

HALF-YEARLY FINANCIAL REPORT 2019

KEY FIGURES

	H1 2019¹ € '000	H1 2018¹ € '000
Earnings		
Sales revenue	3,752	1,993
Other income	351	200
Operating expenses	(8,432)	(6,906)
of which research and development costs	(4,977)	(4,641)
Operating result	(4,329)	(4,713)
Earnings before tax	(4,329)	(4,713)
Net loss for the period	(4,329)	(4,713)
Earnings per share in €	(0.15)	(0.17)
Balance sheet at end of period		
Total assets	26,968	36,900
Cash and cash equivalents	13,109	25,535
Equity	21,578	32,555
Equity ratio ² in%	80.0	88.2
Cash flow statement		
Cash flow from operating activities	(5,740)	(4,103)
Cash flow from investing activities	(587)	(743)
Cash flow from financing activities	0	0
Employees (number)		
Employees as of the end of the period ³	66	65
Employees as of the end of the period (full-time equivalents) ³	60	59

 $^{^{\}mbox{\tiny 1}}$ The reporting period begins on 1 December and ends on 31 May.

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

² Equity/total assets

³ Including members of the Executive Management Board

LETTER TO THE SHAREHOLDERS

Dear Ladies and Gentlemen,

Our activities in the first half of 2019 focused on establishing the manufacturing process for our HDP-101 development candidate for the treatment of multiple myeloma, further developing this candidate, and stepping up our collaboration with Magenta. We are highly satisfied with our business performance and are pleased with the sharp increase in sales revenue. We are well on track to achieving our financial targets.

One of our most important goals is to continue and complete our preparations for the clinical development of HDP-101. Other necessary steps include ensuring that the compound is available in a sufficient quantity and in GMP quality. Producing Amanitin and its building blocks is a complex process that initially presented us and our manufacturing partners with significant challenges. Together with our manufacturer Carbogen, we succeeded in increasing our GMP material manufacturing capacities in recent months. We can now supply our license partners not only on a laboratory scale but also offer them GMP-quality material.

In addition, the manufacture of HDP-101 not only includes the complete ATAC molecule, consisting of the antibody, linker and Amanitin, but also its galenic formulation – that is, preparation of its final dosage form for clinical use. We are currently concentrating on optimizing the formulation within the manufacturing process, as the initial approach did not produce the desired results. Carbogen is working with Heidelberg Pharma on the necessary process adjustments. These additional process steps are currently delaying the continuation of the toxicity studies and thus the overall development program. We expect the preclinical data package for the clinical trial application to be available during the first quarter of 2020, enabling the application to be made thereafter. As a robust and reliable manufacturing process is the top priority for successfully entering the clinical trial phase, we need to accept that this will require additional time and it is important that we take that time to get it right.

At the same time, the first parts of the preclinical toxicology program for HDP-101 agreed with the authorities were successfully completed. We selected and contacted the clinical trial centers and entered into an agreement with the clinical research provider to conduct the clinical trial (CRO).

We are very pleased with the progress of our collaboration with Magenta. In addition to engaging in an intensive scientific dialog, we also negotiated and signed a contractual arrangement to supply GMP-quality Amanitin linkers. This had a positive impact on our revenue performance.

Our partners Link Health and Telix also made progress during the first half of the year. Link Health received IND approval for MESUPRON® from the Chinese authorities and Telix reached an important milestone in modernizing the production process for TLX250-CDx (formerly REDECTANE®). Both resulted in milestone payments to us.

Our Annual General Meeting was held on 21 May 2019. We were pleased to meet many of our shareholders in person. We are confident about the second half of the year and will tackle the next steps with great energy and enthusiasm. We would like to sincerely thank our shareholders for their support.

Ladenburg, 11 July 2019 Yours sincerely,

Dr. Jan Schmidt-Brand

Chief Executive Officer and Chief Financial Officer

INTERIM MANAGEMENT REPORT

Reporting period from 1 December 2018 to 31 May 2019

Introduction

Heidelberg Pharma AG is a biopharmaceutical company and oncology specialist. It is the first company to develop the toxin Amanitin into cancer therapies using its proprietary Antibody Targeted Amanitin Conjugate (ATAC) technology and to advance the biological mode of action of the toxin as a novel therapeutic principle. This proprietary technology platform is being applied to develop the Company's proprietary therapeutic ATACs as well as in third-party collaborations to create a variety of ATAC candidates. The proprietary lead candidate HDP-101 is a BCMA ATAC for multiple myeloma and other hematologic conditions.

Key events in the first six months

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

This technology transfer to industrial-scale production was a key milestone for safeguarding the supply of material both for our own projects and for our licensees. As a result, Heidelberg Pharma is now in a position to provide its license partners with a sufficient quantity of the necessary GMP-quality Amanitin linker material.

After coordinating the conceptual design of this transfer with GMP manufacturer Carbogen AMCIS AG, Bubendorf, Switzerland, (Carbogen) and partner Magenta Therapeutics, Cambridge, MA, USA, (Magenta) we have now successfully negotiated and set out the formal contractual conditions. Heidelberg Pharma will supply its partner Magenta with the necessary GMP-quality Amanitin linker material in cooperation with Carbogen. The production process for this has been initiated.

Poster presentation at the AACR Annual Meeting 2019

In March, Heidelberg Pharma presented preclinical data on an ATAC that targets the breast cancer antigen HER2 at the Annual Meeting of the American Association of Cancer Research (AACR). These data from an experimental case study show that HER2-ATAC has the potential to efficiently target tumors with low HER2 expression, such as those occurring in triple negative breast cancer (TNBC), and to preferentially attack tumor cells in aggressively progressive cancers in connection with a 17p deletion.

Triple negative breast cancer is a subgroup of breast cancer patients where the tumor cell surface has no crosslinking positions (receptors) for the hormones estrogen, progesterone and the human epidermal growth factor receptor type 2 (HER2). Approximately 15–20% of breast cancer patients belong to this type, with tumors often growing quickly and aggressively. They do not respond to anti-hormonal treatment or therapy with HER2 antibodies. These patients therefore have a significantly worse prognosis compared to other breast cancer types.

IND approval and milestone payment from Link Health

In January 2019, Heidelberg Pharma announced that the IND application for carrying out a clinical program with MESUPRON® in China was approved at the end of 2018. Details of the planned trials are not yet available as the Chinese regulatory authorities have changed the trial regulations, as a result of which Link Health will be able to adjust the clinical development plan for MESUPRON®. There is now a chance that a Phase II trial can begin immediately based on earlier data from the USA and Europe. When the IND approval was granted in principle, a milestone payment became payable to Heidelberg Pharma and €421 thousand was recognized in profit or loss.

Annual General Meeting of Heidelberg Pharma AG

On 21 May 2019, the Annual General Meeting of Heidelberg Pharma AG took place. Of the share capital comprising 28,153,323 no par value bearer shares at the time, 22,620,571 shares were represented with the same number of votes. This means that 80.35% of the Company's share capital was present at the Annual General Meeting.

The shareholders adopted the resolutions proposed by the management with a large majority (between 99.81% and 100%). The actions of the Executive Management Board and the Supervisory Board were formally approved and Deloitte GmbH Wirtschaftsprüfungsgesellschaft, Mannheim, was elected to serve as the auditor of the annual financial statements and the consolidated financial statements for the 2018/2019 fiscal year.

Research and development activities

ADC technology (antibody drug conjugates)

Heidelberg Pharma is developing a technology platform for antibody drug conjugates. The core of this technology is to offer new approaches to anti-tumor therapy by exploiting a previously unused biological mode of action for treatment of cancer.

Heidelberg Pharma uses the toxin Amanitin, a member of the amatoxin group of natural poisons occurring in the death cap mushroom (Amanita phalloides), among others. By inhibiting RNA polymerase II, Amanitin triggers natural cell death, or apoptosis. This toxic compound is chemically combined with antibodies so that it can be used for therapy. The resulting products – so called ATACs (Antibody Targeted Amanitin Conjugates) – are designed to transport the cross-linked toxin specifically into the cancer cell. After binding to the tumor cell, the ATAC is taken up and releases the toxin within the cell. The released toxin then destroys the tumor cell without affecting healthy tissue.

ATACs are characterized by improved efficacy also in dormant tumor cells, which are rarely reached with existing standard therapies and contribute to tumor recurrence and resistance formation. These ATACs are also being developed to treat tumors that no longer respond to standard chemotherapy or anti-tumor antibodies. Selective treatment of tumors using Amanitin via specific antibody drug conjugates could thus enable much more effective cancer treatments with acceptable side effect profiles.

Scientists at Heidelberg Pharma have succeeded for the first time in synthesizing Amanitin without having to resort to the natural active ingredient and in producing stable quality.

The Company's business model is based on two pillars. One focus is on business-to-business activities where the compound linker technology developed by Heidelberg Pharma is licensed by pharmaceutical and biotechnology companies to make their antibodies more effective in treating tumors. Within this framework, under license agreements, Heidelberg Pharma gives partners not only the licensing rights but also technological support in the manufacture and purification of the conjugates, the production and delivery of the compound, and selected preclinical research.

Several early-stage collaborations with biopharmaceutical partners are already in place. These partners include the Japanese company Takeda Pharmaceutical Company Limited (Takeda) and the US company Magenta Therapeutics.

In addition to partner collaboration activities, Heidelberg Pharma is also focused on developing its proprietary ATAC candidates. The Company is testing in-licensed or third-party antibodies with its Amanitin linker technology and plans to conduct further research and development activities with these antibodies, if appropriate. It is becoming increasingly important to build up the Company's own pipeline to demonstrate the potential of the platform technology with compelling, proprietary data for different indications. The most advanced project is a BCMA-ATAC, though further trial series are also being advanced with the PSMA-ATAC to fight prostate cancer and further ATACs to fight various hematological tumors.

Project HDP-101 (BCMA-ATAC)

BCMA is a surface protein that is highly expressed in multiple myeloma cells and to which the selected antibodies specifically bind. Based on preliminary work and a license from the Max Delbrück Center for Molecular Medicine at the Helmholtz Association (MDC) in Berlin for BCMA-specific antibodies, Heidelberg Pharma produced and tested several proprietary ATAC molecules. This further development work resulted in the lead candidate HDP-101, which consists of a BCMA antibody, a specific linker and the Amanitin toxin.

Preclinical data showed that HDP-101 had strong *in vitro* anti-tumor activity and led to complete tumor remission in mouse models for multiple myeloma even at very low doses. In addition, tolerability studies conducted in different *in vivo* models identified a very favorable therapeutic window. For the first time, the efficacy of HDP-101 was also shown *ex vivo* with human tumor cells from the multiple myeloma of patients. Multiple myeloma is a cancer affecting bone marrow and the second most common hematologic cancer; it represents a major unmet medical need where new, more effective therapies are urgently needed. HDP-101 also has potential in further hematologic indications.

The Company continued to push ahead with preparations for formal preclinical and clinical development of HDP-101.

Production partner Carbogen, who is also responsible for the production of the Amanitin linkers, manufactured the first technical batch of the development candidate HDP-101 based entirely on a synthetic Amanitin derivative and the BCMA antibody previously manufactured by Celonic AG, Basel, Switzerland, (Celonic).

The material from this batch is being used in preparation for clinical trials. As part of this process, the tolerability of the clinical trial material must be demonstrated in a series of toxicity studies to ensure patient safety. This has shown that the galenic formulation requires further optimization in the final step of the manufacturing process. Heidelberg Pharma is working with Carbogen on the necessary process adjustments. These additional process steps are currently delaying the continuation of the toxicity studies and thus the overall development program. Heidelberg Pharma expects the preclinical data package for the clinical trial application to be available during the first quarter of 2020, enabling the application to be made thereafter.

At the same time, the first parts of the toxicology program coordinated with the authorities were successfully completed. Work proceeded in parallel on the design of the clinical development program for HDP-101. Clinical centers in the USA and Germany have been identified and enlisted for the program.

Other ATAC research projects

Heidelberg Pharma is working on various proprietary projects, including the PSMA-ATAC (PSMA – prostate-specific membrane antigen) and the predictive biomarker project. In addition, several ATACs with antibodies for other antigens have now also been manufactured and tested successfully, both *in vitro* and *in vivo*. Heidelberg Pharma will use the data obtained, the competitive situation, and the investment sums needed as criteria when deciding about the next steps to take for these ATAC candidates.

PSMA-ATAC research project: PSMA is overexpressed in prostate cancer and is a promising target antigen for ATAC technology. In pilot studies, Heidelberg Pharma investigated the anti-tumor efficacy of several monoclonal antibodies targeting PSMA conjugated to Amanitin. After humanization and de-immunization of the chosen anti-PSMA antibody, this was used to produce various ATACs, which will be further optimized preclinically in terms of safety, tolerability and efficacy.

Meanwhile, metastatic castration-resistant prostate cancer (mCRPC), an oncological disease with a high medical need, has been selected as a clinical indication for the PSMA project. In recent weeks, preclinical studies have been conducted to determine *in vitro* and *in vivo* efficacy, tolerability and pharmacokinetics. The data show that the PSMA-ATAC has a promising therapeutic window. This is confirmed by the fact that there is a very high prevalence of a 17p deletion in mCRPC, which is outlined further below. The occurrence of a 17p deletion has already been preclinically validated for prostate cancer.¹

Predictive biomarker p53/RNA polymerase II project: 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 which includes both the gene for the tumor suppressor protein TP53 and the largest subunit for RNA polymerase II. Tumors frequently suppress TP53 in tumor cells to weaken the cells' natural defenses. Since RNA polymerase II is also routinely suppressed, this change makes the tumor cells particularly sensitive to Amanitin. Heidelberg Pharma is now working on the development of a companion diagnostic with the aim of detecting and quantifying a TP53/polymerase II deletion in patients. The associated potential for the identification of especially suitable patient groups could also accelerate the clinical development of appropriate treatments.

¹ https://www.nature.com/articles/s41467-018-06811-z

As part of this biomarker project, Heidelberg Pharma is collaborating with the MD Anderson Cancer Center in Texas, USA, (MD Anderson). Jointly achieved study results showed exceptionally good efficacy of an ATAC in a colorectal cancer subpopulation with changes in the status of the tumor suppressor gene TP53. These data were published in Nature magazine in 2015.²

In December 2018, more preclinical data concerning 17p deletion and HDP-101 were presented at the 60th Annual Meeting of the American Society of Hematology (ASH), the world's premier event for hematological diseases. At this meeting, MD Anderson's research team demonstrated that the Amanitin conjugate HDP-101 was especially effective and efficient at attacking tumor cells from multiple myeloma patients with a 17p deletion.³ The use of TP53 and POLR2A gene status as biomarkers for ATAC sensitivity could permit the stratification of patients who are very likely to benefit from ATAC therapy. There could also be a possible accelerated market approval for this patient population, provided that the preclinical data can be translated into clinical efficacy.

Preclinical services business

Heidelberg Pharma also has the expertise and required infrastructure for *in vivo* pharmacology, cell biology, bioanalytics, molecular biology and chemistry, and offers preclinical research services in the fields of cancer, as well as inflammatory and autoimmune diseases. In its research, the Company focuses on early substances (for example, lead structures to be optimized) up to the profiling of preclinical candidates. Both standard models and innovative developments are offered to customers for specified indications. Heidelberg Pharma also develops customer-specific efficacy models upon request to support customers' own research activities.

Clinical portfolio

MESUPRON®

MESUPRON® (INN: Upamostat) is an oral uPA/serine protease inhibitor designed to block the activity of tumor-relevant serine proteases such as uPA, plasmin and thrombin to prevent tumor growth and metastasis.

License agreements for the development and commercialization of MESUPRON® are in place with Link Health Co., Guangzhou, China, (Link Health) for China, Hong Kong, Taiwan and Macau and RedHill Biopharma Ltd., Tel Aviv, Israel, (RedHill) for the rest of the world. All further development and marketing activities for this product candidate will be carried out by these partners.

In January 2016, the Company's partner Link Health submitted an investigational new drug (IND) application to the National Medical Products Administration (NMPA) for carrying out a Phase I study. The IND application was approved at the end of 2018. Details of the planned trial are not yet available as the Chinese regulatory authorities have changed the trial regulations, as a result of which Link Health will be able to adjust the clinical development plan for MESUPRON®. There is now a chance that a Phase II trial can begin immediately based on earlier data from the USA and Europe.

² https://www.nature.com/articles/nature14418

³ https://ash.confex.com/ash/2018/webprogram/Paper118412.html

In recent years, RedHill has filed a number of patent applications and generated interesting data on newly identified target molecules. While RedHill did not announce any progress in recent months, the company is working on a development plan for the new target molecules to evaluate corresponding indications, patient populations and compound combinations.

TLX250-CDx (formerly REDECTANE®) – diagnostic antibody

The diagnostic agent is a radiolabelled form of the antibody Girentuximab, which binds to the tumor-specific antigen CAIX on clear cell renal cell carcinoma. Under the name REDECTANE®, the project was developed up to an initial Phase III trial (REDECT) at Heidelberg Pharma AG. Accumulation of this antibody in tumor tissue can be visualized by positron emission tomography scans (PET). This could fundamentally change therapy planning for renal cancer patients and avoid potentially unnecessary surgery. The diagnostic agent may also prove suitable for monitoring response to treatment and for diagnosing other kinds of tumors.

The Company has an exclusive license agreement for the global development and marketing of the radiolabelled antibody with the Australian company Telix Pharmaceuticals Limited, Melbourne, Australia, (Telix). The license agreement also covers the development of a therapeutic radioimmunoconjugate program.

Telix first began working on a modernized production process for manufacturing the antibody. One of the contractually defined production milestones has now been reached. For more information, please see the report on post-balance sheet date events.

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Due to more favorable properties in terms of manufacturing and diagnostics, Telix has decided to use zir-conium-89 instead of iodine-124 for radiolabeling, and has defined ⁸⁹Zr-DFO-Girentuximab (TLX250-CDx) as the product candidate. To ensure comparability with the earlier REDECT Phase III trial, a comparability study (ZIR-DOSE) has been started and recruitment for this study is now complete.

In August 2018, Telix submitted a clinical trial application (CTA) to initiate a Phase III trial (ZIRCON) with TLX250-CDx for the diagnostic imaging of renal cancer using positron emission tomography (PET). Subject to the respective regulatory approvals, the study will be conducted as a global multicenter Phase III trial at sites in Europe, Australia, Japan, and the USA, and is scheduled to enroll around 250 renal cancer patients who are to undergo kidney surgery. The study will determine the sensitivity and specificity of TLX250 PET imaging to detect clear cell renal cell cancer (ccRCC) in comparison with histologic ground truth determined from surgical resection specimens. In Europe and Australia, the trial was launched in the first half of 2019 and first patients were enrolled.

Telix is also planning the further development of a therapeutic radioimmunoconjugate (177Lu—girentuximab, TLX250) program based on the lutetium-177-labeled Girentuximab antibody.

Market environment

For further information on the market environment for Heidelberg Pharma's products and product candidates, see pages 18 to 20 of the 2018 Annual Report.

Since the beginning of the year, various clinical and regulatory milestones have been reached on antibody drug candidates (ADCs) for cancer therapy. The brentuximab vedotin (Adcetris®) ADC from Seattle Genetics was approved by the EMA at the start of the year to include treatment of previously untreated CD30+ stage IV Hodgkin's lymphoma in combination with AVD (Adriamycin®, vinblastine und dacarbazine).⁴ Genentech's ADC Polivy™ (polatuzumab vedotin-piiq), which uses Seattle Genetics' ADC technology, also received regulatory approval in the USA.⁵ Trastuzumab deruxtecan (DS-8201) ADC from AstraZeneca and Daiichi Sankyo met its primary endpoint in a Phase II registration study in the breast cancer indication. The application for regulatory approval is likely to be submitted to the FDA and other regulatory authorities in the coming months.⁶ Astellas and Seattle Genetics are also planning to submit an application for regulatory approval this year based on positive data from a Phase II registration study with the enfortumab vedotin ADC on patients with metastatic bladder cancer who did not respond to treatment with checkpoint inhibitors.⁷

The first six months of the year also saw some interesting developments on the transactions side for ADC companies. Daiichi Sankyo has entered into a collaboration with AstraZeneca to develop and market trastuzumab deruxtecan, for which it received an upfront payment of USD 1.35 billion.⁸ Takeda signed a research agreement with LegoChem Biosciences encompassing several target molecules for the development of ADCs in immuno-oncology.⁹ In addition, Everest Medicine secured the rights to Immunomedics' sacituzumab govitecan for China and other Asian countries.¹⁰ In June, ADC Therapeutics raised USD 76 million from its Series E financing.¹¹

Several ADCs that use alternative toxins experienced setbacks in clinical development or the approval process. AbbVie stopped patient recruitment for all clinical trials involving Depatux-M (ABT-414) in May 2019 after the ADC missed its primary endpoint of improving overall survival in a Phase III study in the

- 4 Company announcement Seattle Genetics; Feb 11, 2019: https://seattlegenetics.gcs-web.com/index.php/news-releases/news-release-details/seattle-genetics-achieves-30-million-milestone-payment-european
- 5 Company announcement Seattle Genetics: http://investor.seattlegenetics.com/news-releases/news-release-details/seattle-genetics-antibody-drug-conjugate-technology-utilized
- 6 BioCentury, BC Extra, Clinical News AZ, Daiichi planning global submissions for breast cancer ADC: https://www.biocentury.com/bc-extra/clinical-news/2019-05-08/az-daiichi-planning-global-submissions-breast-cancer-adc
- 7 BioCentury, BC Extra, Clinical News Astellas, Seattle Genetics ADC could provide new option for checkpoint non-responders in bladder cancer: https://www.biocentury.com/bc-extra/clinical-news/2019-06-03/astellas-seattle-genetics-adc-could-provide-new-option-checkpoint-
- 8 BioCentury, BC Extra, Company News Daiichi gets \$1.35B up front from AZ in antibody-drug conjugate deal: https://www.biocentury.com/bc-extra/company-news/2019-03-28/daiichi-gets-135b-front-az-antibody-drug-conjugate-deal
- 9 Company announcement LegoChem: https://www.businesswire.com/news/home/20190321005823/en/LegoChem-Biosciences-Takeda-Enter-Multi-Target-Research-Collaboration
- 10 BioCentury, BC Extra, Company News With Immunomedics ADC deal, Everest bolsters cancer pipeline: https://www.biocentury.com/bc-extra/company-news/2019-04-29/immunomedics-adc-deal-everest-bolsters-cancer-pipeline
- 11 BioCentury, BC Extra, Financial News June 13 Financial Quick Takes: https://www.biocentury.com/bc-extra/financial-news/2019-06-13/june-13-financial-quick-takes-hansoh-prices-1b-hkex-ipo-plus-

glioblastoma indication. Depatux-M is an ADC that consists of an anti-EGFR antibody and the anti-tubulin agent monomethyl auristatin F.¹² The accelerated approval of Immunomedics' sacituzumab govitecan for patients with triple-negative breast cancer was delayed, at least temporarily, in a complete response letter (CRL) issued by the FDA in which the agency expressed its concerns about production of the ADC.¹³

Results of operations, financial position and net assets

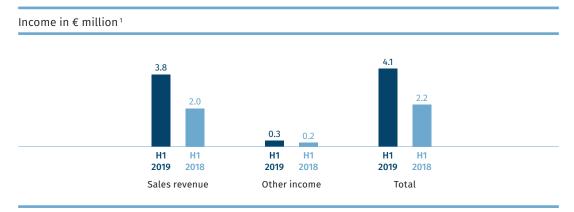
The Heidelberg Pharma Group – as of the reporting date comprising Heidelberg Pharma AG and its subsidiary Heidelberg Pharma Research GmbH – reports consolidated figures. The reporting period referred to below concerns the period from 1 December 2018 to the 31 May 2019 balance sheet date (H1 2019). The period-based comparative figures refer to the period from 1 December 2017 to 31 May 2018 (H1 2018). The reporting date-based comparative figures refer to 30 November 2018 or 31 May 2018.

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

Sales revenue and other income

In the first six months of the 2019 fiscal year, the Heidelberg Pharma Group generated sales revenue and income totaling €4.1 million, thus considerably surpassing the prior-year figure of €2.2 million.

This change is attributable to an 88% increase in sales revenue to €3.8 million (previous year: €2.0 million), which mainly stems from the research collaborations for the ATAC technology and the service business of Heidelberg Pharma Research.



¹ rounded

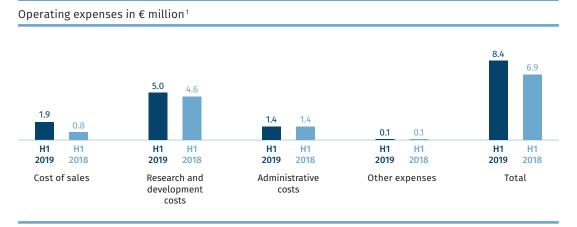
¹² BioCentury, BC Extra, Clinical News – AbbVie's antibody-drug conjugate misses mark in Phase III GBM trial: https://www.biocentury.com/bc-extra/clinical-news/2019-05-17/abbvies-antibody-drug-conjugate-misses-mark-phase-iii-gbm-trial

¹³ BioCentury, BC Extra, Clinical News/Regulatory – FDA delays approval of Immunomedics' ADC for triple-negative breast cancer: https://www.biocentury.com/bc-extra/company-news/2019-01-18/fda-delays-approval-immunomedics-adc-triple-negative-breast-cancer

Other income of \in 0.3 million was higher than the previous year's figure of \in 0.2 million and mainly comprised income from charging on patent costs, EU grants under Horizon 2020 Framework Programme and the reversal of accrued liabilities that were not utilized (\in 0.1 million each). In the previous year, income of \in 0.1 million each was recognized from grants and the reversal of accruals.

Operating expenses

Operating expenses, including depreciation, amortization and impairment, amounted to €8.4 million in the reporting period, slightly higher than the previous year (€6.9 million).



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 supplying Amanitin linkers to our licensing partners. They amounted to €1.9 million (previous year: €0.8 million), representing 23% of operating expenses.

Research and development costs rose year-over-year to €5.0 million (previous year: €4.6 million) due to the expansion of cost-intensive external good manufacturing practice (GMP) production. At 59% of operating expenses, this expense category remained the largest cost item.

Administrative costs of €1.4 million, which include the costs for the holding activities and the stock exchange listing, remained level year-over-year in the first six months of 2019 and accounted for 17% of operating expenses.

Other expenses for business development, marketing and commercial market supply activities in the current reporting period were unchanged year-over-year at €0.1 million and represented 1% of operating expenses.

Financial result

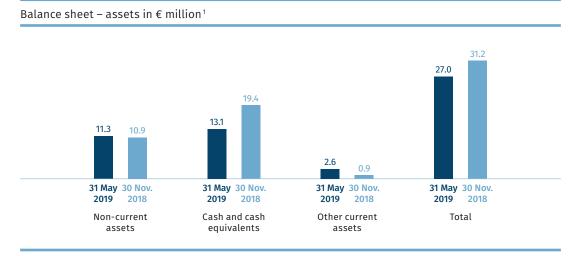
As in the previous six months, the Heidelberg Pharma Group posted a break-even financial result due to the absence of interest income and expenses.

Profit/loss for the period

In the first six months of the year, the Heidelberg Pharma Group reduced its net loss from €4.7 million to €4.3 million year-over-year. Given that expenses were up, this reduction is due in particular to higher sales revenue. Earnings per share was €-0.15, improving in step with the reduction in net loss from €-0.17 in the previous year.

Assets

Total assets as of 31 May 2019 amounted to €27.0 million, down from €31.2 million as of the 30 November 2018 reporting date.



¹ rounded

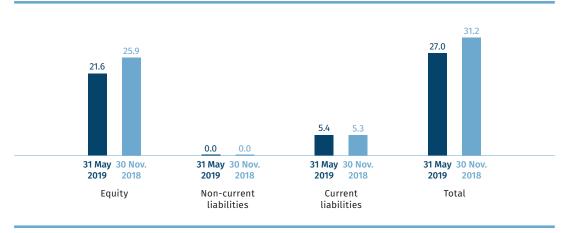
Non-current assets at the end of the reporting period amounted to \in 11.3 million, an increase on the previous year (30 November 2018: \in 10.9 million) due to PPE investments. Non-current assets include property, plant and equipment (\in 2.3 million, previous year: \in 1.9 million), intangible assets (\in 2.8 million, previous year: \in 2.8 million), other non-current assets (\in 0.1 million, as in the previous year), and goodwill of Heidelberg Pharma Research (\in 6.1 million, again as in the previous year).

Current assets totaled €15.7 million (30 November 2018: €20.3 million). The decrease was due to the outflow of cash triggered by operating activities, resulting in cash and cash equivalents of €13.1 million as of 31 May 2019 (30 November 2018: €19.4 million).

Equity

Equity as of the end of the reporting period was €21.6 million (30 November 2018: €25.9 million). This corresponded to an equity ratio of 80.0% (30 November 2018: 83.0%). Further information can be found in the notes to this report.

Balance sheet – equity and liabilities in € million¹



¹ rounded

Liabilities

No non-current liabilities were recognized at the end of the reporting period, the same as at the 2018 reporting date.

Current liabilities increased to €5.4 million as of the end of the reporting period (30 November 2018: €5.3 million).

Whereas trade payables (€1.0 million) increased significantly from the figure on 30 November 2018 (€0.4 million), other current liabilities (obligations for holidays not taken, social security and other taxes, deferred income and liabilities) decreased from €4.9 million to €4.4 million.

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Cash flow statement

Net cash outflow from operating activities of €5.7 million in the first six-months of the current fiscal year increased year-over-year (prior-year period: €4.1 million), reflecting a rise in R&D and manufacturing-related expenses despite higher income.

Cash outflow from investing activities, which is attributable primarily to laboratory expansion, was €0.6 million (previous year: €0.8 million).

There was no net change year-over-year in cash and cash equivalents triggered by financing activities in the first six months of the 2019 fiscal year.

Taking into account exchange rate and other effects of € –5 thousand (previous year: €1 thousand), the net outflow of cash and cash equivalents amounted to €6.3 million (previous year: €4.8 million).

Heidelberg Pharma's average monthly funding requirement in the first six months of the fiscal year was €1.1 million (previous year: €0.8 million).

Cash Flow ¹	H1 2019 € million	H1 2018 € million
Cash as of 1 Dec. 2018 / 1 Dec. 2017	19.4	30.4
Net change in cash from operating activities	(5.7)	(4.1)
Net change in cash from investing activities	(0.6)	(0.8)
Net change in cash from financing activities	0	0
Exchange rate effect/Other	0	0
Cash as of 31 May 2019 / 31 May 2018	13.1	25.5

¹ rounded

Employees and compensation system

Including the members of its Executive Management Board, the Heidelberg Pharma Group had 66 employees (60 FTEs) at the close of the reporting period (30 November 2018: 66 employees /60 FTEs; 31 May 2018: 65 employees/59 FTEs).

Heidelberg Pharma has a performance-related remuneration system for its employees comprising a fixed annual salary and a variable salary component. The 2005, 2011, 2017 and 2018 Stock Option Plans enable employees to participate in the Company's success. Authorization to grant options for 2005 and 2011 has since expired, however, and no new options can now be issued from these plans.

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

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Report on risks and opportunities

Heidelberg Pharma is exposed to the risks typical for a biotechnology company, namely those arising from the development and production of potential drug and diagnostic candidates for the treatment of cancer. The time between the commencement of drug development and marketing approval usually spans many years. As a result of the focus on the ATAC technology, the Company's own activities were shifted to earlier stages of the value chain and are now exclusively related to preclinical development. This shift entails higher development risks but lower costs. It should be noted that collaboration agreements with development partners, including those concerning early-stage research, can be terminated without cause. The Company is currently unable to finance itself solely through product sales and license revenue and is dependent on funding from equity providers or additional licensees. Risks and opportunities in connection with the Heidelberg Pharma Group's business are described in detail on pages 48 to 57 of the 2018 Annual Report. They remain unchanged unless otherwise noted below.

Report on post-balance sheet date events

Milestone payment received from partner Telix

After the end of the reporting period, Heidelberg Pharma AG announced in June that it received a mile-stone payment of USD 250 thousand from its cooperation partner Telix. After licensing the imaging, radio-labelled antibody TLX250-CDx (formerly REDECTANE®), Telix has set up a new and modernized production process for the antibody Girentuximab. As part of this process, one of the contractually defined mile-stones has now been reached and payment became due.

Outlook

Heidelberg Pharma's strategy focuses on the development and marketing of its proprietary ATAC technology by its subsidiary Heidelberg Pharma Research GmbH. Its core elements are the expansion of the Company's own project pipeline, the initiation of research and option agreements and their extension to include long-term license agreements, as well as the broadening of the technology base.

The proprietary ATAC candidate HDP-101 will be tested in patients with multiple myeloma for the first time in 2020. According to the clinical development strategy, applications for the Phase I (dose escalation) and Phase IIa (dose expansion) will be submitted simultaneously in the USA and Germany. The recruitment of patients is then expected to take place based on the activation of the clinical centers. The prerequisites for starting the clinical trial are completing a final GLP toxicity study on primates, drafting a study protocol and contracts with trial centers, GMP manufacturing of HDP-101 to provide the clinical studies with trial material, submitting an application to the regulatory authorities for approval to conduct a Phase I trial, being issued an approval by the regulatory authorities to carry out a Phase I trial, and establishing clinical centers, including approvals by ethics commissions.

At the same time, additional proprietary ATAC candidates will undergo preclinical testing to determine their efficacy and tolerability. The aim is to identify another development candidate from the ATAC portfolio as a follow-up project.

Research/option and license agreements for the development and commercialization of ATAC candidates will be signed with biopharmaceutical companies to test and transfer the therapeutic potential to their antibodies. To this end, Heidelberg Pharma is supplying the toxin Amanitin in GMP quality as well as the Amanitin linker technology.

New target molecules and/or antibodies and alternative conjugation processes are currently being evaluated with academic groups and biotechnology companies as part of further development of the ATAC technology. This work should be carried out systematically to identify additional project candidates or offer our license partners further product optimization opportunities.

Heidelberg Pharma also runs a small preclinical service business that conducts pharmacological studies for other research companies and for its own use of the ATAC technology.

In addition to the ATAC technology, Heidelberg Pharma also has a clinical portfolio that no longer forms part of its core activities and has either been out-licensed to partners or is otherwise available. Former product candidates REDECTANE® and MESUPRON® have already been out-licensed to partners who are expected to continue their development and bring it to a conclusion. Heidelberg Pharma will receive milestone payments if the candidates are approved and marketed.

The Company is not yet in a position to fully finance its own R&D activities using its own funds in the short to medium term. Stable revenue from the services business and increased payments from Heidelberg Pharma Research GmbH's technology partnerships or from license agreements are expected to help finance in-house development work. Depending on the development plan, the Company still needs to raise funds for product development via the capital markets. Heidelberg Pharma's financing is currently secured until at least mid-2020 based on current planning.

The Heidelberg Pharma Group confirms its full-year financial guidance issued on 21 March 2019. Sales revenue and income will primarily comprise the sales revenue generated by Heidelberg Pharma Research GmbH and, to a lesser extent, potential milestone payments to Heidelberg Pharma AG.

Financial outlook	Plan 2019 € million	Actual 2018 € million
Sales revenue and other income	5.0-7.0	4.4
Operating expenses	14.0-18.0	16.0
Operating result	(8.0)-(12.0)	(11.7)
Total funding requirement	10.0-14.0	10.9
Funds required per month	0.9-1.2	0.9

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME (IFRS)

Reporting period from 1 December 2018 to 31 May 2019

	H1 2019 €	H1 2018 €
Sales revenue	3,751,813	1,993,136
Other income	351,036	199,845
Income	4,102,849	2,192,981
Cost of sales	(1,970,896)	(767,948)
Research and development costs	(4,976,773)	(4,641,136)
Administrative costs	(1,409,868)	(1,399,977)
Other expenses	(74,315)	(96,738)
Operating expenses	(8,431,851)	(6,905,800)
Operating result	(4,329,002)	(4,712,819)
Finance income	0	0
Finance costs	0	0
Financial result	0	0
Earnings before tax	(4,329,002)	(4,712,819)
Income tax	0	0
Net loss for the period	(4,329,002)	(4,712,819)
Net currency gain/loss from consolidation	0	0
Other comprehensive income	0	0
Comprehensive income	(4,329,002)	(4,712,819)
Earnings per share		
Basic earnings per share	(0.15)	(0.17)
Average weighted number of shares issued	28,209,639	28,209,639

Quarterly comparison	Q2 2019 €	Q1 2019 €	Q4 2018 €	Q3 2018 €	Q2 2018 €
Revenue	2,681,201	1,070,613	615,797	1,058,880	1,401,165
Other income	105,571	245,465	288,950	216,849	76,254
Operating expenses	(4,031,935)	(4,399,917)	(5,159,397)	(3,980,239)	(3,776,089)
of which cost of sales	(1,282,339)	(688,557)	(932,186)	(507,985)	(391,226)
of which research and development costs	(2,007,920)	(2,968,853)	(3,335,191)	(2,702,673)	(2,566,439)
of which administrative costs	(702,256)	(707,612)	(848,448)	(717,994)	(755,524)
of which other expenses	(39,419)	(34,896)	(43,572)	(51,587)	(62,900)
Operating result	(1,245,163)	(3,083,839)	(4,254,650)	(2,704,511)	(2,298,669)
Financial result	0	0	0	0	0
Earnings before tax	(1,245,163)	(3,083,839)	(4,254,650)	(2,704,511)	(2,298,669)
Net loss for the period	(1,245,163)	(3,083,839)	(4,254,650)	(2,704,511)	(2,298,669)
Comprehensive income	(1,245,163)	(3,083,839)	(4,254,650)	(2,704,511)	(2,298,669)
Basic earnings per share	(0.04)	(0.11)	(0.15)	(0.10)	(0.08)
Average weighted number of shares issued	28,209,639	28,209,639	28,209,639	28,209,639	28,209,639

CONSOLIDATED BALANCE SHEET (IFRS)

as of 31 May 2019 and as of 30 November 2018

Assets	31 May 2019 €	30 Nov. 2018 €
Property, plant and equipment	2,285,958	1,949,922
Intangible assets	2,827,937	2,800,914
Goodwill	6,111,166	6,111,166
Other non-current assets	41,516	41,350
Non-current assets	11,266,577	10,903,351
Inventories	40,056	177,559
Prepayments	750,142	56,032
Trade receivables	1,393,358	365,949
Other receivables	408,823	248,734
Cash and cash equivalents	13,108,808	19,440,352
Current assets	15,701,187	20,288,625
Total assets	26,967,764	31,191,977

Equity and liabilities	31 May 2019 €	30 Nov. 2018 €
Subscribed capital	28,155,630	28,133,308
Capital reserve	214,787,595	214,643,257
Accumulated losses	(221,365,506)	(216,890,476)
Equity	21,577,719	25,886,089
Non-current liabilities	0	0
Trade payables	953,735	405,498
Provisions	44,932	12,101
Other current liabilities	4,391,379	4,888,288
Current liabilities	5,390,046	5,305,887
Total equity and liabilities	26,967,764	31,191,977

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY (IFRS)

Reporting period from 1 December 2018 to 31 May 2019

			Corporate actions/ premium	Stock options		
		Subscribed	Capital res	serve	Accumulated	
	Shares	capital €	€	€	losses €	Total €
			216,121,501	3,668,292		
As of 1 December 2017	22,452,570	22,452,570	219,789,7	793	(205,218,496)	37,023,866
Measurement of stock options				243,538		243,538
Net loss for the year					(4,712,819)	(4,712,819)
Exercise of the mandatory convertible bond	5,677,212	5,677,212	(5,677,212)			0
Net change in equity						(4,469,281)
			210,444,289	3,911,829		
As of 31 May 2018	28,129,782	28,129,782	214,356,	118	(209,931,315)	32,554,585
			210,440,763	4,202,495		
As of 1 December 2018	28,133,308	28,133,308	214,643,2	257	(216,890,476)	25,886,089
Measurement of stock options				166,659		166,659
Net loss for the year					(4,329,002)	(4,329,002)
Effects of initial application of IFRS 15					(146,028)	(146,028)
Exercise of the mandatory convertible bond	22,322	22,322	(22,322)			0
Net change in equity						(4,162,343)
			210,418,441	4,369,154		
As of 31 May 2019	28,155,630	28,155,630	214,787,5	595	(221,365,506)	21,577,719

CONSOLIDATED CASH FLOW STATEMENT (IFRS)

Reporting period from 1 December 2018 to 31 May 2019

	H1 2019 €	H1 2018 €
Net loss for the year	(4,329,002)	(4,712,819)
Adjustment for items in the statement of comprehensive income		
Stock options	166,659	243,538
Depreciation, amortization and impairment losses	223,510	179,630
Exchange rate effects	5,209	(576)
	395,377	422,592
Changes in balance sheet items		
Inventories	137,502	37,210
Prepayments	(694,110)	35,892
Trade receivables	(1,027,409)	185,289
Other receivables	(160,089)	120,819
Other non-current assets	(166)	(71,707)
Trade payables	548,236	(1,262,672)
Other liabilities	(610,106)	1,142,111
	(1,806,141)	186,942
Cash flow from operating activities	(5,739,766)	(4,103,286)
Net cash flow from operating activities	(5,739,766)	(4,103,286)
Cash flow from investing activities		
Purchase of property, plant and equipment	(535,168)	(587,728)
Purchase of intangible assets	(51,401)	(155,456)
Net cash flow from investing activities	(586,569)	(743,183)
Cash flow from financing activities		
Net cash flow from financing activities	0	0
Influence of exchange rate and other effects on cash and cash equivalents	(5,209)	576
Net change in cash and cash equivalents	(6,331,544)	(4,845,893)
Cash and cash equivalents		
at beginning of period	19,440,352	30,381,061
at end of period	13,108,808	25,535,168

SELECTED NOTES

A. General disclosures

The interim consolidated financial statements include the Group's parent, Heidelberg Pharma AG, Ladenburg, Germany, as well as its subsidiary Heidelberg Pharma Research GmbH, Ladenburg, Germany, – jointly, the "Group".

In this half-yearly report for the period ended 31 May 2019, IFRS 15 (Revenue from Contacts with Customers) is applied for the first time using the modified retrospective method. As a result, transition effects are recognized cumulatively in the equity item "Accumulated losses" and the comparative period is presented in accordance with previously applicable regulations. The difference between the disclosure based on the previous standards IAS 18 or IAS 11 and IFRS 15 for the current fiscal year amounts to €146 thousand.

Other than that, this report was prepared in accordance with the same accounting policies as the consolidated financial statements as of 30 November 2018.

The Company's results of operations, financial position and net assets, as well as key items in these financial statements, are explained in detail in the interim management report. The Company's business activities are not subject to seasonal or macroeconomic influences.

The interim consolidated financial statements for the first half of fiscal year 2019 that appear in this report were prepared in accordance with the International Financial Reporting Standards (IFRS) endorsed and adopted by the European Union, specifically in accordance with IAS 34 "Interim Financial Reporting" issued by the International Accounting Standards Board (IASB) and in compliance with the Interpretations of the Standing Interpretations Committee (SIC) and the International Financial Reporting Interpretations Committee (IFRIC).

These interim financial statements are abbreviated, do not include all the information and disclosures required for consolidated financial statements as of the end of a fiscal year, and should be read in the context of the IFRS consolidated financial statements as of 30 November 2018 published for the 2018 fiscal year. They were not subjected to a review by an auditor. Pursuant to the Company's Declaration of Conformity issued in February 2019 concerning Section 7.1.2 of the German Corporate Governance Code, both the interim financial statements and the interim management report for the Group were made available to the Supervisory Board's Audit Committee before being published. This interim report was approved for publication by the Executive Management Board of Heidelberg Pharma AG on 11 July 2019.

B. Change in equity

The exercise of (mandatory) convertible bonds in the first half of the fiscal year resulted in 22,322 new no par value shares that increased the share capital of Heidelberg Pharma AG from €28,133,308 to €28,155,630, divided into 28,155,630 no par value bearer shares.

Equity of the Heidelberg Pharma Group at the end of the reporting period was €21.6 million (30 November 2018: €25.9 million). Capital reserves were €214.8 million (30 November 2018: €214.6 million) and the losses accumulated totaled €221.4 million (30 November 2018: €216.9 million). The equity ratio of the Heidelberg Pharma Group was 80.0% (30 November 2018: 83.0%).

C. Issue and measurement of stock options

Similar to the approach described in the Annual Report as of 30 November 2018, Heidelberg Pharma's obligation vis-à-vis the beneficiaries resulting from the issuance of options under the 2005, 2011 and 2017 Stock Option Plans was recognized in accordance with IFRS 2 in the reporting period. The estimated number of options expected to become exercisable is reviewed at each reporting date. The effects of any adjustments to be considered regarding initial estimates are recognized in the statement of comprehensive income as well as by adjusting equity accordingly.

The measurement of the stock options in the first six months of the 2019 fiscal year entailed staff costs of €167 thousand (previous year: €244 thousand).

As of the 31 May reporting date, no options had been issued during the 2019 fiscal year. No stock options were exercised but 31,550 stock options were returned because employees left the Company.

Heidelberg Pharma issued a total of 2,500,587 subscription rights to employees and members of the Executive Management Board under the 2005, 2011 and 2017 Stock Option Plans, of which 1,269,226 options (538,700 for current or former Executive Management Board members and 730,526 for current or former employees) were outstanding as of the end of the reporting period.

A total of 44,075 options of the Executive Management Board and 43,469 options of employees vested in the first six months of the 2019 fiscal year.

Related party transactions D.

During the reporting period, executives of Heidelberg Pharma AG did not report any transactions subject to disclosure in accordance with Article 19 of the Market Abuse Regulation (Directors' dealings).

The Rittershaus law firm provided legal consulting services for the Heidelberg Pharma Group of approximately €6 thousand during the reporting period. Rittershaus is a related party because the Chairman of the Supervisory Board, Professor Christof Hettich, is a partner in this law firm.

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

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

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Significant events that occurred after the end of the reporting period are explained in the report on post-balance sheet events that is part of the interim management report. There are currently no further significant events to report.

RESPONSIBILITY STATEMENT OF THE EXECUTIVE MANAGEMENT BOARD

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

Ladenburg, 11 July 2019

The Executive Management Board of Heidelberg Pharma AG

Dr. Jan Schmidt-Brand

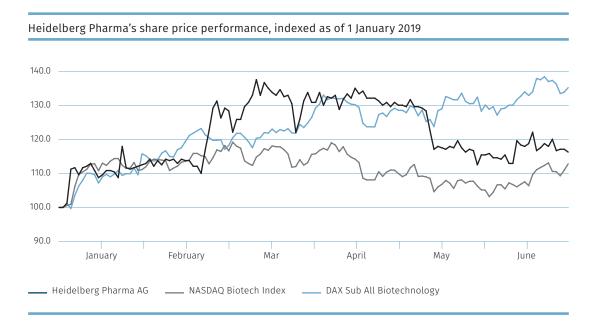
Chief Executive Officer and Chief Financial Officer

Prof. Dr. Andreas Pahl Chief Scientific Officer

HEIDELBERG PHARMA'S SHARES

Share price performance in 2019

Heidelberg Pharma's shares opened 2019 at €2.44, passed the €3.00 mark at the end of February and reached their high for the first half of the year of €3.39 on 17 April. The entire market has been suffering from falling prices and profit taking since May. Despite this, the major indices recorded gains as the first half of the year drew to a close. The DAXsubsector Biotechnology Index was up 35%, significantly outperforming the overall DAX figure of 17.4% and the NASDAQ Biotechnology Index at 12.6%. Heidelberg Pharma's shares reflected this trend. Despite shedding value in the second quarter due to profit taking and weak demand, they closed up 16.2% at the end of June.



The average daily trading volume in the first six months of 2019 was 9,095 shares, down significantly from the previous year's figure of 34,118 shares. Heidelberg Pharma's market capitalization on 30 June 2019 was €78.84 million (30 June 2018: €75.67 million).

Key share figures as of the end of the first half-year	1 Jan. to 30 June 2019	1 Jan. to 30 June 2018
Market capitalization in € million	78.84	75.67
Number of shares issued	28,155,630	28,129,782
Closing price (XETRA) in €	2.800	2.690
High¹ in €	3.390 (17 April 2019)	3.980 (15 Jan. 2018)
Low¹ in €	2.350 (02 Jan. 2019)	2.580 (08 June 2018)
Volatility (260 days¹) in %	45.514	51.534
Average daily trading volume¹ in shares	9,095	34,118
Average daily trading volume¹ in €	27,562.51	108,736.57

¹ All stock exchanges Source: Bloomberg

Shareholder structure of Heidelberg Pharma AG	
Dietmar Hopp, parties related to him and companies controlled by them ¹	74.99%
UCB	4.02%
Corporate bodies (held directly)	0.78%
Free float	20.21%

¹ Also includes dievini Hopp BioTech holding GmbH & Co. KG and DH-Holding Verwaltungs 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.

Annual General Meeting 2019

The Annual General Meeting of Heidelberg Pharma AG took place on 21 May 2019 at the Studio Villa Bosch Conference Center, Wolfsbrunnenweg 33, Heidelberg/Germany. All information is available at https://heidelberg-pharma.com/en/press-and-investors/annual-general-meeting.



Financial calendar 2019

Date	Type of report/event
10 October 2019	Interim management statement on the first nine months of 2019

Date	Upcoming conferences and events in H2 2019	Venue
23–26 September 2019	Baader Investment Conference	Munich
8–11 October 2019	World ADC Congress	San Diego
15–17 October 2019	European Antibody Congress	Basel
11–13 November 2019	BIO-Europe	Hamburg
18–22 November 2019	PEGS Europe	Lisbon
25–27 November 2019	German Equity Forum	Frankfurt/Main
7–10 December 2019	ASH 2019 Annual Meeting	Orlando

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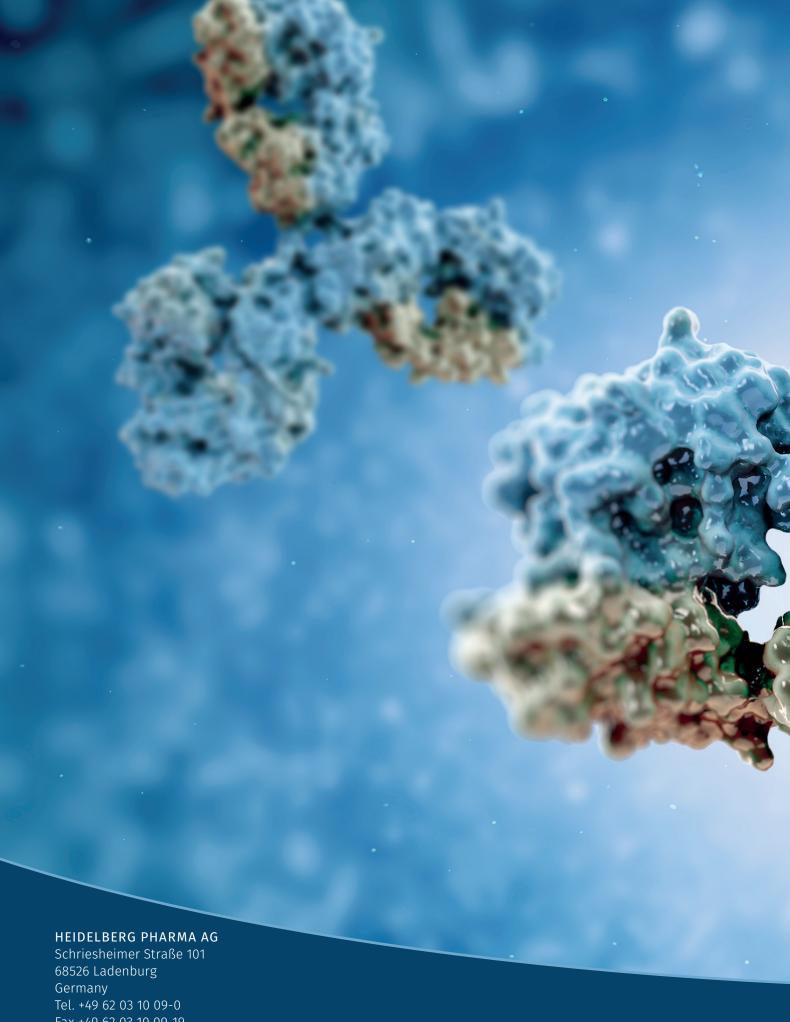
www.heidelberg-pharma.com

Responsible for the project: Sylvia Wimmer, Heidelberg Pharma AG, and Katja Arnold, MC Services AG

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

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

As of: 11 July 2019



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