clinical ATAC candidate to be used for targeted preparation, or conditioning, of patients for stem cell transplants or gene therapy. MGTA-117 is currently tested in a dose escalation clinical trial to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of MGTA-117 as a single dose in patients with relapsed/refractory acute myeloid leukemia (AML) and myelodysplastic syndrome with excess blasts (MDS-EB).

 Glossary

After the reporting period had ended, Magenta presented positive preliminary safety and initial efficacy data from its clinical trial with MGTA-117 at the American Society of Hematology (ASH) Annual Meeting.⁷³ Shortly after making the promising preliminary data public, Magenta announced that it was pausing the dosing in the clinical trial until further notice for safety reasons due to dose-limiting **toxicities** being observed in two dose levels.⁷⁴ On 2 February 2023, Magenta decided to halt all ongoing programs and to conduct a comprehensive review of strategic alternatives.⁷⁵ For more information, please see the report on post-balance sheet date events.

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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 exclusive research agreement, Heidelberg Pharma manufactured several ATACs using antibodies from Takeda's proprietary portfolio. As a result of this work, Takeda acquired an exclusive license in September 2022 for commercial development of an ATAC with a selected target. Takeda is responsible for further preclinical and clinical development, as well as potential commercialization, of the product candidate it licenses.

72 Magenta press release, 8 May 2022: <https://investor.magentatx.com/news-releases/news-release-details/magenta-therapeutics-reports-fourth-quarter-and-full-year-2021>

73 Magenta press release, 12 December 2022: <https://investor.magentatx.com/news-releases/news-release-details/magenta-therapeutics-presents-positive-mgta-117-clinical-data>

74 Magenta press release, 25 January 2023: <https://investor.magentatx.com/news-releases/news-release-details/magenta-therapeutics-voluntarily-pauses-mgta-117-phase-12-dose>

75 Magenta press release, 2 February 2023: <https://investor.magentatx.com/news-releases/news-release-details/magenta-therapeutics-explore-strategic-alternatives>

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

Funded projects

Together with several European universities, research institutions and companies, Heidelberg Pharma Research is taking part in four research projects – MAGICBULLET::Reloaded, INTEGRATA, pHionic and TACT – and receives 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: €252,788.40). The research field 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 receives EU funding totaling €3.7 million (Heidelberg Pharma share: €252,788.40) for all project partners and will run until April 2023.

The pHionic program focuses on research on pancreatic ductal adenocarcinoma. Heidelberg Pharma Research will use this opportunity to assess new target structures for pancreatic cancer and their suitability for therapy with ATACs. The European Union intends to issue a total of approximately €4 million in funding for all the project partners (Heidelberg Pharma share: €252,788.40). The program will end in mid-2023.

TACT is another HORIZON 2020 research project. It will focus on developing 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 issues a total of approximately €3 million in funding for the TACT program (Heidelberg Pharma share: €252,788.40), which is 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. This decrease in importance is due to the increasing internal demand on research resources.

3.3 Clinical portfolio of Heidelberg Pharma AG – partnering

TLX250-CDx (girentuximab) – diagnostic antibody

TLX250-CDx is a radiolabeled form of the antibody **girentuximab**, which binds to the tumor-specific antigen **CAIX** on clear cell renal cell carcinoma 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 avoid potentially unnecessary surgery. The **diagnostic agent** may also prove suitable for monitoring response to treatment, detecting **metastases** and diagnosing other kinds of tumors.



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 on using positron emissions tomography (PET) imaging for diagnosing kidney cancer, which began in August 2019 and involved 300 patients.⁷⁶

The first positive data were reported in November 2022.⁷⁷ The study results delivered 86% sensitivity and 87% specificity, exceeding the pre-determined threshold required to demonstrate the ability of TLX250-CDx to reliably detect the clear cell phenotype.

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

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

A bridging study on ZIRCON is intended to provide complementary data from China to show that previous data can be applied to the Chinese population.

76 Telix press release, 11 July 2022: <https://telixpharma.com/news-views/zircon-phase-iii-kidney-cancer-imaging-study-completes-enrolment-2/>

Telix press release, 7 November 2022: <https://telixpharma.com/news-views/zircon-phase-iii-top-line-data-study-meets-primary-objectives/>

77 Telix press release, 7 November 2022: <https://telixpharma.com/news-views/zircon-phase-iii-top-line-data-study-meets-primary-objectives/>

A number of studies with TLX250-CDx have been initiated and partially completed under Telix's leadership in indications other than ccRCC, specifically urothelial cancer, bladder cancer and triple negative breast cancer.

TLX250 (girentuximab) – therapeutic antibody

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

Glossary

TLX250 will be tested in two Phase II combination studies (STARLITE 1 and 2) with immunotherapies. First patients have been dosed with TLX250 in combination with Opdivo® anti-PD-1 immunotherapy in the STARLITE 2 trial at the Memorial Sloan Kettering Cancer Center in New York. STARLITE 1 has received clearance from the US FDA and is due to commence.⁷⁸ Both studies will investigate the response rate of combining immunotherapy with TLX250 compared to the current standard treatment for solid tumors.

RHB-107 (upamostat) – oral serine protease inhibitor

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

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).

Heidelberg Pharma's partner RedHill is developing upamostat (referred to as RHB-107 by RedHill) for treating COVID-19. RHB-107 has demonstrated both antiviral and potential tissue-protective effects, with RHB-107 strongly inhibiting SARS-CoV-2 replication in a preclinical human bronchial tissue study. The candidate targets human serine proteases that are involved in the virus's entry into target cells. In March 2022, RedHill announced positive efficacy results from the first part of a phase II/III trial in COVID-19 outpatients demonstrating a 100% reduction in hospitalizations due to COVID-19 and a 87.8% reduction in reported new severe COVID-19 symptoms. In early October 2022, RedHill announced study results demonstrating *in vitro* efficacy of its two candidates, RHB-107 and opaganib, against the currently dominant Omicron COVID-19 sub-variant BA.5.

RedHill is currently in talks with regulatory authorities regarding further development steps. RHB-107 is also being tested in development programs against several viral diseases, including influenza and Ebola.⁷⁹

In addition to COVID-19, RedHill also plans to investigate RHB-107 in combination with its other development candidate opaganib for the treatment of advanced cholangiocarcinoma, subject to approval from the FDA.

⁷⁸ Telix Interim Report 2022, 18 August 2022:

<https://telixpharma.com/wp-content/uploads/2022/10/20220818-Telix-Pharmaceuticals-Interim-Report-2022-vFINAL.pdf>

⁷⁹ 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>

3.4 Other key events in fiscal year 2022

Establishment of a strategic partnership with Huadong

Heidelberg Pharma and Huadong Medicine Co., Ltd., Hangzhou, China, (Huadong) announced at the end of February 2022 that the companies had entered into a strategic partnership with the signing of an exclusive licensing agreement as well as an investment agreement. This consists of an exclusive license to develop and commercialize the ATAC candidates HDP-101 and HDP-103 in Asia⁸⁰ with an upfront payment of USD 20 million and milestone payments of up to USD 449 million, as well as tiered royalties ranging from single- to low double-digit percentages for each candidate. Huadong also receives an exclusive option for the research candidates HDP-102 and HDP-104 in Asia with total milestone payments of up to USD 461 million. In addition, Huadong made a strategic equity investment in Heidelberg Pharma totaling €105 million, representing 35% of total shares outstanding after the transaction. To support the Company's cash reach and the ongoing negotiations with Huadong at the beginning of the year, the Company's main shareholder dievini Hopp BioTech holding GmbH & Co. KG, Walldorf, (dievini) confirmed a financing commitment to Heidelberg Pharma AG in February 2022 in which it will provide financing in the amount of up to €36 million if and to the extent that this is not achieved through potential alternative corporate actions. The partnership with Huadong constitutes an alternative corporate action, on whose conclusion the commitment with dievini was rescinded.

Conclusion of a rights issue under the partnership with Huadong

In August 2022, Heidelberg Pharma offered all shareholders a total of 12,408,648 new shares for subscription at a price of €6.44 each. In accordance with the agreement dated 27 February 2022, the partner Huadong participated to a significant extent in the rights issue, acquiring 9,374,156 shares through pre-emption rights from the main shareholder dievini and its affiliated companies. Huadong also acquired 2,464,496 shares that were not subscribed by other shareholders, bringing its equity interest in Heidelberg Pharma to 25%. To reach the targeted 35% shareholding, Huadong bought 4,465,908 more shares from dievini at a price of €6.44 per share.

The corporate action generated total gross issue proceeds of approximately €80 million for Heidelberg Pharma, most of which will be used to carry out the ongoing Phase I trial of HDP-101 and to continue the development of the follow-on projects HDP-102 and HDP-103 as well as the proprietary ATAC technology.

After the execution of the capital increase was recorded in the Commercial Register at Mannheim Local Court on 2 September, the new share capital is now €46,584,457.00 divided into 46,584,457 no par value bearer shares. With this corporate action, Heidelberg Pharma has almost fully utilized Authorized Capital 2020/I available for the issuance of new shares. On 28 June 2022, the Annual General Meeting 2022 approved the creation of new Authorized Capital 2022/I in the amount of €20,992,228.00, which has already been entered in the Commercial Register.

⁸⁰ Asia (excluding Japan, India, Pakistan, Sri Lanka): People's Republic of China, Hong Kong, Macao, Taiwan, South Korea, Indonesia, Singapore, The Philippines, Thailand, Bangladesh, Bhutan, Brunei, Myanmar, Cambodia, Laos, Malaysia, Maldives, Mongolia, Nepal and Vietnam

New preclinical data from the ATAC technology platform presented at the AACR 2022 Annual Meeting

At the American Association for Cancer Research (AACR) 2022 Annual Meeting in April 2022, Heidelberg Pharma presented preclinical data on its ATAC technology. The Company presented data on the synergy of using ATACs together with *immune checkpoint* inhibitors⁸¹, as well as data indicating that repeated treatment with ATACs in preclinical models results in better tolerability without compromising efficacy.⁸²

4 Non-financial performance indicators

Employees

The Heidelberg Pharma Group employed 110 (30 November 2021: 96) people (including members of the Management Board) at the end of the fiscal year. This represented an increase of more than 15%. Heidelberg Pharma Research GmbH employed 91 people at the end of the fiscal year, while Heidelberg Pharma AG employed a team of 19 people (including the two members of the Executive Management Board).

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

Employees	30 Nov. 2022	30 Nov. 2021
Administration	26	25
Research and development	62	52
Manufacturing, service and distribution	22	19
Employees, total	110	96

81 https://heidelberg-pharma.com/images/managed/finanzberichte/629937ff75687_Poster_AACR_2022_1754.pdf

82 https://heidelberg-pharma.com/images/managed/finanzberichte/629937f1ab7d4_Poster_AACR_2022_1761.pdf

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

The 2022 fiscal year concerns the period from 1 December 2021 to 30 November 2022. 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.

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

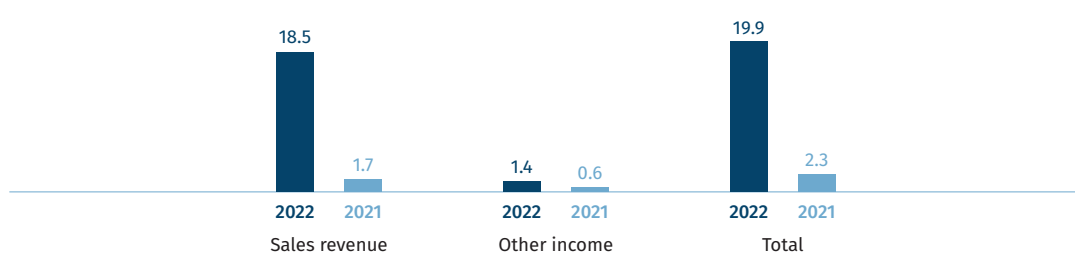
Heidelberg Pharma does not have business units that differ materially in their risk/reward profiles and would therefore require segment reporting.

5.1 Sales revenue and other income

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

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

Income in € million¹



¹ rounded

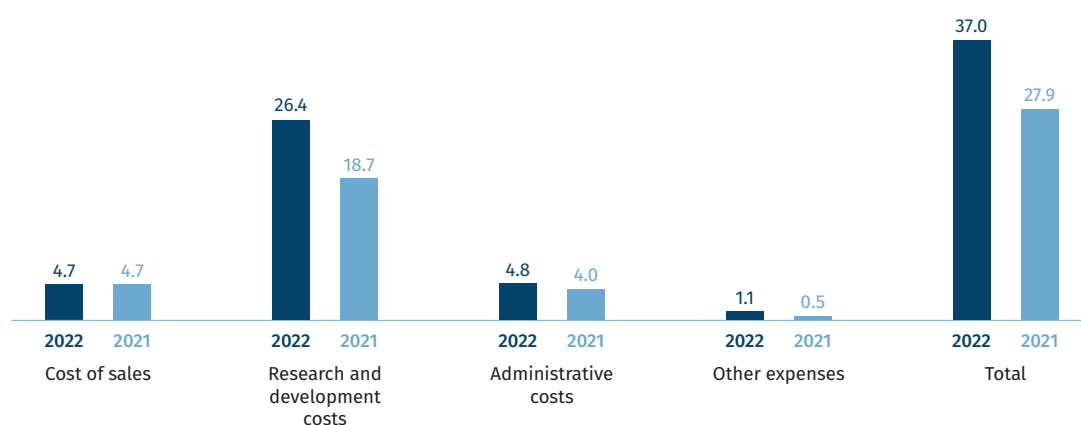
Other income amounted to €1.4 million (previous year: €0.6 million) and largely comprised exchange rate gains of €1.0 million as a result of the appreciation of the US dollar against the euro in the period under review. There was no significant other income in the previous year.

Furthermore, government grants to support projects by Heidelberg Pharma Research (€0.1 million, previous year: €0.3 million), income from the reversal of unused accrued liabilities, income from passing on patent costs and other items of €0.1 million, in each case unchanged on the previous year, increased total income.

5.2 Operating expenses

Operating expenses including depreciation and amortization increased to €37.0 million in 2022 compared with €27.9 million in the previous year, principally because research and development costs increased in line with planning.

Operating expenses in € million¹



¹ rounded

The cost of sales concerns the Group's costs directly related to sales revenue. These costs mainly related to expenses for customer-specific research and for the supply of Amanitin linker material to licensing partners. As in the previous year, they amounted to €4.7 million, representing 13% of operating expenses.

Research and development costs rose considerably year-over-year to €26.4 million (previous year: €18.7 million) due to the cost-intensive external manufacturing for the ATAC projects and the on-going clinical trial with HDP-101. The production of antibodies for HDP-102 and HDP-103 also was a factor. At 71% of operating expenses, R&D remained the largest cost item.

Administrative costs were €4.8 million, an increase on the prior year (€4.0 million), and accounted for 13% of operating expenses.

These include staff costs of €2.6 million (previous year: €2.3 million), of which €0.2 million concerned expenses from stock options, as in the previous year. The increase results from a growing number of employees due to the expansion of business activities. This line item also includes legal and operating consulting costs in the amount of €1.1 million (previous year: €0.7 million) and expenses related to the Annual General Meeting, Supervisory Board remuneration and the stock market listing totaling €0.6 million, as in the previous year. Other items amounted to €0.5 million (previous year: €0.4 million).

Other expenses for business development, marketing and commercial market supply activities, which mainly comprise staff and travel costs, were €1.1 million. They were higher than in the previous year (€0.5 million) and represented 3% of operating expenses.

5.3 Earnings

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

5.4 Financing and liquidity

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

According to the assessment of the Executive Management Board and based on the updated budget, the funds available as of the 30 November 2022 reporting date would be sufficient to finance the business activities of Heidelberg Pharma AG and its subsidiary until mid-2025.

In the fiscal year now ended, finance income of €235 thousand was generated again on bank balances for the first time 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 €840 thousand (previous year: €494 thousand), comprising mainly interest expense for the dievini shareholder loan. This gives a financial result of €–605 thousand (previous year: €–494 thousand).

5.5 Cash flow statement

Net cash outflow from operating activities during the reporting period was €8.9 million (previous year: €26.6 million). The significant decrease is mainly due to higher income.

Total cash outflow from investing activities was €0.6 million (previous year: €1.4 million) and was mainly due to the acquisition of property, plant and equipment, specifically laboratory equipment.

The net increase in funds from financing activities (€84.0 million; previous year: €29.2 million) mainly stems from the capital increase and from the drawdown of a tranche from the dievini shareholder loan.

In addition, a currency gain of €649 thousand (previous year: €4 thousand) was recognized.

The total change in cash in fiscal year 2022 came to €75.2 million (previous year: €1.2 million). This corresponded to an average inflow of cash of €6.3 million per month (previous year: €0.1 million). Adjusted for the effect of the financing activities, i.e. the dievini shareholder loan and the capital increases implemented in the respective fiscal years, the average cash outflow per month was €0.7 million in fiscal year 2022 and €2.3 million in fiscal year 2021.

Cash flow	2022 € million	2021 € million
Cash as of 1 December	6.1	5.0
Net change in cash from operating activities	(8.9)	(26.6)
Net change in cash from investing activities	(0.6)	(1.4)
Net change in cash from financing activities	84.0	29.1
Exchange rate effect	0.6	0.004
Cash as of 30 November	81.3	6.1

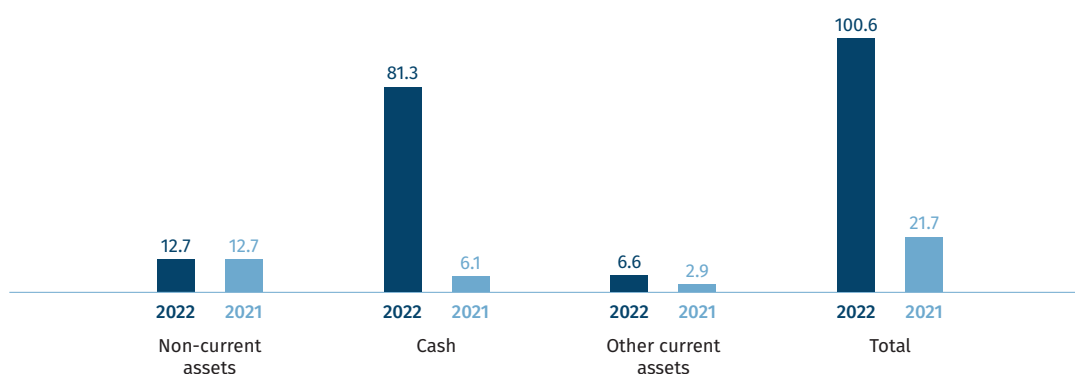
5.6 Assets

The capital increase implemented in the third quarter of fiscal year 2022 significantly extends the cash reach of Heidelberg Pharma if business proceeds as planned. This enabled the Company to prepare its financial statements on a going-concern basis.

Non-current assets at €12.7 million remained almost unchanged as of 30 November 2022. 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.

Property, plant and equipment also remained constant at €3.7 million as of 30 November 2022, due to similarly high levels of depreciation and capital expenditure, particularly in laboratory equipment. Intangible assets excluding goodwill and IP R&D fell slightly to €0.3 million from €0.4 million in the previous year.

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 increased from €9.0 million in the previous year to €87.9 million. Cash included in this item amounted to €81.3 million and as a result of the capital increase and the dievini shareholder loan were up considerably on the prior-year figure of €6.1 million despite of outflows triggered by the business.

Other current assets increased to €6.6 million (previous year: €2.9 million). While both inventories at €4.6 million and trade receivables at €1.1 million included in this figure each rose compared with 2021 (€0.7 million and €1.0 million, respectively), prepayments made decreased (€0.5 million; previous year: €0.7 million). At €0.4 million, other receivables remained constant compared with the previous year's figure.

At the end of the fiscal year, total assets at €100.6 million were several times higher than the prior-year figure (€21.7 million), which is mainly attributable to the higher levels of cash and 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. At €5.9 million, non-current contract liabilities were significantly higher than in the previous year (€23 thousand) due to the Huadong out-licensing and the recognition of a payment as a liability.

Non-current liabilities therefore totaled €6.0 million (2021: €0.1 million).

Current liabilities rose to €28.0 million at the close of the reporting period (previous year: €14.9 million).

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

Current contract liabilities amounted to €5.0 million (previous year: €0.5 million) and, as in 2021, were exclusively comprised of current contract liabilities from research collaborations.

Both trade payables (€3.1 million; previous year: €0.9 million) and other current financial liabilities (€4.0 million; previous year: €3.0 million) increased versus 2021 as a result of an expansion of business activity.

The shareholder loan that Heidelberg Pharma received from dievini and the drawdown of a further €5 million tranche in February 2022 created financial liabilities of €15.8 million. These were composed of the loan principal of €15.0 million and accrued interest of €0.8 million (previous year: €10.5 million comprised of a loan principal of €10.0 million and interest of €0.5 million).

5.8 Equity

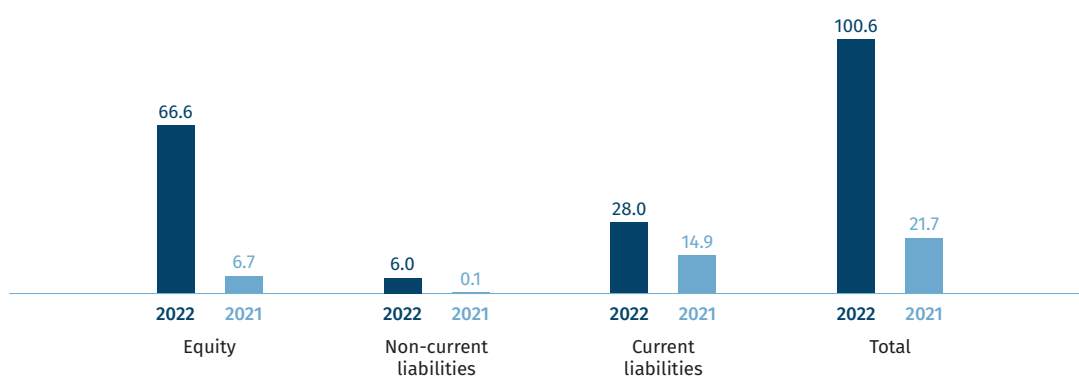
Equity of the Heidelberg Pharma Group at the end of the reporting period was €66.6 million (30 November 2021: €6.7 million).

As a result of a capital increase and the issuance of 12,408,648 shares, the total number of Heidelberg Pharma shares issued as of the reporting date increased from 34,175,809 to 46,584,457.

Taking into account the measurement of stock options, the capital reserve increased by a net €67.3 million to €311.5 million as of the 2022 reporting date (30 November 2021: €244.2 million).

The losses accumulated since the foundation of the Heidelberg Pharma Group totaled €291.4 million (30 November 2021: €271.7 million). The equity ratio was 66.3% (30 November 2021: 30.8%).

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

Important and major milestones in the Company's development were reached, transformative deals were signed, and financing measures were implemented.

The strategic partnership with Chinese pharma company Huadong deserves particular mention. It is transformative for Heidelberg Pharma because in addition to a license for selected Asian countries it entails a substantial strategic equity investment in the Company. The licensing agreement for ATAC candidates HDP-101 and HDP-103 and the exclusive option agreement for HDP-102 and HDP-104 will ensure adequate clinical development and, if successful, commercialization of these candidates in the Asian region. The upfront payment of USD 20 million from Huadong less withholding tax led to a much-improved cash position and a significant increase in sales revenue (for more information, please see section 5.1).

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The strategic investment in Heidelberg Pharma was taken by means of a capital increase that was entered in the Commercial Register in September 2022. Huadong now holds 35% of Heidelberg Pharma shares and is the second-largest shareholder after the main shareholder dievini. As an investor with a long-term outlook, Huadong will support Heidelberg Pharma in achieving its goal of becoming a global ADC player. The Chinese partner's extensive development and commercialization expertise and knowledge of the Asian markets will help to expand the product pipeline and accelerate its development.

After successful preliminary work had been carried out, Heidelberg Pharma initiated its first clinical trial of a proprietary ATAC candidate in February 2022. Dosing of the first patient with a substance developed in its own laboratories is a decisive and transformative step for a research company on the path to becoming a drug developer.

Preclinical and toxicological studies and important production steps for the GMP material have been carried out for successor candidates HDP-102 and HDP-103. Another ATAC candidate, HDP-104, designed for treatment of gastrointestinal tumors, is about to finish the research phase and is currently being prepared for clinical development.

Advances could also be observed in the ATAC technology partnerships. The partner Takeda exercised an option to use ATAC technology for an undisclosed target protein and signed a license agreement with Heidelberg Pharma for this. Heidelberg Pharma signed a research and option agreement with Chiome Bioscience for a defined ATAC candidate.

Telix, the partner for the out-licensed CAIX antibody, made gratifying progress, publishing positive data from its Phase III ZIRCON study of TLX250-CDx in November. The study results delivered 86% sensitivity and 87% specificity, exceeding the pre-determined threshold required to demonstrate the ability of TLX250-CDx to reliably detect the clear cell phenotype and provide a non-invasive method of diagnosing the presence and spread of ccRCC. Based on these positive results Telix intends to file a Biologics License Application (BLA) for regulatory approval with the FDA and global regulatory agencies as a positron emission tomography/computed tomography (PET/CT) imaging agent for use in the diagnosis of indeterminate renal masses previously identified on CT or MRI as ccRCC or non-ccRCC. These results are relevant because not only do they validate the product development previously initiated at Heidelberg Pharma but they also hold out the prospect of attractive revenue from royalties in the short to medium term in the event of market approval.

In October 2022, Heidelberg Pharma adjusted its guidance for the fiscal year published in March 2022 for two main reasons. The license agreement with the partner Huadong and the corresponding license payment increased Heidelberg Pharma's sales revenue significantly. Development expenses remained below planning due to the later production of intermediate steps for the follow-on candidates. Both factors had an influence on the operating result that improved significantly and reduced funding requirements for fiscal year 2022. Actual figures for 2022 are all within the last guidance.

Financials	Guidance 03/2022 € million	Guidance 10/2022 € million	Actual 2022 € million
Sales revenue and other income	7.5–9.5	18.5–20.5	19.9
Operating expenses	41.0–45.0	35.0–39.0	(37.0)
Operating result	(32.5)–(36.5)	(16.0)–(20.0)	(17.2)
Total funding requirement ¹	33.0–37.0	8.0–11.0	8.9
Funds required per month ¹	2.8–3.1	0.6–0.9	0.7

¹ Not including any corporate actions

Similar to the increase in total assets, equity rose sharply year-on-year as a result of the capital increase, more than compensating for the loss posted for the fiscal year.

Based on the existing financial planning and the capital increase that was completed by the end of August, 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 2022 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 (Aktengesetz, 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.

Heidelberg Pharma’s Statement on Corporate Governance was posted on the Company’s website under “Press & Investors > Corporate Governance” on 30 January 2023. 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.

 www.heidelberg-pharma.com

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 on the Company’s website in the “Press & Investor > Corporate Governance” section.

 www.heidelberg-pharma.com

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 corporate action implemented in August 2022, which was entered in the Commercial Register in early September, and the exercise of stock options during the reporting period, the Company’s subscribed capital increased from €34,175,809 to €46,584,457 compared with the end of the previous year.

The share capital is composed of 46,584,457 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 is determinant for 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 2022.

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	45.67%
Huadong Medicine Co., Ltd.	35.00%

¹ Shares of dievini Hopp BioTech holding GmbH & Co. KG, DH-Holding Verwaltungs GmbH, Walldorf, and DH-LT-Investments GmbH (as of 30 November 2022)

The former managing directors of dievini Hopp BioTech holding GmbH & Co. KG, Professor Christof Hettich and Dr. Friedrich von Bohlen und Halbach, and the current managing director, Dr. Mathias Hothum, jointly hold 3.92% 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:

After utilization in the past fiscal year and the new authorized capital approved by the Annual General Meeting, the current authorized capital 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 €15,223,027 (previous year: €15,416,692) as of the 30 November 2022 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. 2021 €	Stock options exercised €	New issue €	Reduction €	As of 30 Nov. 2022 €	Purpose of use: to satisfy
2011/I	559,837	0	0	193,665	366,172	2011 Stock Option Plan
2017/I	661,200	0	0	0	661,200	2017 Stock Option Plan
2018/I	1,490,622	0	0	0	1,490,622	2018 Stock Option Plan
2020/I	12,705,033	0	0	0	12,705,033	Convertible bonds
Total	15,416,692	0	0	193,665	15,223,027	

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 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 2022, 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 and measures that the Company took or failed to take in the 2022 fiscal year during the period from 1 December 2021 to 30 November 2022, and according to the circumstances that were known to the Executive Management Board when those legal transactions were performed or when the Company took or failed to take those measures, the Company received appropriate consideration for each legal transaction and was not placed at a disadvantage due to the Company taking or failing to take those measures.”

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. Managing and controlling risk is important to the management of Heidelberg Pharma. Potential risks with significant ramifications and a reasonable probability of occurrence are recorded, assessed and closely monitored on a regular basis. This system is an important part of corporate control and monitoring.

Based on a process defined in a policy, the Risk Officers from the various divisions identify, analyze and assess the individual 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/quarter) brief the Risk Management Officer, who summarizes these reports and updates management of the status of the risks. On top of this, all employees are required to immediately report any risks that could jeopardize the Company's ability to continue as a going concern. The summaries of the regular reports are set items on the agenda of meetings of Heidelberg Pharma's executive management team and lead to the development of alternative courses of action for the internal management of the Company. This ensures that existing risks are monitored and controlled.

Risk management is designed to detect risks as early as possible, use suitable measures to keep operating losses at a minimum and avert going-concern risks. Heidelberg Pharma uses an IT-based risk management system to identify risks early. Heidelberg Pharma uses this system to identify and assess risks as well as to monitor measures aimed at minimizing risk.

All material risks are addressed in a risk report that is made available to the Executive Management Board monthly. In addition, the risk report is discussed with the Supervisory Board on a regular basis. Comprehensive risk ratings are carried out on a quarterly basis as part of a systematic process designed to ensure that all material risks related to the different departments and the subsidiary are included.

The risk management system, which comprises the same basis of consolidation as the consolidated financial statements and lists risk but not opportunities, is described in detail in both a risk manual and a company policy. These documents are regularly updated and made available to all employees. 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 medium-term period, i.e. between two and 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:

Assessment	Probability of occurrence	Amount of loss
Very low	0 to <20%	0 to €100 thousand
Low	20% to 40%	€100 to €250 thousand
Medium	40% to 60%	€250 to €500 thousand
High	60% to 80%	€500 to <€2,000 thousand
Very high	80% to 100%	>€2,000 thousand

The following table shows risk fields with the associated risk cluster:

Risk description	Net assessment, probability of occurrence	Net assessment, amount of loss	Change year-over-year
General business risks	High	High	–
Going-concern risks	Low	Very high	▼
Operational risks			
Risks of product development and of a lack of market maturity of the proprietary ATAC technology	High	High	–
Risks arising from the performance of clinical trials	Medium	High	▲
Risks arising from production and collaboration with service providers	Low	Medium	–
Risks from license collaborations	Medium	High	▲
License agreements for the use of ATAC technology	Medium	Medium	–
Unsuccessful marketing of product candidates	Medium	High	–

Risk description	Net assessment, probability of occurrence	Net assessment, amount of loss	Change year-over-year
Risks arising from workforce reduction or employee turnover	Medium	Medium	▲
Impact on research and development activities through restrictions on or obstruction of animal experiments	Very low	Very low	–
Financial risks			
Financing risks	Medium	Very high	–
Risks arising from the impairment of assets	Low	Medium	–
Risks related to the allowance of tax losses carried forward	Low	Medium	–
Market risks	Medium	Low	▲
Strategic risks			
Marketing risks	Low	High	–
Risks related to intellectual property rights	Low	Medium	–
External risks			
Risks resulting from competition and technological change	Medium	High	–
Risks and dependencies related to the provision of health care and spending by the pharmaceutical industry	Low	High	–
Other risks			
Legal risks	Low	Medium	–
Termination of the lease for business premises in Ladenburg	Very low	High	–
Risks related to a possible significant influence of major shareholders	Very low	High	–
Compliance and security risks	Low	High	–
Effects of climate change	Very low	Very low	–

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 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.

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 periodically receive a report on the effectiveness of the internal control system to ensure reliable financial reporting. In particular, regular reports on this system are submitted to the Audit Committee of the Supervisory Board, which discusses the audit activities.

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 General business risks

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

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

Heidelberg Pharma is currently unable to finance the Company solely through sales and license revenue and is dependent on funding from equity providers or licensees. Debt financing instruments such as bank loans are generally not applicable for biotechnology companies. While there is an increasing number of venture loans or royalty stream financing, these are usually supplemented with adequate equity financing.

Some of the individual risks set forth below are related and can affect each other in a positive or negative way. Should these risks occur, either individually or together with other risks or circumstances, this may severely compromise Heidelberg Pharma's business activities, its achievement of key corporate goals and/or its ability to fund its operations, as well as significantly adversely affect the results of operations, financial position and net assets of Heidelberg Pharma AG and the Heidelberg Pharma Group and therefore jeopardize the ability of Heidelberg Pharma AG and the Heidelberg Pharma Group to continue as a going concern.

8.4 Going-concern risks

The concrete likelihood of going-concern risks for the coming fiscal year is low due to the financing successfully obtained in August 2022. Based on the assessment of the Executive Management Board and the executive directors' budget, the cash available to the Company as of the 30 November 2022 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 according to the financial planning to ensure the continued existence of the Company as a going concern until mid-2025.

If the Executive Management Board is unable to implement the corporate strategy focused on the ATAC technology as planned 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. As a result, there is currently significant uncertainty about the Group's and/or both Group companies' ability to continue as a going concern.

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 directors expect the Group's operations to continue beyond mid-2025.

8.5 Operational risks

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 not be suitable for patients due to severe side effects or is unable to demonstrate a sufficiently broad therapeutic window (ratio of efficacy to intolerable side effects) in patients in clinical trials.

Furthermore, no assurance can be given that contractual partners will not terminate technology partnerships. The possibility that the technology might be unusable or unsuitable for the market for certain antibodies cannot be ruled out.

Preclinical data collected so far show that undesirable side effects may occur with some of combinations used to date, or the efficacy is insufficient. In particular, there is no certainty that the data obtained to date in animal model testing of promising ATACs will be 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, thus jeopardizing the continued existence as a going concern of the Heidelberg Pharma Group and Heidelberg Pharma AG.

Risks arising from the performance of clinical trials

Drug development is subject to risks typical for the industry, including setbacks in clinical development and the associated discontinuation of clinical development of the respective product candidates. Licensing partners conducting development activities are also exposed to this risk, which thus indirectly affects Heidelberg Pharma as the licensor.

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 preclinical and early clinical trials do not offer any certainty regarding a compound's safety and efficacy in later-stage trials. Heidelberg Pharma cannot eliminate the possibility that the approval of a drug candidate might be delayed or rejected even after a successful registration trial, for instance if the execution or the results of the trial do not satisfy regulatory requirements. There is a risk that new therapeutic approaches in the indications examined will further increase the number of trials and make patient recruitment more difficult than expected. This could have a significant impact on the cost and timing of the clinical trial.

Should the risks described here materialize, the necessary clinical studies could be more elaborate than expected and require additional funds. Furthermore, expected sales revenue could fail to materialize or be lower if no approval is obtained.

Risks arising from production and collaboration with service providers

Heidelberg Pharma does not hold a Good Manufacturing Practice (GMP) certificate. Antibodies, the toxin and the conjugates for the planned trials are manufactured by service providers (contract development manufacturing organizations – CDMOs). Heidelberg Pharma Research has also been responsible for supplying licensees with GMP-quality Amanitin linkers since 2019. To do this, it uses third-party manufacturers as sub-contractors. Heidelberg Pharma Research is exposed to the risk that service providers may not be able to supply the agreed products or could have quality or capacity problems for various reasons. 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. 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 sub-contractors 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. Delays caused by the pandemic cannot be ruled out, although no effects have been identified so far.

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

Risks from license collaborations

Heidelberg Pharma has entered into alliances and partnerships for the development, manufacture and/or commercialization of development or product candidates. Problems relating to development, production or marketing may arise in the course of the partnership.

This may include but is not limited to insufficient allocation of capacity by the contracting party, financial difficulties experienced by the contracting party, a change in business strategy resulting in termination of an agreement, a change in the ownership structure of the contracting party or the partial or entire absence of agreed payments.

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

License agreements for the use of ATAC technology

Heidelberg Pharma Research GmbH has entered into license agreements with various licensors for the use of patents related to the ATAC technology. These license agreements are a key condition for further development of the ATAC technology. They can generally only be terminated by the licensor for good cause, and such cause is generally limited to breaches of duty for which the licensee is liable or insolvency of the licensee. Should material license agreements be terminated nonetheless, there is a risk that further development and marketing of the ATAC technology may not be possible. This would jeopardize the business model based on ATAC technology and thus the continued existence as a going concern of the Heidelberg Pharma Group and Heidelberg Pharma AG.

Unsuccessful marketing of product candidates

Heidelberg Pharma is subject to the usual industry and market risks relating to the marketing of approved pharmaceutical products. 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.

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

Risks arising from workforce reduction or employee turnover

The Group's success depends on its executives and research staff, especially their knowledge of the ATAC technology and its successful development and commercialization. The loss of executives and research staff in key positions could delay the Company's research and development work. The ability of the Group to implement its business strategy will also depend on whether the Company continues to be able to recruit highly qualified staff and executives and retain them over the long term.

Impact on research and development activities through restrictions on or obstruction of animal experiments

In the course of its business and as a service provider when developing drugs for its clients, Heidelberg Pharma Research is legally required to test drug candidates on animals before clinical testing in humans can be initiated. Germany has an animal welfare law in place with very high standards which are reviewed regularly. These standards are the basis for work at Heidelberg Pharma and its service providers. Despite the careful selection and monitoring of service providers, potential violations of relevant regulations cannot be completely ruled out. This could delay Heidelberg Pharma's research and development work or significantly increase its cost. As animal testing is also the subject of heated debate and negative reporting in the media, impediments to animal testing cannot be ruled out, which could also cause a delay in Heidelberg Pharma's research and development activities.

8.6 Financial risks

Financing risks

Cash inflows from sales revenue or royalties are not yet sufficient to sustain the Company's operations.

Based on current planning, the corporate action implemented in August 2022, together with 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 successor candidates HDP-102, HDP-103 and HDP-104, 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.

Should this not be possible, there is a risk (see section 8.4 “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.

To ensure that the Company is able to meet its financial obligations beyond mid-2025, sales revenue will need to be increased both at the level of the subsidiary and the parent company, or further financing measures will need to be reviewed implemented in the short to medium term.

In the event of the subsidiary becoming insolvent, most of the investments in its business and the shareholder loan extended to it by Heidelberg Pharma AG would be lost.

Implementing corporate actions could turn out to be more difficult or less successful, as the capital market suffers from the effects of the war in Ukraine, the related energy crisis and high levels of inflation, resulting in falling share prices for the Company and/or less capital being made available for investments in biotechnology companies.

To date, in addition to sales revenue funds available to Heidelberg Pharma AG have been the main source for funding the expansion and profiling of the ATAC technology. The ability of Heidelberg Pharma Research GmbH to increase its sales revenue from the ATAC technology and the service business and find additional collaboration partners is a key pillar of the business model. The success of such partnerships depends not only on upfront payments and milestone payments by licensing and collaboration partners, but also on the ability of these partners to achieve success in clinical development and to generate the projected sales revenue and any resulting license fees.

The executive directors assume that, despite the risks arising from product research and development described above, the ATAC technology will prove to be marketable in the long term and licensees or buyers for the technology or the product candidates will be found to preserve the solvency of Heidelberg Pharma.

Risks arising from the impairment of assets

Assets, particularly equity investments, goodwill, not yet ready for use in process research and development (IP R&D) and trade receivables are subject to an inherent impairment risk. Such impairment risk might be triggered by a negative business development at Heidelberg Pharma AG or its subsidiary or by the insolvency of a creditor.

The equity investment in Heidelberg Pharma Research GmbH and the receivables from this entity reported in Heidelberg Pharma AG’s HGB annual financial statements were tested for impairment as part of the annual impairment testing and were found to be fully recoverable.

The carrying amounts of the goodwill recognized in the IFRS consolidated balance sheet for the business of Heidelberg Pharma Research GmbH and the intangible asset “IP R&D” were also tested and confirmed as recognized.

Based on the annual impairment testing, these risks will continue to exist in the future and might lead to impairment losses. This would have a negative effect on the earnings and equity of Heidelberg Pharma AG, which in turn could impact the Group's share price as well as its net assets, financial position and results of operations. Furthermore, a potentially negative effect on the value of the intangible assets, as well as on the goodwill recognized in the IFRS consolidated balance sheet, cannot be excluded.

Risks related to the allowance of tax losses carried forward

According to the tax calculation, tax losses carried forward as of 30 November 2022 were mainly attributable to Heidelberg Pharma AG (loss carryforward of €237,836 thousand for corporation tax; €234,798 thousand for municipal trade tax) 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 of €0.7 million were offset in the Group against deferred tax liabilities on loss carryforwards in the past fiscal year. Deferred tax assets were recognized only in the same amount as the deferred tax liabilities.

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).

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.

Market risks

Given its business activities, Heidelberg Pharma is exposed to market risks, particularly currency risks (mainly in USD), interest rate and price risk, 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 Company's ability to finance its business activities. Heidelberg Pharma does not use embedded derivatives or other derivative financial instruments to hedge against risks.

8.7 Strategic risks

Marketing risks

The Company and its licensees will have to cooperate with other entities to market future products. Through license agreements, Heidelberg Pharma generally receives upfront payments, milestone payments and, if regulatory approval has been achieved, royalties on product sales. Hence Heidelberg Pharma's future sales revenue will also depend on the performance of its licensees and their partners. The continued existence of the Group and/or the entities included in consolidation would be materially affected if Heidelberg Pharma AG or its subsidiary Heidelberg Pharma Research GmbH failed to conclude license agreements for development and product candidates on reasonable terms or if cooperation agreements entered into were not successful or were terminated.

Risks related to intellectual property rights

Heidelberg Pharma endeavors to protect its product candidates and technologies in all major markets through patents. Nevertheless, Heidelberg Pharma is unable to ensure that patents will be issued on the basis of pending or future patent applications. Even if patents are issued, there is no certainty that they will not be contested, circumvented or declared invalid. Partners of Heidelberg Pharma could also use the access they have gained to the ATAC technology platform based on a license agreement to file their own patents, which could limit the Company's freedom of action. In such cases, Heidelberg Pharma can normally take legal action to stop the infringement of its own patents in question and demand compensation or payment of a license fee from the infringer, or to gain access to the patents of its partners that were filed in contravention of the contractual agreements. However, patent litigation is usually very expensive and protracted. The litigation costs and time needed to confirm the validity and enforceability of Heidelberg Pharma's patents or to enforce payment claims for infringement of these patents or to transfer rights to unlawfully filed patents (possibly by way of compulsory licenses) could be substantial. Apart from that, justified claims for payment or claims by the Company for the transfer of rights against the opposing parties could remain unfulfilled or be unenforceable. A legal dispute of this nature would tie up staff and financial resources of Heidelberg Pharma. This could have an adverse effect on the Company's net assets, financial position and results of operations.

There is also a risk that Heidelberg Pharma or its licensing partners might infringe the intellectual property rights of third parties, including those of whom Heidelberg Pharma is unaware. This could lead to time-consuming and cost-intensive litigation or force Heidelberg Pharma to purchase licenses from third parties to develop and market the Company's products.

8.8 External risks

Risks resulting from competition and technological change

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

Risks and dependencies related to the provision of health care and spending by the pharmaceutical industry

Following regulatory approval of a drug, the framework within which public health authorities, research institutes, private health insurance providers and other organizations operate impacts the business activities of Heidelberg Pharma and its partners. Healthcare reforms and the persistent debate about prices in the key markets of the United States, Europe and Japan are putting increasing pressure on healthcare budgets and thus on the pharmaceuticals market. Overall, this situation could cause potential partners or investors to refrain from making new commitments in drug development and also pose a risk for Heidelberg Pharma.

8.9 Other risks

Legal risks

Heidelberg Pharma AG or its subsidiary could become party to a legal dispute, for example in a drug safety, patent, licensing, liability or labor law case, as the plaintiff, defendant or intervener. A court case or even an arbitration case could be time-consuming and expensive. There is also a general risk that even if the case is won, the corresponding titles cannot be enforced due to a possible insolvency of the opposing party. Even if litigation was successful or settlements were reached, these could adversely affect the Group's results of operations and shorten the currently expected cash reach.

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.

Risks related to a possible significant influence of major shareholders

The Chinese company Huadong has held 35% of all shares in Heidelberg Pharma AG since September 2022, making it the second-largest shareholder. Together with the previous main shareholder dievini (Dietmar Hopp, parties related to him and companies controlled by them) both companies hold a material proportion of its shares (80.67%) and could exercise a significant influence on the Company in the General Meeting. Together, they could block decisions by the General Meeting or cause their own interests to prevail.

In addition, there is a risk that two dominating shareholders could affect the Company's financing activities. In the event of corporate actions, the influence and control of these shareholders could prevent other investors from participating in a financing of the Company. The low number of shares in freefloat implies a reduced liquidity or tradability of Heidelberg Pharma shares.

Compliance and security risks

Compliance risks can arise when quality standards are not upheld, or when business processes are not carried out flawlessly from a legal perspective. Heidelberg Pharma has taken organizational precautions to fulfill the requirements in question and control the internal processes. Specifically, risks can arise when legal requirements are not met, for instance.

In order to minimize this risk, the responsible internal departments and external attorneys are tasked with closely monitoring and reviewing the preparations for and operation of the Annual General Meeting along with all relevant documents and processes. Auditors handle these tasks with regard to the financial statements.

Risk could arise from the use of computer systems, networks, software and data storage devices despite precautions typical for the industry. Heidelberg Pharma has taken steps regarding both hardware and software to minimize these risks.

The introduction of the EU's General Data Protection Regulation (GDPR) in May 2018 harmonized data protection requirements across Europe. The implementation regulations, rights to protection and information of natural persons, control mechanisms, and sanctions have all been tightened up. Improving data protection can be expensive, and the amount of possible fines can be damaging to the financial situation of small companies in particular.

Other risks related to the protection of the environment and human health, purchasing as well as general safety requirements are not deemed significant.

Effects of climate change

When the consolidated financial statements for the 2022 fiscal year were being prepared, the effects of global climate change on the measurement of assets and liabilities were also examined. This focused on the recoverability and useful life of assets, expected credit risks and other factors affecting the development of business such as regulatory requirements, changed conditions for research and development or a change in the behavior of collaboration partners. It was demonstrated that climate-related issues did not have any material direct financial effects on the assets, liabilities, financial position and profit or loss in the fiscal year.

8.10 Overall assessment of the risk situation

From the current perspective, there are no risks other than the aforementioned risks that would endanger the Company's position as a going concern. Management aims to further refine the business model to maximize the enterprise value in the long term by leveraging opportunities and minimizing risks.

On the one hand, financing risks will increase continually due to the planned utilization of funds until 2025 and beyond. However, in the view of the Executive Management Board, the increasing maturity of the technology will on the other hand produce better marketing opportunities for the ATAC technology, and therefore enhance the revenue potential of Heidelberg Pharma. 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.

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:

- Update provided the Company's partner Magenta on the study with the ATAC candidate MGTA-117

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

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10 Report on expected developments and on opportunities

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

The global economy has entered 2023 in a weaker position than previously expected owing to the ongoing crises, the rising cost of living and higher product development costs, as well as tighter monetary conditions in most regions.⁸³ In its January 2023 World Economic Outlook, the International Monetary Fund (IMF) projects global growth of 2.9% in 2023 (2022: 3.4%).⁸⁴ Growth in the eurozone is projected to reach 0.7% in 2023, well behind the 1.4% anticipated for the United States (eurozone 2022: 3.5%, USA 2.0%). Only very weak growth of 0.1% is expected for Germany (2022: 1.9%), due in particular to the high energy prices.⁸⁵ Supply shortages and inflation are currently having a huge impact on economic development in Europe, even if the IMF believes that worldwide inflation will fall again in 2023 and 2024. On the downside, the uplift provided by the revitalization of economies as the COVID-19 pandemic abated in the eurozone is fading. This is dampening the general mood in the markets and causing consumer sentiment to deteriorate. The fallout of the war in Ukraine for the global economy is also heavier than expected, and there are currently no indications that this situation will improve. The Heidelberg Pharma Group is not directly restricted in its activities and does not see any risks with regard to its research and development activities or supply chains at the present time. However, it does need to factor in price increases.

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

84 <https://www.imf.org/en/Publications/WEO/Issues/2023/01/31/world-economic-outlook-update-january-2023>

85 <https://www.imf.org/en/Publications/WEO/Issues/2023/01/31/world-economic-outlook-update-january-2023>

10.2 Market opportunities in the biotechnology industry

The COVID-19 pandemic continues to impact pharmaceutical markets globally and is estimated to expand the net cumulative pharmaceutical market by around USD 500 billion from 2020 through 2027.⁸⁶

According to an industry report published by the global market research institute IQVIA, global drug spending is expected to rise to more than USD 1.9 trillion annually by 2027, representing an average annual increase of 3% to 6%.⁸⁷ The highest volume growth is expected in Latin America, Asia and Africa, driven by a mix of population growth and improved access to medical care.⁸⁸ The markets in North America and Europe are likely to see a lower rate of growth, with a CAGR of –1 to 2% forecast for the United States.⁸⁹ China, the second-largest market after the USA, is projected to grow by 8% in the five-year period.⁹⁰

In spite of a rising number 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.⁹¹ Global spending on cancer drugs is expected to reach USD 370 billion by 2027 (2021: USD 185 billion).⁹² Biotech drugs will represent a significant 35% of spending globally on oncology drugs.

Biotechs completed 53 IPOs in 2022 (2021: 208), with 19 in the USA and just two in the EU, falling significantly short of the previous year.⁹³ A small number of IPOs is still expected at least for the first half of 2023.⁹⁴

On the stock exchange, the biotechnology industry ended a weak year on the whole with a positive fourth quarter. The NASDAQ Biotechnology Index posted losses of 12% in 2022, which meant that it closed the year more favorably than the S&P 500 (–20%), for example.⁹⁵ The XBI (S&P Biotech ETF) lost 25.8%, the first time it recorded two consecutive negative years.⁹⁶

The years 2019–2021 saw multiple IPOs by early-stage biotech companies that did not yet have clinical data to underpin their approach. Experts believe that some of these companies are unlikely to survive the next 12 to 18 months.⁹⁷ However, experts also expect the sector to recover soon, with an uptrend for 2024–2025 or maybe even in the second half of 2023.⁹⁸

86 IQVIA, The Global Use of Medicine in 2023, Outlook to 2027, 18 January 2023:

<https://www.iqvia.com/insights/the-iqvia-institute/reports/the-global-use-of-medicines-2023>

87 IQVIA, The Global Use of Medicine in 2023, Outlook to 2027, 18 January 2023:

<https://www.iqvia.com/insights/the-iqvia-institute/reports/the-global-use-of-medicines-2023>

88 IQVIA, The Global Use of Medicine in 2023, Outlook to 2027, 18 January 2023

89 <https://www.iqvia.com/newsroom/2023/01/global-market-for-medicines-to-rise-to-19-trillion-by-2027-says-report-from-iqvia-institute>

90 IQVIA, The Global Use of Medicine in 2023, Outlook to 2027, 18 January 2023

91 <https://gco.iarc.fr/tomorrow/en/dataviz/isotype>

92 <https://www.iqvia.com/newsroom/2023/01/global-market-for-medicines-to-rise-to-19-trillion-by-2027-says-report-from-iqvia-institute>

93 BCIQ database, 31 January 2023

94 BioCentury, 13 January 2023: Surviving a year of the haves and have-nots

95 BioCentury, 13 January 2023: Surviving a year of the haves and have-nots

96 BioCentury, 27 January 2023: Biotech is healing. A house clean-up this year can help get it back on track

97 BioCentury, 27 January 2023: Biotech is healing. A house clean-up this year can help get it back on track

98 BioCentury, 13 January 2023: Surviving a year of the haves and have-nots

10.3 Opportunities

ADC technology

The uptick in cancers is driving demand for personalized, highly effective therapies, and ADCs in particular are becoming increasingly important, as evidenced by the continuous growth of the market in recent years. According to a report by Grand View Research, Inc., the global ADC market was valued at USD 5.81 billion in 2021 and USD 8.08 billion in 2022 and is expected to grow to USD 22.87 billion by 2030.⁹⁹ This is compound annual growth rate (CAGR) of 16.4% in the forecast period of 2022 through 2030.¹⁰⁰

To date, the FDA has approved twelve ADCs.¹⁰¹ The number of ADC programs continued to go up compared with the previous year. At the end of 2022, 14 (2021: 12) oncological ADCs were in 16 Phase III clinical trials, of which four have already received approval; others are still being tested. A further 34 (2021: 25) ADCs are being studied in Phase II trials and 126 (2021: 100) in Phase I trials. A total of 120 ADC candidates (2021: 75) are currently in preclinical studies.¹⁰²

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.

Heidelberg Pharma attaches great importance to expanding its product portfolio and continuing the development of the ATAC technology platform. Preclinical and toxicological studies are being carried out with the successor candidates HDP-102 and HDP-103. The Company announced the biological target for another candidate, HDP-104, in fall 2022. HDP-104 is about to finish the research phase and is currently being prepared for preclinical development.

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.

99 Antibody-Drug Conjugates Market Size, Share & Trends Analysis Report Application (Blood Cancer, Breast Cancer, Urothelial/Bladder Cancer), By Technology (Cleavable, Non-cleavable), By Payload Technology, And Segment Forecasts, 2022-2030
<https://www.grandviewresearch.com/industry-analysis/antibody-drug-conjugates-market#>

100 Antibody Drug Conjugates Market Worth \$22.87 Billion By 2030:

<https://www.grandviewresearch.com/press-release/global-antibody-drug-conjugates-market#>

101 <https://premier-research.com/blog-antibody-drug-conjugates/>

102 BioCentury data base BCIQ, as of 4 January 2023

The ATAC partnerships will expand the range of applications for the technology to other oncological applications as well as including possible applications outside oncology and will underpin further 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 ATAC will 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 ongoing, as are negotiations 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 (TLX250-CDx labeled with zirconium) and a therapeutic project (TLX250 labeled with lutetium in Phase II).

Based on the completed Phase III ZIRCON study for diagnosing renal cancer using positron emission tomography (PET), Telix plans to file applications for approval of the diagnostic imaging agent for ccRCC with the FDA and other regulators around the world. Potential future utility may include active surveillance, surgical staging and treatment response monitoring for renal cancer. Telix is conducting further clinical trials to expand the indication. If regulatory approval is obtained, 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. First patients have been dosed with TLX250 in combination with Opdivo® anti-PD-1 immunotherapy in the STARLITE 2 trial. STARLITE 1 has received clearance from the US FDA and is due to commence. Heidelberg Pharma AG is eligible to receive royalties in the single-digit percentage range in the long term for this [therapeutic agent](#) if these trials are successful.

RHB-107 (upamostat)

RedHill is currently in talks with regulatory authorities regarding further development steps based on the published clinical Phase II data. RHB-107 is also being tested in development programs against several viral targets, including influenza and Ebola.

RedHill also plans to trial upamostat (RHB-107) in combination with another development candidate, opaganib, as a third arm in a Phase I/IIa study in advanced cholangiocarcinoma, subject to talks with the FDA.

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 ATAC technology

Heidelberg Pharma believes that Amanitin is an innovative toxin with attractive properties for the development of ATACs and will continue its strategy for the development and marketing of proprietary ATAC technology.

The strategy's core elements are the expansion of the Company's own project pipeline, the development of the pipeline projects until clinical proof of concept, the initiation of further research and option agreements and their extension to include long-term license agreements, as well as the broadening of the technology base.

Own pipeline

The proprietary ATAC candidate HDP-101 is being tested in patients with multiple myeloma for the first time. Patients in the third dose group are currently being treated with increasing dose levels in the Phase I part of the dose escalation study until a safe and optimum dosage for HDP-101 has been determined. During the Phase IIa part, the recommended dose 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 mid-2024. 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.

The Company plans to open additional clinical centers in Poland and Hungary to accelerate recruitment and obtain landmark data for the Phase IIa part during 2024.

Final preclinical and toxicological studies are being carried out with the successor candidates HDP-102 and HDP-103. Due to internal prioritization of the projects, the Phase I clinical trial, which was due to start somewhat earlier, is now expected to kick off at the end of 2024.

The partnership with Huadong is intended to support and significantly strengthen the planned further development of Heidelberg Pharma's own pipeline.

Partner programs

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

Takeda is developing a proprietary Antibody Targeted Amanitin Conjugate under exclusive license with a selected, yet undisclosed target and is responsible for its further preclinical and clinical development as well as for the potential commercialization of the licensed product candidate. The partnership with Chiome is still at an early stage. The partner has an option for an exclusive, antigen-specific license for global development and commercialization rights to the product candidate resulting from the research collaboration.

Heidelberg Pharma is not yet in a position to fully finance its own R&D activities using its own funds in the short to medium term. In addition the implementation of financing measures, increased payments from Heidelberg Pharma Research GmbH's technology partnerships or from license agreements are expected to help finance in-house development work. Due to current financial planning, the Company's financing is secured until mid-2025.

10.5 Financial forecast and non-financial forecast

Expected results of operations

The Executive Management Board expects the Heidelberg Pharma Group to generate between €7.0 million and €10.0 million in sales revenue and other income (2022: €19.9 million) in the 2023 fiscal year. Sales revenue generated by Heidelberg Pharma Research GmbH (especially from ATAC technology), as well as deferred revenue and potential milestone payments to Heidelberg Pharma AG will contribute to this figure in roughly equal measure. Sales revenue from major potential license agreements was not included in this planning.

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 of €37.0 million to €41.0 million, slightly higher than in the reporting year (€37.0 million).

Earnings before interest and taxes (EBIT) in the 2023 fiscal year are expected to be between €–28.5 million and €–32.5 million (2022: €–17.2 million).

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 2023 fiscal year for Heidelberg Pharma AG's business operations are expected to increase considerably compared to 2022 (€8.9 million excluding the capital increase and the dievini shareholder loan). Funds used will be in the range of €32.5 million to €36.5 million. This corresponds to an average monthly use of cash of €2.7 million to €3.1 million (2022: €0.7 million).

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 2022: €66.6 million) would decline despite any corporate actions given the anticipated loss for the 2023 fiscal year.

All measures being discussed to improve the Company's financial situation are described in detail in sections 8.4 "Going-concern risks" and 8.6 "Financial risks", sub-section "Financing risks" of chapter 8 "Risk report."

Financial outlook	Actual 2022 € million	Plan 2023 € million
Sales revenue and other income	19.9	7.0–10.0
Operating expenses	37.0	37.0–41.0
Operating result	(17.2)	(28.5)–(32.5)
Total funding requirement ¹	8.9	32.5–36.5
Funds required per month ¹	0.7	2.7–3.1

¹ Not including any corporate actions

Non-financial forecast

Since Heidelberg Pharma plans to recruit additional employees in research and development, and administration in the upcoming fiscal year, a slight increase in the average number of employees is to be expected.

11 Disclosures on Heidelberg Pharma AG (HGB)

The management report of Heidelberg Pharma AG and the Group management report for the 2022 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 conditions, 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 €–21.6 million (previous year: €–17.4 million) in the 2022 fiscal year (1 December 2021 to 30 November 2022) according to German commercial law. The net loss for the year came to €20.7 million (previous year: €25.2 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 income from profit transfer in the amount of €0.5 million in 2022 (previous year: expenses from loss absorption of €10.1 million).

Both sales revenue and operating income increased significantly year-on-year (combined €10.7 million; previous year combined: €0.1 million), as did operating expenses at €32.3 million (2021: €17.6 million).

Heidelberg Pharma thus failed to meet the previous year's expected target range for income (€0.5 million to €1.0 million) and operating expenses (€22.0 million to €26.0 million), but did meet that for the operating result (€–21.5 million to €–25.5 million). This is thanks to the strategic partnership with Huadong and in particular to the out-licensing agreements recognized in income, the financial impact of which, as described, was not yet fully foreseeable at the time.

Sales revenue and other operating income

Sales revenue of €8,816 thousand (previous year: €0 thousand) was generated within the framework of the strategic partnership with Huadong.

Other operating income of €1,882 thousand (previous year: €139 thousand) primarily comprises income from foreign currency measurement in the amount of €1,751 thousand (previous year: €10 thousand). In addition, there is prior-period income from the reversal of other provisions, which in each case were largely subject to a statute of limitations (€11 thousand; previous year: €33 thousand). €42 thousand (previous year: €68 thousand) was generated by charging on patent costs in the context of out-licensing. Other items added up to income of €78 thousand (previous year: €28 thousand), of which the first-time reimbursement under the Expenditure Compensation Act (Aufwendungsausgleichsgesetz, AAG) alone accounted for €49 thousand in 2022.

Operating expenses

Cost of materials resulting from development activities totaled €24,054 thousand (previous year: €12,615 thousand). Expenses for raw materials, consumables and supplies and for purchased goods were incurred in the amount of €1,304 thousand (previous year: €130 thousand). Expenses for purchased services disaggregate into third-party services (€10,040 thousand; previous year: €6,822 thousand), third-party services charged on (€1,935; previous year: €1,916 thousand) and intragroup cost allocations (€4,771 thousand, previous year: €3,748 thousand). Royalties paid to the subsidiary were incurred for the first time in the context of the strategic partnership with Huadong (€6,004 thousand).

Personnel expenses were up significantly on the 2021 figure (€1,838 thousand) to €2,823 thousand in the fiscal year ended. Besides the rise in headcount, periodic salary increases also had an impact. Personnel expenses comprise salaries (€2,526 thousand; previous year: €1,671 thousand) and social security contributions (€280 thousand; previous year: €162 thousand). Pension expenses amounted to €17 thousand (previous year: €5 thousand).

Amortization of intangible assets and depreciation of property, plant and equipment came to €28 thousand (previous year: €14 thousand). This item also includes the depreciation charge related to low-value assets. It comprised depreciation of tangible assets (€5 thousand; previous year: €3 thousand) and amortization of intangible assets (€23 thousand; previous year: €11 thousand).

Other operating expenses of €5,433 thousand (previous year: €3,121 thousand) in 2022 consisted primarily of legal and consulting costs (€1,536 thousand), which rose compared to 2021 (€1,292 thousand). 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 (€454 thousand; previous year: €398 thousand), the preparation and audit of the annual financial statements (€143 thousand; previous year: €139 thousand), travel costs (€136 thousand; previous year: €27 thousand), Supervisory Board remuneration (€190 thousand; previous year: €181 thousand), insurance and contributions (€67 thousand; previous year: €37 thousand), office costs (€29 thousand; previous year: €28 thousand), other ancillary personnel expenses (€106 thousand; previous year: €74 thousand) and IT costs (€125 thousand; previous year: €45 thousand). There were also costs of capital increases amounting to €766 thousand (previous year: €749 thousand) and foreign currency measurements (€1,507 thousand; previous year: €9 thousand). Expenses for other operating costs made up €374 thousand (previous year: €142 thousand).

All of the aforementioned items gave rise to an operating result of €-21,639 thousand (previous year: €-17,449 thousand).

The income from profit transfer required to be reported as a result of the profit and loss transfer agreement with the subsidiary Heidelberg Pharma Research GmbH was €514 thousand (previous year: expenses from loss absorption of €10,141 thousand).

Interest

Unlike in 2021, other interest and similar income of €3,219 thousand (previous year: €2,916 thousand) no longer consisted solely of interest income from the loan to affiliated company Heidelberg Pharma Research GmbH (€2,984 thousand). After years of zero or negative interest rates, it was possible to generate traditional interest income on monetary assets again (€235 thousand). Interest and similar expenses (€837 thousand; previous year: €485) were incurred for the shareholder loan extended by dievini (€836 thousand; previous year: €465 thousand) and for custodian fees (€1 thousand; previous year: €20 thousand). As a result, net interest income totaled €2,382 thousand (previous year: €2,431 thousand).

Taxes

There were no taxes on income in 2021; however, a total of €1,916 thousand comprised of foreign withholding tax/withholding tax on capital gains tax plus solidarity surcharge was required to be recognized in the fiscal year now ended. The loss after taxes was therefore €20,659 thousand (previous year: €25,159 thousand). Other taxes (€1 thousand; previous year: €1 thousand) comprise vehicle taxes on company cars.

Earnings

All of the aforementioned items resulted in a net loss for the past fiscal year of €20,660 thousand (previous year: €25,160 thousand). Together with the accumulated losses brought forward from the previous fiscal year in the amount of €228,319 thousand (previous year: €203,159 thousand), net accumulated losses came to €248,979 thousand (previous year: €228,319 thousand).

Financing and liquidity

Heidelberg Pharma AG had sufficient funds throughout fiscal year 2022 to ensure the financing of its business operations.

Heidelberg Pharma AG showed cash of €81,271 thousand at the close of the fiscal year (30 November 2021: €6,009 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 8.4).

Capital expenditures

In 2022, additions of €104 thousand were made to tangible assets (€76 thousand), but none in intangible assets (€18 thousand). Additions in 2021 amounted to €1 thousand and €49 thousand, respectively.

Net assets and financial position

Total assets rose by around €68.3 million to €150.1 million compared to €82.8 million in the previous year. The increase in total assets was attributable to a higher level of cash in the context of the capital increase, which more than compensated for the decrease in receivables from affiliates.

The corresponding increase in total equity and liabilities was mainly due to the rise in equity triggered by the capital increase and deferred income that had to be recognized in connection with out-licensing.

Fixed assets were mainly unchanged compared to the previous year at €13.3 million at the end of 2022, 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 2023 to 2025 (clinical phases I and II). This is followed by a second, longer-term 21-year planning phase from 2026 to 2046 (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 8.3% (previous year: 6.8%). 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 2024 onwards with sustained positive cash flows in the market phase from 2029
- Maximum exploitation period for license income until 2046 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 fiscal year ended, 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 toxin Amanitin is reported as raw materials, consumables and supplies in the amount of €26 thousand (2021: €72 thousand). Prepayments of €219 thousand were also posted. In the previous year, €131 thousand was required to be recognized for these items.

Trade receivables of €16 thousand were required to be shown at the end of the 2022 reporting period. No such receivables existed in the previous 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 fell from €62,350 thousand to €55,597 thousand in the fiscal year due to the absorption of the company's loss of €10,141 thousand from fiscal year 2021, where the subsidiary's receivable was offset against the loan. 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 €293 thousand (previous year: €417 thousand) comprise VAT receivables of €218 thousand (previous year: €391 thousand) and security deposits/other items amounting to €75 thousand (previous year: €26 thousand).

Bank balances increased to €81,271 thousand as of the balance sheet date (previous year: €6,009 thousand) as a result of the capital increase carried out during the year and despite cash outflows from operating activities and the financing of the subsidiary Heidelberg Pharma Research GmbH.

For more information on the Company's strained financial position and a possible threat to its continuation as a going concern, refer to sections 8.4 "Going-concern risks" and 8.6 "Financing risks."

Prepaid expenses (€301 thousand; previous year: €561 thousand) are attributable to advance payments to service providers (€142 thousand; previous year: €93 thousand) and project services for clinical development (€159 thousand; previous year: €468 thousand).

As of 30 November 2022 and after a capital increase implemented during the year, subscribed capital consisted of 46,584,457 no par value bearer shares with a notional value of €1.00 per share (previous year: 34,175,809 no par value shares). As of the reporting date, capital reserves amounted to €320,640 thousand (previous year: €253,137 thousand); €67,503 thousand was appropriated to capital reserves in the fiscal year in the context of a capital increase. The losses accumulated since the start of the Company's business activities in 1997 totaled €248,979 thousand as of the end of the fiscal year, of which €228,319 thousand was brought forward to new account from the previous fiscal year and €20,660 thousand was attributable to the net loss for the 2022 fiscal year. The equity of Heidelberg Pharma AG therefore increased from €58,994 thousand in the previous year to €118,245 thousand as of the 2022 reporting date.

Other provisions (€2,276 thousand; previous year: €981 thousand) were recognized for invoices outstanding (€204 thousand; previous year: €124 thousand), project costs within the context of clinical development (€1,244 thousand; previous year: €328 thousand), the Executive Management Board and employee bonus program (€333 thousand, previous year: €197 thousand), vacation entitlements (€163 thousand; previous year: €83 thousand), legal and consulting costs including patent costs (€56 thousand; previous year: €49 thousand), internal financial statement costs (€120 thousand; previous year: €111 thousand) and financial statement auditing and tax advisory costs (€151 thousand; previous year: €84 thousand). As in the previous year, archiving costs totaled €5 thousand).

Trade payables (€1,433 thousand; previous year: €522 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 €2,715 thousand relate to the consolidated VAT tax group and the intra-Group business relationships that exist with the subsidiary. In the previous year, €1,696 thousand was required to be recognized for this item. In addition, the profit and loss transfer agreement in place gave rise to a liability to the consolidated tax group of €10,141 thousand in the previous year.

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 (€15,786 thousand; previous year: €10,465 thousand). The unsecured loan is not limited in time and carries annual interest of 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 (€117 thousand; previous year: €48 thousand) mainly comprises wage and church tax liabilities (€64 thousand; previous year: €47 thousand). Liabilities of €12 thousand for a social insurance body were also recognized (2021: €1 thousand). In addition, miscellaneous other liabilities of €41 thousand were recognized in the fiscal year now ended. As in the previous year, all such liabilities are due for payment within one year.

The deferred income to be presented for the first time at the balance sheet date amounted to €10,510 thousand and resulted from the out-licensing of HDP-103 to Huadong because the license revenue will be accrued in equal amounts over 36 months.

11.2 Other disclosures

Heidelberg Pharma AG employed an average of 15 (previous year: 11) people (salaried employees) during the year, 8 of them in administration, 2 in business development and 5 in clinical development. The Company has also appointed to Executive Management Board members.

11.3 Financial outlook for the parent company, Heidelberg Pharma AG

Expected results of operations

The Executive Management Board expects the Company to generate between €4.5 million and €6.5 million in sales revenue and other operating income in the 2023 fiscal year (2022: €10.7 million). The earnings target for 2023 does not include potential sales revenue from a potential additional license agreement.

Total operating expenses in 2023 are expected to be in the range of €27.0 million to €31.0 million if business proceeds as planned, thus coming in lower in the 2022 reporting period (€32.3 million). The Company also assumes that expenses will continue to exceed income in the next few years.

The operating result in the 2023 financial year is expected to come in between €-21.5 million and €-25.5 million (2022: €-21.6 million). Furthermore, positive interest income of €2.0 million to €3.0 million (2022: €2.4 million) and expenses from loss compensation of €14.0 million to €17.0 million (2022: income of €0.5 million) are expected in 2023.

Heidelberg Pharma AG therefore expects to post a net loss of between €34.5 million and €38.5 million for 2023 (2022: €20.7 million).

Expected financial position and net assets

If income and expenses develop as anticipated, financing requirements in the 2023 fiscal year for Heidelberg Pharma AG's business operations are expected to increase compared to 2022 (€8.9 million excluding the capital increase and the dievini shareholder loan). Funds used will be in the range of €32.5 million to €36.5 million. This corresponds to an average monthly use of cash of €2.7 million to €3.1 million (2022: €0.7 million).

Given the licensing agreement with Huadong, it can be assumed that the funding requirement will also be noticeably reduced compared with the reporting period.

Equity as defined by German commercial law (30 November 2022: €118,245 thousand) would decrease regardless of any corporate actions given the anticipated loss for the 2023 fiscal year.

All measures being discussed to improve the Company's financial situation are described in detail in sections 8.4 "Going-concern risks" and 8.6 "Financial risks", sub-section "Financing risks" of chapter 8. "Risk report."

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Ladenburg, 22 March 2023

The Executive Management Board of Heidelberg Pharma AG



Dr. Jan Schmidt-Brand
Chief Executive Officer and Chief Financial Officer



Professor Andreas Pahl
Chief Scientific Officer

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CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME (IFRS)

for the fiscal year from 1 December 2021 to 30 November 2022

	Note	2022 €	2021 €
Sales revenue	22	18,513,920	1,749,829
Other income	23	1,346,342	563,829
Income		19,860,262	2,313,658
Cost of sales	24	(4,679,340)	(4,712,122)
Research and development costs	24	(26,376,595)	(18,750,257)
Administrative costs	24	(4,816,228)	(3,986,130)
Other expenses	24	(1,169,588)	(496,213)
Operating expenses	24	(37,041,751)	(27,944,722)
Operating result		(17,181,489)	(25,631,064)
Finance income	27	235,214	0
Finance costs	27	(839,883)	(494,492)
Financial result	27	(604,669)	(494,492)
Share of the profit/loss of associates		0	(13,146)
Earnings before tax		(17,786,158)	(26,138,702)
Income taxes	28	(1,915,938)	0
Net loss for the year		(19,702,097)	(26,138,702)
Net currency gain/loss from consolidation		0	0
Other Comprehensive Income		0	0
Comprehensive income		(19,702,097)	(26,138,702)
Earnings per share			
Earnings per share (basic)	29	(0.53)	(0.80)
Average weighted number of shares issued		37,235,476	32,504,068

Rounding of exact figures may result in differences.

CONSOLIDATED BALANCE SHEET (IFRS)

for the fiscal year ended 30 November 2022

Assets	Note	30 Nov. 2022 €	30 Nov. 2021 €
Property, plant and equipment and right-of-use assets	9	3,717,915	3,672,832
Intangible assets	10	2,837,776	2,900,256
Goodwill	10	6,111,166	6,111,166
Other non-current financial assets	12	34,900	34,900
Non-current assets		12,701,758	12,719,154
Inventories	13	4,585,024	745,920
Prepayments	14	513,337	676,284
Trade receivables and contract assets	15	1,098,902	1,019,751
Other receivables	16	353,468	429,559
Cash	17	81,329,482	6,141,451
Current assets		87,880,213	9,012,965
Total assets		100,581,970	21,732,119

Equity and liabilities	Note	30 Nov. 2022 €	30 Nov. 2021 €
Subscribed capital	18	46,584,457	34,175,809
Capital reserve	18	311,454,427	244,215,300
Accumulated losses	18	(291,394,475)	(271,692,378)
Equity	18	66,644,409	6,698,731
Lease liabilities (non-current)	19	100,382	75,568
Contract liabilities (non-current)	19	5,903,032	23,428
Non-current liabilities		6,003,414	98,996
Trade payables	20	3,050,532	903,013
Lease liabilities (current)	20	94,439	91,079
Contract liabilities (current)	20	5,017,266	490,886
Financial liabilities	20	15,785,833	10,465,000
Other current financial liabilities	20	3,986,078	2,984,414
Current liabilities	20	27,934,147	14,934,392
Total equity and liabilities		100,581,970	21,732,119

Rounding of exact figures may result in differences.

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY (IFRS)

for the fiscal year from 1 December 2021 to 30 November 2022

	Note	Shares	Subscribed capital €	Corporate actions/ premium Capital reserve €	Stock options €	Accumulated losses €	Total €
				221,896,978	5,473,884		
As of 1 December 2020		31,061,872	31,061,872	227,370,862		(245,553,676)	12,879,058
Measurement of stock options	24				686,489		686,489
Comprehensive income						(26,138,702)	(26,138,702)
Creation of shares for stock options exercised		7,300	7,300	6,497			13,797
Capital increase after accounting for capital procurement costs	18	3,106,637	3,106,637	16,151,452			19,258,089
Net change in equity							(6,180,327)
				238,054,927	6,160,373		
As of 30 November 2021	18	34,175,809	34,175,809	244,215,300		(271,692,378)	6,698,731
				238,054,927	6,160,373		
As of 1 December 2021							
Measurement of stock options	24				553,836		553,836
Comprehensive income						(19,702,097)	(19,702,097)
Capital increase after accounting for capital procurement costs	18	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	18	46,584,457	46,584,457	311,454,427		(291,394,475)	66,644,409

Rounding of exact figures may result in differences.

CONSOLIDATED CASH FLOW STATEMENT (IFRS)

for the fiscal year from 1 December 2021 to 30 November 2022

	Note	2022 €	2021 €
Net loss for the year		(19,702,097)	(26,138,702)
Adjustment for items in the statement of comprehensive income			
Stock options	25	553,836	686,489
Depreciation and amortization	24	756,583	802,860
Gains (-) and losses (+) on disposal of non-current assets		(14,077)	10,159
Profit/loss from equity-accounted investment	11	0	13,146
Exchange rate effects	26	(648,599)	(4,029)
Finance income	27	(235,214)	0
Finance costs	27	839,883	494,492
		1,252,412	2,003,116
Changes in balance sheet items			
Inventories	13	(3,839,105)	(516,100)
Prepayments	14	162,948	122,664
Trade receivables	15	(79,151)	167,933
Other receivables	16	76,091	(107,461)
Other non-current assets	12	0	10,000
Trade payables	20	2,147,518	(1,908,818)
Contract liabilities	19/20	10,405,985	262,202
Other liabilities	20	1,001,664	(478,698)
		9,875,950	(2,448,279)
Cash flow from operating activities		(8,573,736)	(26,583,865)
Finance costs paid	27	(525,421)	(28,655)
Finance income received	27	235,214	0
Net cash flow from operating activities		(8,863,943)	(26,612,520)
Cash flow from investing activities			
Proceeds from disposal of property, plant and equipment	9	15,367	0
Payments to acquire property, plant and equipment	9	(584,347)	(1,242,138)
Payments to acquire intangible assets	10	(28,585)	(146,669)
Acquisition of equity interests	11	0	(13,146)
Net cash flow from investing activities		(597,565)	(1,401,953)
Cash flow from financing activities			
Change in shareholder loan	20	5,000,000	10,000,000
Proceeds from the capital increases	18	79,911,693	20,006,742
Capital procurement costs of capital increases	18	(817,753)	(748,653)
Income from creating shares for stock options exercised	18	0	13,797
Principal portion of lease payments	24	(93,000)	(102,224)
Net cash flow from financing activities		84,000,940	29,169,662
Exchange rate and other effects on cash	26	648,599	4,029
Net change in cash		75,188,031	1,159,218
Cash			
at beginning of period	17	6,141,451	4,982,232
at end of period	17	81,329,482	6,141,451

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 2021/2022 fiscal year
from 1 December 2021 to 30 November 2022

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 WILEX 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 Wilex AG has been doing business as Heidelberg Pharma AG. The Company's Executive Management Board consists of Dr. Jan Schmidt-Brand and Professor Andreas Pahl.

"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, legal and 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. The subsidiary's Managing Director is Dr. Jan Schmidt-Brand. The registered office of Heidelberg Pharma Research GmbH is also at Gregor-Mendel-Straße 22, 68526 Ladenburg, Germany.

Upon recording in the Commercial Register on 17 March 2011, the subsidiary became a wholly-owned subsidiary of what was then WILEX AG and is now Heidelberg Pharma AG. It has thus become part of the Heidelberg Pharma Group.

In accordance with Section 264 III of the German Commercial Code (HGB), Heidelberg Pharma Research GmbH is exempt from preparing its own management report.

1.2 Change relating to associates

Emergence Therapeutics AG

In November 2019, Heidelberg Pharma AG acquired an equity interest in Emergence Therapeutics AG, Duisburg, (Emergence) through its subsidiary Heidelberg Pharma Research GmbH together with French and German investors. Until fiscal year 2021, this long-term net investment (equity interest and convertible bond) was measured according to the equity method pursuant to IAS 28.10 as an interest in an associate over which significant influence may be exercised (IAS 28.5 ff.). As Heidelberg Pharma's share in Emergence was reduced to 1.49% in the past fiscal year and the Group no longer has significant influence in the form of a supervisory board appointment, Emergence is now reported as an equity investment as defined by IFRS 9.

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 2022 had the following effects on Heidelberg Pharma GmbH's financial statements:

Standard/interpretation		Effective for fiscal years beginning on or after	Adopted by the European Union	Effects on Heidelberg Pharma
IFRS 9/IAS 39/IFRS 7/IFRS 4/IFRS 16 (Amendments)	Interest Rate Benchmark Reform (Phase 2)	1 Jan. 2021	Yes	None
IFRS 4 (Amendments)	Deferral of IFRS 9	1 Jan. 2021	Yes	None
IFRS 16 (Amendments)	COVID-19-Related Rent Concessions beyond 30 June 2021	1 April 2021	Yes	None

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
Annual Improvements to IFRS Standards 2018–2020 Cycles and Amendments to IFRS 3/IAS 16/IAS 37	Amendments to various IFRSs	1 Jan. 2022	Yes	No material effects
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	No	No material effects
IFRS 16 (Amendments)	Lease Liability in a Sale and Leaseback Transaction	1 Jan. 2024	No	None
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 2021 and ends on 30 November 2022. It is referred to hereafter as the “2022 fiscal year” (“2021 fiscal year” 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 22 March 2023 and released for publication in accordance with IAS 10. The consolidated financial statements are to be approved by the Supervisory Board on 22 March 2023. 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 2022, 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 2022: €1 = USD 1.0342 (previous year: €1 = USD 1.1323)
- average exchange rate in fiscal year 2022: €1 = USD 1.0592 (previous year: €1 = USD 1.1899)

Swiss francs:

- closing rate 30 November 2022: €1 = CHF 0.9870 (previous year: €1 = CHF 1.0426)
- average exchange rate in fiscal year 2022: €1 = CHF 1.0092 (previous year: €1 = CHF 1.0848)

British pound:

- closing rate 30 November 2022: €1 = GBP 0.8647 (previous year: €1 = GBP 0.8499)
- average exchange rate in fiscal year 2022: €1 = GBP 0.8510 (previous year: €1 = GBP 0.8643)

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 and to the non-controlling interests. 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 Discontinuing the use of the equity method

An associate is an entity over which the Group has significant influence. Significant influence is the power to participate in the financial and operating policy decisions of the investee but is not control or joint control of those policies.

According to IAS 28.6, in general one or more of the following indicators points to significant influence:

- representation on the board of directors and/or governing body of the investee;
- participation in policy-making processes;
- material transactions between the entity and its investee;
- interchange of managerial personnel;
- provision of essential technical information.

The use of the equity method is discontinued from the date on which significant influence can no longer be exercised (see note 1.2).

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If the retained interest in the former associate is a financial asset, the entity measures that interest at fair value. The fair value of the retained interest must be regarded as its fair value on initial recognition as a financial asset in accordance with IFRS 9. The difference between the following amounts shall be recognized in profit or loss:

- (i) fair value and
- (ii) the carrying amount of the investment at the date the equity method was discontinued.

A financial instrument is generally required to be recognized and measured in accordance with IFRS 9.

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 laboratory and office equipment and right-of-use assets.

Both property, plant and equipment and right-of-use assets are recognized at historical cost less accumulated depreciation and, if applicable, impairment losses. 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, impairment charges 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:

- Laboratory equipment 5 to 14 years
- Other office equipment 3 to 13 years
- Right-of-use assets (based on the term of the contract) 3 to 4 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.

Impairment losses 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, impairment charges are recognized if assets are impaired as defined by IAS 38.111 in conjunction with IAS 36. This did not apply in 2022, however.

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

- Licenses and patents 5 to 20 years
- Software 3 to 10 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) and the acquired customer base 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.

Up until the fiscal year ended, in subsequent periods intangible assets with a definite useful life that were acquired in a business combination were measured in the same way as separately acquired intangible assets: at cost less accumulated amortization and any accumulated impairment losses.

The following useful life is assumed here:

- Acquired customer base 9 years

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).

 Glossary

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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. 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.

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.

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).

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

This category is the most important one for the consolidated financial statements. 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 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.

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.

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 and accumulated deficits. Equity as of the end of the reporting period was €66.6 million (30 November 2021: €6.7 million).

As a result of a capital increase implemented in the second half of the fiscal year and the exercise of stock options during the year, the total number of Heidelberg Pharma shares issued as of the reporting date increased from 34,175,809 by 12,408,648 new shares to 46,584,457 (30 November 2021: 34,175,809 shares).

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 fiscal year ended, a capital increase was implemented and a shareholder loan from dievini 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. 2022 €'000	30 Nov. 2021 €'000
Liquidity	81,329	6,141
In % of total capital	80.9	28.3
In % of current liabilities (cash ratio)	291.1	41.1
Equity	66,644	6,699
In % of total capital	66.3	30.8
Liabilities	33,938	15,033
In % of total capital	33.7	69.2
Total capital	100,582	21,732

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

While the ratio of liquidity to total capital rose from 28.3% to 80.9%. Similarly, the cash ratio, defined as cash divided by current liabilities, increased from 41.1% to 291.1%.

The equity ratio was 66.3% as of 30 November 2022. This is higher than in the previous year (30.8%), mainly due to the capital increase in the past financial year. Total liabilities rose as a result of deferred revenues, expanded business operations, and utilization of the shareholder loan. In relation to total capital, however, they fell to 33.7% as of the 2022 reporting date, down from 69.2% 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 withholding tax on capital in 2022 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.

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.

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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 provision 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. The income from the plan assets and the expenses from the defined benefit pension commitment at Heidelberg Pharma AG are recognized in the fiscal year they arise.

3.20.4 Employer's contributions to the statutory pension insurance scheme

In the 2022 fiscal year, Heidelberg Pharma paid €521 thousand in employer contributions to the statutory pension insurance scheme; this expense is allocated to staff costs (previous year: €454 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 B52 ff. 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;
- 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.

Such sales revenue is recognized over time according to the percentage of completion. The percentage of completion is determined as follows: Income from the customer specific service business is calculated on a time-and-materials basis and recognized at the contractually agreed hourly rates and directly incurred costs to ensure a faithful depiction of the transactions.

Heidelberg Pharma measures progress in the discharge of performance obligations on the basis of output methods, such as access to intellectual property recognized on a linear basis over a defined research period, and 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.

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 government grants, such as those from the Federal Ministry of Education and Research (BMBF). 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. The cash amounts received in advance are recognized over the underlying service period according to the research project's stage-of-completion. There was also income 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.

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 guidelines and training ensure that every employee is aware of their tasks and duties in connection with the risk management system and duly carries them out.

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 that bears a fixed interest rate of 6.00% p.a. 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".

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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.

The maximum default risk in connection with trade receivables is €1,099 thousand and corresponds to the trade receivables balance sheet item. The maximum default risk from other receivables is €353 thousand.

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, the Company was able to generate interest cash flow in 2022 in contrast to 2021. This conservative investment approach ensures that there is no nonpayment risk (see note 3.15).

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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 21):

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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 8.4 "Going-concern risks" and 8.6 "Financial risks" of the Group's combined management report.

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7 Critical estimates and discretionary decisions

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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.

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 (€18.5 million; previous year: €1.7 million) and other income (€1.3 million; previous year: €0.6 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

Heidelberg Pharma recognizes expenses in the amount of €554 thousand (previous year: €686 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.

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7.2 Impairment testing pursuant to IAS 36

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.

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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 impairment testing in January 2023 (previous year: January 2022) 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 impairment test was modified in 2021 to include HDP-103 in addition to the primary development program, HDP-101.

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.

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 2022 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 €0.5 million in the period from 2023 to 2025. Following planned out-licensing and the associated expansion of internal resources for this business unit, increasing sales revenue of €0.6 to €0.7 million is planned for the years 2026 to 2028. Continuous annual growth of 1.75% is assumed from 2029 to 2046. For the period after 2046, a terminal value of €1.0 million and a growth rate of 0% was taken into account for the service business.

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 business used for the impairment test comprises detailed planning over a three-year period from 2023 to 2025 (clinical phases I and II). This is followed by a second, longer-term 21-year planning phase from 2026 to 2046 (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 2024 onwards with sustained positive cash flows starting in the market phase;
- maximum exploitation period for license income until 2046 through patents granted and new patent applications;
- discounts for the success rates of individual clinical phases based on scientific literature.

In the first phase of the three-year period from 2023 to 2025, negative cash flows (discounted) are expected for 2023 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 2024 due to the material royalties expected. Overall, a sustained positive cash flow is expected from 2029 onwards.

In the phase from 2023 to 2025, the model projects cumulative discounted cash flows (adjusted for tax effects) of €20.2 million in total, while for the phase starting in 2026 it assumes cumulative discounted cash flows (adjusted for tax effects) of €49.6 million (including terminal value).

The carrying amount of the cash generating unit analyzed was €17.5 million as of the reporting date (previous year: €12.9 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% (previous year: 10.0%) before taxes and 8.3% after taxes (2021: 6.8%).

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 €6.4 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 2022.

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 2021 and 30 November 2022, property, plant and equipment comprised the following:

	Laboratory equipment €'000	Right-of-use assets			Total €'000
		Buildings €'000	Office equipment €'000	Other office equipment €'000	
2021 fiscal year					
Opening carrying amount	2,381	163	36	533	3,114
Additions	1,039	65	0	203	1,307
Disposals	(58)	0	(16)	(22)	(95)
Impairment	167	0	16	(91)	93
Reclassification	(101)	0	0	75	(26)
Depreciation	(411)	(77)	(25)	(207)	(719)
Net carrying amount as of 30 Nov. 2021	3,019	151	11	492	3,673
As of 30 Nov. 2021					
Cost	7,118	292	61	1,793	9,273
Accumulated depreciation	(4,099)	(141)	(51)	(1,301)	(5,600)
Net carrying amount as of 30 Nov. 2021	3,019	151	11	492	3,673

	Right-of-use assets				Total €'000
	Laboratory equipment €'000	Buildings €'000	Office equipment €'000	Other 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

Unless allocable to cost of sales, depreciation totaling €666 thousand (previous year: €719 thousand) was recognized in profit or loss as R&D costs and as general and administrative expenses. Impairment losses (or write-downs) of €44 thousand and €93 thousand were recognized on the value in use in fiscal years 2022 and 2021, respectively. 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 €93 thousand in depreciation and €9 thousand in interest expense was recognized for right-of-use assets in the fiscal year ended (previous year: €102 thousand and €9 thousand, respectively).

As in 2021, no expense relating to short-term leases pursuant to IFRS 16.53(c) has been recognized. As in the previous year, the expense relating to leases of low-value assets according to IFRS 16.53(d) was €1 thousand.

In the cash flow statement, payments for operating leases (€102 thousand; previous year: €111 thousand) were split up into interest paid and a principal of lease liabilities. While the interest paid (€9 thousand) will continue to be allocated to the net change in cash from operating activities, the principal portions will be included in financing activities (€93 thousand) (previous year: €9 thousand and €102 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 2021 and 30 November 2022, 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
2021 fiscal year							
Opening carrying amount	58	0	267	0	2,493	6,111	8,929
Additions	143	0	3	0	0	0	147
Disposals	0	0	0	0	0	0	0
Impairment	(33)	0	26	0	0	0	(7)
Reclassification	57	0	(31)	0	0	0	26
Amortization	(56)	0	(27)	0	0	0	(83)
Net carrying amount as of 30 Nov. 2021	169	0	238	0	2,493	6,111	9,011
As of 30 Nov. 2021							
Cost	961	1	1,590	320	2,493	6,111	11,476
Accumulated amortization	(791)	(1)	(1,352)	(320)	0	0	(2,465)
Net carrying amount as of 30 Nov. 2021	169	0	238	0	2,493	6,111	9,011
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

All of the additions stem from separate acquisitions. Unless allocable to cost of sales, €91 thousand (previous year: €83 thousand) in amortization were recognized in profit or loss as research and development costs and as general and administrative expenses. No impairment loss (or write-down) was recognized in fiscal year 2022 (2021: €7 thousand). The prior-year write-down was recognized in profit or loss as R&D costs.

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 2011 business combination of Heidelberg Pharma AG with Heidelberg Pharma Research GmbH. 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).

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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.

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 2022 during the impairment test carried out in January 2023. 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 Equity investment according to IFRS 9

In November 2019, the Company acquired an equity interest in Emergence Therapeutics AG, Duisburg, (Emergence) 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. Continued recognition of undisclosed reserves and liabilities and impairment of goodwill are therefore not necessary. On grounds of materiality, the carrying amount as of last year's balance sheet date has not been restated. There is a one-month gap between Emergence Therapeutics AG's reporting date and the reporting date of Heidelberg Pharma Research. On grounds of materiality, even in subsequent periods no adjustment will be made for the reporting date.

The cost of acquisition increased by €7 thousand to €20 thousand via a capital increase in 2020. Emergence also issued convertible bonds to Heidelberg Pharma with a value of €51 thousand in 2020 and further convertible bonds with a value of €13 thousand in 2021. These are convertible into a fixed number of equity instruments of the issuer. No interest is paid on these bonds. These convertible bonds are measurable at fair value through profit or loss in accordance with IFRS 9 and, as part of the net investment, in accordance with IAS 28.

Upon termination of the significant influence over Emergence (no more representation on the supervisory board, the interest had decreased to 1.49%, and Emergence had abandoned a key technology provided by Heidelberg Pharma) the equity interest in the entity and the convertible bond are recognized at a fair value of €0.

12 Other non-current financial assets

The other non-current assets in the amount of €35 thousand (previous year: €35 thousand) include security for leased equipment and property in the amount of €30 thousand (previous year: €30 thousand) – all of which is deposited in bank accounts. As in 2021, other items accounted for €5 thousand.

Heidelberg Pharma expects no non-current financial assets to be realized within the next 12 months.

13 Inventories

The inventories and work in progress recognized at cost (2022: €4,585 thousand; previous year: €746 thousand) mainly concern work in progress, which increased in the course of the supply of Amanitin to the cooperation partners (supply model).

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.

14 Prepayments

Prepayments are comprised as follows:

	30 Nov. 2022 €'000	30 Nov. 2021 €'000
Prepayments related to clinical development	159	468
Prepayments to insurance companies	25	24
Prepayments to other service providers	329	184
Prepayments	513	676

All prepayments made are of a current nature (< 12 months).

15 Trade receivables and contract assets

The trade receivables and the contract assets arising for the first time amounting to €1,099 thousand (previous year: €1,020 thousand) mainly result from collaborations including related material supplies and services invoiced by Heidelberg Pharma Research GmbH.

	30 Nov. 2022 €'000	30 Nov. 2021 €'000
Trade receivables	973	1,020
Contract assets	126	0
Total	1,099	1,020

The aging structure of trade receivables as of the reporting date was as follows:

	30 Nov. 2022 €'000	30 Nov. 2021 €'000
0–30 days	231	760
30–90 days	742	177
More than 90 days	0	83
Total	973	1,020

As of the balance sheet date, trade receivables of €742 thousand were past due and remained unpaid more than 30 days after their due date (previous year: €260 thousand). Heidelberg Pharma expects all trade receivables and contract assets to be realized within the next 12 months.

16 Other receivables

Other receivables are comprised as follows:

	30 Nov. 2022 €'000	30 Nov. 2021 €'000
VAT claim	218	394
Other items	135	36
Other receivables	353	430

Heidelberg Pharma expects all other receivables to be realized within the next 12 months.

17 Cash

	30 Nov. 2022 €'000	30 Nov. 2021 €'000
Cash	81,329	6,141
Total	81,329	6,141

Cash consists exclusively of bank balances and in spite of the cash outflows from operating activities were up considerably on the prior-year figure due to the capital increase implemented during the year.

The following table shows the change in the Group's liabilities from financing activities, including cash changes during fiscal year 2022:

	1 Dec. 2021 €'000	Loans taken out from affiliated companies €'000	Principal portion of lease payments €'000	30 Nov. 2022 €'000
Loans from affiliated companies	10,000	5,000	0	15,000
Lease liabilities	167	0	(93)	195

18 Equity

As of 30 November 2022, the share capital consisted of 46,584,457 (30 November 2021: 34,175,809) no par value bearer shares with a notional value of €1.00 per share.

Heidelberg Pharma AG formally completed a capital increase in September 2022 during which the shareholders, mainly Huadong, subscribed for 12,408,648 new no par value bearer shares at a subscription price of €6.44 per share. The capital increase increased the Company's share capital by €12,408,648.00, from €34,175,809.00 to €46,584,457.00, after it was entered in the Commercial Register on 2 September 2022.

No stock options were exercised in the 2022 fiscal year.

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. 2020		31,061,872	31,061,872
Exercise of stock options in the first half of the fiscal year	10 June 2021	4,500	4,500
15 June 2021	17 June 2021	3,106,637	3,106,637
Exercise of stock options in the second half of the fiscal year	4 Jan. 2022	2,800	2,800
On 30 Nov. 2021		34,175,809	34,175,809
30 August 2022	2 Sep. 2022	12,408,648	46,584,457
On 30 Nov. 2022		46,584,457	46,584,457

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 capital increase results in an increase in the capital reserve of €66,685 thousand. The costs of €818 thousand directly attributable to the capital increase were not recognized as an expense, but charged to the capital reserve in accordance with IAS 32.37.

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 €554 thousand (previous year: €685 thousand) was recognized in this context in the period under review (see note 25).

As of the reporting date of 30 November 2022, the capital reserves thus amounted to €311,454 thousand (previous year: €244,215 thousand).

Taking into account the cumulative losses of €291,394 thousand accumulated from the date of the Company's establishment through to the reporting date (previous year: €271,692 thousand), the equity of Heidelberg Pharma amounted to €66,644 thousand (previous year: €6,699 thousand).

19 Non-current liabilities

19.1 Lease liabilities (non-current)

Non-current lease liabilities – which must be reported separately – total €100 thousand (previous year: €76 thousand) and consist of liabilities for office, laboratory and archive space as well as vehicles.

19.2 Contract liabilities (non-current)

There were non-current contract liabilities at the end of the 2022 reporting period amounting to €5,903 thousand (previous year: €23 thousand). These were significantly higher 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.

20 Current liabilities

20.1 Trade payables

Current trade payables increased as of the reporting date from €903 thousand in fiscal year 2021 to €3,051 thousand at the end of the 2022 reporting period.

20.2 Lease liabilities (current)

Current lease liabilities totaled €94 thousand (previous year: €91 thousand) and consisted of liabilities for office, laboratory and archive space as well as vehicles.

20.3 Contract liabilities (current)

Current contract liabilities increased from €491 thousand in the previous year to €5,017 thousand, mainly as a result of the advance payment from Huadong (see note 19.2).

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20.4 Financial liabilities

Financial liabilities in the amount of €15,786 thousand (previous year: €10,465 thousand) are attributable to the shareholder loan carrying 6.00% interest and include the loan disbursement from dievini (€15,000 thousand), which increased by €5,000 thousand year-over-year, and the resulting interest liability (€786 thousand) (see notes 3.2 and 6).

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20.5 Other current financial liabilities

Other current financial liabilities included the following:

	30 Nov. 2022 €'000	30 Nov. 2021 €'000
Obligation for holidays not taken	406	311
Social security and other taxes	294	270
Employee bonuses and profit-sharing bonuses	332	197
Costs of preparing the financial statements and tax advisory costs	253	151
Deliveries/services	2,701	2,056
Other current liabilities	3,986	2,984

Heidelberg Pharma recognizes accruals 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.

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.

21 Other disclosures on financial instruments

In summary, Heidelberg Pharma applied the following classification to financial assets:

21.1 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):

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30 November 2022	Measurement category according to IFRS 9 €'000	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
Convertible bond, Emergence	FVtPL					0	0
Cash	AC	81,329	81,329				
Liabilities							
Trade payables	AC	(3,051)	(3,051)				
Lease liabilities (current/non-current)	AC	(195)	-				
Accrued liabilities	AC	(2,954)	(2,954)				
Financial liabilities	AC	(15,786)	(15,786)				

Trade receivables all have remaining maturities of less than one year. No default risks are discernible in connection with the assets.

The carrying amounts of other assets and liabilities such as cash and trade payables correspond to their fair values on account of their current nature.

Interest expense of €786 thousand arose from financial liabilities carried at amortized cost.

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The convertible bonds issued by Emergence in 2021 and subscribed for by Heidelberg Pharma (see note 11) are measurable at fair value through profit or loss.

21.2 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).

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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 2022 and 2021, 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.

21.3 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).

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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 (€81,329 thousand; previous year: €6,141 thousand) are denominated in euros, with a smaller amount denominated in US dollars, 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 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	2,887	18	0	0	3,051
Other liabilities	43	2,811	100	0	0	2,954
Financial liabilities	0	15,786	0	0	0	15,786

30 November 2021	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	56	840	7	0	0	903
Other liabilities	732	1,416	58	0	0	2,206
Financial liabilities	0	10,465	0	0	0	10,465

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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 (€973 thousand; previous year: €1,020 thousand) at the close of the fiscal year were attributable to business customers; they were mainly invoiced as of the 30 November 2022 reporting date or immediately preceding it. Trade receivables in the amount of €742 thousand were past due as of the reporting date (see note 15). 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.

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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 2022, there were foreign currency risks concerning trade payables in the amount equivalent to €76.5 thousand in US dollars (USD), €159.2 thousand in Swiss francs (CHF) and €75.2 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	76.5	7.0	(8.5)
Euro vs. Swiss franc	159.2	14.5	(17.7)
Euro vs. British pound	75.2	6.8	(8.4)

In 2022 and 2021, 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 €13.9 million in USD in the 2022 fiscal year (previous year: €0.9 million).

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An increase of 10% in the average USD exchange rate in fiscal year 2022 as part of a sensitivity analysis (i.e. the USD appreciates against the euro) would have lifted sales revenue by €1,543 thousand (previous year: €103 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 €1,263 thousand (previous year: €84 thousand). Sales revenue in foreign currencies other than the US dollar was not generated in 2021 or 2022.

Heidelberg Pharma's only cash held in foreign currencies (USD only) 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 2022 reporting date were equivalent to €8,774 thousand (30 November 2021: €69 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.

No significant net gains or losses from financial instruments were recognized in the 2022 fiscal year or in the previous year.

22 Sales revenue

Sales revenue (or revenue from contracts with customers) of the Heidelberg Pharma Group in the fiscal year just ended totaled €18,514 thousand (previous year: €1,750 thousand).

	2022 €'000	2021 €'000
ATAC technology sales revenue	17,477	1,226
Sales revenue from portfolio out-licensing	498	0
Service business sales revenue	539	524
Sales revenue	18,514	1,750

The increase in sales revenue mainly stems from granting the development and commercialization rights to HDP-101 and HDP-103 for parts of Asia to Huadong (€8.2 million; previous year: €1.2 million). There was also sales revenue of €9.3 million from the ATAC business and, as in the previous year, €0.5 million from the service business. In addition, a milestone payment of €0.5 million, which was fully recognized in income, became due 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 2021 was fully realized in the amount of €0.5 million in fiscal year 2021 (previous year: €0.3 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 €10,920 thousand (previous year: €514 thousand).

Heidelberg Pharma estimates that €5,017 thousand of the total transaction price of €10,920 thousand allocated to contract liabilities will be realized in the 2023 fiscal year.

Regional distribution

The following table shows the regional distribution of 2022 sales revenue in terms of a customer's or collaboration partner's domicile:

Region	2022		2021	
	€'000	%	€'000	%
Germany	549	3%	477	27%
Europe	52	0%	38	2%
of which CH	52	–	38	–
USA	8,982	49%	1,122	64%
Rest of the world	8,931	48%	113	6%
of which China	8,204	–	0	–
Total	18,514	100%	1,750	100%

All sales revenue was generated in euros (€4.6 million) and US dollar (€13.9 million) in 2022.

More than 10% of sales revenue (€8.9 million) was generated in each case with two US companies in 2022 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 (€8.2 million).

In the previous financial year, more than 10% of sales revenue (€0.9 million) was generated in each case with two US companies under a research and license agreement.

	30 Nov. 2022 €'000	30 Nov. 2021 €'000
Trade receivables	973	1,020
Contract assets	126	0
Contract liabilities	10,920	514

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 2022 and 2021. 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. Due to a new strategic partnership, the outstanding balances in these accounts increased compared to 2021.

23 Other income

Other income (€1,346 thousand; previous year: €564 thousand) comprises the following items:

Other income	2022 €'000	2021 €'000
Income from exchange rate gains	963	3
Income from grants	124	284
Provisions not utilized to date	69	118
Proceeds from non-monetary benefits	47	39
Income from passing on patent costs	42	68
Income from sales of fixed assets	15	0
Other items	86	52
Total	1,346	564

Other income was up year-over-year. It is influenced by exchange rate gains of €1.0 million as a result of the appreciation of the US dollar against the euro in the period under review, which had a positive effect on the cash held by Heidelberg Pharma in this foreign currency (previous year: €3 thousand).

There were also German and European grants, which support Heidelberg Pharma Research GmbH projects in the amount of €0.1 million (previous year: €0.3 million).

Furthermore, income of €0.1 million was generated from the reversal of unutilized provisions, the same as in the previous year.

The parent company generated €42 thousand from passing on patent costs in the context of out-licensing (previous year: €68 thousand). As in 2021, all other items amounted to income of €0.1 million.

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 considerably to €37.0 million compared to 2021 (€27.9 million).

Operating expenses	2022 € million	2021 € million
Cost of sales	4.7	4.7
Research and development costs	26.4	18.7
Administrative costs	4.8	4.0
Other expenses	1.1	0.5
Total	37.0	27.9

The cost of sales concerns the Group's costs directly related to sales revenue. These costs mainly related to expenses for customer-specific research and for the supply of Amanitin linkers to licensing partners. As in the previous year, they amounted to €4.7 million, representing 13% of operating expenses.

Research and development costs rose considerably year-over-year to €26.4 million (previous year: €18.7 million) due to the cost-intensive external manufacturing for all three ATAC projects and the on-going clinical trial with HDP-101. The production of antibodies for HDP-102 and HDP-103 also was a factor. At 71% of operating expenses, R&D remained the largest cost item.

Administrative costs were €4.8 million, an increase on the prior year (€4.0 million), and accounted for 13% of operating expenses.

These include staff costs of €2.6 million (previous year: €2.3 million), of which €0.2 million concerned expenses from stock options, as in the previous year. The increase results from a growing number of employees due to the expansion of business activities. This line item also includes legal and operating consulting costs in the amount of €1.1 million (previous year: €0.7 million) and expenses related to the Annual General Meeting, Supervisory Board remuneration and the stock market listing totaling €0.6 million, as in the previous year. Other items amounted to €0.5 million (previous year: €0.4 million).

Other expenses for business development, marketing and commercial market supply activities, which mainly comprise staff and travel costs, were €1.1 million. They were higher than in the previous year (€0.5 million) and represented 3% of operating expenses.

The following expenses are recognized in the statement of comprehensive income:

	2022 € '000	2021 € '000
Staff costs	9,938	8,152
Travel costs (incl. conference fees)	379	98
Office costs (incl. utilities and maintenance)	543	462
Other internal costs	543	341
External research and development costs/laboratory	19,694	14,181
Legal and consulting costs (incl. patent costs)	3,349	2,752
Depreciation and amortization	757	803
Stock market listing	647	613
IT/licenses	352	200
Expenses from exchange rate differences	364	1
Other expenses	476	342
Total	37,042	27,945

The increase in staff costs in the past fiscal year is attributable to the higher number of employees (13 FTEs as of the reporting date) and general salary increases. Expenses from the granting of stock options under IFRS 2 Share-based Payments decreased (see note 25).

Travel costs increased significantly after the travel restrictions imposed during the Covid pandemic in 2021.

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 €77 thousand (previous year: €72 thousand).

The expansion of business activities is reflected in higher expenses in other internal costs and legal and consulting costs. 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 increased compared to the previous year due to the cost-intensive implementation of a clinical trial.

Depreciation and amortization decreased as a result of the lower level of investment in depreciable assets in the reporting periods compared to previous periods, such as the laboratory expansion, which has now largely been completed.

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 increased considerably year-over-year as a result of increasing digitalization.

In contrast to previous years, the expense from exchange rate differences in accordance with IAS 1.35 needs to be presented separately at €364 thousand in 2022. In the previous year, there were only immaterial expenses of €1 thousand from exchange rate differences.

25 Staff costs

In the comparative periods, Heidelberg Pharma employed the following number of staff on average (headcount):

	2022	2021
Administration	27	25
Manufacturing, service and distribution	21	18
Research and development	55	48
Average number of employees¹	102	91

¹ Including the Executive Management Board

Staff costs for this purpose are comprised as follows:

	2022 €'000	2021 €'000
Wages and salaries	6,833	5,827
Social security costs	1,126	986
Costs of pensions	137	98
Expense from provisions for holidays	95	26
Bonuses	560	267
Expenses from share-based payment	554	686
Continuing professional development	83	68
Recruitment	111	65
Occupational safety and employer's liability insurance association	82	68
Other staff costs	357	61
Total staff costs	9,938	8,152

The wages and salaries, social security costs and bonuses items rose year-over-year due to the increased headcount and salary structure.

The granting of stock options in accordance with IFRS 2 “Share-based Payments” resulted in lower staff costs of €554 thousand in 2022 (previous year: €686 thousand), because no new stock options were issued 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 2022 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 incurred staff costs of €3 thousand under the 2017 Stock Option Plan in 2022 (previous year: €51 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 €551 thousand under the 2018 Stock Option Plan in 2022 (previous year: €635 thousand).

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	
Issue	Tranche 2	Tranche 1	Tranche 1	Tranche 2
Measurement date	2 June 2016	23 April 2018	19 June 2019	5 August 2021
Measurement method	Monte Carlo model in each case			
Fair value per option	€ 1.41	€ 1.07	€ 1.12	€ 3.07
Exercise price (uniform and therefore also average) ¹	€ 1.89	€ 3.41	€ 2.79	€ 7.28
Price of the Heidelberg Pharma share as of the measurement date	€ 1.83	€ 2.82	€ 2.83	€ 6.90
Maximum term	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
Expected volatility of the Heidelberg Pharma share ²	89.42%	54.96%	48.59%	60.33%
Expected dividend yield of the Heidelberg Pharma share	0.00%	0.00%	0.00%	0.00%
Risk-free interest rate	-0.47%	-0.19%	-0.70%	-0.82%
Remaining term as of 30 Nov. 2022	3.50 years	5.39 years	6.51 years	8.68 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 and 2018 plans with respect to their issue:

All information provided in no. of options	2011 Plan	2017 Plan	2018 Plan	Total
Max. number of stock options to be issued acc. to plan terms	1,156,412	661,200	1,490,622	3,308,234
of which Executive Management Board	346,924	201,200	298,100	846,224
of which employees	809,488	460,000	1,192,522	2,462,010
Stock options actually issued	685,726	653,430	1,116,140	2,455,296
of which Executive Management Board ¹	364,000	201,200	223,050	788,250
of which employees	321,726	452,230	893,090	1,667,046
Max. number of stock options still available for issue	0	0	374,482	374,482
of which Executive Management Board	0	0	75,050	75,050
of which employees	0	0	299,432	299,432

All information provided in no. of options	2011 Plan	2017 Plan	2018 Plan	Total
Exercise of stock options by beneficiaries	38,600	0	0	38,600
of which Executive Management Board	0	0	0	0
of which employees	38,600	0	0	38,600
of which Executive Management Board 2022	0	0	0	0
of which employees 2022	0	0	0	0
Return of stock options by beneficiaries leaving the Company	97,743	45,405	52,927	196,075
of which Executive Management Board	26,500	0	0	26,500
of which employees	71,243	45,405	52,927	169,575
of which Executive Management Board 2022	0	0	0	0
of which employees 2022	0	162	17,136	17,298
Expiry of stock options without replacement after ten-year term	183,211	0	0	183,211
of which Executive Management Board	85,500	0	0	85,500
of which employees	97,711	0	0	97,711
of which Executive Management Board 2022	85,500	0	0	85,500
of which employees 2022	97,711	0	0	97,711
Stock options outstanding	366,172	608,025	1,063,213	2,037,410
of which Executive Management Board	252,000	201,200	223,050	676,250
of which employees	114,172	406,825	840,163	1,361,160
Vested stock options (outstanding)	366,172	608,025	714,009	1,688,206
of which Executive Management Board	252,000	201,200	158,169	611,369
of which employees	114,172	406,825	555,840	1,076,837
of which have vested in 2022	0	36,159	262,322	298,482
of which Executive Management Board	0	12,575	55,763	68,338
of which employees	0	23,584	206,560	230,144
Non-vested stock options (outstanding)	0	0	349,204	349,204
of which Executive Management Board	0	0	64,881	64,881
of which employees	0	0	284,323	284,323
Exercisable stock options (outstanding)	366,172	608,025	0	974,197
of which Executive Management Board	252,000	201,200	0	453,200
of which employees	114,172	406,825	0	520,997

¹ When options under the 2011 Stock Option Plan were issued, Dr. Schmidt-Brand had not yet been appointed as a member of the Executive Management Board of Heidelberg Pharma AG. The options granted to him were added to the portion attributable to the Executive Management Board after his appointment.

26 Currency gains/losses

Heidelberg Pharma posted an unrealized currency gain of €649 thousand (previous year: €2 thousand) in the 2022 fiscal year.

27 Financial result

In the fiscal year now ended, finance income of €235 thousand was generated for the first time in years. In the preceding year, finance income was unable to be generated owing to the lack of interest accruing on credit balances. 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 €836 thousand (previous year: €465 thousand). These will be paid out in the first fiscal quarter of the following year. Deposit fees (€2 thousand; previous year: € 20 thousand) and the interest portion of leases (€2 thousand; previous year: €9 thousand) were also added to finance costs.

This gives a financial result of €-605 thousand (previous year: €-494 thousand).

	2022 €'000	2021 €'000
Interest income from bank accounts/Other	235	0
Finance income	235	0
Interest expense from shareholder loans	(836)	(465)
Interest expense from leasing agreements	(2)	(9)
Interest expense from other items	(2)	(20)
Finance costs	(840)	(494)
Financial result	(605)	(494)

28 Income taxes

Due to operating losses in previous periods, no significant income tax expense has been incurred to date. However, 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 in 2022. Neither expenses nor income from deferred taxes were included in tax expenses in 2021 and 2022.

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.

	2022 €'000	2021 €'000
Earnings before tax	(17,786)	(26,139)
Tax rate	28.43%	28.43%
Expected tax income (earnings x tax rate)	5,056	7,430
Deferred taxes on losses for the period not qualifying for recognition	(2,451)	(6,677)
Change in non-recognized temporary differences	(40)	24
Non-deductible operating expenses/Other	(649)	(777)
Reported tax expense	1,916	0

The existing deferred tax assets and deferred tax liabilities as of 30 November are attributable as follows:

	2022 €'000	2021 €'000
Deferred tax assets		
Other current assets	0	0
Other non-current assets	265	263
Different carrying amount of the equity investment	94	94
Loss carryforwards taken into account	687	647
Other liabilities/provisions	33	54
	1,079	1,058
Deferred tax liabilities		
Intangible assets	709	709
Other liabilities	370	349
	1,079	1,058
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:

	2022 €'000	2021 €'000
Loss carryforwards		
for corporation tax	304,960	285,381
for trade tax	300,348	280,769
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 €237,836 thousand; trade tax loss carryforward of €234,798 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 €687 thousand) were recognized in the fiscal year just ended for €2,416 thousand in tax loss carryforwards and offset against correspondingly high deferred tax liabilities (€2,275 thousand and €647 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 capital increase implemented in September 2022, the total number of Heidelberg Pharma shares issued as of the reporting date increased to 46,584,457.

		2022	2021
Net loss for the year attributable to equity providers	€'000	(19,702)	(26,139)
Level of capital and corporate actions in the fiscal year			
Number of issued shares at the beginning of the fiscal year	in thousand	34,176	31,062
Number of shares newly issued during the fiscal year	in thousand	12,408	3,107
Number of new shares created by converting stock options	in thousand	–	7
Average number of shares issued during the fiscal year	in thousand	37,235	32,504
Basic earnings per share based on the weighted average number shares issued in the reporting period	in € per share	(0.53)	(0.80)

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).

Basic earnings per share in 2021

In fiscal year 2021, basic earnings per share amounted to €–0.80 based on the weighted average number of shares issued in the reporting period (32,504,068 shares and earnings attributable to equity providers of €–26,139 thousand).

29.2 Diluted

The Company's Annual General Meetings in 2011, 2017 and 2018 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 2022.

Since in the past financial 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), diluted earnings per share need to be reported. The following parameters are to be used for diluted earnings per share in 2022 (see note 24):

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- Number of stock options exercisable as of 30 November 2022:
 - 366,172 options at €1.89 each
 - 608,025 options at €3.41 each
 - Total: 974,197 options
- Average number of shares: 37,235 thousand + 974 thousand = 38,209 thousand shares
- Effect on earnings if fully exercised:
 - €1.89 x 366,172 options = €692,065
 - €3.41 x 608,025 options = €2,073,365
 - Total €2,765,430
- Attributable profit/loss for the year: €-19,702 thousand + €2,765 thousand = €-16,937 thousand
- €-16,937 thousand/38,209 thousand shares = €-0.44

This gives diluted earnings per share of €-0.44 for 2022.

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 2025. 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
2022	102
of which from tenancy agreements (property)	85
of which from other leases (cars)	17
2021	111
of which from tenancy agreements (property)	83
of which from other leases (cars)	28

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. 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.

Below are previous year's figures:

Obligations as of 30 Nov. 2021	Up to 1 year €'000	1–5 years €'000	More than 5 years €'000	Total €'000
Rental obligations for laboratory and office premises ¹	86	0	0	86
Obligations under other leases (laboratory and other office equipment, vehicles)	12	0	0	12
	98	0	0	98

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 2022 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 Financial Officer and Chief Executive Officer (appointed until 31 August 2024)

Professor Andreas Pahl, Chief Scientific Officer (appointed until 31 December 2023)

In parallel to his work as a member of the Executive Management Board, Dr. Jan Schmidt-Brand acts as the Managing Director of Heidelberg Pharma Research GmbH, a position he has held since 2004. 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.

31.2 Supervisory Board

The Supervisory Board of Heidelberg Pharma AG as of 30 November 2022 comprised the following seven members:

Professor Christof Hettich (Chairman of the Supervisory Board)

- 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 (Vice Chairman of the Supervisory Board)

- Managing partner of an agricultural business

Dr. Mathias Hothum (Vice Chairman of the Supervisory Board)

- 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. Brady Xumin Zhao, MD, PhD

- Vice President, China Grand Enterprise, Inc., Beijing, China, 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 pre-selection of the auditor of the financial statements and the monitoring of its independence.

The Research and Development Committee tasked with issues related to Heidelberg Pharma's oncological product candidates was dissolved during the year.

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
Professor Christof Hettich	2010	2025		C
Dr. Georg F. Baur (IAE)	2000	2025	C	M
Dr. Mathias Hothum (IFRE)	2015	2025	M	
Dr. Friedrich von Bohlen und Halbach	2005	2025		
Dr. Birgit Kudlek	2012	2025	M	
Dr. Dongzhou Jeffery Liu	2022	2025		M
Dr. Brady Xumin Zhao	2022	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	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
• AaviGen GmbH, Heidelberg, Germany	Member of the Advisory Board

In addition to being a member of the Supervisory Board of Heidelberg Pharma AG, Dr. Georg F. Baur is also the Chairman or a member of the following bodies:

Company	Position
• J.F. Müller & Sohn AG, Hamburg, Germany	Vice Chairman of the Supervisory 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

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
• Immatix N.V., Tübingen, Germany	Member of the Supervisory Board

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 Gruppe), 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

The Supervisory Board members Dr. Dongzhou Jeffery Liu and Dr. Brady Xumin Zhao 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

A detailed description of the remuneration model and the information on remuneration of each Executive Management Board and Supervisory Board member are included in the remuneration report.

In the 2022 fiscal year, the members of the Executive Management Board were paid total remuneration of €717 thousand (previous year: €689 thousand). The members of the Supervisory Board were paid remuneration of €190 thousand (previous year: €181 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 Directors' Dealings

Article 19 of the Market Abuse Regulation (MAR) requires that members of the Executive Management Board, the Supervisory Board and the inner circle of Heidelberg Pharma AG's executives and parties related to them must disclose any personal trading of Heidelberg Pharma shares to the extent that such trading surpasses the statutory threshold of €20,000 per calendar year.

In fiscal year 2022, executives of Heidelberg Pharma AG carried out the following reportable transactions:

Name	Date	Transaction	Marketplace	Price in €	Volume in €
Dr. Birgit Kudlek	2 Sep. 2022	Acquisition of shares by exercising subscription rights	Outside a trading venue	6.44	7,496.16

32.2 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 has an interest rate of 6% per annum. Heidelberg Pharma AG is 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.
- Under the 2011, 2017 and 2018 stock option plans, Heidelberg Pharma AG issued a total of 736,250 subscription rights to current members of the Executive Management Board, of which 676,250 are still outstanding. As of the end of the reporting period, 611,369 of these options are vested, of which 68,338 options vested in 2022. In the past fiscal year, 60,000 options held by the current Executive Management Board and 25,500 options held by former members of the Executive Management Board expired without replacement after a ten-year term. No options have yet been exercised by current or former members of the Executive Management Board.
- In fiscal year 2022, transactions took place between Heidelberg Pharma Research GmbH and entities controlled by dievini or its affiliated companies, namely Apogenix AG, Heidelberg. 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.

32.3 Disclosures regarding the majority shareholder

The main shareholder in Heidelberg Pharma AG is dievini Hopp BioTech holding GmbH & Co. KG, Walldorf, (dievini). Together with all entities attributable or affiliated to 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 51.67% 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.

After a capital increase implemented in September 2022, the interest held by dievini and its affiliated companies together with the shares in Heidelberg Pharma AG held personally by Mr. Dietmar Hopp most recently decreased to approximately 45.67% of Heidelberg Pharma shares compared with the end of the previous year (75.31%).

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. 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.

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 28 June 2022. The Supervisory Board commissioned Deloitte with the audit.

The fee for the auditor of the consolidated and annual financial statements of Heidelberg Pharma AG recognized as an expense in fiscal year 2021/2022 amounted to €186 thousand relating to audits of the financial statements (of which €5 thousand for the previous year) and a further €132 thousand for other assurance services. The latter relate to the issuance of a comfort letter in accordance with IDW AuS 910 in respect of the EU Recovery Prospectus for the rights issue of Heidelberg Pharma AG.

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 January 2023. It has been made permanently available to all shareholders and interested parties on the Company's website.

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35 Events after the reporting period

Magenta Therapeutics explores strategic alternatives

Magenta Therapeutics, Cambridge, MA, USA, (Magenta), technology partner of the subsidiary Heidelberg Pharma Research GmbH, announced on 25 January 2023 that in their clinical study at the Cohort 3 level a grade 5 serious adverse event resulting in death occurred, deemed to be possibly related to MGTA-117. For safety reasons, Magenta subsequently paused dosing in the clinical trial until further notice. On 2 February 2023, Magenta announced that it has completed a review of its business, including the status of its programs, resources and capabilities. Magenta has made the determination to halt further development of its programs and conduct a comprehensive review of strategic alternatives. At the end of February 2023, the Amanitin linker supply contract was terminated by Magenta, which will result in Heidelberg Pharma losing sales revenue in the low single-digit million range for fiscal year 2023. Further consequences for the contract situation depend on the course of Magenta's strategic realignment and cannot be estimated at present.

Ladenburg, 22 March 2023

Heidelberg Pharma AG, the Executive Management Board



Dr. Jan Schmidt-Brand
Chief Executive Officer & Chief Financial Officer



Professor Andreas Pahl
Chief Scientific 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, 22 March 2023

The Executive Management Board of Heidelberg Pharma AG



Dr. Jan Schmidt-Brand
Chief Executive Officer and Chief Financial Officer



Professor Andreas Pahl
Chief Scientific 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 2022, 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 2021 to 30 November 2022, 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 2021 to 30 November 2022. 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.

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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 2022, and of its financial performance for the fiscal year from 1 December 2021 to 30 November 2022, 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 8.4 "Going-concern risks" and 8.6 "Financial risks" 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 2022 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.

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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 Company 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 annual financial statements on a going-concern basis and the presentation of the Company's going-concern risks in the annual financial statements and in the 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 2021 to 30 November 2022. 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 this key audit matter has 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 6.1% 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 3.9, 7.2, 8 and 10.1 of the notes to the consolidated financial statements.

- 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 and approved by the Supervisory Board and through reconciliation with general and sector-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.

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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.

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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 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 for 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 overall presentation, structure and content of the consolidated financial statements, 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 related safeguards.

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 value f3326b98fa42981a5f0fe7a7cc6f4555eb1035c51a8c8568fdf34bf850234c54 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 2021 to 30 November 2022 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 (10.2021)). 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 IDW Standard on Quality Management: Requirements for Quality Management in Audit Firms (IDW QS 1).

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 28 June 2022. We were engaged by the Supervisory Board on 22 December 2022/8 January 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 – including the versions to be published in the Federal Gazette – 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 Jörg Wegner.

Frankfurt am Main, 22 March 2023

Deloitte GmbH
Wirtschaftsprüfungsgesellschaft

signed Jörg Wegner
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.

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.

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.

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.

CD37: Surface molecule expressed by B-cells.

CDMO: Contract Development and Manufacturing Organization.

Chemotherapy: Use of cell toxins to destroy tumor cells in the body.

Diagnostic agent: A tool, gene or protein that aids in the diagnosis of an illness.

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.

Immune checkpoint: Immune checkpoints are receptors on the surface of T-cells. They serve to modulate the T-cell response in an enhancing (so-called proinflammatory checkpoints) or inhibitory (anti-inflammatory; e.g. PD-1) manner. Checkpoint inhibitors are drugs that occupy the immune checkpoints and thus inhibit them.

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.

Metastasis: Malignant spread of a tumor in an organism.

MGTA-117: Development name for the ATAC candidate of our licensing partner, Magenta.

Molecule: A chemical structure composed of at least two particles (atoms).

Monoclonal antibodies: Monoclonal antibodies are produced by cells created by fusing an antibody-producing cell (such as B-lymphocytes) with an immortalized (immortalized) cancer cell. This process is performed in the laboratory and creates a hybrid cell (hybridoma) that has the characteristics of both cells. These cells are all identical because they are derived from one cell, and are referred to as "monoclonal." They each produce large amounts of a specific antibody that binds to a specific antigen.

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 malign 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

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.

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.

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.

Serine protease: A type of peptidase (i.e. enzymes which catalyze the split of proteins and peptides).

Therapeutic agent: Drug applied for the treatment of illnesses.

Thrombin: Enzyme that enables blood to coagulate.

TLX250-CDx: Development name for the zirconium-89 (⁸⁹Zr) radiolabeled antibody girentuximab for PET diagnosis of kidney tumors (partner Telix).

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).

Toxic: Poisonous to cells.

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.

FINANCIAL CALENDAR 2023

Date	Type of report/event
24 March 2023	Annual Report 2022
27 March 2023	Financial press conference and analysts' meeting
13 April 2023	Interim management statement on the first three months of 2023
25 May 2023	Virtual Annual General Meeting 2023
13 July 2023	Half-yearly Financial Report 2023
12 October 2023	Interim management statement on the first nine months of 2023



Please see our website for the current list of conferences 2023.

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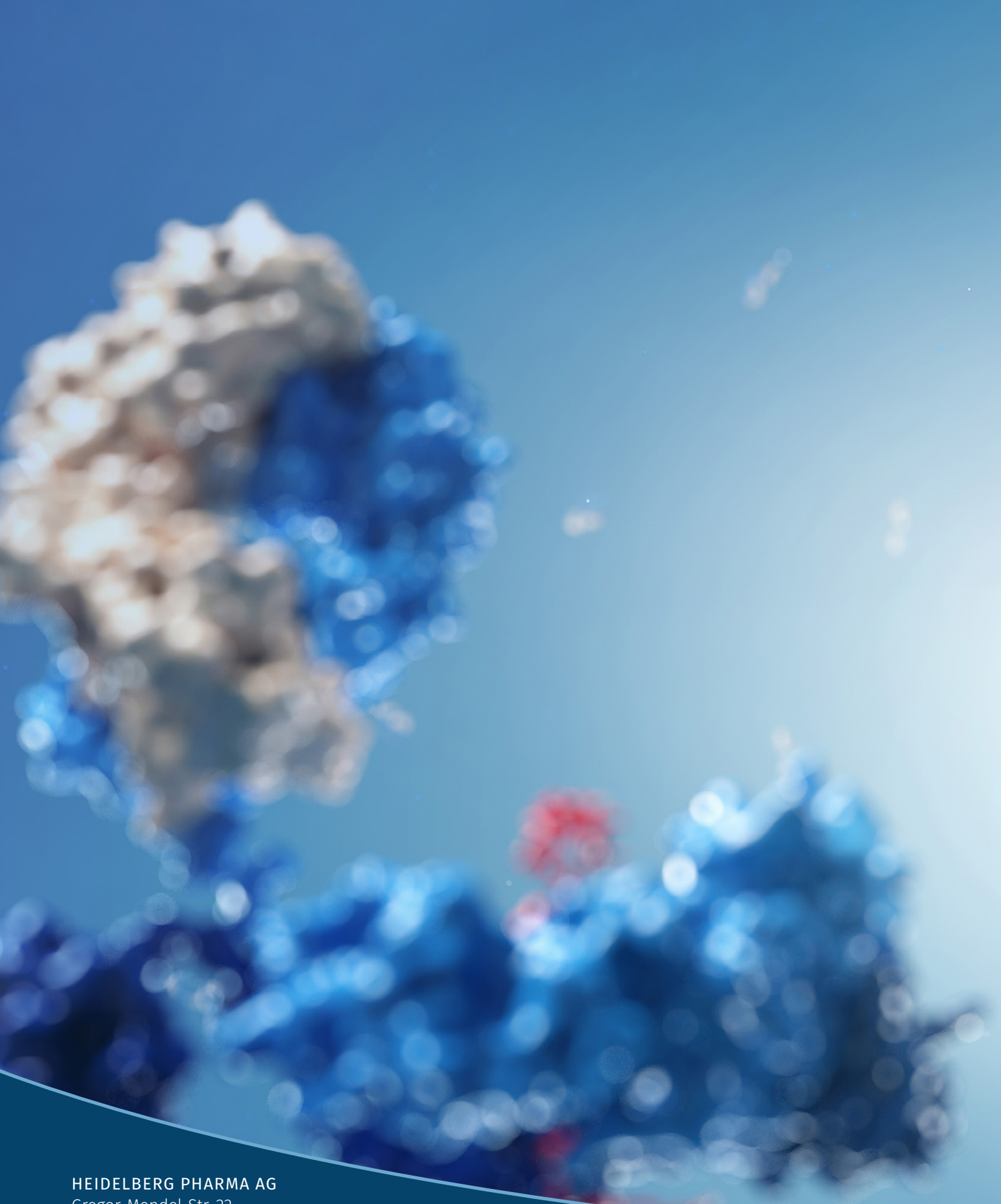
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The Annual Report is also published in German and is available for download from our website at www.heidelberg-pharma.com. The English translation of the Annual Report is provided for convenience only. The German original is definitive.

As of: 22 March 2023



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