

ANNUAL REPORT 2012

Retaining value –
creating opportunities

RX
DX
Cx

Key figures

	2012 € million	2011 € million	2010 € million
Earnings			
Sales revenue	16.1	9.9	0.0
Other income	1.7	1.8	1.3
Operating expenses	(26.8)	(25.1)	(24.4)
Operating result	(8.9)	(13.4)	(23.1)
Earnings before tax	(9.4)	(13.9)	(23.1)
Net loss for the period	(9.4)	(13.9)	(23.1)
Earnings per share in €	(0.36)	(0.67)	(1.38)
Balance sheet at end of period			
Total assets	37.7	20.8	5.6
Cash and cash equivalents	23.4	3.4	1.9
Equity	19.9	(4.5)	(1.3)
Equity ratio ¹ in %	52.8	(21.7)	(23.2)
Cash flow statement			
Cash flow from operating activities	(5.1)	(9.0)	(19.3)
Cash flow from investing activities	(0.2)	0.6	(0.5)
Cash flow from financing activities	25.3	9.8	18.2
Employees (number)			
Employees as of 30.11. ²	128	124	80

¹ Equity/total assets

² Including Heidelberg Pharma (from March 2011) and members of the Executive Management Board

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

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

DEC

JAN

FEB

DECEMBER 2011

WILEX Inc. lists CAIX IHC kit as an in vitro diagnostic with the FDA

JANUARY 2012

Phase I trial completed with MEK inhibitor WX-554 and healthy volunteers

FEBRUARY 2012

Rights issue for EUR 9.9 million completed
Grant by the BMBF for WX-037 as part of the „m4 Leading-Edge Cluster Initiative“

MILESTONES

Contents

	Page
>About us	
About us	2
WILEX portfolio	3
Values	
Letter to the shareholders	4
Report of the Supervisory Board	6
Investor relations	10
Combined management report	
Business and general parameters of the WILEX Group	14
Economic conditions	16
Business performance in 2012	21
Non-financial performance indicators and contracts	29
Earnings, financial position and net assets of the Group	34
Corporate governance	44
Report on risks and opportunities	56
Events after the reporting period	69
Anticipated developments	69
Disclosures on the annual financial statements of WILEX AG (HGB)	73
Consolidated financial statements	
Consolidated statement of comprehensive income	80
Consolidated balance sheet	81
Consolidated statement of changes in equity	82
Consolidated cash flow statement	83
Consolidated notes	84
Responsibility statement of the Executive Management Board	137
Auditors' report	138
Glossary	139
Publishing information	

 = Glossary (term marked in red) or cross reference

 = Internet reference

MAR

APR

MAY



APRIL 2012

MAY 2012

Walter Carney returns to
WILEX Inc. as Chief Scientific
Officer

First patient trial (Phase Ib/II)
with MEK inhibitor WX-554 started

Annual General Meeting 2012

About us

WILEX is a biopharmaceutical company focused on oncology with an attractive portfolio of diagnostic and therapeutic products for the detection and the targeted treatment of various types of cancer. Our therapeutic product candidates are based on antibodies and small molecules.

As a disease, cancers are as diverse as the people they affect. This is why we want to take the approach of personalised medicine and with our portfolio help to ensure that cancer patients receive a thorough diagnosis and a targeted, tailor-made course of treatment that is effective and as well tolerated as possible.

The Group's business activities are organised in three segments: Therapeutics (Rx), Diagnostics (Dx) and Customer Specific Research (Cx). In addition to the development of product candidates at WILEX AG, the US subsidiary WILEX Inc. markets oncological biomarker tests that can be used as companion diagnostics in future clinical trials and for therapy monitoring. The subsidiary, Heidelberg Pharma GmbH, offers an innovative technology platform for therapeutic antibody drug conjugates and operates a preclinical service business within the scope of Customer Specific Research.

WILEX's customers and partners include international pharmaceutical and biotech companies as well as important scientific research institutions and clinics.

◀	JUN	JUL	AUG
JUNE 2012 MESUPRON® again demonstrates proof of concept in Phase II breast cancer trial	JULY 2012 Prometheus pays USD 17.5 million under the licence agreement Oncologic Drugs Advisory Committee (ODAC) delivers positive vote on diagnostic imaging	AUGUST 2012 Combined capital increase against cash and contributions in kind for a total of EUR 23.9 million successfully executed	

WILEX portfolio

Segment	Product	Technology	Research + preclinical	Clinical development phase			Market	Partners
				I	II	III		
Rx	RENCAREX®	Antibody (therapeutic)	Non-metastatic ccRCC ¹					Esteve (Southern Europe) Prometheus (USA)
	MESUPRON®	uPA inhibitor	Pancreatic cancer Breast cancer					
	WX-554	MEK inhibitor	Cancer					UCB (worldwide)
	WX-037	PI3K inhibitor	Cancer					UCB (worldwide)
	2 Antibodies		Cancer					UCB (worldwide)
Dx	REDECTANE®	Antibody (diagnostic)	Renal mass ²					IBA (worldwide)
	Oncogene Science diagnostic tests	ELISA/IHC	HER2/neu, CAIX, uPA, PAI-1, EGFR, TIMP-1					Immundiagnostik (Germany/Austria/ Switzerland) Genediagnostics (China) IBL-America (USA)
Cx	ADC platform	Antibody drug conjugates	Cancer					Different pharma partners ³

¹ The Phase III ARISER trial in the adjuvant therapy of clear cell renal cell carcinoma missed the trial endpoint.

² Clear cell renal cell carcinoma

³ Not disclosed

SEP

OCT

NOV

SEPTEMBER 2012

Professor Andreas Pahl is appointed Chief Scientific Officer of Heidelberg Pharma

Dr Jan Schmidt-Brand is appointed Chief Financial Officer of WILEX AG

OCTOBER 2012

Agreement with the FDA on the further development of REDECTANE®

Phase III ARISER study with RENCAREX® misses trial endpoint

NOVEMBER 2012

Restructuring programme initiated

MILESTONES

Letter to the shareholders

Dear shareholders,

For WILEX, the past financial year was a year of major challenges and significant events, including an extremely painful setback in the clinical development of our therapeutic antibody RENCAREX®, which unfortunately had serious repercussions for our share price, our enterprise value and our entire organisation. As a consequence, we were forced to lay off around 25 % of our workforce in Munich. These events cast a shadow over the otherwise quite respectable results for the 2012 financial year, which saw operational advances in our Rx (Therapeutics), Dx (Diagnostics) and Cx (Customer Specific Research) business segments.

Rx: ARISER trial with RENCAREX® misses endpoint – MESUPRON® delivers positive data

The question why our Phase III ARISER project in adjuvant therapy of renal cell carcinoma did not reach the trial endpoint has been at the forefront of our minds ever since the data were released in October 2012. Since publication of the data, the Company, its scientific advisers and service providers have conducted a detailed analysis of all processes in the trial, examined the implementation of the study in the trial centres and scrutinised the quality of the data collection and evaluation. We did not identify any irregularities in the execution of the trial and can confirm that the trial was well conducted and managed.

As regards scientific follow-up work, we decided to conduct further analyses of biomarkers and subgroups. These results could shed light on the opening question but unfortunately will not change the outcome of the ARISER trial. While this Phase III trial produced important scientific findings, it failed to meet our therapeutic and commercial expectations.

Notwithstanding the dramatic events of the fourth quarter, important operational advances were also made in our therapeutic portfolio that we would like to mention. With our uPA inhibitor MESUPRON® we presented clinical data from a proof of concept study in breast cancer showing an improvement in disease-free survival in subgroups. Our ongoing trials are also advancing well. The MEK inhibitor WX-554 is currently in a Phase Ib/II trial for cancer patients with different tumours, while clinical development is being prepared for the PI3K inhibitor WX-037. We attribute great medical significance to these two candidates, especially when used in combination.

Dx: Clear regulatory pathway for REDECTANE® following positive ODAC recommendation

In the 2012 financial year, the delays in the regulatory process once again presented us with considerable challenges, which we were nevertheless able to master. Back in 2010, the diagnostic antibody REDECTANE® had already achieved good results in a Phase III trial in clear cell renal cell carcinoma. The discussions on the data and the regulatory pathway for marketing approval with the FDA threw up a number of issues requiring clarification. It was not until the 2012 financial year was drawing to a close that we, in agreement with the FDA, were able to clarify the further development pathway for regulatory approval. The FDA is following a positive recommendation from an important committee of experts, the ODAC (Oncologic Drugs Advisory Committee). We are currently preparing the protocol for a second trial with REDECTANE® with the goal of confirming the diagnostic performance of our product candidate, which could lead to regulatory approval.

The business with the Oncogene Science in vitro diagnostic tests, which is incorporated into our subsidiary WILEX Inc., is making good progress from an organisational and regulatory perspective. So far, the economic results have fallen short of our expectations, however. On the strength of international partnerships for Germany/Austria/Switzerland, China and the United States that were recently announced in 2013, we hope to inject momentum into the sales activities of WILEX Inc.

Cx: Growth in services and ADC technology

The individual subsidiaries' responsibility for the Group's overall earnings increased in the past financial year. Our subsidiary Heidelberg Pharma is already living up to this growing responsibility. Progress is being made at an operational level as well as in revenue and earnings. Both the services and the technology platform for therapeutic antibody drug conjugates managed in this segment are to be marketed in collaboration with pharmaceutical and biotechnology partners. Meanwhile, talks with potential pharmaceutical partners are proceeding unnoticed. Quiet efficiency is the approach taken in this business.

Financials: Further improvements in sales revenue and earnings

The WILEX Group improved its financial figures for sales revenue, earnings and cash flows once again in 2012. The payments made by our partner Prometheus gave a particularly strong boost to sales revenue and cash flows. At the same time, we succeeded in strengthening our balance sheet and extending our cash reach through the capital measures executed in February and August. We ended the year with cash and cash equivalents of over €23 million. This currently guarantees our ability to act into the second quarter of 2014 and we will be able to reach key milestones with our own resources.

Outlook: Our business model will be the basis for new growth

Our Company now has a broader basis than it had prior to the acquisition of our subsidiaries. Although the operational milestones reached by the Rx, Dx and Cx segments in 2012 cannot make up for the massive drop in our enterprise value following publication of the ARISER trial data, they provide support and supply important building blocks for new growth. Last year in particular, we determined that the portfolio structure and the business segments that were newly established in 2011 provide a more robust starting point and a more flexible commercial basis, enabling us to compensate for and alleviate setbacks in individual segments. For this reason, we are cautiously optimistic about the new financial year, in which we are expecting important news from our therapeutic and diagnostic portfolio with the Phase Ib/II data on WX-554 and decisions on the trial design for REDECTANE®. One of the focal points of the year will be the partnering activities for our product candidates and our ADC technology.

We would like to extend warm thanks to our shareholders and business partners for their continuing support and confidence in us. Special thanks also go to all our employees for their contribution.

Munich, 26 February 2013

Yours sincerely,
For the Executive Management Board



Professor Olaf G. Wilhelm
Chief Executive 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 in managing 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. 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). Without exception, all documents that were prepared by the Executive Management Board and the respective departments and submitted to the Supervisory Board were examined. 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, strategy implementation and achievement of goals, development and management of WILEX AG and its subsidiaries. The Chairman of the Supervisory Board, in particular, regularly discussed the strategy and reviewed the progress of business with the Chairman of the Executive Management Board and the other members of 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 sub-committees.

Main topics at the meetings of the Supervisory Board in the 2012 financial year

In the 2012 financial year (1 December 2011 to 30 November 2012), the Supervisory Board met for eight regular meetings. All members of the Supervisory Board attended at least half of the meetings. In addition, several conference calls were conducted as part of the regular monitoring and advisory activities with regard to the Executive Management Board.

In the 2012 financial year, the Supervisory Board dealt in particular with the following topics requiring its approval:

- The budget and the corporate goals for the 2012 financial year;
- Increase in share capital and determination of the final scope of the rights issue against cash in February 2012;
- Increase in share capital and determination of the final scope of the combined capital increase against cash and contributions in kind in August 2012;
- Decision on calling a further payment under the licence agreement with Prometheus Laboratories Inc. (Prometheus), San Diego, CA, USA, for out-licensing of the US marketing rights to RENCAREX®;
- The director's contracts of Professor Olaf G. Wilhelm, Peter Llewellyn-Davies and Dr Paul Bevan; and
- The appointment of Dr Jan Schmidt-Brand as the Company's new Chief Financial Officer.

The full Supervisory Board approved all of these actions following in-depth reviews and discussions. The Supervisory Board followed the recommendation of the Compensation Committee regarding the reappointment of

Professor Olaf G. Wilhelm and resolved to extend the term of office of Professor Wilhelm, renew his contract and adjust his compensation accordingly. This applies in equal measure to the reappointment of Dr Paul Bevan as a member of the Executive Management Board in December 2012. The Supervisory Board also concurred with the recommendation by the Compensation Committee and appointed Dr Jan Schmidt-Brand as the Company's new Chief Financial Officer after Peter Llewellyn-Davies left the Executive Management Board of WILEX AG when his contract expired after six years of successful service on the Executive Management Board. Both the compensation system applicable to the members of the Executive Management Board and the adequacy of their compensation packages were reviewed in this connection and deemed to be appropriate.

The Supervisory Board was also 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.

In addition, the Supervisory Board approved the strategy for WILEX AG's research and development projects and its clinical programmes. It focused in particular on the clinical Phase III trials of REDECTANE® and RENCAREX®. The Supervisory Board was concerned in particular with the preparation and recommendation of the Oncologic Drugs Advisory Committee (ODAC) and the positive vote on diagnostic imaging as well as the results of the meeting with the FDA regarding the next regulatory steps for approval of REDECTANE® and a second trial of the diagnostic efficacy of REDECTANE®. Particular topics of discussion in the fourth quarter were the disappointing results of the Phase III ARISER trial with RENCAREX® for the adjuvant treatment of clear cell renal cell cancer (ccRCC) and the consequences of the recommendation by the Independent Data Monitoring Committee (IDMC) to discontinue the Phase III ARISER trial. The Supervisory Board deliberated on the proposal by the Executive Management Board on performing additional detailed analyses to better understand the results and, if necessary, develop further strategic options.

The Supervisory Board also monitored the ongoing development of the programmes that the Company took over from UCB under their strategic alliance. Here the focus was on the first Phase Ib/II trial of the oral MEK inhibitor WX-554.

The Supervisory Board was also regularly briefed on the business activities of the Company's two subsidiaries, Heidelberg Pharma GmbH and WILEX Inc. In the case of WILEX Inc., the focus was on broadening the customer base and negotiating distribution agreements for commercialising the HER-2/neu ELISA assay and the CAIX-IHC test. The focus at Heidelberg Pharma GmbH was on expanding its activities in preclinical contract research as well as on refining and marketing its technology platform for therapeutic antibody drug conjugates.

Corporate governance

The Supervisory Board together with the Executive Management Board decided on 7 February 2013 to implement the recommendations and suggestions of the German Corporate Governance Code ("GCGC") in part. The new joint Declaration of Conformity by the Executive Management Board and the Supervisory Board was adopted on the same day and is available on the [Company website](#) under the tab "Press + Investors > Corporate Governance > Declaration of Conformity". For more information on corporate governance at WILEX, please see the „Corporate Governance“ chapter of the Group management report.

 www.wilex.com

 Page 44

Conflicts of interest on the Supervisory Board

Any conflicts of interest affecting members of the Supervisory Board pursuant to Section 5.5 GCGC were disclosed to the remaining 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:

The Supervisory Board members, Professor Christof Hettich and Professor Friedrich von Bohlen und Halbach, are managing directors of dievini Verwaltungs GmbH, which in turn is the general partner of dievini Hopp BioTech holding GmbH & Co. KG, and did not participate in the Supervisory Board's deliberations or resolutions relating to the shareholder loan including interest granted by dievini Hopp BioTech holding GmbH & Co. KG as part of the combined capital increase of cash and contributions in kind.

The role of Professor Christof Hettich, the Chairman of the Supervisory Board, as partner of the Rittershaus law firm, which provides legal consulting services for the WILEX Group, has been identified as a further conflict of interest by the Supervisory Board. 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 some Supervisory Board members also hold positions on supervisory boards of other companies in the pharmaceutical and biotech sectors, none of these companies can be considered major competitors of WILEX, which complies with GCGC requirements.

Activities of the Committees

The Supervisory Board established three committees with the aim of ensuring efficient fulfilment of its responsibilities; each committee is responsible for preparing issues within its purview for the full Supervisory Board. At every Supervisory Board meeting, the respective committee chairmen report to the Supervisory Board on the work of their committee.

For reasons of efficiency, a joint Compensation and Nomination Committee was established, which covers both areas separately in its meetings. The Compensation Committee met two times in the 2012 financial year. The main focus of these meetings was on the target achievement for the 2011 financial year, determining performance targets for bonuses for the members of the Executive Management Board in the 2012 financial year, as well as the prolongation of director's contracts. It also prepared the renewal of the director's contract for Professor Wilhelm and a new director's contract for Dr Schmidt-Brand, and submitted it to the Supervisory Board for approval. The Nomination Committee met once and discussed the proposal to the Annual General Meeting to elect Dr Birgit Kudlek as a new member of the Supervisory Board.

The Audit Committee met seven times in the year under review. It dealt with the proposals for selecting the new auditor and recommended to the Supervisory Board that it propose to the Annual General Meeting to elect Deloitte & Touche, Wirtschaftsprüfungsgesellschaft, Munich, to serve as the auditor for the 2012 financial year. The Supervisory Board followed this recommendation. Deloitte & Touche GmbH Wirtschaftsprüfungsgesellschaft was elected by the Annual General Meeting on 25 May 2012 pursuant to the Supervisory Board's proposal and was subsequently commissioned by the Supervisory Board to audit the Company's annual financial statements for the 2012 financial year. The Supervisory Board obtained a declaration of the auditor's independence in advance in accordance with Section 7.2.1 of the GCGC. The Audit Committee also discussed the annual report for 2012 with the auditor, Deloitte & Touche Wirtschaftsprüfungsgesellschaft. The Audit Committee discussed the quarterly reports and the half-yearly report for 2012 with the Executive Management Board prior to publication. The Supervisory Board also dealt in depth with the Company's risk management system.

The Research and Development Committee held one meeting during the financial year just ended at which it dealt with the FDA's proposal for an Advisory Committee Meeting (ODAC) and the associated preparations. The further regulatory procedure for REDECTANE® was also discussed.

The Supervisory Board did not establish any other committees.

Adoption of the annual financial statements

The auditors, Deloitte & Touche GmbH Wirtschaftsprüfungsgesellschaft, have audited the combined management report, the annual financial statements of WILEX AG and the consolidated financial statements as of 30 November 2012, including the underlying accounting, and issued an unqualified audit certificate. The auditors conducted their audit in compliance with the generally accepted German standards for the audit of financial statements determined by the German Institute of Public Auditors (IDW). The combined management report, the annual financial statements of WILEX 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 (IFRS) as adopted by the EU, taking Section 315a of the German Commercial Code into account.

Both the aforementioned documents and the audit reports of Deloitte & Touche GmbH Wirtschaftsprüfungsgesellschaft were made available to all members of the Supervisory Board in good time and discussed in detail at the meetings of the Audit Committee on 23 January and 5 February 2013 as well as at today's financials meeting of the Supervisory Board in the presence of the auditors. The auditors reported to the Supervisory Board on the material results of their audit and 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 are suitable for identifying at an early stage any developments which may jeopardise 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 took note of the audit result and itself 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 concurs 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.

Recognition of commitment

The Supervisory Board would like to take this opportunity to thank the Executive Management Board and all employees of WILEX AG and its subsidiaries for the impressive commitment they showed in the 2012 financial year. It is due to their commitment that key clinical and business milestones were reached. Particular thanks go to the employees who conducted the ARISER trial in an exemplary manner and whom WILEX unfortunately had to let go after the failure to meet the endpoint of the trial. We wish these valued employees success in their new professional endeavours.

Munich, 26 February 2013

For the Supervisory Board



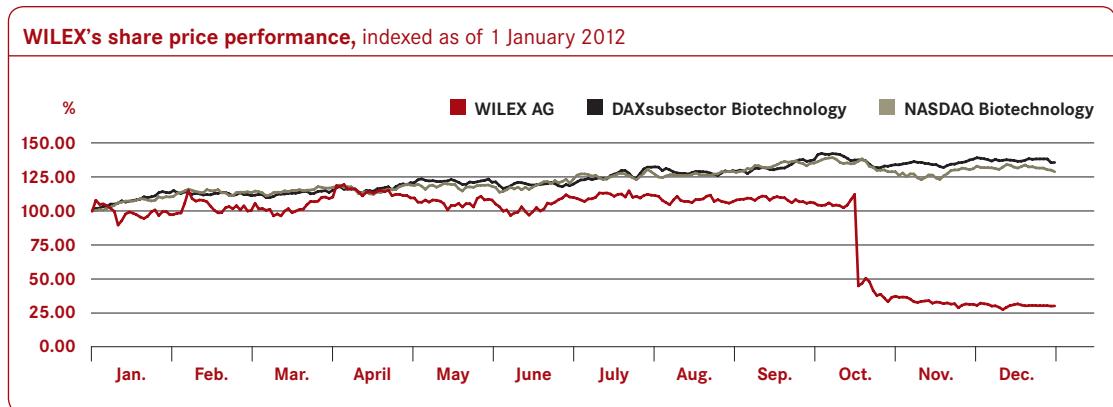
Professor Christof Hettich
Chairman of the Supervisory Board

Investor relations

Share price performance

The year 2012 was a very successful one for the German stock market and for biotechnology indices in particular. While the DAX climbed 29 % and the TecDAX rose by 21 %, the DAXsubsector Biotechnology Index gained a substantial 37 % after a weak 2011. The NASDAQ Biotechnology Index continued its strong performance of the preceding years, recording an increase of 30 %.

However, owing to the results of the ARISER trial, WILEX shares ended 2012 on a disastrous note. Starting 2012 at €3.43 and performing reasonably well, peaking at €4.13 in early April, the stock plummeted on the news that the endpoint in the Phase III trial with RENCAREX® had been missed. The shares were unable to recover the lost ground, closing the year at €0.97, down 72 % on their opening price.



Trading and liquidity

At 46,052 shares, the average daily trading volume of WILEX's shares in the 2012 financial year was up substantially from the previous year's level of 24,909 shares per day. Market capitalisation, however, at the end of November 2012 was €32.8 million and thus significantly lower than in the previous year (€80.4 million).

Key share figures as of the end of the reporting period	FY 2012	FY 2011	FY 2010
Number of shares issued	31,275,507	21,613,035	18,413,035
Market capitalisation in €million	32.80	80.40	91.70
Closing price (XETRA) in €	1.05	3.72	4.98
High ¹ in € (on 07.12.2011)	4.67	5.38	7.30
Low ¹ in € (on 23.11.2012)	0.88	2.88	3.35
Volatility (260 days; XETRA) in %	104.69	56.65	59.41
Average daily trading volume ¹ in shares	46,052	24,909	43,295
Average daily trading volume ¹ in €	108,152	103,222	214,046
Earnings per share in €	(0.36)	(0.67)	(1.38)

¹ All stock exchanges

Source: Bloomberg

General Meetings

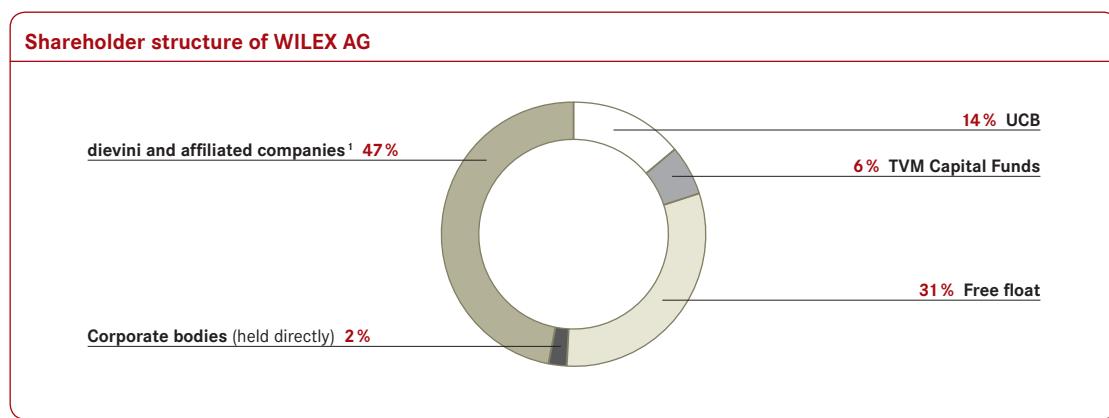
The Annual General Meeting of WILEX AG took place on Friday, 25 May 2012 in Munich. A total of 18,200,048 shares (corresponding to an equivalent number of votes) out of WILEX AG's share capital of € 24,814,963.00 (which is denominated in 24,814,963 no par value bearer shares) were present at the time of voting at the Annual General Meeting. This corresponds to 73.34 % of the Company's share capital.

The Annual General Meeting resolved to formally approve of the actions of both the Executive Management Board and the Supervisory Board; appoint Deloitte & Touche GmbH Wirtschaftsprüfungsgesellschaft as the new auditor of the financial statements; revoke the existing Authorised Capital 2010/II; and create new Authorised Capital 2012/I including an amendment of the Articles of Association to reflect this. Furthermore, Dr Birgit Kudlek was elected to the Company's Supervisory Board. All proposed resolutions were adopted by majorities of more than 99 %.

Capital measures

WILEX carried out a rights issue in February 2012 during which 3,201,928 new shares were subscribed at the subscription price of € 3.10 per share in accordance with subscription and oversubscription rights. Shareholders exercised subscription rights for a total of 2,417,077 new shares. The total number of WILEX shares issued increased to 24,814,963. WILEX AG received gross proceeds of approximately € 9.9 million from the rights issue.

A combined capital increase against cash and contributions in kind was carried out in August 2012 and a total of 6,460,544 new shares were issued. The subscription or purchase price was € 3.70 per share. In the form of a contribution in kind, the Company's shareholder dievini converted its existing claim to repayment from a loan extended to WILEX AG amounting to approximately € 7.8 million, including interest, into 2,100,337 new shares. A total of 4,360,207 new shares were subscribed in the cash capital portion, bringing the total gross issuing proceeds for the Company to around € 16.1 million. The total number of WILEX shares issued increased to 31,275,507.



¹ Comprises dievini Hopp BioTech holding GmbH & Co. KG, Curacyte AG and Verwaltungsgesellschaft Golf Club St. Leon-Rot mbH.
All figures are assumptions by WILEX 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 information	
Listed:	Regulated Market (Prime Standard)
Stock exchange symbol:	WL6/WL6G.DE/WL6.GR
WKN/ISIN:	661472/DE0006614720
Share capital:	€ 31.275.507,00
Authorised capital:	31.275.507 bearer shares of common stock
Designated sponsors:	Close Brothers Seydler Bank AG Equinet Bank
Investor relations contact:	Katja Arnold (CIRO) Tel.: +49 (0)89 41 31 38-126 E-mail: katja.arnold@wilex.com

Financial calendar

Date	Type of report/event
27 February 2013	Annual Report 2012, Financial press conference and analysts' meeting
11 April 2013	3-month Financial Report 2013
14 June 2013	Annual General Meeting 2013
11 July 2013	Half-yearly Financial Report 2013
10 October 2013	9-month Financial Report 2013

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Please see our [website](#) for the current financial calendar. The current list of conferences for 2013 is also available there.

COMBINED MANAGEMENT REPORT

 Contents	Page
1. Business and general parameters of the WILEX Group	14
2. Economic conditions	16
3. Business performance in 2012	21
4. Non-financial performance indicators and contracts	29
5. Earnings, financial position and net assets of the Group	34
6. Corporate governance	44
7. Report on risks and opportunities	56
8. Events after the reporting period	69
9. Anticipated developments	69
10. Disclosures on the annual financial statements of WILEX AG (HGB)	73

Combined management report for the WILEX Group and WILEX AG, Munich

for the financial year from 1 December 2011 to 30 November 2012

1. Business and general parameters of the WILEX Group

This management report is WILEX's first combined management report for the WILEX Group (IFRS) and WILEX AG (HGB).

Glossary

1.1. Corporate structure, locations and reporting

WILEX AG is a **biopharmaceutical** company focused on **oncology**. It develops highly specific **diagnostic agents** designed to detect cancer and **therapeutic agents** for treating tumour diseases. The Company was founded in 1997 by a team of physicians and cancer research specialists from the Technische Universität München (TUM). WILEX was converted into a stock corporation (Aktiengesellschaft) under German law in 2001 and Wilex AG (hereafter referred to as "WILEX AG") was recorded in the Commercial Register in the same year. WILEX AG has been listed on the Regulated Market (Prime Standard segment) of the Frankfurt/Main stock exchange since November 2006. WILEX AG is headquartered in Munich, Germany. The Company does not own property. Its offices and laboratories are located in rented premises.

WILEX AG founded its US subsidiary WILEX Inc. in October 2010. It is headquartered in Cambridge, MA, USA, and was established in accordance with the State of Delaware's General Corporation Law. It is represented by its Managing Directors, Professor Olaf G. Wilhelm and Dr Thomas Borcholte. WILEX Inc. does not own property. Its offices and laboratories are located in rented premises.

WILEX AG acquired all shares in Heidelberg Pharma AG (hereafter referred to as "Heidelberg Pharma") in return for WILEX shares in March 2011 upon the recording in the Commercial Register. Heidelberg Pharma AG was converted into a "GmbH" (limited liability company according to German law) effective 1 December 2011. The company's Managing Director is Dr Jan Schmidt-Brand. Heidelberg Pharma is domiciled in Ladenburg and does not own any property. Its offices and laboratories are located in rented premises.

Pursuant to Section 315a (1) German Commercial Code (Handelsgesetzbuch, HGB), WILEX AG submits its consolidated financial statements in accordance with the International Financial Reporting Standards (IFRS) adopted by the European Union. The IFRS consolidated financial statements comprise WILEX AG as the parent as well as WILEX Inc. and Heidelberg Pharma GmbH as subsidiaries for the full 2012 financial year (1 December 2011 to 30 November 2012). The previous year's comparative figures included Heidelberg Pharma from 17 March to 30 November 2011.

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

Applying IFRS 8 Operating Segments, WILEX has been reporting on three operating segments since 2011: Therapeutics (Rx), Diagnostics (Dx) and Customer Specific Research (Cx). WILEX also prepares segment reporting.

The WILEX Group had 128 employees (120 full-time equivalents) at the close of the financial year.

1.2. Business activities

The objectives of WILEX AG are the research, development, production, approval and marketing of diagnostic agents and drugs in the field of oncology, as well as the respective in-licensing and out-licensing of intellectual property rights. The Company's therapeutic product candidates comprise small **molecules** and special therapeutic **antibodies**. These form the basis of highly-specific diagnostic agents and patient-tailored therapies which the Company is developing clinically for subsequent marketing approval. At the time of preparing this

management report, the following product candidates were in development at WILEX AG: **REDECTANE®**, **MESUPRON®**, WX-554 and WX-037.

 **Glossary**

WILEX Inc. specialises in the manufacture of oncological **biomarker tests**, which it markets under the Oncogene Science brand. Its product portfolio includes **Enzyme-Linked ImmunoSorbent Assays (ELISA)** and **immunochemical (IHC)** assays. With the objective of supporting treatment regimens for cancer patients worldwide, WILEX Inc. offers research use only (RUO) and **in vitro** diagnostic (IVD) tests for measuring different biomarkers. These products, which are already available on the market, will be used to develop the promising **companion diagnostics** market, which could constitute an important factor in WILEX's success.

Heidelberg Pharma offers customer specific contract services in two fields. First, an innovative technology platform for therapeutic **antibody drug conjugates (ADCs)** is being utilised in the further development of antibodies. This ADC technology has the potential to improve the efficacy of many antibody-based therapies, including those currently on the market. Heidelberg Pharma intends to license this technology to partners on a per-customer basis as a means of achieving revenue growth in the short and medium term. Heidelberg Pharma also operates a service unit for **preclinical** work on **pharmacokinetics** and **pharmacology** in oncology and inflammatory diseases. The associated infrastructure and expertise are offered as a service to third parties, which are already generating revenue.

For detailed information regarding the products and the current status of clinical development, please see chapter 3, "Business performance in 2012". A summary of markets and competitors is contained in chapter 2, "Economic conditions".

 **Pages 21 and 16**

1.3. Management and control

In keeping with the dual management structure codified in German law, the Company is managed and controlled by both an Executive Management Board and a Supervisory Board. The Company's Executive Management Board and Supervisory Board cooperate closely. The Supervisory Board regularly advises and monitors the Executive Management Board with respect to its management of the Company. The Supervisory Board of WILEX is comprised of six members, in accordance with the Company's Articles of Association. Three committees have been established to enhance the Supervisory Board's efficiency: a joint Compensation and Nomination Committee, an **R&D** Committee and an Audit Committee. For detailed information on corporate governance, please see chapter 6, "Corporate governance".

 **Page 44**

1.4. Value-oriented corporate strategy

WILEX is committed to the interests of all significant parties associated with the Company. Patients, physicians, employees and shareholders are the central focus of the Company's strategic, value-driven management.

WILEX focuses on clinical indications for which there is a high unmet medical need and which could provide great benefits for patients. All of the product candidates undergoing research and development at WILEX AG are designed to enable better diagnostics and monitoring of various forms of cancer as well as specific treatment. To date, the research and development projects have also been financed from advance payments and milestone payments by development partners. Once product approval has been obtained, royalties will make a substantial contribution to the value chain. The acquisition and ongoing development of the oncology portfolio of **UCB** Pharma S.A., Belgium, expanded WILEX's product pipeline and established the basis for tapping into the associated revenue potential from both milestone and licence payments.

WILEX's business model has been broadened through the strategic acquisitions of Oncogene Science's business (via WILEX Inc.) and Heidelberg Pharma. The Oncogene Science biomarker tests manufactured and marketed by WILEX Inc. have expanded WILEX's diagnostic expertise and range of services. They also give WILEX exclusive access to licences and patents in key areas of its product development. The business activities of

 **Glossary**

Heidelberg Pharma also open up additional perspectives. Heidelberg Pharma intends to initiate new development projects and research alliances with partners in the pharmaceutical industry via its technology platform for antibody drug conjugates (ADC technology). Out-licensing will take place exclusively for specific **antigens** (biological target proteins). This will facilitate multiple alliances with various pharmaceutical and biotech companies, which may be concluded for different products and in different indications. Heidelberg Pharma's pre-clinical customer specific research has expanded WILEX's know-how in the field of ADC technology and generates continuous revenue through the services business.

All of this has broadened the WILEX Group's positioning and enables it to pursue different approaches to generating value. WILEX's strategic goal is to finance its expenses for research and development increasingly from its operating cash flow in the next years. Besides recurring revenue streams from subsidiaries' products and services, this is also due to the out-licensing of the portfolio of novel drug and diagnostic candidates for treating cancers successfully developed by WILEX in recent years.

1.5. Internal control system

Sales revenue, other income from licence agreements as well as operating expenses, reviewed at least once a month, are the key performance indicators of both WILEX AG and the WILEX Group. Particularly expenses related to the research and development activities of the projects constitute an important measure of performance. Expenses are still significantly higher than income. Hence the Company's average cash burn is a key financial indicator. The cash usage is defined as the average monthly cash flow from operating and investing activities during a specific period. The ratio of liquid funds to cash usage shows how long sufficient cash will be available.

Additional non-financial performance indicators are used to manage the Company. Patient-related indicators include clinical findings regarding the safety, tolerance and efficacy of the drug and diagnostic candidates being developed. WILEX measures the efficiency of its internal processes using for example, the progress of clinical trials compared to schedules and budgets. A stable equity base is considered a key indicator at WILEX AG.

 **Page 41**

The section entitled "Overall assessment of the financial year by the Executive Management Board of WILEX" in chapter 5, "Earnings, financial position and net assets of the Group", contains a qualitative and quantitative assessment of the Company's internal control system.

2. Economic conditions

2.1. Macroeconomic environment

Global economic output rose by about 3.2 % in 2012, thus falling short of projected growth and the previous year's figure (3.9%).¹ Growth is mainly driven by the emerging economies and the United States.

The German economy grew at a much slower pace in 2012 than in the two preceding years. Figures published by the Federal Statistical Office showed that GDP rose by just 0.7 % (previous year: 3.0%).² Due not only to sluggish euro zone demand but also to weaker sales markets, for example in China and Brazil.

In contrast, compared with the previous year, 2012 was a very satisfactory year on the stock exchange for many companies and most indices. By the end of the year, the DAX had gained 29 %, the TecDAX 21 % and the DAXsubsector Biotechnology Index nearly 37 %. Major listed German biotechnology companies in particular posted very strong gains on the back of their successful development and marketing activities. In contrast,

¹ International Monetary Fund, World Economic Outlook Update, January 2013

² Tagesschau.de, 15 January 2013

WILEX shares were trading almost 72 % lower at the end of December 2012 than at the beginning of the year, due to the announcement of the results of the **ARISER** trial.

 [Glossary](#)

 [Page 21](#)

2.2. Sector environment

According to the latest industry report from IMS Health, pharmaceutical spending in the coming years will jump from USD 956 billion in 2011 to as much as USD 1.2 trillion in 2016.³ IMS Health states that the biggest increase to up to USD 375 billion by 2016 is expected in what are known as the “pharmerging markets” (countries such as Brazil, Russia, India and China etc.). A growth rate of between 1% and 4% is anticipated for the United States in spite of the large number of patents expiring there within the next five years. Income generated from new drugs and the health care reform in the US will be the main drivers of this growth. Europe, which is being squeezed by all-encompassing savings and cost-cutting programmes, is likely to grow by just 1% to 2%.⁴

The higher mandatory discount, voluntary discounts given by manufacturers, expiring patents and stiffer competition have helped to push down outlay on drugs in Germany. In 2011, pharmaceutical spending decreased by around € 1.2 billion (a drop of 4% compared with 2010) to € 29.1 billion. The drop in total spend was principally induced by the reduction in pharmaceutical prices, mostly stemming from the discounts prescribed by law.⁵

Industry associations of biotechnology companies in Germany have also criticised the consequences of the new legislation and no longer consider the European markets to be traditional growth markets. They are calling for a reasonable adjustment of the economic conditions to make the medical biotechnology field more competitive.⁶ It is not just the legal framework but also the generally high risk inherent in drug development that presents the biotechnology industry with challenges. In addition, companies are still having trouble securing financing because there is very little venture capital available for the sector any more. Nevertheless, the industry association BIO Deutschland reports that the situation was better in 2012 than in 2011. In 2012, many small and medium-sized companies from the industry raised over € 240 million in rounds of private financing or through capital increases on the stock exchange. This represents an increase of around 50% in venture capital and around 26% in capital increases compared with 2011.⁷

2.2.1. Oncology

More than 12.4 million people worldwide were newly diagnosed with cancer in 2008, resulting in more than 7.4 million deaths.⁸ In Germany, more than 218,000 people died of cancer in 2011. The most common cancer deaths were caused by lung and bronchial cancer (42,972 cases), breast cancer (17,573 cases), colorectal cancer (17,161 cases) and pancreatic cancer (15,488 cases).⁹

WILEX's drug candidates focus primarily on three indications: renal cancer, breast cancer and pancreatic cancer.

Currently, around 273,500 new cases of renal cancer are diagnosed worldwide each year. The number of new cases will rise to over 460,000 annually by 2030.¹⁰ The highest rates occur in North America, the lowest in Asia and Africa. Clear cell renal cell cancer (ccRCC) is the most prevalent form of kidney cancer.

³ IMS Institute for Healthcare Informatics, The Global Use of Medicines: Outlook through 2016, July 2012

⁴ Ibid.

⁵ Verband Forschender Arzneimittelhersteller e.V. (vfa), August 2012

⁶ The Boston Consulting Group GmbH, Medizinische Biotechnologie in Deutschland 2012, June 2012

⁷ BIO Deutschland, 2012 Yearbook, November 2012

⁸ GLOBOCAN 2008, International Agency for Research on Cancer (IARC), latest available data 2008

⁹ Federal Statistical Office, February 2012

¹⁰ GLOBOCAN 2008, IARC, January 2012

Breast cancer is one of the most common forms of cancer among women. As a study by the Institute for Health Metrics and Evaluation of the University of Washington in 2011 showed, the incidence of breast cancer is rising significantly worldwide. At 1.6 million newly diagnosed cases, the number of patients with breast cancer in 2010 was double the figure for 1980.¹¹ The biggest increase was seen among women aged between 15 and 49 in developing countries. In the United States alone, some 230,480 new cases were diagnosed in 2011.¹² Ethnicity features heavily in the incidence of breast cancer, with Caucasian women most at risk, followed by African women. Women of Hispanic, Asian or Indian origin have a lower breast cancer risk.¹³

Pancreatic cancer is a particularly aggressive form of the disease. According to the Robert Koch Institute, the five-year survival rate for men is just 6.4%, compared with 7.6% for women. Every year, almost 280,000 people worldwide contract the disease, which most often affects men aged between 50 and 60. As there is no screening test like that for breast or prostate cancer, this type of cancer is usually only detected in an advanced, metastatic stage.

According to a survey recently published in the journal Lancet Oncology, the incidence of new cases of cancer could swell by 75% worldwide by 2030. Developing countries might witness an increase of as much as 90%.¹⁴ The massive surge in cancer rates is being fuelled by changing living conditions and the spread of the typical western lifestyle. This means that there is an increasing need for cancer therapies that are both effective and well tolerated.

According to a study by Global Industry Analysts Inc., the market volume for cancer therapies will continue to grow steadily over the next few years. The authors forecast a market volume of USD 225 billion by 2017.¹⁵ Targeted cancer therapies in particular will see rapid growth alongside conventional cancer therapies. Data-monitor is forecasting an annual growth rate of 13.7% and a market volume of up to USD 13.7 billion in 2014 in the seven largest pharmaceutical markets (the US, Japan, France, Germany, Italy Spain and the UK).¹⁶ This growth trend is nevertheless restricted somewhat by pricing in the euro zone as well as the focus of drug development companies on niche populations and the associated fragmentation of the market.

2.2.2. Therapies using monoclonal antibodies

Antibodies are part of the fastest-growing sector in the pharmaceutical industry. Based on a growth rate of 6.9% per year, it is estimated that revenue from antibodies will increase to over USD 63 billion per year by 2015.¹⁷ Demand for products used in the treatment of cancer and autoimmune diseases in particular will continue to rise.

Glossary

Therapies based on **monoclonal antibodies** are currently considered among the most promising areas of treatment in medicine. By 2017, the market for these powerful types of molecule is predicted to reach USD 31.7 billion, after growing at an annual rate of 10.6%.¹⁸ Sales figures will rise in both existing and developing markets, and particularly in the US, Japan, China and India.

¹¹ The Lancet: "Breast and cervical cancer in 187 countries between 1980 and 2010: a systematic analysis", October 2011

¹² American Cancer Society, Breast Cancer Facts & Figures 2011–2012

¹³ Division of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Health Promotion, November 2012

¹⁴ Lancet Oncology, Global cancer transitions according to the Human Development Index (2008–2030): a population-based study, August 2012

¹⁵ GIA, Cancer Therapies – Global Strategic Business Report, October 2011

¹⁶ Datamonitor, Market and Product Forecasts: Targeted Cancer Therapies 2011–21 – Eurozone price cuts impact targeted cancer therapies market, July 2012

¹⁷ Visiongain, 8th Monoclonal Antibodies-Conference, Examining advances in target identification, next-generation technologies & competition from biosimilars, May 2012

¹⁸ GBI Research, Monoclonal Antibodies Market to 2017 – Multiple Indication Approvals and the Potential for MAbs in Oncology and Autoimmune Diseases are Re-Shaping the Market, December 2011

WILEX AG examined in the **Phase III** ARISER trial whether **RENCAREX®**, which is based on the antibody **Girentuximab**, can prevent the occurrence of **metastases** in the indication clear cell renal cell carcinoma. The trial data from October 2012 did not show a significant benefit compared to **placebo**. As a result, this project is currently no longer pursued by the Company. So far, no drug has been approved by the **FDA** or the **EMA** for the **adjuvant therapy** of renal cell carcinoma. Numerous drugs including Torisel® from Wyeth, Sutent® from Pfizer, Nexavar® from Bayer/Onyx, Avastin® from Roche and Afinitor® from Novartis were approved in recent years for the treatment of advanced metastatic renal cancer.

 **Glossary**

2.2.3. Therapies using small-molecule compounds

Targeted therapies using small-molecule compounds present a potential option for cancer therapy. Numerous compounds for targeted therapies are currently in development.¹⁹ According to a recent report by Visiongain, this market will generate revenue of over USD 37.6 billion by 2016 and continue its solid growth up to 2023, propelled by the increasing demand for cancer therapies stemming from a rise in the number of cases.²⁰

 **Page 22**

To the Company's knowledge, the small-molecule candidate **MESUPRON®** is the first **uPA inhibitor** worldwide in a clinical **Phase II** programme. The positive final data from the Phase II trials in the pancreatic cancer and breast cancer indications further underscore the leading role of WILEX AG in the field of uPA inhibition and provide a solid foundation for the continued development of **MESUPRON®**.

 **Page 23**

WILEX AG is developing an **MEK inhibitor** under the name **WX-554**, for which a Phase Ib/II trial is currently under way. MEK stands for **MAPK/ERK kinase** or mitogen-activated protein kinase kinase and is a promising target for tumour therapy. Several pharmaceutical companies are currently involved in developing more than 20 MEK inhibitors. Ardea Biosciences Inc., for example, brought an MEK inhibitor (BAY 86-9766) for the treatment of liver cell carcinoma in combination with Sorafenib as well as for the treatment of advanced pancreatic carcinoma in combination with **Gemcitabine** into clinical Phase II. GlaxoSmithKline announced positive results for the MEK inhibitor Trametinib (GSK1120212) from a Phase III trial in advanced **malignant** melanoma at the beginning of 2012.

 **Page 23**

The substance **WX-037** is an inhibitor of the **PI3K** signalling pathway, which, like MEK, is a promising target for tumour therapies. More than ten companies (e. g. Novartis, Genentech/Roche and AstraZeneca) are working on roughly 30 PI3K product candidates in this area. The most advanced of these is the inhibitor developed by Gilead Sciences (GS 1101) for chronic lymphatic leukaemia. Almost all of the preclinical work for WX-037 has been completed in order to commence clinical development.

2.2.4. Therapies with antibody drug conjugates (ADCs)

Demand for new treatment alternatives based on antibodies and small molecules will remain high. Furthermore, innovative technologies such as antibody drug conjugates (ADCs) have opened up new perspectives. ADCs offer a highly interesting combination of a targeted approach and high efficacy and are now part of the development portfolios of a large number of pharmaceutical companies. The FDA approved Seattle Genetics' antibody drug conjugate Adcetris in 2011. Adcetris combines the antibody Brentuximab, which binds to lymphoma cells, with a cytostatic agent.²¹ The European Commission granted regulatory approval for Adcetris throughout the European Union in October 2012.

Another advanced ADC project is Roche's Trastuzumab-Emtansin (T-DM1), which demonstrated significantly longer survival of patients with **HER2** positive metastatic breast cancer in a Phase III trial. Genentech has filed

¹⁹ Markets and Markets, Market research report on small molecule targeted cancer therapies, April 2010

²⁰ Visiongain, Small-Molecule Targeted Cancer Therapies: World Market 2013 –2023, October 2012

²¹ Ärzteblatt.de: „FDA: „Bewaffneter“ Antikörper gegen Lymphome zugelassen“, August 2011

an approval application for this product candidate with the FDA and Roche will shortly file one with the EMA.²² Revenue from antibody drug conjugates is estimated to reach up to USD 2.3 billion in 2015.²³ Heidelberg Pharma has innovative, promising **ADC technology** that could participate in this growth market. Several research cooperation projects with third parties have already been started.

Page 26

2.2.5. Cancer diagnostics: monoclonal antibodies and in vitro diagnostics

Monoclonal antibodies are also used in diagnostic imaging as disease-specific contrast agents. The FDA has already approved five diagnostic monoclonal antibodies, four of which for cancer diagnosis.²⁴ For tumour diagnosis, imaging techniques such as positron-emission tomography (**PET**) – where radioactive substances are administered to render the tumour visible – play an increasingly important role. In the Company's view, the potential use for diagnostic purposes of the radiolabelled antibody **REDECTANE®** could greatly enhance the precision of renal cancer diagnosis and thus bring about significant changes in therapy monitoring. WILEX is not aware of a similar imaging procedure for diagnosing clear cell renal cell carcinoma.

Glossary

Page 24

The market volume for in vitro diagnostics was measured at USD 44 billion in 2011 and is expected to grow at an annual rate of 7.8% up to 2016. The United States accounts for the lion's share of this market (47%). Within Europe (market share: 31%), Germany, France and Italy are the largest markets for in vitro diagnostics. The market in Asia is dominated by China and India, which will show the highest growth rates up to 2016.²⁵

Page 25

In vitro diagnostics (IVD) are based on bioanalytical methods that identify biomarkers in blood or tissue. In vitro diagnostics determine which patients should be treated, how patients will respond to specific medical therapies (patient selection) and monitor both the treatment regimen and its outcome. They are becoming increasingly important especially in oncology. The budding era of personalised medicine is set to revolutionise the healthcare industry. Through an approach tailored to an individual, the combination of companion diagnostics with targeted therapies is expected to not only generate more successful treatment but also reduce health care spending. Companies such as Roche, Qiagen, Abbott Molecular and Siemens are the industry leaders in this field. In oncology, WILEX Inc. markets diagnostic tests under the **Oncogene Science** brand with the objective of supporting treatment regimens for cancer patients.

2.3. Legal and regulatory factors

As a biopharmaceutical company, WILEX AG operates in highly regulated markets. Drugs are subject to approval by the Food and Drug Administration (FDA) in the United States and the European Medicines Agency (EMA) in the European Union, and by other national regulatory and supervisory authorities.

Before marketing approval for a drug is granted, the regulatory authorities require comprehensive preclinical and clinical trials (subject to strict criteria) to be conducted for each indication. In the United States, a clinical trial can only be conducted after the FDA has issued an **Investigational New Drug (IND)** status. In the European Union, an **Investigational Medicinal Product Dossier (IMPD)** for the drug must be submitted in accordance with the guidelines for clinical studies to obtain approval for clinical trials (**Clinical Trial Application, CTA**). The manufacturer and the supplier of the substances must be certified in accordance with Good Manufacturing Practice (GMP).

For a new drug to be granted marketing approval, an application must be compiled containing the results of all preclinical and clinical trials as well as other information pertaining to the drug.

²² Roche press release: „Neue Daten der Phase-III-Studie EMILIA mit Trastuzumab-Emtansin (T-DM1) von Roche zeigen signifikant verlängertes Überleben von Patientinnen mit HER2-positivem metastasierendem Brustkrebs“, August 2012

²³ Informa Life Sciences, www.bioportfolio.com, June 2012

²⁴ The Oncologist: „Immuno-PET: A Navigator in Monoclonal Antibody Development and Applications”, van Dongen et al., November 2007

²⁵ Markets and Markets, „In-vitro Diagnostic (IVD) Market (Applications, End-users & Types), Trends & Global Forecasts (Major & Emerging Markets – G7, Japan & BRIC) (2011–2016)”, January 2012

3. Business performance in 2012

3.1. Research and development of the product candidates

WILEX has an attractive portfolio of diagnostic and therapeutic product candidates. Via its subsidiaries WILEX Inc. and Heidelberg Pharma, WILEX is now also active in the areas of in vitro diagnostic tests, preclinical contract research and ADC technology. WILEX started reporting on three operating segments with the 2011 half-yearly report: Therapeutics (Rx), Diagnostics (Dx) and Customer Specific Research (Cx).

3.1.1. Therapeutics (= Rx)

3.1.1.1. RENCAREX® – therapeutic antibody

RENCAREX® (INN: Girentuximab) is a (**chimeric**) monoclonal antibody made from human and murine genetic sequences that binds to a tumour-specific antigen (carbonic anhydrase IX or “**CAIX**”). This antigen is expressed in several types of cancer but is generally not present in healthy tissue. The fact that the antibody binds to the antigen makes the tumour visible to the endogenous immune system such that natural killer cells can bind to destroy the tumour. CAIX is also present in renal, bladder and colon cancer, for instance.

 Glossary

Renal cell cancer, or RCC, is the most common type of kidney cancer and accounts for more than 90% of malignant kidney tumours. Two-thirds of RCC patients with no evidence of metastases at the time of first diagnosis have a high risk of relapse within a few years after surgery. WILEX AG developed the product candidate RENCAREX® with the aim of preventing metastases (adjuvant therapy). So far, no drug has been approved by the FDA or the EMA for the adjuvant therapy of this form of renal cell carcinoma.

RENCAREX® was tested in the **double-blind**, placebo-controlled Phase III trial for adjuvant therapy (Adjuvant RENCAREX® Immunotherapy trial to Study Efficacy in non-metastatic Renal cell carcinoma, “ARISER trial”) and failed to meet the primary endpoint. The final analysis performed in October 2012 showed no improvement in median disease-free survival (approximately 72 months) following treatment with RENCAREX® compared with a placebo.

The ARISER trial had enrolled 864 patients who had either the whole kidney or the diseased part of the kidney removed and who had no detectable metastases after surgery. Half of the patients received RENCAREX® while the other half received a placebo drug. In 2012, the data from all included patients were analysed by independent radiologists and were then transferred to a database by an external service provider after having been blinded and quality-checked. The final analysis was carried out at the service provider and communicated to the **IDMC** members in October 2012. After presenting the final data to the Executive Management Board and the partners, the IDMC recommended terminating the Phase III ARISER trial because the endpoint had not been reached.

The Executive Management Board of WILEX AG initiated other intensive analyses of the unblinded data, which showed that the patients had been included in the trial in accordance with the study protocol and that there were no indications of errors or discrepancies within the study. One reason for the negative study result was that the patients in the placebo group showed a considerably longer median disease-free survival time than expected based on previously available scientific data.

In December 2012, WILEX AG announced that it was discontinuing its development of RENCAREX® for adjuvant therapy of clear cell renal cell carcinoma. On the basis of detailed evaluations of subgroups and biomarkers, WILEX is currently testing to what extent the properties and strengths of the antibody Girentuximab could be interesting for third parties in other indications or other applications.

 Glossary

3.1.1.2. MESUPRON® – oral uPA inhibitor

WILEX AG is developing a substance called MESUPRON® (INN: Upamostat) under the uPA programme to inhibit the Urokinase **Plasminogen Activator (uPA) system**. The uPA system seems to play a key role in tumour cell invasion and **metastasis**, as well as in **primary tumour** growth, of various **solid tumours** including breast, ovarian, gastric, colon and pancreatic cancer. The uPA programme of WILEX can be considered a promising new **non-cytotoxic** approach in cancer therapy to specifically block tumour metastasis in solid cancers.

The tumour-associated proteolytic factor uPA and its inhibitor **PAI-1** enables doctors to predict the statistical likelihood of a patient's survival: Patients whose tumours exhibit high levels of uPA/PAI-1 have a statistically lower chance of survival than patients whose tumours exhibit low levels of uPA/PAI-1. This conclusion resulted from a meta-analysis of 18 different European studies involving 8,377 patients which examined survival times relative to the uPA/PAI-1 level in a tumour. uPA and its inhibitor PAI-1 are the only tumour biological factors to have achieved the highest "**level of evidence**" (LOE1) in terms of their prognostic significance. The determination of the uPA/PAI-1 level in a breast cancer patient's primary tumour was incorporated into the treatment guidelines of the American Society of Clinical Oncology (ASCO) in 2007.

With MESUPRON®, WILEX AG developed an **oral uPA/serine protease** inhibitor designed to block the activity of tumour-relevant serine proteases such as uPA, plasmin and **thrombin**. In the Company's view, MESUPRON® was already successfully tested in a Phase II study (proof of concept) in the pancreatic cancer indication in 2010.

Data for the Phase IIa clinical trial with MESUPRON® in metastatic, HER2 **receptor** negative breast cancer in first-line treatment were published in June 2012. The objective of the study was to evaluate the efficacy of the combination of 200 mg of MESUPRON® and Capecitabine compared to Capecitabine alone by assessment of progression free survival (PFS). The study also evaluated the objective response rate, overall survival, safety and tolerance as well as pharmacokinetics. Patient recruitment for the **randomised**, double-blind study was completed in May 2011, with 132 patients (n = 132) being enrolled in 20 centres in five countries (Belgium, Brazil, Germany, Israel and the USA).

In the total study population (intent to treat; ITT), MESUPRON® led to a modest increase of median progression-free survival from 7.5 months in the control group to 8.3 months with the **combination therapy**. The tumour response rate in the control group was 9 %. Co-administration of MESUPRON® 200 mg almost doubled the response rate to 17 %. The combination therapy proved to be safe and well tolerated. Pharmacokinetic analysis demonstrated no drug-drug interactions between MESUPRON® and Capecitabine.

Breast cancer is a heterogeneous disease. To test whether MESUPRON® also shows efficacy in a more homogeneous patient population two subgroups were evaluated which had sufficient numbers of patients to allow separate analysis: In the subgroup of patients who were Caucasian (n=109), median PFS improved from 7.5 months in the control group to 9.1 months in patients treated with MESUPRON®. In the other subgroup of patients (n=95) who had received adjuvant **chemotherapy** following the primary diagnosis of breast cancer, PFS improved from 4.3 months in the Capecitabine group to 8.3 months in the MESUPRON® combination group.

Achieving an improvement in progression-free survival and meeting the secondary objectives (objective response rate, safety and tolerability as well as pharmacokinetics) in this proof-of-concept study successfully confirmed that MESUPRON® could play an important role in cancer therapy. The trial data were presented at the San Antonio Breast Cancer Symposium in December 2012.

The goal is to sign a licence agreement with a partner for MESUPRON® and decide the further development strategy together with the future partner.

3.1.1.3. WX-554 – oral MEK inhibitor

WX-554 is an inhibitor of mitogen-activated protein kinase (MEK), which has been shown to play a key role in signal transduction. Mitogens are proteins that are linked to a multitude of biological processes such as cell division, cell differentiation and cell death. The MEK signalling pathway is **overexpressed** in more than 30% of cancers, resulting in uncontrolled cell growth and proliferation.

 **Glossary**

The small-molecule MEK inhibitor WX-554 was acquired from UCB in the preclinical stage and brought to clinical development during the 2009 financial year. The first **Phase I** trial with the **intravenously** administered substance WX-554 was successfully completed in the summer of 2010. WILEX started a second Phase I trial in healthy volunteers in September 2011 – this time involving the orally administered agent WX-554. This trial was completed in January 2012. The study tested three increasing dose levels of WX-554, which proved to be safe and well tolerated.

A Phase Ib/II dose escalation study in cancer patients was initiated in April 2012 within the Experimental Cancer Medicine Centre (ECMC) network in the UK. This open-label trial investigates the safety, pharmacokinetics, **pharmacodynamics** and clinical activity of WX-554 in patients with solid tumours. The first part of the study serves to confirm the biologically effective dose by way of a dose escalation. This is followed by the second part in which this dose is administered primarily to patients with MEK pathway relevant mutations to investigate clinical activity. The plan is to complete patient recruitment for the second part by the end of 2013 and to present data in the second half of 2014.

3.1.1.4. WX-037 – PI3K inhibitor

Another project acquired from UCB is a small-molecule PI3K inhibitor, for which the drug candidate WX-037 was selected as the lead compound. The phosphatidylinositol-3-kinase/protein kinase (PI3K) signalling pathway sends a “growth” signal to the nucleus of a tumour cell. It has also been shown that mutations of the PI3K signalling pathway are present in many types of cancer. Identifying an inhibitor for the PI3K signalling pathway is thus of therapeutic interest.

WX-037 is in preclinical development. In the financial year just ended, several preclinical trials concerning **toxicology**, pharmacology and pharmacokinetics were conducted and the process for producing WX-037 in capsule form was developed.

With the WX-037 project, WILEX AG is participating in the m4 Personalised Medicine and Targeted Therapies initiative of the Munich-based m4 Biotech Cluster, prize winners of the “Leading-Edge Cluster” competition run by the Federal Ministry of Education and Research (**BMBF**). WILEX AG is eligible to receive funding of up to €2.6 million from the BMBF for the preclinical and clinical development of the PI3K inhibitor since 2012. Within the project, WX-037 will be tested in preclinical models as a monotherapy and in combination with the MEK inhibitor WX-554 before being transferred to clinical development in cancer patients.

3.1.1.5. Preclinical and research

Two of the three antibody-based projects acquired from UCB are currently in the research phase. The third project is currently not being pursued. The aim was to identify a specific antibody that binds to each new target structure. The as yet unpublished molecular targets of the antibody-based projects play different roles in the spread of cancer or are overexpressed on tumour cells of various carcinomas. They could, however, also be developed in other indications.

3.1.2. Diagnostics (= Dx)

3.1.2.1. REDECTANE® – diagnostic antibody

Even modern imaging procedures such as computer tomography or MRI scans are unable to provide a clear indication of whether a kidney tumour is benign or malignant. Satisfactory evidence can only be obtained by means of a histological examination after surgery when either the whole kidney or the diseased part of the kidney has been removed. The most aggressive **phenotype**, clear cell renal cell carcinoma, occurs in about 65% of patients with kidney cancer. In WILEX's view, the ability to diagnose aggressive clear cell renal cell carcinoma prior to surgery represents a significant medical need.

REDECTANE® (INN: 124I-Girentuximab) is a radiolabelled form of the antibody Girentuximab, which binds to the antigen CAIX on clear cell renal cell carcinoma. Accumulation of this antibody in tumour tissue can be visualised by means of positron emission tomography (PET). Additional information provided by computer tomography (CT) can be used to localise the accumulation of the antibody.

The antibody-based radiopharmaceutical REDECTANE® is designed to support physicians in diagnosing renal cancers. Determining that no clear cell renal cell cancer is present constitutes an important goal. This could fundamentally change therapy planning for renal cancer patients and avoid potentially unnecessary surgery. Furthermore, REDECTANE® may also prove suitable for monitoring response to treatment and for diagnosing other kinds of tumours.

In the Phase III **REDECT** trial, which was completed in 2010, 226 patients with suspected renal cancer were examined prior to surgery by **PET/CT** scan using the imaging diagnostic agent REDECTANE® and CT alone. All patients then had surgery and either the whole kidney or the diseased part of the kidney was removed. Subsequently, all patients' PET/CTs and CTs were analysed to determine whether or not clear cell renal cell cancer was present. Histological examination of the surgically removed tumours was performed in parallel in order to review the analyses by the nuclear medicine specialists and radiologists. The final data showed that REDECTANE® can differentiate between clear cell and non-clear cell renal cell cancer and that PET/CT with REDECTANE® was clearly superior to CT.

The FDA suggested in the second quarter of 2011 that an outcomes-based study could produce additional evidence of the product's clinical benefit prior to submitting an application for approval. However, WILEX AG and its partner were of the opinion that such a trial could only be conducted as a Phase IV trial after market approval. This is why in the fourth quarter of 2011, a so-called Type C meeting took place at the FDA, in which the further development of REDECTANE® was outlined, including the scheduling of a second trial and the options to conduct an outcome-based study or a confirmatory study similar to the REDECT trial to confirm the candidate's diagnostic performance. The FDA suggested resolving the question of clinical usefulness and the resulting regulatory pathway with an FDA Advisory Committee.

The Oncologic Drugs Advisory Committee (ODAC) discussed in July 2012 whether the identification of a clear cell renal cell carcinoma through imaging provides clinically relevant information in patients with indeterminate renal masses. The Advisory Committee voted by 16 to 0 (1 abstention) in support of the imaging information being clinically useful. In September 2012, the FDA and WILEX discussed the recommendations of the ODAC and the development strategy for REDECTANE® at a further Type C meeting. The FDA subsequently confirmed in writing that the ODAC's positive recommendation had been accepted. Agreement was also reached with the FDA to conduct a confirmatory diagnostic performance study instead of an outcomes-based study. The FDA requires a second study to provide an additional indication of the diagnostic performance and safety of REDECTANE®. WILEX AG assumes that this trial must be successfully completed prior to approval.

WILEX AG is currently developing the protocol for this Phase III trial (REDECT 2) for submission to the FDA under a **Special Protocol Assessment (SPA)**. The details of the design of this trial will be released once the protocol has been approved and the trial started.

 **Glossary**

3.1.2.2. *In vitro* diagnostic tests

The subsidiary WILEX Inc. has been marketing biomarker tests in oncology since November 2010 under the brand name Oncogene Science with the aim of supporting treatment regimens for cancer patients. WILEX Inc. currently offers seven biomarker tests for a range of oncological target structures. These tests are intended to support not only scientists working in cancer research, but also drug researchers and developers at scientific institutions, universities and pharmaceutical companies.

Diagnostic tests are the basis for the future of personalised medicine – i. e. the provision of targeted and specific patient diagnostic options and therapies. The objective is to select patients with a disease for certain therapies based on specific medical parameters. This enables the classification of tumours that share morphological aspects, but behave differently as regards growth or dissemination (tumour aggression, metastasis), or differ in terms of therapeutic response. Patient selection that combines protein measurement with the corresponding bioanalytical methods may make it possible to predict whether and how patients will respond to a therapy and to monitor the progress of their treatment.

WILEX Inc. focuses on the production and marketing of ELISA and IHC assays. ELISA assays are used to detect antigens or proteins in the blood for instance. Measuring proteins in the blood and using the respective bioanalytical methods could make it possible to predict whether a patient will respond to a particular therapy. At the same time, the progression of the disease could be monitored. IHC assays are used for histological examinations of tissue.

In the “Research Use Only” (RUO) field, ELISA assays are available for CAIX, uPA, PAI-1, **EGFR** and TIMP-1. For patient use, the FDA-registered *in vitro* diagnostic tests HER2/neu ELISA and CAIX IHC are available. The HER2/neu ELISA assay is the only FDA-cleared ELISA assay for quantifying the blood serum HER2/neu level deployable as part of treatment management and therapy monitoring for women with metastatic breast cancer. The CAIX IHC assay for the identification of the CAIX antigen in tissue or cell samples is registered as a “Class I 510(k)-exempt medical device”. The protein CAIX is overexpressed in many types of cancer and its **expression** is induced by **hypoxia**, among others. In a variety of human cancers, tumour hypoxia is associated with an increased incidence of metastases.

WILEX Inc. successfully completed the process for awarding the CE marking for the CAIX ELISA test in November 2012 in accordance with the In Vitro Diagnostics Directive (98/79/EC). CE labelling is a passport for the distribution of products in the European Union.

At the end of November 2012, WILEX Inc. entered into an exclusive distributor agreement with Immundiagnostik AG, Bensheim, for the commercialisation of the Serum HER2/neu and CAIX ELISA tests in Germany, Austria and Switzerland. Immundiagnostik is an expert and highly experienced partner with an extensive product and services portfolio in the field of *in vitro* diagnostics. It has a large network and has forged partnerships with universities, hospitals, international research institutes and laboratory facilities for distribution of the biomarker tests.

3.1.3. Customer Specific Research (= Cx)

The Customer Specific Research segment comprises the two areas of business of Heidelberg Pharma.

3.1.3.1. ADC technology (antibody drug conjugates)

WILEX AG's subsidiary Heidelberg Pharma is expanding the WILEX portfolio with an innovative technology platform for therapeutic antibody drug conjugates (ADCs). The technology consists of using a chemical compound ([linker](#)) to crosslink a suitable antibody to a specific toxin (= ADC). The role of the antibody is to transport the crosslinked toxin specifically to – and then into – the cancer cell. After binding to the tumour cell, the ADC is taken up and releases the toxin within the cell. The released toxin then destroys the tumour cell without affecting healthy tissue.

The combination of antibody specificity and toxin efficacy offers new approaches to tumour therapy. New cytotoxic substances that break with conventional resistance patterns and destroy quiescent tumour cells that up to now could not be treated can be developed in this way for tumour therapy. Selective treatment of tumours using cytotoxins via specific antibody drug conjugates could thus enable much more effective treatment of tumours with acceptable side effects.

Heidelberg Pharma has set itself the goal of developing a platform for second-generation ADCs on the basis of a toxin with an innovative mode of action so as to cross-link these with suitable antibodies from cooperation partners. The second-generation ADCs will be characterised by improved efficacy, also as regards quiescent tumour cells, which are scarcely reached with existing standard therapies and contribute to tumour recurrence and resistance formation. There are indications that these ADCs could also be used to treat therapy-resistant tumours that no longer respond to standard chemotherapy or anti-tumour antibodies. Heidelberg Pharma carries out preclinical optimisation of the various linker structures, dosage and administration schemes for ADCs based on antibodies provided by the customer.

A joint licence agreement with the German Cancer Research Center (DKFZ) and Professor Heinz Faulstich (professor emeritus at the Max Planck Institute) gives Heidelberg Pharma access to know-how and patents concerning the amanitin toxin, which can be coupled to a range of antibodies. Amanitin is a member of the amatoxin group of natural poisons, which occur in the death cap (*Amanita phalloides*), among others.

Heidelberg Pharma aims to enter into customer specific collaborative partnerships with research institutes as well as pharmaceutical and biotech companies and performs contract work for customers related to designing, optimising, profiling and manufacturing new ADCs. During 2012, several contracts were signed with pharmaceutical and biotechnology companies concerning the testing of the applicability of ADC technology for specific and proprietary antibodies of these contract partners. Under these agreements, toxin linker prototypes will be made available to cross-link these to antibodies developed by partners and test them biologically. These collaborations take place under technology cooperation agreements and are intended to tap into short-term and long-term future potential for generating sales revenue and creating added value through licence agreements.

3.1.3.2. Customer specific preclinical service business

Heidelberg Pharma GmbH has the expertise and suitable premises for [in vivo](#) pharmacology, cell biology, bio-analytics, molecular biology and chemistry and offers preclinical research services in the field of cancer as well as inflammatory and autoimmune diseases. In its research process, the company concentrates on early substances (for example, lead structures to be optimised) up to the profiling of preclinical candidates. Heidelberg Pharma's expertise lies in offering not only tried-and-trusted standard models but also customised experimental designs plus development and validation of new models for customers. The associated infrastructure and expertise are utilised within the Group and offered as a service to third parties.

3.1.3.2.1. Tumour implantation models

Heidelberg Pharma uses both syngenic and human tumour implant models based on human tumour cells to conduct in-depth studies of potential oncological compounds. These models can be used to define parameters such as tumour growth, tumour regression or metastasis in comparison to reference agents. The visualisation of metastases and orthotopic tumours via innovative imaging techniques is also part of the portfolio. Heidelberg Pharma complements its human tumour implantation programme with syngenic mouse and rat tumour models. For preliminary testing, in vitro models are offered, for which Heidelberg Pharma has access to more than 100 types of tumour cell lines.

3.1.3.2.2. Inflammatory and autoimmune diseases

In the field of inflammatory and autoimmune diseases, Heidelberg Pharma offers a broad range of models and methods for examining the mechanisms of new compounds. For this purpose, Heidelberg Pharma can draw on in vivo models for autoimmune diseases, such as for experimental autoimmune encephalomyelitis (EAE), for multiple sclerosis, for collagen-induced arthritis (CIA) and for Type 1 diabetes.

3.1.3.2.3. Bioanalytics

Bioanalytics analyses substance levels from in vivo experiments, particularly within the scope of pharmacokinetic investigations. This process involves determining the substance level in e.g. blood, serum or plasma, as well as a range of organs or tumours. In vitro analyses test substances in terms of e.g. protein binding and metabolic stability. All investigations can also be conducted with radiolabelled substances. In addition, Heidelberg Pharma also offers the identification, synthesis and the in vitro and in vivo profiling of metabolites aimed at determining the substance's biological activity profile.

3.1.3.2.4. Molecular biology

Heidelberg Pharma complements this offer with in vitro profiling of substances. This work involves target protein expression analysis in cell lines and in tissue, standard assays and other specialised techniques. Complementing the assays for efficacy and signal transmission, a range of in vivo tests can also be used to test the ADME properties of the compounds.

In the services business, longer-term master agreements on contracted work in the field of pharmacology and bioanalytics were negotiated and signed in 2012 once again with new customers in the pharmaceutical and biotechnology industries.

3.2. Other key events in the 2012 financial year

3.2.1. Marketing partnership for RENCAREX® with Prometheus Laboratories

In April 2011, WILEX AG and Prometheus Laboratories Inc., San Diego, CA, USA, ([Prometheus](#)) signed a licence agreement for out-licensing the marketing rights to RENCAREX® in the United States to Prometheus. Prometheus is an established speciality pharmaceutical and diagnostics company with a proven track record in gastroenterology and oncology.



WILEX was paid USD 19.0 million under this licence agreement on signing. In addition, WILEX is entitled to milestone payments and to royalty payments on net sales of RENCAREX® in the United States. Prometheus co-funds the development of RENCAREX®. The contract covers the potential development of RENCAREX® in indications other than the adjuvant therapy of non-metastatic clear cell renal cell carcinoma (ccRCC). Under the terms of the agreement, WILEX AG had the option either to be paid USD 15.0 million six months or USD 20.0 million twelve months after contract signing, or to be granted the commercial rights to an undisclosed product from Prometheus in Europe.

Regarding this option, WILEX AG on 6 July 2012 opted for a further cash payment according to the licence agreement with Prometheus. The parties agreed on an immediate payment of USD 17.5 million and a milestone payment of €2.5 to be paid later; this milestone can no longer be achieved. The parties mutually terminated the negotiations for the commercial rights to an undisclosed product in Europe.

3.2.2. Implementation of two capital measures

WILEX AG carried out a rights issue in the first quarter of 2012. The shareholders exercised their subscription and oversubscription rights for all 3,201,928 new no par value bearer shares at a price of €3.10 per share by the end of the subscription period on 30 January 2012. Following the entry of the capital measure in the Commercial Register on 3 February 2012, the total number of WILEX shares issued increased to 24,814,963. WILEX AG received gross proceeds of approximately €9.9 million from the rights issue.

A combined capital increase against cash and contributions in kind was implemented in the third quarter of 2012 and a total of 6,460,544 new shares were issued. The subscription or purchase price was €3.70 per share. In the form of a contribution in kind, the Company's Walldorf-based shareholder **dievini** Hopp BioTech holding GmbH & Co. KG (**dievini**) converted its existing claim to repayment from a loan extended to WILEX AG amounting to approximately €7.8 million, including interest, into 2,100,337 new shares. As a result, the greater part of the shareholder loan was repaid and the financial liabilities of the WILEX Group were reduced, without adversely affecting its liquidity. In the cash portion of the rights issue, 4,360,207 new shares were subscribed through the exercise of subscription rights and using the oversubscription option as well as through private placements. Following the entry of the capital measure in the Commercial Register on 27 August 2012, the total number of WILEX shares issued increased to 31,275,507. The Company received gross proceeds of approximately €16.1 million.

Glossary

3.2.3. Change on the Executive Management Board

Peter Llewellyn-Davies stepped down from the Executive Management Board of WILEX AG on 31 August 2012 when his contract expired. He was succeeded as CFO of WILEX AG on 1 September 2012 by Dr Jan Schmidt-Brand, who continues to serve as Managing Director of the subsidiary Heidelberg Pharma.

3.2.4. Restructuring measures

The missed endpoint in the Phase III ARISER trial with RENCAREX® in October 2012 led to the adoption of restructuring measures in November 2012. WILEX AG will focus on its other projects in development – WX-554, WX-037 and REDECTANE® – and on the out-licensing of MESUPRON®. The scaling back of activities at WILEX will lead to a reduction of the workforce at the Munich site by approximately 25% in the coming months. Most of these lay-offs took place in November 2012, affecting the areas of preclinical and clinical development, CMC, quality assurance, approval and administration. The Executive Management Board reported this to the Supervisory Board at the beginning of December who also resolved that WILEX AG would discontinue the RENCAREX® project. The subsidiaries Heidelberg Pharma and WILEX Inc. are excluded from the restructuring measures.

4. Non-financial performance indicators and contracts

4.1. Drug manufacturing permit

WILEX AG possesses a drug manufacturing permit pursuant to Section 13 (1) and Section 72 (1) German Medicines Act (Arzneimittelgesetz) for Girentuximab, MESUPRON® and WX-554. This permit authorises the Company to release, package and label the respective drug candidates for use in clinical trials involving healthy volunteers and patients. As before, the production, formulation and filling of the drug candidates are carried out by subcontractors certified by national and international supervisory authorities.

4.2. Manufacturing and supply

All of WILEX AG's manufacturers and suppliers are certified subcontractors.

Girentuximab (the antibody) is manufactured by Avid Bioservices, Inc., Tustin, CA, USA (Avid), most recently as part of process validation. Solupharm Pharmazeutische Erzeugnisse GmbH, Melsungen (Solupharm), and Rentschler Biotechnologie GmbH, Laupheim (Rentschler), filled the antibody Girentuximab manufactured by Avid into suitable containers (50 ml vials, 4 ml vials) and label them in accordance with statutory requirements.

Once Solupharm and Rentschler have completed the filling operations, the Girentuximab necessary for manufacturing (radiolabelling) REDECTANE® is delivered to IBA Molecular North America Inc., Dulles, VA, USA. IBA supplies the trial centres with REDECTANE® through its existing infrastructure.



For MESUPRON®, production of the active pharmaceutical ingredient was carried out by Bayer HealthCare AG, Leverkusen, while formulation and production of the dosage form is the responsibility of RIEMSER Specialty Production GmbH, Laupheim (formerly Rentschler Pharma GmbH) (Riemser).

For WX-554, production of the active pharmaceutical ingredient (API) is performed by Central Glass Germany GmbH, Halle/Westphalia, formulation and production of the oral dosage form by Riemser.

Whilst Synpha-Base AG, Pratteln, Switzerland, is responsible for manufacturing the active pharmaceutical ingredient of WX-037, PharmaVize N.V., Mariakerke, Belgium, is tasked with the formulation development.

4.3. Certification pursuant to GLP, GMP and ISO

The GLP test laboratory of WILEX AG in Munich (bioanalysis laboratory) is certified in accordance with the principles of **Good Laboratory Practice (GLP)**. The GLP certification pursuant to Section 19b (1) German Chemicals Act (Chemikaliengesetz) enables WILEX AG to carry out analytical tests on biological substances and, to a limited extent, other types of examinations. Such certification is a prerequisite for the recognition by national and international supervisory authorities of preclinical or clinical data produced in the Company's laboratories. The bioanalysis laboratory has been GLP-certified since July 2002 and was recertified for test categories 8 and 9 through the periodic inspections in November 2006 and January 2011. The authorities responsible for this are the Bavarian Health and Food Agency as well as the government of Upper Bavaria.

The Munich premises are certified by the Central Drug Monitoring Office of the government of Upper Bavaria as being in compliance with the principles and guidelines of **Good Manufacturing Practice (GMP)**. The GMP certificate is an important prerequisite, e. g. for marketing all of WILEX AG's product candidates.

WILEX Inc.'s production facility in Cambridge, MA, USA, has been certified in accordance with 9001:2008 and ISO 13485:2003 since 2011. These two international standards confirm product properties such as quality, safety and reliability. They also ensure quality management for regulatory purposes, especially risk management for safe design and the manufacture of in vitro diagnostic tests. They also enable simplified registration and licensing of the diagnostic tests for worldwide marketing and sales.

4.4. Licence agreements und important contracts

WILEX has signed several licence agreements and other important contracts essential to the Group's business activities.

4.4.1. Contracts entered into by WILEX AG

4.4.1.1. Contracts relating to the antibody Girentuximab

Several of these agreements concern the development and future commercial use of Girentuximab, an antibody on which both REDECTANE® and RENCAREX® are based. The Company licensed the antibody in 1999 from Centocor Inc., Malvern, PA, USA, and Leiden University, The Netherlands. A further licence for the antibody's target antigen has been granted by the Bayer Corporation Business Group Diagnostics, Tarrytown, NY, USA. To exclude possible patent violations, WILEX AG also acquired a non-exclusive licence for the Cabilly II patent from Genentech Inc., San Francisco, CA, USA.

4.4.1.2. Contracts relating to REDECTANE®

In June 2008, WILEX AG signed an exclusive worldwide licence agreement with IBA Pharma S.A., Louvain-la-Neuve, Belgium, (IBA Pharma S.A.) for its diagnostic candidate REDECTANE®. Under this agreement, WILEX AG is responsible for manufacturing the antibody Girentuximab and for the clinical development of REDECTANE®. IBA is responsible for the radiolabelling of Girentuximab and will take over the distribution, sales and marketing of REDECTANE®. WILEX AG has received an advance payment and is also entitled to receive milestone payments and royalties as well as contributions in kind. Once the envisioned marketing approval has been granted, WILEX AG will be paid 20% of the sales revenue ex works up to a sales volume of €7 million, after which its share will rise to 45% of all subsequent sales revenue ex works. WILEX AG retains the international co-promotion rights to introduce REDECTANE® to urologists and oncologists.

The legal form of IBA Pharma S.A. was changed in March 2012 and the company now goes by the name of IBA Pharma SPRL (IBA Pharma SPRL). According to IBA Pharma SPRL, a transaction was concluded on 2 April 2012 with the private US financial investor SK Capital Partners under which the licence agreement with WILEX AG was transferred on 29 March 2012 to the newly founded IBA Molecular Compounds Development SARL, Luxembourg, (IBA Molecular Compounds Development), a subsidiary of IBA Molecular Holding SA, Belgium, which was also recently formed. IBA Molecular Compounds Development is owned by IBA Molecular Holding SA and SK Rose SARL, Luxembourg, in equal shares.

IBA Molecular North America Inc. is responsible for the radiolabelling of the antibody Girentuximab. This company is a subsidiary of the newly founded Rose Holdings SARL, Luxembourg, which is owned by IBA Molecular Holding SA (40%) and SK Rose SARL (60%).

WILEX AG objected to the transfer of the licence agreement from IBA Pharma SPRL to IBA Molecular Compounds Development and negotiations are currently underway. Independent of their company law structure, IBA Pharma SPRL, IBA Molecular North America Inc., IBA Molecular Compounds Development SARL, IBA Molecular Holding SA, and Rose Holdings SARL are together referred to as "IBA".

4.4.1.3. Contracts relating to RENCAREX®

An exclusive sales and marketing agreement for RENCAREX®, as well as an option regarding future Girentuximab products in certain southern European countries has been in place with the Spanish pharmaceutical company Laboratorios del Dr Esteve S.A., Barcelona, Spain, ([Esteve](#)) since 2004. Esteve was granted the marketing rights for Spain, Italy, Portugal, Greece and Andorra, as well as an option for the Turkish market, in return for undisclosed licence payments.

In April 2011 WILEX AG and Prometheus Laboratories Inc., San Diego, CA, USA, (Prometheus) signed a licence agreement for marketing rights to RENCAREX® in the United States. Prometheus is an established speciality pharmaceutical and diagnostics company with a proven track record in gastroenterology and oncology. WILEX was paid USD 19.0 million under this licence agreement on signing. In addition, WILEX AG is entitled to receive milestone payments and royalties on net sales of RENCAREX® in the United States on meeting certain preconditions. Prometheus co-funds a portion of the ongoing development of RENCAREX®. Under the terms of the agreement WILEX AG had the option either to receive an additional payment or to be granted the European commercial rights to an undisclosed product from Prometheus. In July 2012, WILEX AG opted for receiving cash and received an immediate payment of USD 17.5 million. The agreement remains in effect regardless of the results of the ARISER trial. The parties are reviewing additional avenues of collaboration.

4.4.1.4. Contracts relating to MESUPRON®

In 2006, WILEX AG acquired five patent families and patent applications for its uPA programmes from Penta-pharm AG, Basel, Switzerland, related to WX-UK1 and MESUPRON®. In 2007, WILEX AG also acquired a portfolio from the Dendreon Corporation, Seattle, WA, USA, which comprises all of their proprietary patents and patent applications for uPA inhibitors. In addition to these patents directly held by the Company, this patent portfolio provides protection against third parties copying the WILEX drugs or the therapeutic use of the relevant serine protease inhibitors.

4.4.1.5. Contracts relating to the strategic alliance with UCB

In January 2009, WILEX AG and the biopharmaceutical company UCB Pharma S.A., Brussels, Belgium, (UCB) entered into a comprehensive strategic alliance (Collaboration Agreement). WILEX AG acquired the worldwide rights to continue developing UCB's entire preclinical oncology portfolio, which comprised two small-molecule inhibitors and three antibody programmes. The MEK inhibitor WX-554 is currently in a Phase I programme, and the PI3K inhibitor WX-037 is in the preclinical stage. Two of the three antibody programmes are in the research phase, and the third was discontinued back in 2011 in agreement with UCB. UCB retains exclusive rights to buy back each of the five programmes and assume the responsibility for further development and commercialisation of each product (Reversion Rights Agreement). In this case, WILEX AG will receive development milestone payments and royalties from UCB. Alternatively, in the event UCB does not exercise its buy-back right for a given programme, WILEX AG will retain rights to develop as well as commercialise that programme and UCB will receive milestone payments and licence payments from WILEX. Furthermore, the two partners may jointly continue developing the programmes. In 2009, UCB had acquired WILEX shares worth € 10 million under the agreement and paid an additional € 10 million as two milestone payments. WILEX has gained an important development partner and strategic investor in UCB.

4.4.2. Contracts entered into by WILEX Inc.

Through a licence agreement with Siemens Healthcare Diagnostics Inc., Deerfield, Illinois, USA (Siemens) dated November 2010, WILEX Inc. gains exclusive access to the intellectual property rights held by Siemens relating to diagnostic ELISA and IHC tests and pays licence fees to Siemens on the sale of the diagnostic tests in a low to medium single-digit percentage. Siemens retains the rights to the Oncogene Science products, especially to Serum HER2/neu and CAIX, for its own automated platform.

At the end of November 2012, WILEX Inc. entered into an exclusive distributor agreement with Immundiagnostik AG, Bensheim, for the commercialisation of the Serum HER2/neu and CAIX ELISA tests in Germany, Austria and Switzerland.

4.4.3. Contracts entered into by Heidelberg Pharma GmbH

An exclusive patent and expertise licence agreement exists between Heidelberg Pharma as the licensee and Prof Heinz Faulstich as well as the German Cancer Research Centre, Heidelberg (together the "licensors").

The licensors jointly develop oncological amanitin antibody conjugates and have specialist expertise in this ADC technology. The patents underlying the technology have been registered with the European and the US Patent Offices as an invention. In accordance with the contractual arrangements, the licensors grant Heidelberg Pharma GmbH an exclusive license to the licensed patent rights and the know-how for the development, production and distribution of amanitin antibody conjugates.

4.5. Cooperation with clinical test centres and contract research organisations

In conducting its trials, WILEX AG collaborates primarily with clinical test centres, clinical trial managers and clinical research physicians as well as contract research organisations (CROs) and other service providers. This entails setting in motion a selection process of both trial centres and CROs during the planning phase of a clinical trial based on the specifications of the study protocol; the process culminates in the determination of the trial centres and CROs. As far as CROs are concerned, particular attention is paid to the scope of their experience in the respective indication and whether the network of trial centres will fulfil the trial's requirements given the number of patients.

4.6. Patents

WILEX AG owns more than 80 patents and has filed about 50 patent applications in more than 25 patent families. Whilst most of these patent families were developed by the Company itself, WILEX AG has expanded its industrial property rights in targeted ways through strategic acquisitions of patent portfolios.

Fourteen patents and 22 patent applications apply to the Girentuximab antibody programme. WILEX AG owns a European patent that was issued in 2006 for the hybridoma cell line that produces the antibody Girentuximab. This patent covers the hybridoma cell line in and of itself as well as the production of the Girentuximab antibody or a pharmaceutical compound containing this antibody by means of the hybridoma cell line. Patents related to the aforementioned family have also been issued in Australia, Japan, Canada and Mexico.

More than 70 patents concerning the uPA-based programme have been issued in Australia, China, Canada, Europe, India, Japan, Mexico, the Russian Federation, Singapore and the United States. In addition, approximately 30 patent applications concerning the uPA programme are pending. The patents and patent applications related to the uPA programme cover a variety of uPA inhibitors (including MESUPRON® and WX-UK1) developed by WILEX AG. Patent protection applies to both the active ingredients (claim to the compound, i.e. the chemical structure is patented) and the application of the given ingredients (claim to the medical preparations and the applications, i.e. the medical use of the ingredients), as well as to both formulation and production.

The oncology portfolio that was acquired from UCB comprises two small-molecule programmes (WX-554 and WX-037) and currently two antibody programmes. These four projects are protected by nine patent families currently comprising 23 granted patents and more than 40 patent applications.

For the Oncogene Science biomarker tests, WILEX Inc. has access to industrial property rights held by Siemens Healthcare Diagnostics Inc. These eleven patent families with 13 issued European and US patents as well as a large number of patent applications are related to the HER2/neu, EGFR, VEGF, PDGFR, p53, RAS p21 and uPA/PAI-1 programmes. A licence for numerous families of industrial property rights related to the CAIX programme was also acquired.

In addition to the three in-licensed patents, Heidelberg Pharma has applied to register three new patents in Europe in the field of ADC technology. All applications concern components of the ADC technology (such as methods for binding to the toxin). The first application was granted in Europe in September 2011. The European patent was registered in the following countries: Switzerland/Liechtenstein, Germany, Denmark, Spain, Finland, France, the United Kingdom, Ireland, Italy, the Netherlands, Sweden and Slovenia. Based on this application, an international patent application was also filed in the Patent Cooperation Treaty (PCT) member

states in September 2011. On the basis of the second application for a new patent, a further international PCT application was filed in March 2012. A third application was also filed in July 2012 as an application for a new European patent. Once the national phases take place, applications will definitely be filed in the United States and, in the case of the second and third applications, in Europe (specifying all states party to the European Patent Convention). Depending on the given country's relevance, national phases will also be initiated in Canada, Australia, Japan, China, Korea, the Russian Federation, South Africa and Mexico.

4.7. Employees and compensation system

The development of a new generation of cancer drugs and diagnostic agents is owed to the special dedication, the know-how and the scientific expertise of WILEX's employees. The positive relationships that are maintained with scientists and potential cooperation partners in particular are critical to the successful development and commercial exploitation of its product portfolio and future enterprise value.

Including the members of its Executive Management Board, WILEX had 128 employees at the close of the financial year (30 November 2011: 124). They are distributed as follows among business areas. However, the employee figures are not fully comparable because one subsidiary was added in each of 2010 and 2011.

Employees	30.11.2012	30.11.2011	30.11.2010 ¹
Administration ²	25	31	21
Research and development	71	64	49
Manufacturing, service and distribution	32	29	10
Employees, total	128	124	80

¹ Excluding Heidelberg Pharma

² In 2011 und 2010, this also included business development staff, which has been allocated to sales since 2012.

A restructuring programme was launched at the end of November 2012, which will lead to a reduction of the workforce at the Munich site by approximately 25%.

The Company has a performance-related compensation system for its employees. Every employee is paid variable compensation based on defined goals in addition to an annual fixed salary. The 2005 and 2011 Stock Option Plans give employees a stake in the Company's performance, though no further options can be issued under the Stock Option Plan 2005. The Company's Annual General Meeting in May 2011 authorised the Executive Management Board to issue, with the approval of the Supervisory Board, up to 1,156,412 new options (stock options) under the new WILEX 2011 Stock Option Plan valid up to and including 1 July 2016. The corresponding amount of new Contingent Capital was created and recorded in the Commercial Register.

In the 2012 financial year, a total of 270,500 stock options were issued under the 2011 Stock Option Plan, of which 158,500 stock options were issued to employees and 112,000 to members of the Executive Management Board; 8,000 of the latter had been returned by 30 November 2012. Employees of WILEX Inc. and Heidelberg Pharma were also taken into consideration for the first time. As a result, WILEX issued a total of 1,431,931 subscription rights to employees and members of the Executive Management Board under the 2005 and 2011 plans, of which 991,375 options had vested as of the end of the reporting period. No stock options have been exercised to date.

Independent of this, employee inventions that lead to patent applications are compensated under the Patent Incentive Programme.

5. Earnings, financial position and net assets of the Group

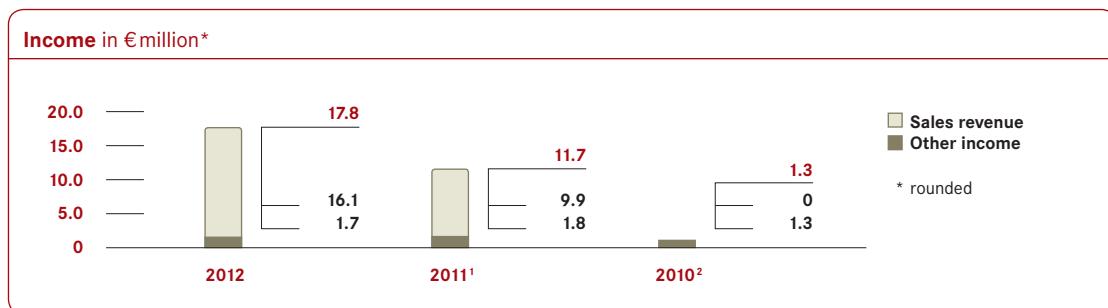
The 2012 financial year concerns the period from 1 December 2011 to 30 November 2012. Due to rounding, it is possible that individual figures in this combined management report may not add up exactly to the totals and that percentages given may not precisely reflect the absolute figures to which they relate. The earnings, financial position and net assets according to the German Commercial Code (HGB) of WILEX AG as an independent company are explained separately in chapter 10.

When analysing the Company's earnings, financial position and net assets, it is important to state at the outset that the disappointing results of the ARISER trial with RENCAREX® for the adjuvant treatment of clear cell renal cell cancer had no significant adverse effect on the Group's current financials. A major factor pushing down earnings is the provision for restructuring measures in the amount of €0.4 million, which was mainly recognised for salaries and termination benefits. There were no other effects adversely impacting earnings such as provisions for anticipated losses. Instead, around 10% of the prepayments recognised as deferred income from Prometheus under the licence agreement for the US marketing rights to RENCAREX® from May 2011 was recognised in profit or loss and thus reversed, improving earnings. This generated an additional € 1.1 million in sales revenue. The reason for this partial reversal was that the costs yet to be incurred to wind up the trial owing to the failure to meet the endpoint will be lower than the originally planned costs, including for approval, which would have arisen with positive trial results. Prometheus is not entitled to claim repayment of the prepayments made. As a result, an adjustment to the amount and duration of the pro rata reversal was already made as of the balance sheet date. From the present perspective, income will be recognised pro rata until December 2013, which is when the trial wind-up is expected to be completed. Due to the additional reversal of income undertaken in the financial year, the future monthly reversal amounts, and therefore income, will be slightly lower.

WILEX recognised earnings before tax of –€ 9.4 million (previous year: –€ 13.9 million) in the 2012 financial year. The net loss for the year was also € 9.4 million (previous year: € 13.9 million); income taxes were € 3 k. Earnings per share improved due to the capital increases executed during the financial year from –€ 0.67 in the prior year to –€ 0.36. As expected, expenditures were higher than revenue and other income. The WILEX Group is made up of three operating segments – Rx, Dx and Cx – which are explained in the segment reporting section.

5.1. Sales revenue and other income

WILEX posted sales revenue of € 16.1 million (previous year: € 9.9 million) in the 2012 financial year, € 13.9 million of which – the majority – stemmed from the individual components of the licence agreement with Prometheus. This also includes the aforementioned income from the reversal of € 1.1 million in deferred income attributable to the ARISER trial results. Due to the contract signing with Prometheus during 2011, the comparable sales revenue in the previous year amounted to only € 6.5 million.



¹ Heidelberg Pharma consolidated from 17.03.2011

² WILEX Inc. consolidated from 25.10.2010

At € 1.7 million, other income dropped 7 % compared to the previous year (€ 1.8 million). In addition to significant exchange rate gains of € 1.0 million (previous year: € 0.5 million), other income also includes grants from the Federal Ministry of Education and Research (BMBF). Projects by both WILEX AG and Heidelberg Pharma received subsidies from the BMBF totalling € 0.6 million in the past financial year.

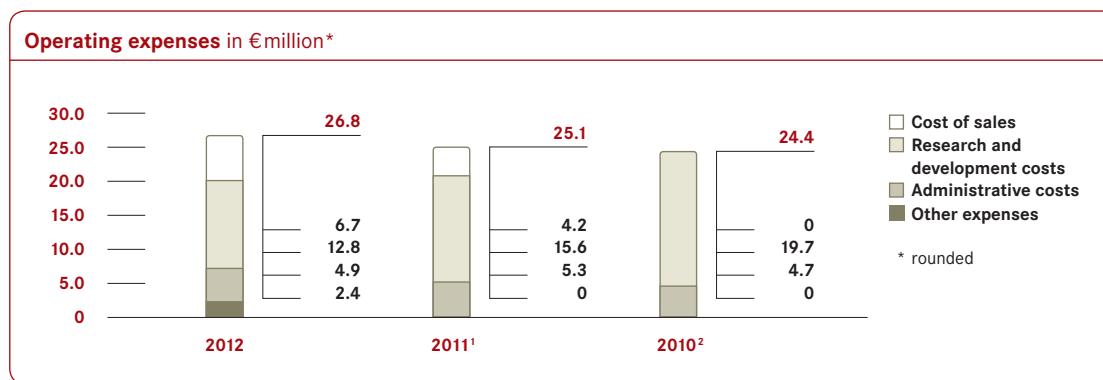
Other income	2012 €'000	2011 ¹ €'000	2010 ² €'000
Other grants	642	1,249	293
Income from exchange rate gains	1,013	486	0
Other	45	101	1,021
Total	1,700	1,836	1,314

¹ Heidelberg Pharma consolidated from 17.03.2011

² WILEX Inc. consolidated from 25.10.2010

5.2. Operating expenses

Operating expenses including depreciation and amortisation rose to € 26.8 million in 2012 (previous year: € 25.1 million).



¹ Heidelberg Pharma consolidated from 17.03.2011

² WILEX Inc. consolidated from 25.10.2010

Cost of sales were shown for the first time in the previous year owing to the consolidation of the two subsidiaries and the cost reimbursements for development services. Due to the increasing importance of this item, the Company began showing other expenses for business development and the increasing commercialisation of the respective projects in the first quarter of 2012.

Costs of sales concern costs directly related to revenues of the respective segments. The Rx segment reports the development costs for RENCAREX®, for which it has received cost reimbursements from Prometheus since May 2011 that are reported in sales revenue, under cost of sales. These costs stopped being allocated to research and development costs as of 30 November 2011. As a result of higher revenue, costs of sales thus rose to € 6.7 million (previous year: € 4.2 million) and now make up 25 % of total costs.

Research and development costs, which were € 15.6 million the previous year, fell by 18% to € 12.8 million. Research and development costs account for 48% of all costs (previous year: 62%). The decline is due to both the aforementioned reclassification of development costs as cost of sales in the Rx segment and the current status of the trials, especially REDECTANE® and MESUPRON®, with the associated decrease in costs. Research and development costs mainly comprise the estimated restructuring costs in the amount of € 0.4 million.

Administrative costs were € 4.9 million (previous year: € 5.3 million) and account for 18% of operating expenses. In a year-on-year comparison, it should be noted that in the same period the previous year, € 0.7 million in business development costs were still included in administrative costs. Without this reclassification, administrative costs would have been only slightly higher than the previous year's level for the entire current reporting period – despite the consolidation of Heidelberg Pharma for the full year. When the figure is adjusted for the extraordinary effect of the measurement or repricing of the stock options issued (see the notes to the consolidated financial statements), administrative costs even fall below the previous year's level.

At the start of the financial year, a decision was made due to the increased marketability of RENCAREX® to report the costs of business development activities totalling € 0.8 million – which in the previous year made up € 0.7 million of administrative costs – and of marketing and commercial supply totalling € 0.9 million (previous year: € 0) as other expenses for the first time. Other expenses were incurred in the amounts of € 0.4 million for biomarker tests and € 0.3 million for customer specific research.

The operating expenses contain € 0.7 million (previous year: € 0.2 million) in expenses from exchange rate differences that are mainly attributable to the US dollar's strong fluctuations vis-à-vis the euro. These are allocated among functions based on cost type.

5.3. Segment reporting

The WILEX Group comprises three operating segments, each of which is explained below, along with its separate core business and core projects.

The Therapeutics (Rx) segment comprises the following programmes: MESUPRON®, WX-554, WX-037 as well as all preclinical and research activities of WILEX AG. The RENCAREX® programme and thus the winding-up of the ARISER trial continue to be allocated to the Rx segment.

The Diagnostics (Dx) segment includes the development of WILEX AG's imaging diagnostic candidate REDECTANE® and the in vitro diagnostic and biomarker tests of WILEX Inc. The Customer Specific Research (Cx) segment comprises services related to the ADC technology platform and the preclinical services business.

Income and expense items and assets not allocated to any specific segment cannot be apportioned accurately to the therapeutic programmes and diagnostic agent of WILEX AG. This applies mainly to exchange rate effects and interest, and to laboratory equipment in terms of assets.

	Rx €'000	Dx €'000	Cx €'000	Not allocated €'000	Consoli- dation €'000	Group €'000
Sales revenue	13,873	353	2,064	0	(148)	16,142
Other income	388	9	245	1,064	(7)	1,700
Operating expenses	(18,346)	(3,837)	(4,724)	0	155	(26,751)
Operating result	(4,084)	(3,474)	(2,415)	1,064	0	(8,910)
Financial result	0	(144)	(104)	(230)	0	(478)
Income taxes	0	(3)	0	0	0	(3)
Profit/loss for the year	(4,084)	(3,621)	(2,520)	834	0	(9,391)
Net currency gain/loss from consolidation	0	(10)	0	0	0	(10)
Total comprehensive income	(4,084)	(3,631)	(2,520)	834	0	(9,401)

5.4. Financing and liquidity

WILEX carried out a rights issue in February 2012 during which the shareholders subscribed for all 3,201,928 new no par value bearer shares by exercising their subscription and oversubscription rights at a subscription price of €3.10 per share. The gross issuing proceeds totalled €9.9 million.

A payment of USD 17.5 million was made by licensing partner Prometheus in July 2012.

A combined capital increase against cash and contributions in kind was completed in August and a total of 6,460,544 new shares were issued. The subscription price was €3.70 per share. As a result, the shareholder loan from dievini (€7.8 million including accrued interest) was converted to 2,100,337 shares. The gross issuing proceeds from the cash component were €16.1 million.

Due to a higher investment volume as a result of the cash inflow from the Prometheus payment and the capital increases implemented, finance income increased to €30 k (previous year: €7 k) in the reporting period. WILEX exclusively used short-term deposits for investing its liquid funds (e.g. overnight money). At no time did WILEX invest cash and cash equivalents in stock or share-based financial instruments. Finance costs were approximately €508 k (previous year: €548 k) and include interest expense, particularly the interest portion of the shareholder loans from dievini (loan: €7.5 million) and UCB (€2.5 million) taken out in December 2010. The interest on the loans is 6% annually in each case.

Loan liabilities were reduced significantly and limited to the share from UCB thanks to contribution of the shareholder loan from dievini as an in-kind contribution in the capital measure carried out in August. The loan agreements between UCB and WILEX remain unchanged. The unsecured loan is not limited in time. The lender is entitled to terminate the loan. In that case, it would have to be repaid within one month. In lieu of asking for repayment of the loan, the lender may also contribute their claims to repayment as an in-kind contribution in connection with a rights issue or convert it into shares subject to a convertible bond programme yet to be resolved. These two repayment options are subject to the proviso, for one, that the rights issue or the convertible bond programme are adopted and carried out and, for another, that an external assessor confirms the value of the respective claim to repayment.

The financial result in 2011 was –€478 k due to the finance costs (previous year: –€541 k).

The Group had cash and cash equivalents of €23.4 million (30 November 2011: €3.4 million) at the close of the financial year. The Company's liquidity ratio (cash positions plus bank credit balances divided by current liabilities) improved markedly due to the inflow of funds and was 140% as of 30 November 2012 (previous year: 17%).

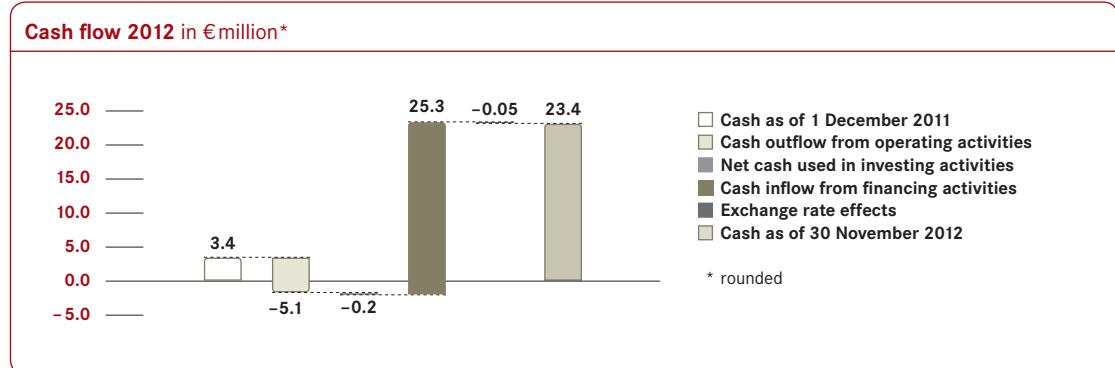
5.5. Cash flow statement

The net cash flow from operating activities during the reporting year was –€5.1 million (previous year: –€9.0 million). The significant improvement is attributable to the larger inflows of cash from Prometheus during the period than in the previous year.

The total cash outflow from investing activities was €0.2 million (previous year: cash inflow of €0.6 million) and is attributable to the acquisition of equipment and intangible assets by WILEX AG and Heidelberg Pharma. In the previous year, the cash inflow was due to the integration of Heidelberg Pharma and the acquisition of its cash funds.

The cash inflow from financing activities was €25.3 million (previous year: €9.8 million) and was generated by the capital increases executed in the first and third quarter of the financial year.

Total net outflow of cash and cash equivalents in the 2012 financial year was €19.9 million (previous year: €1.5 million). This corresponds to an average cash inflow of €1.7 million per month in 2012 (previous year: €0.1 million per month). Adjusted for the effects of the capital measures and the one-time payment from Prometheus in July 2012, WILEX's average use of cash per month in the reporting period was €1.7 million. Adjusted also for the cost reimbursement from Prometheus, the monthly use of cash rises to €1.9 million (previous year: €2.0 million, adjusted for the effects of the shareholder loan and the Prometheus payments).



5.6. Assets

Total assets as of the close of the financial year were €37.7 million and thus considerably higher than the previous year's level of €20.8 million. The major changes compared with the previous year are mainly the result of the capital measures and the Prometheus payment as part of the licence agreement.

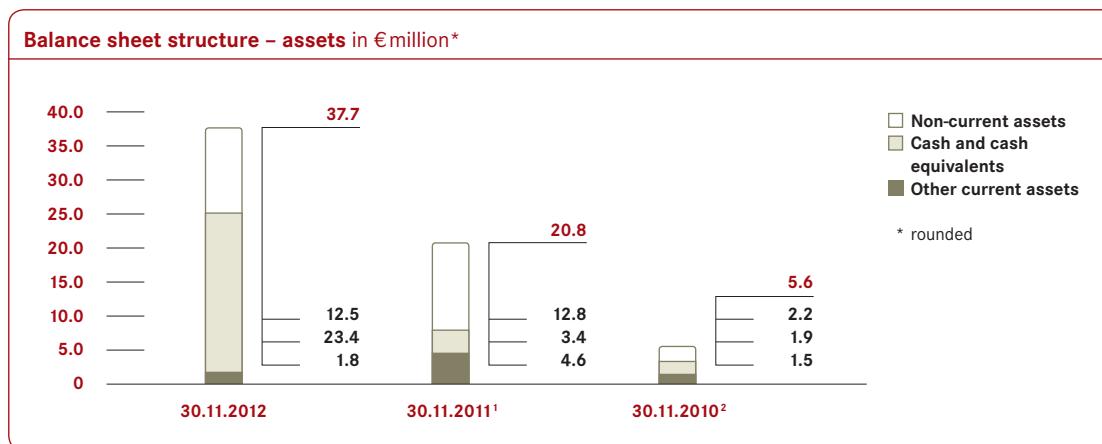
Non-current assets decreased slightly by 2% to €12.5 million as of 30 November 2012 (previous year: €12.8 million). The slight decline is largely due to the depreciation of property, plant and equipment and amortisation of intangible assets. Furthermore, an impairment loss of €46 k (approximately 20% of the net carrying amount) was recognised on the customer base acquired from Heidelberg Pharma in the Cx segment. The

customer base was valued at €0.3 million as of the acquisition date. Despite rising revenues and a steadily growing customer base at Heidelberg Pharma, this impairment was necessitated by the loss of one customer who was a key account at the acquisition date in March 2011.

Non-current assets mainly comprise Heidelberg Pharma's goodwill (€6.1 million) as well as the recognition of the intangible assets (€2.7 million) identified in connection with the purchase price allocation.

Property, plant and equipment as of 30 November 2012 remained unchanged at €2.1 million. Besides expanding the laboratory, the additions in the amount of €0.5 million served primarily to replace and buy laboratory equipment and furnishings as well as office furniture and equipment.

Development expenses for WILEX's product candidates are not capitalised because they are not deemed as fully meeting the requirements of IAS 38 for capitalisation. They are expensed in full as current research and development costs.



¹ Heidelberg Pharma consolidated from 17.03.2011

² WILEX Inc. consolidated from 25.10.2010

Current assets rose to €25.2 million (previous year: €8.0 million). The cash and cash equivalents included in this figure increased from €3.4 million in the previous year to €23.4 million because two capital increases were implemented during the financial year and payments from the licence agreement were received from Prometheus totalling the equivalent of €16.8 million.

The decrease in other current assets to €1.8 million (previous year: €4.6 million) is the result of the reversal of a receivable in respect of Prometheus. WILEX has been entitled to another payment of at least USD 15.0 million since the licence agreement was signed, which was accrued as a receivable on a pro-rata basis each month over the estimated time remaining until the approval of RENCAREX®. In certain circumstances that were tied to a timeline (see chapter 4.4 entitled "Licence agreements and important contracts" for more details), Prometheus could have been required to also make a USD 20 million payment instead of a USD 15.0 million payment. WILEX and Prometheus agreed on a payment of USD 17.5 million in July 2012, which led to the receivable being reversed and the surplus from the prepayment received in return for the provision of trial services being recognised as deferred income and reversed monthly on a pro rata basis and recognised in profit or loss.

5.7. Liabilities

Non-current liabilities declined from € 5.1 million as of 30 November 2011 to € 1.1 million at the end of this reporting period.

The deferred income from the Prometheus payment recognised after the contract was signed in the second quarter of 2011 (USD 19.0 million) amounted to € 4.9 million at the end of the previous year. An additional payment in the amount of USD 17.5 million to be accrued was added in the 2012 financial year to this accrual for the initial payment in the previous year. Despite the failure to meet the endpoint of the ARISER trial, the income from these payments must continue to be accrued because services must still be provided during the winding-up of the trial and expenses will be incurred from service providers. Due to the curtailed remaining wind-up period (13 months as of the reporting date) only € 0.9 million must be shown as non-current for one month. The accrual period is currently scheduled to end in December 2013.

The non-current liabilities also contain security deposits related to rented offices, leasing liabilities, liabilities for service anniversaries and pension obligations.

Current liabilities decreased to € 16.7 million at the close of the reporting period (previous year: € 20.2 million). This figure includes € 0.9 million in trade payables (previous year: € 1.4 million) and € 0.2 million in current lease liabilities (previous year: € 0.3 million). Current liabilities are influenced primarily by the financial liabilities amounting to € 2.6 million (€ 10.5 million) stemming from the remaining shareholder loan (including interest) from UCB and especially by other current liabilities of € 13.0 million (previous year: € 8.0 million).

The key item in other current liabilities is the current portion of the aforementioned accrual of the Prometheus payments until 30 November 2013, which totals € 9.4 million (previous year: € 4.8 million). This amount takes into account the additional reversal to profit and loss of € 1.1 million as of 30 November 2012 after announcement of the failure to meet the endpoint of the ARISER trial with RENCAREX®.

In other current liabilities, accrued liabilities, mostly in respect of service providers, and provisions for employee bonuses, royalties, restructuring measures initiated, service anniversaries and liabilities for vacation not yet taken in the amount of € 3.4 million were recognised as other items.

Other current liabilities	30.11.2012 € million	30.11.2011 ¹ € million	30.11.2010 ² € million
Accrued liabilities	3.4	2.6	3.4
Accruals Prometheus (current portion)	9.4	4.8	0
Other	0.2	0.6	1.0
Total	13.0	8.0	4.4

¹ Heidelberg Pharma consolidated from 17.03.2011

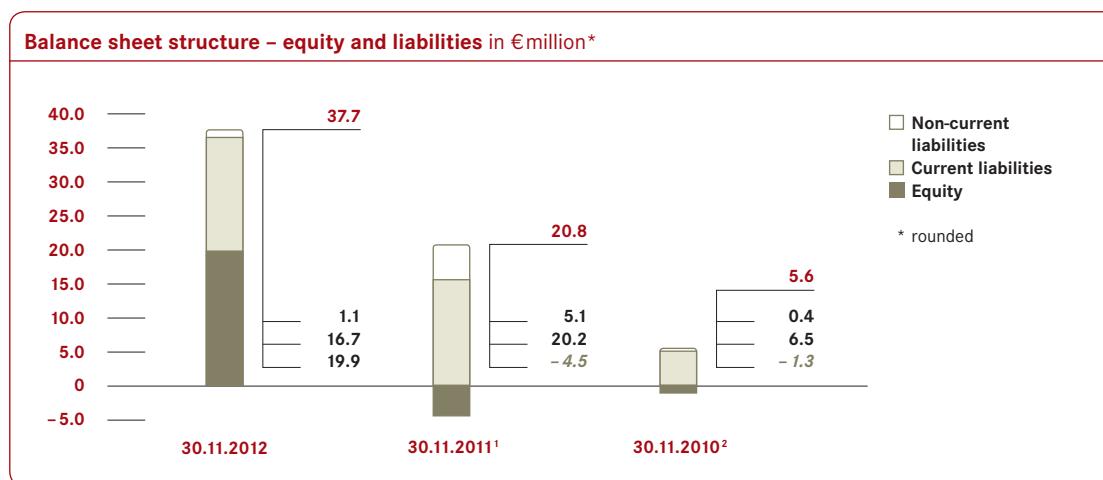
² WILEX Inc. consolidated from 25.10.2010

5.8. Equity

Consolidated equity as of 30 November 2012 was € 19.9 million (previous year: -€ 4.5 million). The subscribed capital rose to € 31.3 million as of 30 November 2012 as a result of the capital measures (30 November 2011: € 21.6 million).

Capital reserves climbed to € 159.2 million (previous year: € 135.0 million) due to both the capital increases and the measurement of stock options. The two capital measures in the past financial year resulted in an increase in the capital reserve of € 23.6 million after calculation of the difference between the par value and subscription price of the shares and deduction of the costs of the capital increase. The measurement of the stock options gave rise to staff costs of € 0.6 million in 2012 which also increased the capital reserve. Essentially, this was influenced by the reduction of the exercise price of the stock options from the 2005 Stock Option Plan in the first quarter of 2012 (repricing) and by the new issue of stock options as part of the 2011 Stock Option Plan in the second quarter.

The accumulated losses rose by the net loss of € 9.4 million for the year to a total of € 170.5 million (previous year: € 161.1 million). A currency loss of € 48 k arising on consolidation was recognised in equity. The equity ratio as of 30 November 2012 was 52.8% (previous year: - 21.7%) and was positively impacted by the aforementioned capital measures.



¹ Heidelberg Pharma consolidated from 17.03.2011

² WILEX Inc. consolidated from 25.10.2010

5.9. Overall assessment of the financial year by the Executive Management Board

Despite the severe setback in October 2012, many projects were successfully advanced by the WILEX Group in the 2012 financial year. In addition to the clinical and regulatory success of MESUPRON® and REDECTANE®, the Group's financial base was strengthened by two capital measures and in particular by the payment received from our partner Prometheus. The Company's strategy proved to be correct thanks to acquisitions and the expansion of the business model to three segments.

The failure to meet the endpoint in the Phase III ARISER trial with RENCAREX® in October 2012 is a major disappointment for the Executive Management Board and all employees, both from a scientific and a personal perspective. As a result, a restructuring programme consisting of a considerable reduction of the workforce by 25% in Munich and the focus on three programmes was decided in November 2012. These cost-cutting measures and the financing secured during the year are important prerequisites for refining WILEX AG's development portfolio and enhancing the activities of subsidiaries so as to continue the Group's growth course. Although a net loss was recorded in 2012, as in previous years, the Group nevertheless succeeded in giving a further substantial boost to its income and significantly reducing its net loss.

5.9.1. Comparison of target and actual performance in relation to certain targets and key indicators in the 2012 financial year:

Goals	Targets 2012	Actual 2012
Rx		
RENCAREX®	<ul style="list-style-type: none"> Decision on option under the licence agreement with Prometheus Final analysis of efficacy in the Phase III ARISER trial 	<ul style="list-style-type: none"> Additional payment of USD 17.5 million received in Q3/2012 Analysis was carried out according to plan Result of the trial in Q4/2012: Endpoint "Improvement of disease-free survival" was missed; IDMC recommendation to discontinue the trial was accepted
MESUPRON®	<ul style="list-style-type: none"> Final data from Phase IIa breast cancer trial 	<ul style="list-style-type: none"> Positive data in selected subgroups published in H1/2012
WX-554	<ul style="list-style-type: none"> Continuation of the Phase I programme 	<ul style="list-style-type: none"> Phase I trial with WX-554 in volunteers started and completed successfully Protocol approved for further study Phase Ib/II trial with WX-554 in cancer patients started
WX-037	<ul style="list-style-type: none"> Continuation of the preclinical programme and preparation of clinical development 	<ul style="list-style-type: none"> Participation in leading-edge cluster's m4 project funded by the German Federal Ministry of Education and Research Completion of toxicological tests, documentation of the data for clinical development Design of a Phase I study protocol
Dx		
REDECTANE®	<ul style="list-style-type: none"> FDA decision to convene an Advisory Committee FDA decision what kind of Phase III trial is necessary, if any 	<ul style="list-style-type: none"> ODAC decision by 16 to 0 (1 abstention) in support of the imaging information being clinically useful FDA accepts confirmatory diagnostic performance study
IVD	<ul style="list-style-type: none"> Expansion of business activities and revenue growth 	<ul style="list-style-type: none"> Sales revenue generated only at previous year's level Establishment and marketing of contract manufacturing started
Cx	<ul style="list-style-type: none"> Out-licensing agreement for ADC technology Increase revenue in service business 	<ul style="list-style-type: none"> Additional material transfer agreements and the first licence agreements concluded for assessing the technology Revenue stabilised
Group	<ul style="list-style-type: none"> Secure the Company's funding 	<ul style="list-style-type: none"> Inflow of €9.9 million (gross) via a rights issue in Q1/2012 Repayment of a €7.5 million shareholder loan and cash inflow of €16.1 million as part of a combined capital increase in return for cash and in-kind contributions in Q3/2012

The Group's economic development in the financial year, specifically in the Rx and Cx segments, was better than forecast, which led to the targets for both revenue and income being revised in the half-yearly report. Operating expenses were fully in line with the financial guidance. As a consequence of rising revenue, the net loss for the year and the financing requirements for the past year were in the lower range of the guidance. Total assets were substantially higher year on year due to the inflow of funds from licence agreements and capital measures. Equity and the equity ratio showed a significant improvement compared to the end of the previous financial year, also on account of the two capital increases.

Financial outlook	Plan (02/2012) €million	Adjustment (07/2012) €million	Actual 2012 €million
Sales revenue and other income	14.0 – 16.0	16.0 – 18.0	17.8
Operating expenses	25.0 – 29.0	25.0 – 29.0	26.8
Operating result	(10.0) – (14.0)	(8.0) – (12.0)	(8.9)
Total funding requirement	20.0 – 24.0	20.0 – 24.0	20.0
Funds required per month	1.7 – 2.0	1.7 – 2.0	1.7

6. Corporate governance

6.1. Statement on Corporate Governance pursuant to Section 289a German Commercial Code for the 2012 financial year

The Statement on Corporate Governance pursuant to Section 289a 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 German Stock Corporation Act (Aktiengesetz, AktG). Both corporate bodies had an in-depth discussion regarding compliance with the requirements of the GCGC as amended on 26 May 2010 and 15 May 2012, respectively.

In addition, the Statement addresses the principles of proper corporate governance and makes relevant disclosures on 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 both the composition and the procedures of their committees.

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The Statement on Corporate Governance was posted on [WILEX's website](#) under the tab "Press + Investors > Corporate Governance" on 7 February 2013. Pursuant to Section 317 (2) sentence 3 of the German Commercial Code, the statement on corporate governance in accordance with Section 289a German Commercial Code is not part of the audit of the financial statements.

6.2. Corporate governance report

Responsible corporate governance is integral to WILEX's philosophy. As an instrument of self-regulation, the German Corporate Governance Code (GCGC) contains recommendations and suggestions for transparent and exemplary corporate governance. This code, compliance with which is voluntary, is designed to enhance the trust of the financial markets and the public in the management of listed companies based on transparent descriptions of management and control mechanisms as well the disclosure of the rules of corporate governance. Both the Executive Management Board and the Supervisory Board of WILEX AG expressly endorse the Code and have implemented it with exceptions.

6.2.1. Compensation of the Executive Management Board and the Supervisory Board

© Page 48

WILEX AG complies with the recommendations of the German Corporate Governance Code to disclose all compensation paid to the Executive Management Board and the Supervisory Board broken down by individual. Please see chapter 6.3 "Compensation Report" for more detailed disclosures on the compensation of the Executive Management Board members (broken down by fixed and variable components as well as other ancillary benefits) and the compensation of the Supervisory Board members. The compensation paid to the members of the Executive Management Board and the Supervisory Board is also disclosed on the [Company's website](#) under the tab "Press + Investors > Corporate Governance > Corporate bodies".

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6.2.2. Directors' dealings

The German Securities Trading Act (Wertpapierhandelsgesetz, WpHG) sets out that members of the Executive Management Board, the Supervisory Board and the inner circle of WILEX AG's executives and parties related to them must disclose any personal trading with WILEX shares, to the extent that such trading surpasses the statutory de minimis limit of €5,000 per calendar year. WILEX's policy is to disclose each and every transaction irrespective of its volume.

In the 2012 financial year, WILEX AG's executives reported the following transactions subject to disclosure in accordance with Section 15a German Securities Trading Act (Wertpapierhandelsgesetz) (Directors' dealings), which were also posted on [WILEX's website](#) under the tab "Press + Investors > Announcements > Directors' Dealings".

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Name	Date	Trans- action	Market- place	Price €	Number	Volume €
dievini ¹	29.08.2012	Subscription/ purchase	OTC	3.70	8,477	31,364.90
dievini ¹	21.08.2012	Subscription obligation	OTC	3.70	2,100,337	7,771,246.90
dievini ¹	21.06.2012	Sale	OTC	3.51	112,454	394,713.54
dievini ¹	21.06.2012	Sale	OTC	3.51	140,390	492,768.90
dievini ¹	21.06.2012	Sale	OTC	3.51	28,077	98,550.27
dievini ¹	21.06.2012	Sale	OTC	3.51	2,954	10,368.54
dievini ¹	21.06.2012	Sale	OTC	3.51	260,018	912,663.18
dievini ¹	21.06.2012	Sale	OTC	3.51	608,358	2,135,336.58
dievini ¹	21.06.2012	Securities loan	OTC	0.00	1,152,251	0.00
Professor Olaf G. Wilhelm (Executive Management Board) ²	06.02.2012	Subscription/ purchase	OTC	3.10	2,000	6,200.00
Dr Georg F. Baur (Supervisory Board)	06.02.2012	Subscription/ purchase	OTC	3.10	26,840	83,204.00
Andreas R. Krebs (Supervisory Board)	03.02.2012	Subscription/ purchase	OTC	3.10	10,000	31,000.00
dievini ¹	03.02.2012	Subscription/ purchase	OTC	3.10	1,144,334	3,547,435.40
dievini ¹	01.02.2012	Subscription/ purchase	OTC	3.10	975,997	3,025,590.70
dievini ¹	30.01.2012	Subscription/ purchase	OTC	3.10	168,337	521,844.70

¹ The Supervisory Board members Professor Christof Hettich and Professor Friedrich von Bohlen und Halbach have management responsibilities at dievini Hopp BioTech holding GmbH & Co. KG, which is a shareholder of WILEX AG.

² The wife of Professor Olaf G. Wilhelm, Dr Sabine Wilhelm, subscribed further 2,000 shares.

6.2.3. Shares held by the Supervisory Board and the Executive Management Board

The following members of the Supervisory Board directly held 258,023 shares and indirectly held 9,976,356 shares in the Company as of 30 November 2012; two members of the Executive Management Board directly held 242,717 shares:

Name	Function	Shareholdings	Number
Dr Georg F. Baur	Deputy Chairman of the Supervisory Board	Direct	208,023
Andreas R. Krebs	Member of the Supervisory Board	Direct	50,000
Professor Friedrich von Bohlen und Halbach	Member of the Supervisory Board	Indirect ¹	9,841,138
Professor Christof Hettich	Chairman of the Supervisory Board	Indirect ¹ Indirect ²	9,841,138 135,218
Professor Olaf G. Wilhelm ³	Chairman of the Executive Management Board	Direct	122,331
Dr Jan Schmidt-Brand	Member of the Executive Management Board	Direct	120,386

¹ In his capacity as Managing Director of dievini Verwaltungs GmbH, the general partner of dievini BioTech holding GmbH und Co. KG

² In his capacity as Managing Director of NewMarket Venture Verwaltungs GmbH

³ The wife of Professor Olaf G. Wilhelm, Dr Sabine Wilhelm, holds a further 122,331 shares.

Changes in the shareholdings of members of the Company's corporate bodies are posted at on [WILEX's website](#) under the tab "Press + Investors > Corporate Governance > Shareholdings".

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6.2.4. Shareholders and Annual General Meeting

The shareholders of WILEX AG exercise their co-determination and control rights at the Company's Annual General Meeting, which takes place at least once a year. It resolves all matters determined by law with binding effect on all shareholders and the Company. Each share grants one vote at the Annual General Meeting. Every shareholder who registers in due time has the right to participate in the Annual General Meeting. The Company makes it easy for its shareholders to exercise their voting rights without attending the Annual General Meeting in person through proxies bound by instructions. In addition, shareholders may also appoint proxies of their own choosing. WILEX AG makes the Executive Management Board's speech and presentation as well as all voting results available to all shareholders unable to attend the Annual General Meeting in person immediately after it has ended. The notice of the Annual General Meeting as well as the reports and information required for the resolutions are published in accordance with the requirements of German stock corporation law and are also made available on the [website](#) under the tab "Press + Investors > Annual General Meeting".

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6.2.5. Transparency and timeliness

WILEX AG regularly informs shareholders and analysts, as well as the media and the interested public, of the Company's position and any major changes; in so doing, it complies with all requirements of the German Corporate Governance Code in terms of transparency, timeliness, openness and equal treatment. Our corporate communications aim first and foremost to make identical information available to all target groups at the same time and in a timely manner. It goes without saying that on this basis WILEX AG makes publications of the Company available in German and English simultaneously.

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All information relevant to the capital markets – such as annual and quarterly reports, ad-hoc announcements, press releases, directors' dealings and voting share notifications – are posted on the [Company's website](#) under the "Press + Investors" tab. Presentations at conferences, investor and analyst meetings as well as all information related to the Company's Annual General Meeting are also posted there. The financial calendar contains information on dates relevant to the capital market, e.g. financial reports and Annual General Meetings. Analyst and media conferences are held at least once per year. In addition, the "Press + Investors" section also provides disclosures related to corporate governance in both German and English, which are updated on a regular basis. This includes the Declaration of Conformity, the Statement on Corporate Governance, the Articles of Association, the Report of the Supervisory Board, the Compensation Report and all

archived Declarations of Compliance. The [Company website](#) also offers comprehensive information on the Company and its share.

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6.2.6. Compliance in the 2012 financial year

Ethical standards, professionalism and compliance with statutory requirements are among the key ingredients of WILEX AG's corporate governance. In the 2012 financial year, there were no deviations from the Declaration of Conformity applicable to this period. There were no conflicts of interest among members of the Executive Management Board as defined in Section 4.3 of the German Corporate Governance Code. Any conflicts of interest affecting members of the Supervisory Board pursuant to Section 5.5 of the German Corporate Governance Code were disclosed to the remaining 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:

The Supervisory Board members, Professor Christof Hettich and Professor Friedrich von Bohlen und Halbach, are Managing Directors of dievini Verwaltungs GmbH, which in turn is the general partner of dievini Hopp Bio-Tech holding GmbH & Co. KG, and did not participate in the Supervisory Board's deliberations or resolutions relating to the shareholder loan including interest granted by dievini Hopp BioTech holding GmbH & Co. KG as part of the combined capital increase in return for cash contributions and contributions in kind.

The role of Professor Christof Hettich, the Chairman of the Supervisory Board, as partner of the Rittershaus law firm, which provides legal consulting services for the WILEX Group, has been identified as a further conflict of interest by the Supervisory Board. All consulting contracts agreed with the Rittershaus law firm were approved by the Supervisory Board. 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 some Supervisory Board members also hold positions on supervisory boards of other companies in the pharmaceutical and biotech sectors, none of these companies can be considered major competitors of WILEX, which complies with GCGC requirements.

WILEX has explained the legal regulations on insider trading to all members of its corporate bodies and employees and pointed out the need to handle sensitive information at WILEX in a responsible manner.

Under compliance rules, all of WILEX's employees are obligated to report violations of compliance rules to their supervisor or the responsible member of the Executive Management Board. Moreover, to comply with the applicable statutory requirements, the Company has appointed numerous officers who monitor compliance with the respective statutory requirements in their given departments (e. g. drug safety, radiation protection, manufacturing, quality assurance, archiving, waste and safety, biological safety, data protection, IT security); they also analyse and report violations to the responsible member of the Executive Management Board and initiate the necessary measures in coordination with that Board member. Many guidelines (so-called Standard Operating Procedures or corporate guidelines) have been issued for these areas, and both WILEX and its employees must comply with them; compliance is monitored by the compliance officers. Regular training sessions are also organised in this connection.

6.2.7. Risk management

The responsible treatment of risks constitutes a material element of functional corporate governance. WILEX has established a systematic risk management, which enables the Executive Management Board to detect the relevant risks and market trends in due time and respond to them. Please see chapter 7, "Report on risks and opportunities" for details on the Company's risk management and for the risk report. The report on the internal control system relevant to the financial reporting process required since the German Accounting Law Modernisation Act (Bilanzrechtsmodernisierungsgesetz) took effect is a part of the Statement on Corporate

Governance pursuant to Section 289a German Commercial Code, which has been published on the [Company website](#) under the tab “Press + Investors > Corporate Governance”.

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Both of these systems are continuously refined and adjusted to the changing environment. The Executive Management Board discusses the given risk report and any actions that might be required at its meetings and regularly briefs the Supervisory Board on existing risks and their development.

6.2.8. Accounting and audit of financial statements

WILEX regularly informs both its shareholders and third parties by means of its consolidated financial statements and quarterly reports. As a corporation located within the European Union, WILEX AG must prepare and publish its consolidated financial statements in accordance with the International Financial Reporting Standards (IFRS), taking Section 315a German Commercial Code into account. Both the consolidated financial statements and the annual financial statements are prepared by the Executive Management Board, audited by the auditor and reviewed by the Supervisory Board. The auditor elected by the Annual General Meeting and commissioned by the Supervisory Board participates in the deliberations of both the Audit Committee and the Supervisory Board regarding the Company's financial statements and reports on the material findings of its audit. The Audit Committee uses this information for its own assessment of the Company's financial statements and reports. The combined management report, the annual financial statements of WILEX AG and the consolidated financial statements for the 2012 financial year are audited by Deloitte & Touche GmbH Wirtschaftsprüfungsgesellschaft (Deloitte). These audits also review the risk early warning system defined by Section 91 (2) German Stock Corporation Act as to its general suitability for the early detection of going-concern risks. Deloitte reports to the Chief Financial Officer and the Audit Committee of the Supervisory Board. The auditor also checks whether the Declaration of Conformity in accordance with Section 161 German Stock Corporation Act has been issued and published.

6.3. Compensation report

The compensation report summarises the principles used to determine the total compensation of the Executive Management Board of WILEX AG and explains the structure as well as the compensation received by the Executive Management Board members. The principles and the amount of compensation received by the members of the Supervisory Board are also described. The compensation report follows the recommendations of the German Corporate Governance Code and satisfies the requirements in accordance with the applicable provisions of Section 314 (1) no. 6a, Section 315 (2) no. 4 and Section 289 (2) no. 5 German Commercial Code. The compensation report takes the provisions of the German Commercial Code and the German Management Board Compensation Disclosure Act (Vorstandsvergütungs-Offenlegungsgesetz) as well as the requirements of the German Corporate Governance Code into account.

6.3.1. Compensation of the Executive Management Board

The full Supervisory Board is responsible for determining the compensation of the Executive Management Board in accordance with Section 107 (3) German Stock Corporation Act. Compensation consists of a salary (fixed compensation), other benefits (non-cash compensation), a variable compensation component and a stock option programme with a long-term incentive and a risk element.

In the event of the termination of an Executive Management Board member's service for WILEX, there is no contractual entitlement to a settlement.

6.3.2. Salary and benefits

The annual salary of members of the Executive Management Board is determined for the term of office and paid in equal amounts over twelve months. It depends on the financial position of WILEX AG and the level of compensation paid by competitors. In addition to their salaries, members of the Executive management Board receive the following benefits:

A company car is made available to Executive Management Board members Professor Olaf G. Wilhelm, Dr Paul Bevan and Dr Jan Schmidt-Brand. Executive Management Board member Dr Thomas Borcholte does not have a company car.

WILEX AG also pays the premiums for a personal pension plan up to the maximum amount permissible under Section 40b of the German Income Tax Act (Einkommensteuergesetz) and the premiums for an occupational disability insurance on behalf of Professor Olaf G. Wilhelm, Chairman of the Executive Management Board. A pension commitment as part of a deferred salary plan was also granted to Professor Wilhelm in 1999, and a provision has been recognised for this. The allocation to the pension provision corresponds to the increase in the entitlements under the associated reinsurance policy and totalled €941 (2011: €909) in the financial year just ended. WILEX AG makes payments into a pension fund on behalf of Dr Schmidt-Brand; an amount of €672 was recognised for this in the reporting period.

The Company has no such obligations towards any other Executive Management Board members.

For the Executive Management Board member Dr Paul Bevan, WILEX AG covers the costs of up to 24 economy class flights between Germany and the UK per calendar year (return flight).

6.3.3. Variable compensation

Variable compensation is contingent on the achievement of personal targets and WILEX's performance targets. The performance-based compensation of the members of the Company's Executive Management Board is primarily tied to the corporate goals of WILEX, i. e. the achievement of defined milestones in clinical development, the securing of the Company's further funding and the performance of its shares.

The variable compensation of Professor Olaf G. Wilhelm amounts to a maximum of 50 % of his fixed compensation (previous year: 50 %). For Dr Paul Bevan and Dr Thomas Borcholte it amounts to a maximum of 33 % of their respective fixed compensation (previous year: 33 % in each case). For the first time, Dr Jan Schmidt-Brand will receive the maximum annual bonus of €80 k calculated on a pro rata basis over the 2012 calendar year. Of this figure, he will be entitled to receive a maximum of €40 k for his work as a member of the Executive Management Board of WILEX AG and a maximum of €40 k as Managing Director of Heidelberg Pharma. In addition, the members of the Executive Management Board are entitled to stock options above and beyond their base salary as a component of their bonus, the granting of which depends on achievement of milestones. In Professor Wilhelm's case, this might yield a maximum of 28,000 stock options a year, and a maximum of 8,000 stock options a year each for Dr Bevan, Dr Borcholte and Dr Schmidt-Brand.

6.3.4. Compensation component with incentive and risk features

The compensation component with incentive and risk features is based, for one, on the 2005 Stock Option Plan adopted by the Annual General Meeting on 8 September 2005. A total of 900,000 stock options could be granted to the Executive Management Board members under the **2005 Stock Option Plan**. No options were issued to members of the Executive Management Board under this plan in the 2012 and 2011 financial years. The authorisation to grant options under the 2005 Stock Option Plan has expired in the meantime. Including the options already issued to members of the Executive management Board in financial years 2006 and 2007, the active members of the Executive management Board at the reporting date 30 November 2012 held a total of 587,950 options granted under the 2005 Stock Option Plan. At the reporting date 30 November 2012, two former members of the Executive Management Board held a total of 141,385 options. The stock options can be exercised after an initial waiting period of two years from the grant date.

Each of these options entitles the holder to the acquisition of one new share in return for payment of the exercise price, which was €3.10 as of the balance sheet date.

All options issued to the Executive Management Board could only be exercised until the reporting date if the average closing price of WILEX shares during the preceding ten trading days prior to the expiry of the waiting period or for ten consecutive trading days at any other point in time following this date exceeds by a minimum of 10% the exercise price of €3.10 per share. Accordingly, the reference price was set at €3.41. No stock options have been exercised to date under the 2005 Stock Option Plan.

For another, this compensation component is based on the 2011 Stock Option Plan adopted by the Annual General Meeting on 18 May 2011. Up to 173,462 stock options (15% of the total volume) may be granted to the members of the Executive Management Board thereunder. This authorisation remains in effect through 1 July 2016. The stock options may only be exercised when they have vested after four year and the performance target has been achieved. In order for the performance target to be achieved, the price of WILEX's share on the ten trading days preceding the onset of the respective exercise period must exceed the exercise price by a minimum of 20% as well as surpass the gains of the TecDAX during the maturity of the given stock option. Each of these options entitles the holder to the acquisition of one new share in return for payment of the exercise price, which was €3.53 as of the balance sheet date. Accordingly, the reference price was set at €4.24. In the past financial year (option issue date: 31 March 2012), 112,000 options were issued to members of the Executive Management Board, of which 8,000 stock options were returned after a former Executive Management Board member stepped down during the year. Dr Schmidt-Brand received 60,000 stock options in his capacity as Managing Director of Heidelberg Pharma; however, due to his subsequent appointment to the Group's Executive Management Board, these are included in the report. No stock options have been exercised to date under the 2011 Stock Option Plan.

Overall, the following fixed and variable compensation components as well as non-cash compensation for Executive Management Board members were recognised as an expense in the 2012 financial year:

Executive Management Board member	Fixed compensation €		Variable compensation ¹ €		Other compensation (non-cash compensation) €		Total compensation €	
	2012	2011	2012	2011	2012	2011	2012	2011
Professor Olaf G. Wilhelm	299,000	286,000	74,750	74,750	13,182	10,844	386,932	371,594
Dr Paul Bevan	264,500	253,340	43,643	43,643	16,050	12,730	324,193	309,713
Dr Thomas Borcholte ²	253,000	225,500	41,745	34,243	180	180	294,925	259,923
Dr Jan Schmidt-Brand ³	54,311	0	15,000	0	2,640	0	71,951	0
Peter Llewellyn-Davies ⁴	226,279	253,000	101,026	41,745	21,187	11,851	348,492	306,596
Total	1,097,090	1,017,840	276,164	194,381	53,239	35,605	1,426,493	1,247,826

¹ The exact variable compensation is usually determined and paid in the following financial year. The figures shown here for the 2012 financial year are based on provisions that were determined on the basis of assumptions and historical data.

² Dr Borcholte has waived his non-cash compensation in the form of a company car.

³ Dr Schmidt-Brand was appointed to the Executive Management Board of WILEX AG effective 1 September 2012. The compensation refers to his work as Chief Financial Officer of WILEX AG and as Managing Director of Heidelberg Pharma GmbH since 1 September 2012. A portion of €37 k of the total compensation is attributable to his work as a member of the Executive Management Board of WILEX AG.

⁴ Mr Llewellyn-Davies stepped down from the Executive Management Board of WILEX AG on 31 August 2012. His compensation includes the pro rata variable compensation for 2012 as well as the settlement of remaining holiday entitlements and other items.

Professor Olaf G. Wilhelm, Dr Thomas Borcholte (from 1 September 2012) and Peter Llewellyn-Davies (until 31 August 2012) did not receive compensation for their activities as executive directors of WILEX Inc. in 2012 and 2011.

The following overview shows the stock options held by members of the Executive Management Board during the year under review and changes in these holdings as well as the portion of staff costs per beneficiary attributable to these stock options:

Executive Management Board member	01.12.2011 Number	Additions Number	Expiry/return Number	Exercise Number	30.11.2012 Number
Professor Olaf G. Wilhelm	262,770	28,000	0	0	290,770
Dr Paul Bevan	175,180	8,000	0	0	183,180
Dr Thomas Borcholte	150,000	8,000	0	0	158,000
Dr Jan Schmidt-Brand ^{1,2}	0	60,000	0	0	60,000
Peter Llewellyn-Davies ³	131,385	8,000	8,000	0	131,385
Total	719,335	112,000	8,000	0	823,335

¹ Dr Schmidt-Brand was appointed to the Executive Management Board of WILEX AG effective 1 September 2012.

² The 60,000 stock options listed were granted to him in his capacity as Managing Director of Heidelberg Pharma GmbH and before he was appointed to the Executive Management Board.

³ Mr Llewellyn-Davies stepped down from the Executive Management Board of WILEX AG on 31 August 2012.

Executive Management Board member	Expense in the IFRS statement of comprehensive income €	Fair value of the options ¹ €
Professor Olaf G. Wilhelm	134,082	676,052
Dr Paul Bevan	84,300	433,767
Dr Thomas Borcholte	71,999	436,170
Dr Jan Schmidt-Brand ²	17,255	95,256
Peter Llewellyn-Davies ³	63,064	325,835
Total	370,700	1,967,079

¹ As of the respective issue date

² Dr Schmidt-Brand was appointed to the Executive Management Board of WILEX AG effective 1 September 2012.

³ Mr Llewellyn-Davies stepped down from the Executive Management Board of WILEX AG on 31 August 2012.

The year-on-year increase in expenses arises from the across-the-board reduction in the exercise price for the tranches from the 2005 Stock Option Plan of €3.10 as part of the February 2012 capital increase. An expense of 5k (2011: €0 k) was recognised for a former member of the Executive Management Board.

The following figures apply to the previous financial year:

Executive Management Board member	01.12.2010 Number	Additions Number	Exercise Number	Sales Number	30.11.2011 Number
Professor Olaf G. Wilhelm	262,770	0	0	0	262,770
Dr Paul Bevan	175,180	0	0	0	175,180
Peter Llewellyn-Davies	131,385	0	0	0	131,385
Dr Thomas Borcholte	150,000	0	0	0	150,000
Total	719,335	0	0	0	719,335

Executive Management Board member	Expense in the IFRS statement of comprehensive income €	Fair value of the options ¹ €
Professor Olaf G. Wilhelm	0	631,599
Dr Paul Bevan	0	421,066
Peter Llewellyn-Davies	0	325,835
Dr Thomas Borcholte	21,197	423,469
Total	21,197	1,801,969

¹ As of the respective issue date

6.3.5. Compensation of the Supervisory Board

In accordance with the Company's Articles of Association, the members of the Supervisory Board receive a fixed compensation of € 15,000 for each full financial year of service on the Supervisory Board. The Chairman of the Supervisory Board receives a fixed compensation of € 35,000 and the Deputy Chairman € 25,000. The Supervisory Board compensation is paid in four equal instalments on the last day of February and on 31 May, 31 August and 30 November of each financial year.

Members of a Supervisory Board committee are paid a flat fee of € 3,000, while chairpersons of such committees are paid € 7,000 per financial year and committee. In each case, compensation is limited to activities in a maximum of two committees. Over and above this individual limit, WILEX AG does not pay more than € 39,000 per financial year for committee activities. If this cap is not sufficient to cover all memberships and chairmanships of Supervisory Board committees, it is distributed proportionally among all committee members and chairpersons in line with the above provisions, unless the Supervisory Board unanimously resolves a different regulation.

An additional allowance is paid for attendance at a maximum of six Supervisory Board meetings in each financial year. Meeting chairpersons are paid a flat fee of € 3,000 and all other members € 1,500 each per meeting. Supervisory Board members who attend meetings by telephone receive only half of the allowance. This allowance must be paid with the Supervisory Board member's fixed compensation. Members of Supervisory Board committees do not receive an attendance allowance for committee meetings.

The compensation paid to Supervisory Board members who were not in office for a full financial year is pro rated in accordance with the duration of their membership on the Supervisory Board.

The Supervisory Board members do not receive variable compensation, nor are they granted options or similar rights. Supervisory Board members are not entitled to a settlement if their membership ends.

The total compensation paid by WILEX AG to the Supervisory Board for the 2012 financial year amounted to €207,847 plus expenses (previous year: €219,000). The table below shows the individual compensation.

Supervisory Board member	Fixed compensation €		Attendance allowance €		Committee fee €		Total compensation €	
	2012	2011	2012	2011	2012	2011	2012	2011
Professor Christof Hettich (Chairman)	35,000	35,000	18,000	18,000	7,000	7,000	60,000	60,000
Dr Georg F. Baur (Deputy Chairman)	25,000	25,000	9,000	9,000	7,000	7,000	41,000	41,000
Professor Friedrich von Bohlen und Halbach	15,000	15,000	9,000	7,500	10,000	10,000	34,000	32,500
Andreas R. Krebs	15,000	15,000	9,000	9,000	6,000	6,000	30,000	30,000
Professor Iris Löw-Friedrich	15,000	15,000	9,000	8,250	3,000	3,000	27,000	26,250
Dr Birgit Kudlek ¹	7,782	0	6,000	0	1,500	0	15,282	0
Dr Alexandra Goll ²	565	15,000	0	8,250	0	6,000	565	29,250
Total	113,347	120,000	60,000	60,000	34,500	39,000	207,847	219,000

¹ Dr Kudlek has been a member of the Supervisory Board since 25 May 2012.

² Dr Goll stepped down from the Supervisory Board effective 14 December 2011.

6.4. Disclosures under Section 289 (4) and 315 (4) German Commercial Code as well as explanatory report

6.4.1. Summary of subscribed capital

The Company's subscribed capital amounted to €31,275,507.00 at the end of the financial year. It is composed of 31,275,507 no par value bearer shares. These shares are fully paid in. The Company does not hold any treasury shares.

6.4.2. 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.

Beyond this, no shareholder was prohibited from selling, pledging or otherwise disposing of the Company's securities (shares and options) as of 30 November 2012.

6.4.3. Equity interests exceeding 10 % of voting rights

Section 315 (4) 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
dievini Hopp BioTech holding GmbH & Co. KG (dievini) ¹	approx. 47 %
UCB Pharma S.A. (UCB)	approx. 14 %

¹ Including the shares of Verwaltungsgesellschaft des Golf Club St. Leon-Rot mbH and Curacyte AG

6.4.4. 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.

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

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

6.4.6. 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 – 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 German Stock Corporation Act.

Pursuant to Section 179 (1) German Stock Corporation Act, any amendment to the Articles of Association requires a resolution by the Annual General Meeting to be passed with a majority of at least three-quarters of the share capital represented at the adoption of the resolution.

6.4.7. Authority of the Management Board to issue and buy back shares

In accordance with Article 5 (3) of the Articles of Association, the share capital is contingently increased by up to € 18,400.00 through the issue of up to 18,400 no par value bearer shares (Contingent Capital). The contingent capital increase serves to grant options to the Company's employees and Executive Management Board members as resolved by the Annual General Meeting on 20 July 2001 (Item 6 on the agenda) taking into consideration the amendments as resolved by the Annual General Meetings on 29 April 2005 and 8 September 2005. The contingent capital increase will only be implemented to the extent that the holders of options make use of their option rights. The shares participate in profits for the first time in the financial year for which – at the time of the effective submission of the option exercise notice – the Company's Annual General Meeting had yet to adopt a resolution concerning the allocation of net retained profits.

In accordance with Article 5 (4) of the Articles of Association, the Company's share capital is contingently increased by €986,491 through the issue of up to 986,491 new no par value bearer shares (Contingent Capital II). The contingent capital increase will only be implemented to the extent that holders of the stock options issued by the Company on the basis of and subject to the terms and conditions of the authorisation by the Annual General Meeting on 8 September 2005 (resolution in accordance with item 9.1) make use of their stock options. In accordance with item 9.1 (5) of the above-mentioned resolution by the Annual General Meeting, the shares will be issued at the exercise price set in each case as the issue price and also at the specific terms and conditions determined in this resolution. The new shares participate in profits from the start of the financial year in which they are issued.

In accordance with Article 5 (6) of the Articles of Association, the Company's share capital is contingently increased by € 1,156,412.00 through the issue of up to 1,156,412 new no par value bearer shares (Contingent Capital 2011/I). The contingent capital increase is exclusively for the purpose of satisfying subscription rights issued on the basis of the authorisation resolved by the General Meeting on 18 May 2011 in respect of Agenda item 6. The conditional capital increase will only be implemented to the extent that the holders of the subscription rights issued under the "WILEX 2011 Stock Option Plan" exercise their right to subscribe for shares of the Company and the Company does not grant treasury shares or offer a cash settlement to satisfy the option rights. The new shares participate in profits from the start of the financial year for which, at the time they are issued, a resolution regarding the appropriation of net profits has not yet been adopted.

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 authorised to determine any other details concerning the contingent capital increase and its implementation in connection with all contingent capital. The Supervisory Board is authorised to change the wording of the Articles of Association to reflect the scope of the respective capital increase from Contingent Capital.

As of the reporting date, the Executive Management Board was authorised 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 € 5,946,937.00 by issuing up to 5,946,937 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 24 May 2017 (Authorised Capital 2012/II).

The shareholders generally have a subscription right in connection with cash capital increases. The shares may also be acquired by one or more banks, subject to the obligation to offer them to the shareholders for subscription. The Executive Management Board is authorised, however, subject to the approval of the Supervisory Board, to exclude shareholders' subscription right in connection with cash capital increases in the following cases:

- (a) In the event of a cash capital increase, if the issue price of the new shares is not substantially lower than the market price and if the total share of the new shares issued in direct or analogous application of section 186 para. 3 clause 4 of the German Stock Corporation Act in return for cash contributions subject to the exclusion of shareholders' subscription right while this authorisation is in effect does not exceed a total of 10 % of the share capital, specifically, neither at the date this authorisation takes effect nor at the time it is exercised. Shares that are, or shall be, issued for the purpose of satisfying bonds that are issued with conversion rights or options shall be counted toward this 10 % limit of the share capital, to the extent that and insofar as these bonds are issued in analogous application of section 186 (3) sentence 4 of the German Stock Corporation Act subject to the exclusion of shareholders' subscription right while this authorisation is in effect; or
- (b) to avoid fractions of shares.

The Executive Management Board is also authorised to exclude shareholders' subscription rights in connection with capital increases in return for contributions in kind with the approval of the Supervisory Board. Finally, the Executive Management Board is authorised to determine both the additional content of the rights embodied in the shares and the conditions of the share issue, subject to the approval of the Supervisory Board. The Supervisory Board is authorised to amend the wording of the Articles of Association to reflect the scope of the capital increase from Authorised Capital 2012/I.

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

6.4.8. Key agreements entered into by the Company providing for a change of control following a takeover bid

WILEX AG and UCB agreed a strategic alliance on 8 January 2009, under which five oncological programmes were taken over from UCB. If WILEX AG is subject to a change of control following a takeover bid, UCB is entitled but not obligated to make use of its buyback option for the five oncological programmes (WX-554, WX-037 and three undisclosed antibody projects) (so-called opt-in right) prematurely.

Initially, a change of control as defined by the agreement is deemed to have taken place in particular if a party holds at least 50 % of the shares in WILEX AG. The requirements of the German Stock Corporation Act regarding the allocation of voting shares shall apply. In the event of a takeover bid as defined in the German Securities Acquisition and Takeover Act, acceptance of an offer for 50 % or more of the voting shares suffices.

Furthermore, the transfer to a third party of all or essentially all assets of WILEX AG as well as the acquisition of the right to appoint or dismiss 50 % or more of the members of the Supervisory Board of WILEX AG are considered a change of control.

In particular, the parties also stipulated that if 50 % or more of the Company's Executive Management Board members and second management tier (vice presidents or higher) leave the Company within a period of three years from the closing of the strategic alliance, UCB may exercise the change of control provision inasmuch as these persons occupy key positions in regards to the expertise of WILEX, i.e. to develop and market drug candidates for oncological indications.

All stock options issued to employees and the Executive Management Board vest at the time of the change of control and may be exercised immediately without regard for any waiting period.

6.4.9. Compensation agreements between the Company and members of the Executive Management Board or employees concluded in the event of a takeover bid

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

7. Report on risks and opportunities

7.1. Risk strategy

Managing and controlling risk is important to the management of WILEX AG. The tasks involved include the recording and assessment of risk, as well as the efficient controlling of operational and strategic risks. All potential risks with substantial ramifications and a reasonable probability of occurring are closely monitored at regular intervals. All overriding entrepreneurial decisions are made after a comprehensive assessment of all related risks.

The Company's risk strategy is defined by the Executive Management Board and coordinated with the Supervisory Board. The Chief Financial Officer is responsible for the Company's risk management and control. The Controlling department regularly reports the current status of risk management to the full Executive Management Board.

WILEX is exposed to relatively high risks, since it is engaged in research and development in the biopharmaceutical industry and has not yet achieved sustainable earnings. Such risks may affect various operational functions and have a significant negative impact on profit and loss, net assets and financial position, as well as on the Company's enterprise value.

7.2. Risk management and control

WILEX has established a comprehensive and efficient system across the Group including its subsidiaries, functions and processes in order to detect, assess, communicate and manage risks. Risk management serves to detect risks as early as possible, use suitable measures to keep operating losses at a minimum and avert going-concern risks. WILEX uses an IT-based risk management system for purposes of early risk identification; the system complies with the requirements of the German Control and Transparency in Business Act (Gesetz zur Kontrolle und Transparenz im Unternehmensbereich). WILEX uses this system to identify and assess risks as well as to monitor the measures aimed at minimising risk. Potential risks are classified into 16 risk areas, and all risks are unequivocally assigned to specific risk officers, most of whom belong to WILEX's second management tier (depending on the significance of the given risk). Risks are assessed in terms of their quantifiable effect on the WILEX Group even before any risk management measures or the process of mitigating the given risk have been initiated.

All material risks are addressed in a risk report that is made available to the Executive Management Board fortnightly; shorter intervals are adopted to report on material risks should the need arise. 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 subsidiaries are included.

WILEX distinguishes between short-term risks that might affect the Company in the next 12 months and longer-term strategic risks that are particularly important for WILEX's programmes of developing its own products with development cycles of ten to 15 years. Unforeseen risks are discussed alongside the usual risk management process, and countermeasures are put in place at short notice. The risk management system is described in detail in both a Risk Manual and a company guideline. These documents are regularly updated and made available to all employees. The risk early warning system is reviewed by the Company's auditor at least once a year in order to ensure that it meets the requirements of Section 91 (2) German Stock Corporation Act.

7.3. Internal control system for financial reporting

Pursuant to Section 315 (2) no. 5 German Commercial Code in conjunction with Section 91 and 93 German Stock Corporation Act, the Executive Management Board is responsible for ensuring compliance with and due reporting on an effective internal control system designed to ensure reliable financial reporting. The Company's internal control system 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. WILEX AG fulfils the requirements of the German Commercial Code.

In this connection, both the Executive Management Board and the Supervisory Board of WILEX AG have the obligation to conduct regular reviews of the functionality of the internal control system in ensuring reliable financial reporting. Internal reviews have not uncovered any material weaknesses, and minor defects were

remedied immediately. These matters are also reported to the Supervisory Board's Audit Committee on a regular basis, and the activities related to the reviews are discussed.

To ensure reliable financial reporting, WILEX AG observes the International Financial Reporting standards (IFRS) and the provisions of the German Commercial Code (HGB). In addition, the Company uses an internal control system (ICS) which 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 as well as
- Monitoring the internal control system.

The Company's internal control system is intended to ensure compliance with applicable accounting principles to ensure reliable financial reporting. The system comprises actions that are managed automatically and manually. Preventive and downstream risk controls are carried out. Care is taken in that connection to maintain both the division of responsibilities in Finance and compliance with corporate guidelines (e.g. four-eyes principle when approving expenditures). These controls also include the utilisation of automated solutions that define different access and permission rights and thus grant limited access, especially in connection with the Group's finance and accounting system.

In addition, WILEX AG also includes external experts in the process, e.g. in connection with questions related to the measurement of stock option grants, the preparation of securities prospectuses and purchase price allocations.

Specific risks related to the Group's financial reporting process may arise from unusual or complex transactions. Transactions that are not routinely processed also entail inherent risks. Additional risks related to the financial reporting process arise from the latitude given to employees in regards to the recognition and measurement of assets and liabilities. To prevent these risks, WILEX AG consults with renowned auditing firms, e.g. the auditor of the Company's annual financial statements, and has established a team of professional finance specialists. These risks are monitored both as part of the monthly reporting system and during the year via the internal control system (ICS). External third-party opinions are solicited and the Audit Committee is consulted in connection with special topics.

However, all aspects of the internal control system that serve to provide a proper and reliable financial reporting process ensure complete and timely recording of all transactions in compliance with all requirements under the law and the Company's Articles of Association. These control activities also serve to ensure that the bookkeeping records provide reliable and plausible information.

WILEX AG is convinced therefore that all of the measures it has put in place significantly reduce the risk of negative effects on the Company's financial reporting. Thanks to WILEX's organisational, control and monitoring structures, the internal control and risk management system 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 by the very nature of the matter at hand and, as a result, may limit the effectiveness and reliability of the internal control and risk management system such that even groupwide application of the systems utilised 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.

7.4. General business risks

Since the development of drugs and diagnostics is subject to numerous risks and uncertainties, it is difficult to predict whether WILEX AG will ever generate revenue from product sales and profits from its operations.

WILEX AG is exposed to the risks typical for a biotechnology company, which arise from the development and production of drugs used in cancer therapies. The time between the commencement of drug development and marketing approval spans many years. Even though WILEX AG's portfolio is constantly maturing, there is a continued risk that none of the drug and diagnostic candidates in the current product pipeline will receive regulatory approval. In fact, it became clear in the 2012 financial year that even a late-stage product can miss its clinical development targets.

To date, WILEX AG has not successfully completed all phases of preclinical and clinical development or achieved regulatory approval for any of its drug or diagnostic candidates.

7.5. Product development risks

The development of WILEX AG's core drug and diagnostic candidates – either by WILEX alone or in cooperation with partners – could fail for a variety of reasons. These include difficulties related to patient recruitment or involving cooperation with clinical study sites or contract research organisations. It is impossible to make any predictions based on preclinical and early clinical trials and such trials do not offer any certainty in regard to issues of safety and efficacy in a later trial. We 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 documentation concerning the manufacturing process, quality control or methods of analysis does not satisfy regulatory requirements.

A Phase III trial was conducted for RENCAREX®. The final analysis in October 2012 showed that the primary endpoint of the study had not been reached. Compared with a placebo, there was no improvement in median disease-free survival following treatment with RENCAREX®.

A Phase III trial for the product candidate REDECTANE® was completed in 2010 with good results on the basis of a special protocol assessment. However, the talks on the further development and regulatory approval of REDECTANE® that were subsequently conducted with the FDA showed that a further trial was needed to determine the diagnostic performance and safety of REDECTANE®.

7.6. Manufacturing risks

WILEX AG does not maintain production facilities of its own at its Munich site and obtains all material for its clinical trials from subcontractors. This situation involves risks, including potential problems concerning quality or capacity, or problems arising from the interruption of supplies in the event of the termination of a contract.

To obtain regulatory approval for drug and diagnostic candidates, the manufacturer in question must prove that it or a company commissioned by it can consistently produce these at top quality. The manufacturer must also demonstrate that components, precursors and the end product all have a certain minimum shelf life. As part of the approval programme, the regulatory authorities must receive, in addition to the clinical and pre-clinical data, an exact outline of the manufacturing method, the corresponding quality controls as well as stability studies including the analysis method used, known as the "CMC part". If the CMC part does not comply with the official requirements, WILEX AG may be required to interrupt or even discontinue the relevant clinical trials for the drug or diagnostic candidates concerned. In this case, the placing on the market and sale of these drug or diagnostic candidates might be prohibited altogether or made dependent on further research and development. An application for regulatory approval could also be rejected.

Authorities have the right to inspect production facilities at any time. If an inspection by an authority reveals any defects, WILEX AG or manufacturers it has commissioned might be required to remedy the defects, suspend production or even close the production facilities. This would interrupt the manufacturing process and might hamper delivery of the affected drugs, diagnostic agents or product candidates. WILEX AG might be required furthermore to interrupt or discontinue current clinical trials and the placing on the market and sale of the affected drugs, diagnostic agents or product candidates might be prohibited altogether.

Changes in the manufacturing process (including the manufacturing method) or changes in the place of manufacture or the manufacturer could also be subject to inspection, approval or re-approval by authorities. This might make it necessary to redo or repeat clinical trials. The related inspections might be time-consuming and cost-intensive and might delay or completely prevent the approval and market launch of a drug or diagnostic candidate.

Should one contract manufacturer terminate or not extend the contract manufacturing agreement with the Company, WILEX AG would be forced to find another suitable contract manufacturer. Changing the contract manufacturer might lead to adaptation difficulties, especially delays in production, delivery bottlenecks and substantial other costs. Production problems may also arise in the course of the cooperation, however. These include insufficient allocation of capacity by the contracting party for the purposes of the cooperation, financial difficulties experienced by the contract manufacturer, a change in its business strategy, or a change in the contract manufacturer's ownership structure. Such circumstances could impair the contractual relationships, delay the production of the drugs and diagnostics concerned and increase the costs of their production.

This dependence on production by contract manufacturers presents additional risks to which in-house production is not exposed. One of these is non-compliant production that may lead to product liability claims and other compensation claims being brought against WILEX AG by third parties, especially patients.

All this can have a negative effect on Group's net assets, financial position and earnings.

7.7. Risks arising from collaboration with service providers

In conducting its preclinical and clinical trials, WILEX AG collaborates with clinical test centres, clinical trial managers and clinical research physicians as well as clinical contract research organisations (CROs) and other service providers. Although WILEX AG conducts reviews and audits of its CROs and other providers at regular intervals, despite contractual agreements these entities might fail to comply with applicable study protocols as well as with requirements governing data quality, the archiving of documents and data, the human and financial resources invested for implementing clinical trials, other rules and regulations and the timelines. These entities might neglect WILEX AG's projects or fail to satisfy their obligations in other ways if the fees WILEX AG pays to its CROs and service providers are lower than those paid by its competitors or if these fees fail to cover the expenses of these entities. In turn, this could have a negative impact on the development of WILEX AG's drug and diagnostic candidates and delay or prevent their approval. In addition, any violation by the trial centres, CROs or service providers of the respective clinical study protocols and other rules and regulations could harm the reputation of WILEX AG itself or that of its products.

7.8. Risks arising from collaboration with licensees

WILEX AG has entered into multiple alliances and partnerships for the development, manufacture and/or marketing of its drug and diagnostic candidates. For example, the Company has signed a licence agreement with IBA Pharma S.A. (now referred to as IBA Pharma SPRL), Louvain-la-Neuve, Belgium, concerning its diagnostic candidate REDECTANE® under which IBA Pharma SPRL is responsible for the radiolabelling of the antibody Girentuximab as well as for the marketing, sales and distribution of REDECTANE® and has received the exclusive worldwide rights and licences required for this. The radiolabelling is performed by IBA Molecular North America Inc., Dulles, VA, USA.

WILEX AG has also signed a licence agreement with Prometheus Laboratories Inc., San Diego, CA, USA (Prometheus) concerning the out-licensing of the marketing rights to RENCAREX® (Girentuximab) in the United States.

Problems relating to production or marketing may arise in the course of the partnership. These include insufficient allocation of capacity by the contracting party for the purposes of the cooperation, financial difficulties experienced by the contracting party, a change in its business strategy, a change in the ownership structure of the contracting party or the partial or entire absence of agreed payments such as milestone payments or licence payments. Such circumstances could impair the contractual relationships, delay the production of the drug and diagnostic candidates concerned and increase the costs for their production. This could have a significantly negative impact on the Company's net assets, financial position and earnings.

7.9. Risks resulting from competition and technological change

Those in competition with WILEX AG include pharmaceutical, chemical and biotechnology companies that have access to greater financial, technological and sales resources than WILEX. Some biotechnology companies have also set up alliances with established companies with the aim of intensifying the research, development and marketing of competitive products. Likewise, various research and scientific institutes operate in areas similar to those in which WILEX AG is active. The first product that is marketed generally has a considerable advantage over products launched at a later date, since subsequent market players must prove that their products possess improved features when compared to established products. Like other pharmaceutical and biotechnology companies, WILEX AG operates with the risk that competing technologies could turn out to be safer, more economical and more effective than its own technologies. In addition, there is the risk that these technologies could be used to produce products that reach the market earlier and might be more successful than the products developed by WILEX. Additional risks arise from the fact that competitors might offer their technology to cooperation partners at a lower cost, with the intention of gaining market share.

7.10. Marketing risks

WILEX AG has not yet marketed any products and does not possess a distribution or marketing structure. The Company thus must cooperate with other entities to market its drug and diagnostic candidates. Hence the sales revenue of WILEX AG will also depend on the performance of its cooperation partners. The extent to which the Company can influence the given entities is limited moreover. WILEX AG will generally participate in the revenue generated from its products through licence fees and payments contingent on reaching certain targets (milestone payments). The Group's net assets, financial position and earnings might be negatively affected to a material extent if the Company fails to close the requisite distribution and marketing cooperation agreements at reasonable terms, if such cooperation agreements do not bring about the expected success or if existing cooperation agreements are terminated or their terms are modified.

A decision by WILEX to establish its own distribution and marketing organisation in certain regions would entail a substantial expenditure in terms of money and time. The establishment of such entities can also run into unforeseen difficulties or fail altogether. In turn this could delay the market launch of the Company's products in these regions. This could have a significantly negative impact on the Group's net assets, financial position and earnings.

7.11. Risks related to industrial property rights

WILEX AG endeavours to protect its new and existing drug and diagnostic candidates and technologies in all major economies through patents. Nevertheless, the Company is unable to ensure that patents will be issued on the basis of pending or future patent applications or that WILEX AG will be able to develop patentable drug and diagnostic candidates. Even if patents have been or will be issued, there is no certainty that the scope of current or future patents is or will be broad enough to offer protection against third parties that is financially significant or safeguards competitive advantages for the Company.

Any termination of the licence agreements for the Girentuximab antibody and the CAIX target antigen would have far-reaching negative consequences. Such an event might make it impossible to further develop the antibody Girentuximab or a modified form (REDECTANE®) and market these products. Any infringement by third parties of the patents or the industrial property rights used by WILEX AG could have a negative impact on the Company's business operations. WILEX AG must protect its own products through patents and other industrial property rights and enforce all related rights. In the absence of patent protection the Company might not be able to generate sufficient revenue to cover its development costs or generate sufficient profits. WILEX AG in turn might infringe the industrial property rights of third parties, including those of which it is unaware. This could lead to time-consuming and cost-intensive litigation or force WILEX AG to purchase licences from third parties for developing or marketing its drug and diagnostic candidates.

7.12. Product risks

The marketing and sale of pharmaceuticals and services for specific indications is subject to product liability risks. Product liability actions against WILEX AG at a later stage cannot be ruled out. In connection with this, there is no guarantee that WILEX AG would be able to purchase insurance coverage at both a reasonable cost and acceptable terms or that such insurance would be sufficient to protect it from lawsuits or a loss.

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

WILEX AG is dependent on various sources of income, in particular, milestone payments and licence fees from licensees and cooperation partners. The framework within which public health authorities, research institutes, private health insurance providers and other organisations operate also impacts our business activities. Although health care costs are generally less exposed to economic fluctuations, health care reforms and price reductions for drugs in the US, Europe and Japan – key markets all – will increase the pressure on health care budgets and thus on the pharmaceuticals market on the whole. Overall, this situation could cause potential cooperation partners or investors to refrain from making new commitments. This could also pose a risk for WILEX AG and its subsidiaries.

7.14. Environmental and health risks

WILEX AG uses hazardous substances in its research and development programmes, one example being the use of radioactive material. These activities are subject to health and environmental laws and regulations; non-compliance with these may result in financial losses.

7.15. Legal risks

In principle, WILEX AG and its subsidiaries could become party to a legal dispute, for example in a drug safety, patent, licensing, liability or labour law case, as the plaintiff, defendant or intervenor. A court case or even an arbitration case may be time-consuming and expensive. This could affect the Company's net assets, financial position and earnings. No litigation is pending at present.

7.16. Risks at subsidiaries

7.16.1. Heidelberg Pharma

The ADC technology developed by Heidelberg Pharma is still in its infancy and not yet mature enough to be sold and used on the market. We cannot preclude that the technology might turn out to be useless or unsuitable for the market. The risks described in 7.4 to 7.15 might also appear at the level of Heidelberg Pharma, in which case we would have to rethink Heidelberg Pharma GmbH's business model. This may have an adverse effect on WILEX's net assets, financial position and earnings.

It cannot be precluded that Heidelberg Pharma would require further financial support of WILEX AG if it fails to achieve profitability in the medium term. Such financial support – for instance through additional shareholder

loans or capital increases – might also become necessary to avoid insolvency because Heidelberg Pharma's business continues to generate deficits. In such a case most of WILEX AG's investments related to Heidelberg Pharma would be lost.

There is always a risk for WILEX AG that the current carrying amount of the equity investments recognised in the single-entity financial statements of WILEX AG cannot be confirmed in the annual impairment testing and will result in the recognition of impairment losses. This would have a negative effect on the earnings and equity of WILEX AG, which in turn could impact the Company's share price as well as its net assets, financial position and results of operations. Above all, a decline in the value of WILEX AG's equity investment in Heidelberg Pharma could have significant adverse effects on the HGB balance sheet of WILEX AG due to the high value of the investment. Furthermore, a potentially negative effect on the value of the intangible assets as well as on the goodwill recognised in the IFRS consolidated balance sheet can not be excluded.

7.16.2. WILEX Inc.

WILEX Inc. engages in the production and sales of biomarker tests. The attendant risk resides in not manufacturing these diagnostic tests to the quality customers desire and not fulfilling delivery commitments in a timely manner. Furthermore, FDA restrictions on the existing manufacturing permit could make it impossible for WILEX Inc. to supply key markets and customers.

WILEX Inc. is not profitable at this time. WILEX Inc. can only be expected to become profitable once its marketing activities have been strengthened, its customer base has been successfully expanded worldwide and its revenue shows sustained growth. It cannot be precluded that future marketing activities might fail to bring about the desired outcome and that WILEX Inc. will remain unprofitable. In such a case WILEX AG might be forced to continue to provide financial support to WILEX Inc. to prevent an insolvency. The facts mentioned above can have a negative effect on WILEX's net assets, financial position and earnings.

Despite an improved outlook but in view of unsatisfactory earnings in the past, a 50% impairment loss was recognised as of 30 November 2012 on the carrying amount of the investment in WILEX Inc. as well as on the loan receivables (including the interest rate receivables) from this subsidiary. WILEX AG continues to be exposed to the risk that the carrying amount of the investment in WILEX Inc. recognised in the parent company's single-entity financial statements as of 30 November 2012 cannot be confirmed in the annual impairment testing and would need to be written down for HGB purposes. This would have a negative effect on the earnings and equity of WILEX AG, which in turn could impact the Company's share price as well as its net assets, financial position and results of operations.

7.17. Dependence on employees

The Company mainly employs experts in clinical development, quality assurance and regulatory affairs. To date, WILEX AG has not had any problems recruiting suitable executives and research staff. However, in terms of recruitment effort, the Company must succeed in the face of competition from other companies, universities, public and private sector research institutes and other organisations. Success in recruiting employees and maintaining low employee turnover also depends on total compensation, including stock options. If the share price falls, WILEX AG could become less attractive for both potential and existing employees. The failed ARISER trial and the restructuring measures initiated as a result of this might have damaged WILEX's reputation and might make it more difficult to recruit new staff or result in a higher level of employee turnover. Any failure on the part of WILEX in recruiting qualified staff in the future could delay implementation of the Company's business strategy and considerably impair its business prospects.

Some of the employees of Heidelberg Pharma GmbH have expertise which is material to the operation and further development of its business. The departure of these employees from this company might adversely affect the continued development of Heidelberg Pharma's business operations and have a negative effect on the net assets, financial position and earnings of this subsidiary and hence on those of the WILEX Group.

The employees of WILEX Inc. have expertise that is material for the development and production of the biomarker tests. The departure of some of these employees from WILEX Inc. might adversely affect the further development and production of the diagnostic tests, which could have a negative effect on the net assets, financial position and earnings of WILEX Inc. and hence on those of WILEX AG.

7.18. Currency risks

The Company works with several service providers and cooperation partners worldwide and is thus exposed to currency risks, particularly in connection with currency positions in US dollars and Swiss francs, on account of service costs incurred in foreign currency. Any appreciation of the US dollar or the Swiss franc against the euro could increase the expenses the Company reports in euros. As in the past, in the future WILEX AG expects a proportion of the Company's anticipated revenue, other income and expenses including income from future research and development alliances, originally in other currencies, to be generated mainly in US dollars or Swiss francs. The effects of exchange rate fluctuations on the Company's earnings and financial position may therefore have a negative impact, depending on the trend.

7.19. Financing risk

It is reasonable to assume that WILEX will continue to have a considerable capital requirement in future. For one, the scope of the Company's future capital requirements depends on whether one of the drug and diagnostic candidates the Company is currently developing is successfully approved and when such an approval is granted, making it possible to generate revenue from marketing the product. Costs incurred by research and development and by product approval as well as the enforcement of patent rights may exceed cash returns from these products.

For another, the Company's ability to identify commercialisation partners and enter into cooperation deals is essential. The success of such cooperation ventures depends not only on milestone payments but also on the partners' ability to realise the planned sales revenue and the licence fees resulting from this. Raising additional funds by means of development and marketing agreements or other cooperation and licence agreements might force the Company to surrender material rights to WILEX AG's technologies or drug and diagnostic candidates or entail the granting of licences at terms unfavourable to the Company. This could have a lasting negative impact on WILEX's ability to continue expanding its business.

WILEX AG will have to raise equity capital by issuing new shares under a public or private offering of shares if the funds required cannot be raised by entering into partnerships and cooperation agreements. This might dilute the shareholdings of existing shareholders.

On 17 December 2010, the Company signed a loan agreement for €2.5 million with UCB Pharma S.A., Brussels, Belgium, (UCB) as the lender, subject to subordination. The Company is exposed to the risk of possible termination of the loan agreement at any time by the lender in the total amount of €2.5 million plus interest. If instead the loan repayment claim is contributed as a contribution in kind as part of a rights issue, for example, there is a risk that the existing shareholders' holdings will be diluted. The unsecured loan is not limited in time. The lender is authorised to terminate all or part of the loan, in which case the principal of the terminated loan would have to be repaid within one month. If the lender exercises its right and the Company is required to repay the loan, the Company would be required to repay the loan principal to the lender within one month. This would have a negative effect on the Company's net assets, financial position and earnings.

If WILEX AG were unable to raise sufficient funds at financially reasonable terms as needed, the Company might not be able to continue expanding its business or might have to limit or even terminate the development or marketing of its drug and diagnostic candidates in future. Should the subsidiaries be unable to sustainably cover their costs through higher revenue in the future, this could also lead to the discontinuation of operations. All this can have a significantly negative effect on Group's net assets, financial position and earnings and pose a going-concern risk (see chapter 7.21).

7.20. Balance sheet risks

7.20.1. Risks arising from the impairment of assets

Assets, in particular equity investments, goodwill, licences as well as trade receivables are subject to an inherent impairment risk. Such impairment risks might be triggered by a negative development of business of WILEX AG or its subsidiaries (see chapter 7.16.1 and 7.16.2) or by the insolvency of a creditor. An impairment loss must be recognised if the regular impairment test reveals that there are objective indications of impairment which, in turn, arise from events that may have occurred after the initial measurement of the asset. This would have a negative effect on the net assets, financial position and earnings of the WILEX Group or the individual Group companies because such impairment losses must be recognised in profit or loss.

Pages 62 and 63

7.20.2. Halving of the share capital due to an increasing accumulated deficit

WILEX AG is not yet a profitable company and has posted operating losses in all of its past financial years. Due to the high expenses, particularly for research and development, the net losses each year add up to a large accumulated deficit that reduces equity. There is a risk, therefore, that the share capital in the single-entity financial statements according to HGB could be halved, which would trigger a mandatory notification.

As soon as half of the equity has been depleted by accumulated deficit, the Executive Management Board is required by Section 92 (1) German Stock Corporation Act to convene the Company's General Meeting immediately and disclose this fact. Convening a General Meeting would entail both organisational and financial costs for WILEX AG and might also have a negative impact on the Company's share price.

7.20.3. Risks related to the allowance of tax losses carried forward

The tax losses carried forward as of 30 November 2011 are mainly attributable to WILEX AG (loss carryforward of € 166.2 million for corporation tax; € 163.6 million for municipal trade tax) and may be carried forward indefinitely. Other losses carried forward relate to the subsidiaries, Heidelberg Pharma GmbH and WILEX Inc. Heidelberg Pharma GmbH carried forward a loss of € 41.0 million for corporation tax and municipal trade tax, while WILEX Inc. carried forward a loss of € 1.7 million. Deferred taxes of € 0.9 million were recognised on losses carried forward in the past financial year. Deferred tax assets were recognised in the same amount as the deferred tax liabilities.

The Group companies have not yet been subject to a tax audit. Due to the capital increases as part of the fourth financing round in April 2005 and the IPO in November 2006, WILEX AG may have lost its losses carried forward accumulated until the end of 2006, which amount to € 67.2 million (corporation tax) and € 65.0 million (municipal trade tax). Effective 1 January 2008, under newly enacted Section 8c German Corporation Tax Act (Körperschaftsteuergesetz) the acquisition by an acquirer or parties related to it of 25 % to 50 % of the subscribed capital of a loss corporation results in the pro-rated elimination of its tax loss carryforwards whilst the acquisition of more than 50 % of the subscribed capital results in the complete elimination thereof. Because capital increases also cause shifts in shareholdings and thus adverse acquisitions of equity as defined in Section 8c German Corporation Tax Act, the capital increases carried out since 2008 might possibly have led to the pro-rated elimination of the tax loss carryforwards. The full transfer of Heidelberg Pharma's tax loss carry-forward in excess of the value of the hidden reserves may also be jeopardised by WILEX AG's acquisition of this company in March 2011.

7.21. Risks related to a possible significant influence of main shareholders

Certain shareholders of WILEX AG hold a material proportion of its shares and could exercise a significant influence on the Company in the General Meeting. They could block decisions by the General Meeting or cause their own interests to prevail. The following shareholders and groups of shareholders each hold more than 5 % of the Company's share capital and together well over 25 % of the Company's share capital: dievini Hopp BioTech holding GmbH & Co. KG, Verwaltungsgesellschaft des Golf Club St. Leon-Rot mbH and Curacyte AG (dievini and affiliated companies that together already hold around 47 %) as well as UCB S.A. Depending

on their presence at the General Meeting of WILEX AG, these shareholders could possibly exert a controlling influence over the resolutions passed at the General Meeting of WILEX AG. This applies in particular to dievini and Verwaltungsgesellschaft des Golf Club St. Leon-Rot mbH, because Mr Dietmar Hopp and his son, Mr Oliver Hopp, have an indirect investment in dievini, while Verwaltungsgesellschaft des Golf Club St. Leon-Rot mbH is held by Dietmar Hopp. Each shareholder or group of shareholders that controls over 25% of the voting capital represented at a General Meeting is able to block any resolution of the General Meeting that is required to be passed with a 75% majority. Such resolutions include capital increases with exclusion of the subscription rights of existing shareholders, capital reductions, the creation of authorised capital with exclusion of subscription rights, the creation of contingent capital, certain reorganisation measures such as mergers and split-offs, the liquidation of the Company or a change in its legal form, as well as other fundamental measures changing the structure of the Company. The above-mentioned concentration of the shareholding could also create a conflict of interests between the existing shareholders and the investors.

7.22. Going-concern risks

As of 30 November 2012 and from today's perspective, the Company's cash and cash equivalents and receivables are sufficient to meet its short-term liabilities (including provisions) for at least the next 12 months.

The fact that the endpoint was missed in the ARISER trial with RENCAREX® makes an application for approval and regulatory approval of this product impossible. WILEX AG therefore initiated a restructuring programme and took steps to reduce its workforce in Munich by some 25%. Reduced external costs for research and development, internal savings and lower staff costs will therefore trim operating expenses significantly by 2014 compared to 2012. Cash and cash equivalents should be sufficient until the second quarter of 2014 with the measures described and without any cash flow from the planned commercialisation of the product candidates.

Whilst the WILEX Group substantially reduced its net loss in the 2012 financial year thanks to revenue from licence agreements, it is still not in a position to close a year with a positive result because the required expenses for clinical research and development remain high. The revenue of the Company's subsidiaries, Heidelberg Pharma and WILEX Inc., is not yet sufficient to make a positive contribution to consolidated earnings either. WILEX has prepared an action plan intended to extend its cash reach significantly.

It is vital that earnings in the subsidiaries be improved in 2013 through higher revenue from product sales (Dx) and customer-specific research (Cx). This was the reason that WILEX Inc. concluded a marketing and distribution agreement with Immundiagnostik AG for German-speaking regions and plans to enter into further distribution partnerships. Furthermore, since the end of the financial year, the Cambridge site has been offering contract manufacturing services to third parties in a move designed to improve the utilisation of the facility's development and manufacturing capacity and thus generate additional revenue. At Heidelberg Pharma, longer-term master agreements on contracted work in the field of pharmacology and bioanalytics were negotiated and signed with new customers in the services business. During 2012, several technology cooperation agreements were also signed with pharmaceutical and biotechnology companies concerning the testing of the applicability of ADC technology for specific and proprietary antibodies developed by these contract partners. The aim of these agreements is to generate a steady stream of revenue, ideally leading to the conclusion of licence agreements for specific antibody drug conjugates. Through the setting up of this ADC technology platform, various partnerships and consequently significant milestone payments and licence payments are expected in the future.

On the back of positive data on progression-free survival from the breast cancer trial, WILEX AG commenced and/or stepped up its talks with potential partners for MESUPRON®. The plan is to enter into an out-licensing agreement – preferably with a partner on a global scale – that would significantly improve the Company's financial position.

In the ARISER trial, tests are currently being conducted on the basis of detailed evaluations of subgroups and biomarkers to determine the extent to which the properties and strengths of the antibody Girentuximab could be interesting for third parties in other indications or other applications and the value of the antibody could be increased with a reasonable level of commercial exploitation.

The Executive Management Board cannot predict with any certainty from today's standpoint when and at what terms agreements might be made because the ongoing clinical development of the product candidate in question, the manufacturing terms and the marketing parameters must be negotiated along with the financial terms of such agreements. The Executive Management Board aims to ensure that the product candidate generates the greatest possible return for the Company.

If, contrary to its expectations, the Executive Management Board is unable to sign a commercialisation agreement for a product candidate, the Company would be forced to implement drastic cost-cutting measures in the WILEX Group. In this case, WILEX AG might be unable to satisfy its payment obligations and/or become overindebted from the second quarter of the 2014 financial year. This would jeopardise the Company's existence as a going concern and the shareholders could lose some or all of their invested capital.

7.23. Overall assessment of the risk situation

From today's perspective, no risks that would jeopardise the existence of WILEX AG and the WILEX Group as a going concern in the short term are discernible, notwithstanding all aforementioned risks and provided that all available funding options can be tapped successfully. WILEX is convinced that the Company's opportunities clearly outweigh the risks that are associated with the development of drugs and diagnostic agents or arise from the funding of biotechnology companies. WILEX has pushed the clinical development of its product candidates to a very advanced stage in recent years and succeeded in lowering its risk by building up a broad portfolio and different operating segments.

WILEX AG and its subsidiaries, WILEX Inc. and Heidelberg Pharma, are not yet in a position to contribute a positive cash flow to consolidated earnings. But all of these companies have made progress in broadening their business and increasing revenue.

It remains the primary objective of WILEX to commercialise its product portfolio, particularly by entering into licence agreements. The Company might not be able to satisfy its payment obligations and/or might become overindebted if it were to fail to implement the steps described in the section "Going-concern risks" in 2013/2014, jeopardising the Company's existence as a going concern.

7.24. Opportunities

7.24.1. WILEX AG

7.24.1.1. Market opportunities

WILEX has specialised in the development of drugs and diagnostic agents for cancer diseases and has built a broad development portfolio. Tumour diseases are amongst the most frequent causes of death in industrialised countries, and the number of cancer diagnoses will continue to rise as a result of numerous factors such as higher life expectancy, unhealthy lifestyles or changes in the environment. According to the estimates of the American Cancer Society, roughly 27 million new cases of cancer will be diagnosed in 2050 and there will be 17.5 million deaths from cancer. Accordingly, there is an urgent medical need for cancer therapies that are both effective and well tolerated.

7.24.1.2. Business opportunities

WILEX AG established its presence in the field of personalised medicine early on and is developing different approaches for controlling cancers as a chronic disease in future. With its drug candidates, WILEX AG concentrates on therapies designed to inhibit the further progression of cancer by preventing tumour growth and metastasis.

To the best of WILEX's knowledge, MESUPRON® is the first uPA inhibitor worldwide to have successfully completed a clinical Phase II trial and produced positive data. WILEX AG believes that MESUPRON® could reach a potential annual peak sales volume of up to USD 1 billion because it could be used in different indications. The Executive Management Board believes that it will be able to bring ongoing talks with partners in the pharmaceutical industry on the out-licensing and further development of MESUPRON® to a successful conclusion based on the data presented.

The strategic alliance with UCB in January 2009 enabled WILEX AG to take over UCB's entire preclinical oncology portfolio for purposes of ongoing development. These promising candidates complemented and expanded the Company's own advanced oncological pipeline. In UCB, the Company has found not only an important partner but also a strong strategic investor to support the Company's successful future development. UCB retains exclusive rights to buy back each of the programmes, following completion of initial clinical proof of concept studies for each drug, and assume the responsibility for further development and commercialisation of each product. In this case, WILEX AG will receive development and commercialisation milestone payments and commercialisation licence payments from UCB. Alternatively, in the event UCB does not exercise its buy-back right for a given programme, the Company will retain rights to develop as well as commercialise that programme and UCB will receive milestone and licence payments from WILEX. Furthermore, the two partners may jointly develop the programmes after the successful completion of the proof of concept studies. WX-554 is currently being examined in a Phase Ib/II (proof of concept) trial. Clinical development of the second project, WX-037, is scheduled to begin in the first half of 2013. The Company believes that if the initial clinical data for the PI3K inhibitor WX-037 are positive, its further development as combination therapy with the MEK inhibitor WX-554 could open up a very interesting therapeutic application.

In spite of missing the endpoint in the ARISER trial with RENCAREX®, WILEX AG is conducting subgroup and biomarker analyses to determine whether the good properties and the specificity of the antibody Girentuximab can be used for other applications, allowing scientific or commercial exploitation of this antibody. WILEX AG has furnished evidence of Girentuximab's functionality through the REDECT trial and the Phase II trials with RENCAREX® and is working to further increase the antibody's value. The key data on safety and tolerability obtained from this trial will also give significant support to the second REDECT study and the data in the regulatory approval process WILEX AG hopes to undergo for REDECTANE®.

The diagnostic agent REDECTANE®, which is currently under development, is intended to improve tumour detection and post-treatment therapy monitoring. REDECTANE® confirmed in a Phase III trial that imaging with REDECTANE® and PET/CT can improve diagnosis compared to the standard procedure (CT only) and the FDA confirmed that the diagnosis of clear cell renal cell carcinoma has a clinical benefit. REDECTANE® could significantly improve and simplify treatment planning for patients suspected of having renal cancer. WILEX is not aware of a similar imaging procedure existing today for clear cell renal cell carcinoma. REDECTANE® could reach an annual peak sales potential of USD 100 million in clear cell renal cell carcinoma diagnosis alone.

7.24.2. WILEX Inc.

WILEX Inc. complements WILEX AG's diagnostic and therapeutic approach with its expertise in the field of in vitro diagnostics. Under the established brand of "Oncogene Science", the company markets biomarker tests and offers companion diagnostics, an increasingly important field for personalised medicine. WILEX has access to strategically important patents, rights and licences for both CAIX and uPA, the target proteins of the antibody Girentuximab and the uPA inhibitor MESUPRON®, and thus will be able to decisively expand its

leading position in these important areas. Aside from the biomarker tests for research purposes (research use only – RUO), two tests have been registered with the FDA for use in trials involving patients as well; additional tests are to see regulatory expansion. The revenue stream from the product sale of biomarker tests will be expanded. For the only FDA-cleared HER2/neu ELISA assay, marketing and distribution agreements for the US and German markets are in place, which are intended to acquire new customers and open up new sales channels.

7.24.3. Heidelberg Pharma

Heidelberg Pharma offers a novel technology platform for therapeutic antibody drug conjugates (ADC) which is to be tested in contract research projects with third parties and to be out-licensed to them in the future. Heidelberg Pharma also offers research capacities for pharmaceutical companies and institutions; it also conducts preclinical trials for WILEX's product portfolio. Significant sales potential could result from the research and development alliances for therapeutic antibodies with the ADC platform.

7.24.4. The WILEX Group

The WILEX Group's portfolio of products and services comprises the development of therapeutic and diagnostic product candidates as well as oncological biomarker tests that can be used by pharmaceutical companies and research groups in product development. The preclinical service business and the ADC platform for therapeutic antibodies are being offered through contract research. The Company will maintain its exclusive focus on oncology; to that end, it has extended the value chain from research to marketing and sales.

8. Events after the reporting period

The restructuring measures announced on 4 December 2012 are being implemented according to plan. No labour tribunal proceedings are pending in connection with the business-related lay-offs. The restructuring will not have a financial effect until the second quarter of 2013.

After the end of the reporting period, no other significant events occurred which have a direct influence on the business performance of the WILEX Group.

9. Anticipated developments

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

9.1. Economic environment

The World Bank has revised its global economic forecast for 2013 downwards from growth of an estimated 3.0% to just 2.4%. The dampened growth prospects are primarily attributable to the ongoing economic crisis in the industrialised countries that is putting a brake on global development.²⁶ The European Commission anticipates a gradual return to growth in the euro zone in 2013, a trend that is expected to stabilise further in 2014. It has also essentially confirmed the economic guidance for Germany given by the five members of the German Council of Economic Experts and expects the domestic economy to grow by 0.8% this year and next year. For 2014 the Commission is forecasting GDP growth in Germany of as much as 2.0%.²⁷

²⁶ Handelsblatt.de, 16 January 2012, report on the World Bank's global growth forecast

²⁷ Tagesschau.de, 7 November 2012, report on the EU Commission's autumn forecast

Demand for diagnostic agents, drugs and special therapies will continue to grow in industrialised countries and above all in emerging markets, with antibody-based biotechnology treatment options and small-molecule compounds still playing a major role. Of the ten highest-revenue products worldwide, eight are biotech products. Innovative technologies such as ADC technology are opening up new perspectives for the industry and are starting to bear fruit with one market approval last year and a further candidate in the accelerated approval programme. Applications of specific diagnostic agents and companion diagnostics in both drug development and therapy will also continue to grow. Interesting new applications are continually being identified in the diagnostics market and diagnostic agents help to avoid unsuitable therapies. WILEX believes that it is well positioned in these fields.

The trend toward cooperation agreements between and takeovers or mergers of pharmaceutical and biotech companies is unlikely to change because biotech is the engine for innovations with highly promising drug candidates, diagnostic agents and technologies as well as full development pipelines. Entering into cooperation agreements with major pharmaceutical companies has evolved into a key funding alternative for biotech companies. There has been a further decline in the willingness of venture capital companies and institutional investors to underwrite the industry's risks – especially at the early stage of a development project. Investors now increasingly tend to be interested in companies that have a more balanced risk profile and can be expected to generate cash flows. The out-licensing of products, milestone payments under partnerships, as well as successes in both clinical development and regulatory decisions are the factors that rekindle the willingness to invest in biotech companies.

9.2. Strategy

WILEX's corporate strategy is aimed at commercialising its entire development, product and service portfolio. In the past, WILEX entered into attractive cooperation and partnership agreements resulting in milestone payments and licence payments.

WILEX's strategic objective is to develop its research and development programmes with partners to the point where they can be brought to market. Likewise, WILEX will continue to maintain a cost-conscious approach to its work in order to keep the outflow of funds as low as possible. The main goal of the Executive Management Board is to commercialise the product candidates lucrative so as to drive forward the further development of the WILEX Group using its own funds and independently of the capital markets.

WILEX expanded its business model in 2011 to strengthen research and clinical development by means of complementary activities. The three pillars on which the Company's business is based have not only created new opportunities for the Company but also mitigated the risks of a major setback in product development. All the same, the disappointing outcome of the ARISER trial in October 2012 has systematically led to the development structures being adjusted to the remaining tasks. A restructuring programme that includes a workforce reduction of approximately 25% at the Munich site was therefore approved and implemented at the end of November.

The following measures are planned for the individual segments.

9.2.1. Therapeutics (= Rx)

In the Therapeutics segment, WILEX AG focuses on the further development of the product candidates WX-554 and WX-037. Besides clinical development, the segment will concentrate on the commercialisation and the commercial exploitation of patents and licensing rights.

For the discontinued ARISER trial with RENCAREX®, all work has to be duly concluded in accordance with good clinical practice, for example, preparation of the trial report, scientific publication of the results of the trial and closure of all 140 trial centres in cooperation with external service providers. This work is expected to be completed in the third quarter of 2013.

The clinical data will continue to be examined to determine whether approaches for advanced trials for new applications can be found.

Based on the positive Phase II data with the drug candidate MESUPRON®, a partnership is being sought for the further development and commercialisation of the uPA inhibitor. WILEX AG will follow its strategy of not commencing a Phase III programme for this candidate on its own and looking for a licensing and development partner. Whilst no exact forecast can be made as regards such a selection process and the conclusion of a licence agreement, the Company's aim is to finalise such an agreement in the 2013 financial year.

The ongoing Phase Ib/II trial with the MEK inhibitor WX-554 is expected to deliver data from the first part of the trial (dose escalation) in the first half of 2013. These data will include pharmacokinetic (PK) profiles in relation to the pharmacodynamic (PD) profiles as well as safety and tolerability information in the different dose levels. The aim is to define the dosage scheme so that the safety, tolerability, PK and PD of the chosen dosages as well as their efficacy in patients with specific tumours (such as melanoma) can be analysed in the Phase II part of the trial. Patient recruitment for Phase II is expected to follow, lasting up to the end of 2013, with data becoming available in the second half of 2014.

Based on the completed preclinical work and an approved study protocol, plans are to commence clinical development of the PI3K inhibitor WX-037 in the second quarter of 2013. Safety and tolerability in patients will initially be tested in a Phase I trial.

All activities in the field of preclinical research and development will be performed to a minimal extent only.

9.2.2. Diagnostics (= Dx)

WILEX AG develops the product candidate REDECTANE® in the Diagnostics segment. The second Phase III trial, which is intended to confirm the diagnostic performance of this drug candidate, is currently being prepared and coordinated with the FDA. The trial design will determine the start, scope, duration and hence the costs of the trial. WILEX AG is not planning to start the trial until it has secured the financing for the entire study.

The Company plans to expand the manufacture and marketing of the biomarker tests by its US subsidiary, WILEX Inc. This is to be achieved with two strategies. First, the ELISA tests developed for research use only will be increasingly developed for clinical purposes and sales revenue will be increased. Second, the revenue potential of the in vitro diagnostic tests (HER2/neu ELISA and CAIX-IHC), which have been registered with the FDA for clinical use and may also be marketed in Europe, will also be exploited to a greater extent. To this end, development and marketing alliances have been forged for the United States and the German-speaking market; other partnerships are planned worldwide.

In addition to manufacturing the Oncogene Science tests, WILEX Inc. has developed a range of contract manufacturing services for third parties which will increase capacity utilisation at the ISO- and GMP-certified laboratories and make the company's extensive expertise available to partners. It is planned to extend the possible applications for the HER2/neu ELISA test in conjunction with the development partners beyond the quantitative measurement of the HER2 level in the serum so as to better exploit the test's potential in the breast cancer indication and expand the marketing activities. WILEX Inc.'s objective in implementing all of the planned measures is to become profitable in the medium term.

9.2.3. Customer Specific Research (= Cx)

The Customer Specific Research (Cx) segment comprises a preclinical services business and the ADC platform technology for which customer specific development work is performed under research contracts. WILEX plans to further increase sales revenue from the services business and acquire new customers for this service by expanding our offering for inflammatory diseases, oncology and bioanalytics. Additional partnerships planned

for the ADC technology shall provide the basis for successfully commercialising this platform. Expenses are likely to be higher than income because the business activities related to the ADC technology are still in an early stage.

9.3. Expected earnings

If the projects proceed as planned, the Executive Management Board expects the WILEX Group to generate between € 15.0 million and € 19.0 million in revenue and other income (2012: € 17.8 million) in the 2013 financial year. In 2013, most of this revenue and other income, i. e. between € 12.0 million and € 14.0 million (2012: € 14.3 million) will again be generated in the Therapeutics segment (Rx) from the Prometheus payments, from cost reimbursement by partners and from grants. The Diagnostics (Dx) segment is to generate between € 1.0 million and € 2.0 million in sales revenue (2012: € 0.4 million); this target is based solely on the marketing of biomarker tests by WILEX Inc. and its distribution partners. The Customer Specific Research (Cx) segment is to generate increasing revenue in the 2013 financial year from the preclinical services business and advanced cooperation agreements related to the ADC technology platform as well as between € 2.0 million and € 3.0 million in other income from government grants (2012: € 2.3 million). The earnings target for 2013 does not include potential sales revenue from a licence agreement for MESUPRON® or possible commercial exploitation of the antibody Girentuximab.

Based on current planning and following the successful implementation of the restructuring programme, operating expenses will be in the range of € 22.0 million to € 27.0 million, thus probably below the previous year's level (€ 26.8 million). Research and development costs, which are part of operating expenses, are projected to be between € 11.0 million and € 15.0 million (2012: € 12.8 million). Other expenses concern cost of sales, administrative costs and other operating expenses, which are also expected to be lower than in the reporting year.

The Company expects earnings before interest and taxes (EBIT) in the 2013 financial year to improve to between –€ 5.0 million and –€ 9.0 million (2012: –€ 8.9 million).

The earnings over the next few years will depend to a considerable extent on whether and how WILEX succeeds in concluding additional licence agreements for its product candidates. For the projects acquired from UCB (WX-554 and WX-037), WILEX plans to push ahead with the clinical validation to the extent where UCB might make use of the agreed “opt-in right”, which would lead to licence payments accruing to WILEX or the projects being available for other commercialisation by WILEX. Over time, sales revenue from the marketing of the biomarker tests (Dx) should rise on the back of the marketing alliances forged, the positive market prospects in the area of personalised medicine and the contract manufacturing offering created in Cambridge, Massachusetts. In the Customer Specific Research (Cx) segment, revenue from the preclinical services business will be lifted further by extending the range of services and the customer base. The expansion of existing framework agreements and the conclusion of new agreements for ADC collaborations with various pharmaceutical partners is also expected to boost sales revenue.

Operating expenses will depend to a large extent on which clinical trials will be performed in the future.

WILEX anticipates earnings to improve further after 2013 even though expenses will continue to be higher than income.

9.4. Expected net assets and financial position

If income and expenses develop as anticipated, the net change in cash and cash equivalents in the 2013 financial year is expected to be between –€ 16.0 million and –€ 20.0 million. This corresponds to an average monthly use of cash of € 1.3 million to € 1.7 million.

This planning does not take into account additional potential cash inflows. The marketing rights for MESUPRON® are available for out-licensing. Additional cash inflows could be generated from the marketing of the ADC technology and the commercial exploitation of the antibody Girentuximab. The current planning does not take into account a possible repayment of the shareholder loan from UCB. Based on the assumptions in respect of the funding options set out in the “Going-concern risks” section of chapter 7, “Report on risks and opportunities”, WILEX would be funded into the second quarter of 2014.

Equity (30 November 2012: € 19.9 million) will continue to decline given the anticipated loss for the 2013 financial year and because no capital measure is planned at this time. All measures being discussed in view of improving the Company’s financial situation are described in detail in the “Going-concern risks” section of chapter 7, “Report on risks and opportunities”.

 Page 66

 Page 66

Financial outlook for the 2013 financial year	Actual 2012 €million	Forecast for 2013 €million
Sales revenue and other income	17.8	15.0 – 19.0
Operating expenses	26.8	22.0 – 27.0
Operating result	(8.9)	(5.0) – (9.0)
Total funding requirement	20.0	16.0 – 20.0
Funds required per month	1.7	1.3 – 1.7

10. Disclosures on the annual financial statements of WILEX AG (HGB)

The management report of WILEX AG and the Group management report for the 2012 financial year have been combined in accordance with Section 315 (3) in conjunction with Section 298 (3) German Commercial Code (HGB). The annual financial statements of WILEX AG prepared in accordance with the German Commercial Code and the combined management report will be published in the Federal Gazette at the same time.

Domiciled in Munich, WILEX AG is the parent company of the WILEX Group. WILEX AG wholly owns the companies WILEX Inc. and Heidelberg Pharma GmbH.

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

10.1. Earnings, financial position and net assets of WILEX AG

WILEX AG recognised a result from ordinary activities of – € 16.4 million (previous year: – € 20.2 million) in the 2012 financial year (1 December 2011 to 30 November 2012) according to German commercial law. The net loss for the year decreased by € 3.8 million, also to € 16.4 million (previous year: net loss of € 20.2 million).

As in the previous year, earnings were dominated by research and development expenses which, in line with expectations, were considerably higher than sales revenue and other operating income. The encouraging earnings trend can be attributed to the revenue generated from the Prometheus licence agreement, which was up substantially on the previous year. One-off effects were also recorded from exchange rate gains. The earnings of WILEX AG came under pressure from the extraordinary factors described below such as the recognition of a provision for restructuring measures, the additional write-down of the capitalised business start-up and

expansion expenses in accordance with Section 269 of the old version of the German Commercial Code, as well as the 50% write-down on all assets in connection with the subsidiary WILEX Inc.

10.1.1. Extraordinary factors affecting WILEX AG

The analysis of the earnings, financial position and net assets must be preceded by noting that the results of the ARISER trial with the product candidate RENCAREX® had the following significant effects on the figures of WILEX AG:

In the 2008, 2009, and 2010 financial years, business start-up and expansion expenses were capitalised in accordance with Section 269 of the old version of the German Commercial Code. This capitalisation extended to the two RENCAREX® and REDECTANE® programmes, both of which are based on the antibody Girentuximab. The missing of the endpoint in the ARISER trial led to these capitalised expenses being tested for impairment. The test revealed that the capitalised expansion expenses for RENCAREX® do not have to be written down in full, however, because capitalised expenses were and continue to be offset by income generated under the licence agreements. The data obtained from the subgroup and biomarker analyses and, in particular, the clinical safety data from the ARISER trial will also be used for the approval process for REDECTANE® as well as for possible further commercialisation of the antibody Girentuximab. For this reason, the Executive Management Board of WILEX AG believes that a 30% reduction of the net carrying amount totalling € 1.5 million in respect of the capitalised expenses for RENCAREX® is appropriate.

Another accounting effect that pushed down earnings is the provision for restructuring measures of € 0.4 million, which was mainly recognised for salaries of employees that were made redundant and for termination benefits. Other factors that drag down earnings such as write-downs on acquired licences or possible provisions for anticipated losses were not recorded.

Once again, the earnings of WILEX Inc. remained below expectations, which is why a 50% write-down on the carrying amount of the investment is deemed fair and reasonable. Due to the recently signed distribution partnerships for the products of WILEX Inc., the carrying amount of the investment – in spite of expectations not being met – is still regarded as partially recoverable. This is the reason the carrying amount of the investment was not written down in full. Similarly, the value of the loan receivables (including interest rate receivables) from WILEX Inc. was reduced by 50%.

In addition to the revenue recognised as planned and pro rata temporis, corresponding to deferred income, additional extraordinary revenue was recognised. The missing of the primary endpoint of the ARISER trial did not lead to an abrupt end of the trial because contractually agreed and ethically imperative winding-up activities and follow-up examinations must be carried out. The costs yet to be incurred will, however, decline compared with the previously projected costs associated with meeting the trial targets. The winding-up of the trial also reduces the forecast period compared with a scenario in which the trial had continued. There is no obligation to repay the prepayments received from Prometheus. Nonetheless, the change in the parameters for the accrual also increased the reversal of income, which led to an additional unplanned reversal of the accrued prepayments recognised in profit or loss amounting to € 1.1 million as of the reporting date.

10.1.2. Other own work capitalised

The Company made use of the option to recognise expenses in the 2008, 2009 and 2010 financial years in accordance with Section 269 of the old version of the German Commercial Code. As already explained, the expenses capitalised for RENCAREX® were written down by 30%, which corresponds to an impairment loss of € 1.5 million. Following the write-down as of 30 November 2012, the net carrying amount of own work capitalised for RENCAREX® and REDECTANE® still comprises the net carrying amounts of the capitalised tranches from 2009 and 2010, which continue to be amortised. The net carrying amount as of 30 November 2012 was € 5.7 million (2011: € 15.5 million).

10.1.3. Sales revenue and other operating income

WILEX posted sales revenue of € 13.9 million in the 2012 financial year (previous year: € 8.4 million). Almost all of the sales revenue in 2012 was generated under the licence agreement with Prometheus. Sales revenue in 2011 was lower because it was generated in just seven months due to the fact that the contract was only signed during 2011.

In spite of a change in the composition of the individual income components, other operating income remained constant at € 1.6 million (2011: € 1.6 million) and mainly comprises income from the grant by the Federal Ministry of Education and Research (BMBF) that subsidises one of WILEX's research projects and contributed € 0.4 million to other operating income in the past financial year. Other grants such as the one from the US Department of Defense expired at the end of the previous year. Income from exchange rate differences of € 1.0 million was also recognised. The positive currency effects are mainly attributable to the substantial fluctuations in the US dollar/euro exchange rates.

10.1.4. Other operating expenses

Personnel expenses increased from € 6.7 million in 2011 to € 7.4 million in the past financial year as a result of two factors. During the year, in preparation for and with the expectation of positive RENCAREX® data, the workforce was expanded slightly, which initially raised staff costs. At the end of the financial year, the fact that WILEX missed the endpoint of the ARISER trial led to lay-offs. The provision recognised for restructuring measures in the amount of € 0.4 million comprises salary payments for employees made redundant and, in particular, termination benefits.

Other operating expenses in 2012 were down compared to the previous year at € 12.3 million (2011: € 14.6 million) due to the progress made in the clinical trials. Compared with the initial and peak phases (protocol implementation and initiation of the study centres), costs have fallen over time.

Net interest income improved to –€ 0.2 million (previous year: –€ 0.5 million). In spite of higher interest income from the loans to the subsidiaries WILEX Inc. and Heidelberg Pharma, expenses in the 2012 financial year exceeded income mainly on account of interest expense for the dievini and UCB shareholder loans. In the future, only interest on UCB's loan will accrue because dievini converted its loan including interest into contributions in cash and in kind during the year as part of a combined capital increase. Although the UCB loan principal of € 2.5 million will remain as it is with annual interest of 6.0%, going forward WILEX AG's total interest expense will consequently be substantially lower than in 2012.

10.1.5. Financing and liquidity

Throughout 2012, WILEX AG had sufficient liquidity to finance its various R&D projects entirely from its own funds. The financing of these projects was never at risk during the financial year.

The financial management of WILEX AG serves to strengthen its equity base in a sustainable manner. 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.

WILEX AG implemented a number of **different measures to enhance its liquidity** in the financial year just ended.

WILEX carried out a **rights issue** in the first quarter of 2012 during which the shareholders subscribed for all 3,201,928 new no par value bearer shares by exercising their subscription and oversubscription rights at a subscription price of € 3.10 per share. The gross issuing proceeds totalled € 9.9 million.

Furthermore, a **combined capital increase against cash and contributions in kind** was implemented in the third quarter of 2012 and a total of 6,460,544 new shares were issued. The subscription price was € 3.70 per share. As a result, the shareholder loan from dievini (€ 7.8 million including accrued interest) was converted to 2,100,337 shares. The gross issuing proceeds from the cash component were € 16.1 million.

The Executive Management Board of WILEX AG resolved in July 2012 with the approval of the Supervisory Board to call a **further cash payment from the licence agreement with Prometheus** for the out-licensing of the US commercial rights for RENCAREX®. This payment serviced the previously recognised receivable from an option between the commercial rights to a Prometheus product or a cash payment. WILEX AG received a payment of USD 17.5 million.

WILEX AG has agreed a package of **restructuring measures** with the Company's Supervisory Board and has begun implementing them. The Executive Management Board is reacting to the results of the Phase III ARISER study with RENCAREX®, which missed the primary endpoint. The measures are designed to tailor development activities to the remaining projects, reduce the risks inherent in the business model and lower operating costs substantially. As a consequence, the workforce at the Munich site will be reduced by around 25 %. The restructuring costs are expected to come to around € 0.4 million and have already been factored into the 2012 annual financial statements.

10.1.6. Investments

The funds used in connection with the further development of drug and diagnostic candidates was recorded in its entirety under current research and development expenses, which are reported under other operating expenses.

A further € 0.3 million was spent on increasing the value of the investment in WILEX Inc. Additions to tangible fixed assets in the amount of € 0.3 million were mainly attributable to the expansion of the laboratory started in the previous year. Additions to intangible fixed assets of € 43 k were also recognised that predominantly related to the implementation of process-optimising software for the accounting department.

10.1.7. Net assets and financial position

Total assets rose substantially once more by around 22 % to € 55.6 million from € 45.7 million the year before, mainly due to the cash injected by the capital measures and the payment made by Prometheus in July 2012.

The capitalised business start-up and expansion expenses relating to RENCAREX® and REDECTANE® declined substantially. The carrying amount of € 15.5 million in the previous year decreased to € 5.7 million as of 30 November 2012 as a result of amortisation of € 8.3 million and impairment losses of € 1.5 million owing to the primary endpoint of the ARISER trial being missed.

Fixed assets fell slightly from € 21.4 million in 2011 to € 21.3 million at the end of the 2012 financial year, mainly due to the reduction of the carrying amount of the investment in WILEX Inc. by € 0.4 million. As a consequence of this impairment, depreciation, amortisation and write-downs exceed additions, which produced this slight decrease in the carrying amount of fixed assets. At € 19.6 million, the investments in subsidiaries account for around 92 % of non-current assets. Impairment testing of these investments using a present value method as of 30 November 2012 confirmed the figure of € 19.2 million recognised for Heidelberg Pharma, but for precautionary reasons a 50 % write-down on the carrying amount of the investment in WILEX Inc. was recognised at the same time.

In addition to the impairment of the carrying amount of the investment in WILEX Inc., the loan receivables from WILEX Inc. were also written down by 50 % or € 1.6 million.

The figure recognised for inventories is a fixed amount of € 34 k for raw materials, consumables and supplies as well as laboratory materials that remained unchanged compared with the previous year.

Cash and bank balances totalled €23.1 million at the end of the year (previous year: €3.4 million). This increase is attributable to the capital measures implemented as well as to the Prometheus payment. It means that WILEX AG can build on a stable liquidity base and pave the way for a successful future in spite of missing the endpoint in the ARISER trial with RENCAREX®.

Prepaid expenses of €0.7 million (previous year: €0.9 million) mainly relate to advance payments to the service providers for the clinical trials.

Equity according to commercial law rose to €38.6 million in the reporting year (previous year: €21.4 million). The Company's subscribed capital increased to €31.3 million as a consequence of the capital increases (previous year: €21.6 million). The capital reserves rose to € 171.3 million (previous year: € 147.3 million) and the losses accumulated since the Company's foundation increased from € 147.6 million to € 164.0 million owing to the net loss for the year of € 16.4 million.

Other provisions increased by €0.2 million, from €2.9 million in the previous year to €3.1 million on the basis of the provision recognised for restructuring measures.

Trade payables fell from € 1.3 million in 2011 to € 0.9 million, principally as a consequence of the agreement reached with a service provider for clinical trials (CRO) on its amounts due.

Liabilities arising from the shareholder loan to UCB (€2.6 million including accrued interest) are recognised as liabilities to other long-term investees and investors. These fell significantly compared to the end of 2011 (€ 10.5 million) through the contribution of the dievini share (€7.5 million) during the year in return for shares.

Deferred income of € 10.2 million (previous year: € 9.6 million) relates exclusively to the deferral for the pre-payments made by Prometheus for the out-licensing of the US commercial rights for RENCAREX®. Since May 2011, after the contract was signed at the end of April, this advance payment of USD 19.0 million by Prometheus has been deferred over the expected residual term of the project. In addition, the payment of USD 17.5 million made in July 2012 will be similarly deferred up until the end of the trial. Following the announcement of the outcome of the trial, the end of the study relates to the finalisation of the trial and the winding-down of activities at the trial centres, which according to current planning is scheduled for December 2013.

10.1.8. Cash flow statement

The cash outflow from operating activities during the reporting period was € 1.3 million (previous year: € 6.6 million). The main factors affecting this item are other operating expenses, which exceed income, and the associated loss for the year. This figure was pushed up by the Prometheus out-licensing agreement and the cash flows generated.

The total cash outflow from investing activities was €4.6 million (previous year: cash outflow of € 1.7 million), largely due to the ongoing granting of loans to the subsidiaries.

The net cash inflow from financing activities in the 2012 financial year was €25.6 million (previous year: €9.9 million) and can be attributed to the two capital measures.

Total net inflow of cash and cash equivalents was € 19.7 million (previous year: € 1.6 million). This corresponds to an average inflow of cash of € 1.6 million per month in 2012 (previous year: € 0.1 million).

At the end of the period, the Company had cash and bank balances of €23.1 million (previous year: €3.4 million), which will ensure its financing for a period of more than twelve months.

10.2. Other disclosures

Averaged over the year, WILEX AG had 72 salaried employees, 53 of whom worked in research and development and 19 in administrative positions (averages in each case). These figures include members of the Executive Management Board.

10.3. Financial outlook for the parent company, WILEX AG

10.3.1. Expected earnings

Assuming the projects proceed as planned, the Executive Management Board expects the WILEX Group to generate between € 12.0 million and € 14.0 million in sales revenue and other operating income in the 2013 financial year (2012: € 15.6 million). Most of this revenue will stem from the Prometheus payments and from income generated from government grants. The earnings target for 2013 does not include potential sales revenue from a licence agreement for MESUPRON® or possible commercial exploitation of the antibody Girentuximab.

Total operating expenses in 2013 will be in the range of € 19.0 million to € 23.0 million if business proceeds as planned, thus falling significantly short of the level recorded for the 2012 reporting period (€ 31.3 million). This range includes amortisation of own work capitalised which – assuming straight-line amortisation – are estimated at approximately € 4.2 million.

The lower expenses are attributable to an overall decrease in research and development costs. While WILEX assumes that the costs for winding-up the trial with RENCAREX® will remain more or less on a par with the previous year, much lower costs are forecast for MESUPRON® in 2013 because the Phase II trial in the breast cancer indication has been concluded.

WILEX AG is expecting its expenses to increase sharply over 2012 for the MEK inhibitor, for which the Phase Ib/II trial will be continued in the 2013 financial year. Higher costs year-on-year are also budgeted for the PI3K inhibitor WX-037 owing to the start of clinical development. Both of these projects receive support in the form of government grants, however. The costs for preclinical programmes will probably be much lower than in 2012 and will no longer be considered significant. Total operating expenses will depend to a large extent on which clinical trials will be performed in the future.

The operating result in the 2013 financial year is expected to come in between – € 6.0 million and – € 10.0 million (2012: – € 15.7 million).

New licence agreements or partnerships providing for milestone payments are planned for the coming years. If these fail to materialise, earnings in the 2014 financial year could deteriorate, as a result of which expenses would presumably exceed income in the short and medium term.

10.3.2. Expected net assets and financial position

If income and expenses develop as anticipated, the net change in cash and cash equivalents in the 2013 financial year is expected to be between – € 12.0 million and – € 16.0 million. This corresponds to an average monthly use of cash of € 1.0 million to € 1.3 million.

Equity (30 November 2012: € 38.6 million) will continue to decline given the anticipated loss for the 2013 financial year. All measures being discussed in view of improving the Company's financial situation are described in detail in the "Going-concern risks" section of chapter 7, "Report on risks and opportunities".

CONSOLIDATED FINANCIAL STATEMENTS

➡ Contents

	Page
Consolidated statement of comprehensive income	80
Consolidated balance sheet	81
Consolidated statement of changes in equity	82
Consolidated cash flow statement	83
 Consolidated notes	
1. Business and the company	84
2. Application of new and revised standards	85
3. Key accounting policies	87
4. Segment reporting in accordance with IFRS 8	97
5. Financial risk management	101
6. Going concern risk	102
7. Critical estimates and discretionary decisions	103
8. Impairment testing pursuant to IAS 36	104
9. Property, plant and equipment	106
10. Intangible assets	107
11. Other non-current assets	109
12. Inventories	110
13. Other assets and prepayments	110
14. Trade and other receivables	110
15. Cash and cash equivalents	111
16. Equity	112
17. Pension obligations	113
18. Lease liabilities and other non-current liabilities	114
19. Lease liabilities, trade payables, financial liabilities and other current liabilities	114
20. Other disclosures on financial instruments	116
21. Sales revenue	119
22. Other income	120
23. Types of expenses	120
24. Staff costs	121
25. Net currency gains/losses	126
26. Financial result	127
27. Income taxes	127
28. Earnings per share	129
29. Leases, guarantees and obligations	130
30. Corporate bodies and compensation	132
31. Related party transactions	135
32. Expenses for the auditors	136
33. Declaration of Conformity with the German Corporate Governance Code in accordance with Section 161 German Stock Corporation Act	136
34. Events after the reporting period	136

Consolidated statement of comprehensive income (IFRS)

for the financial year from 1 December 2011 to 30 November 2012

	Note	2012 €	2011 €
Revenue	21	16,141,569	9,877,293
Other income	22	1,699,603	1,835,858
Income		17,841,171	11,713,151
Cost of sales	23	(6,746,092)	(4,165,054)
Research and development costs	23	(12,780,437)	(15,641,219)
Administrative costs	23	(4,855,641)	(5,289,977)
Other expenses		(2,369,191)	0
Operating expenses		(26,751,361)	(25,096,251)
Operating result		(8,910,189)	(13,383,099)
Finance income	26	30,455	6,599
Finance costs	26	(508,497)	(547,618)
Financial result		(478,042)	(541,019)
Earnings before tax		(9,388,231)	(13,924,118)
Income tax	27	(2,565)	(1,608)
Net loss for the year		(9,390,797)	(13,925,727)
Net currency gain/loss from consolidation		(9,710)	(47,324)
Comprehensive income		(9,400,507)	(13,973,051)
Earnings per share	28		
Basic and diluted earnings per share		(0.36)	(0.67)
Average number of shares issued		25,931,980	20,683,720

Rounding of exact figures may result in differences.

Consolidated balance sheet (IFRS)

for the financial year as of 30 November 2012

Assets	Note	30.11.2012 €	30.11.2011 €
Property, plant and equipment	10	2,086,534	2,074,278
Intangible assets	9	4,106,758	4,355,771
Goodwill	9	6,111,166	6,111,166
Other non-current assets	11	227,674	276,563
Non-current assets		12,532,132	12,817,778
Inventories	12	258,210	514,627
Prepayments	13	734,759	952,400
Trade receivables	14	269,550	159,254
Other receivables	14	562,894	2,949,762
Cash and cash equivalents	15	23,363,335	3,420,640
Current assets		25,188,748	7,996,682
Total assets		37,720,880	20,814,460

Equity and liabilities	Note	30.11.2012 €	30.11.2011 €
Subscribed capital	16	31,275,507	21,613,035
Capital reserve	16	159,211,811	135,030,430
Accumulated losses	16	(170,518,867)	(161,128,070)
Net currency gain/loss from consolidation		(47,637)	(37,926)
Equity		19,920,815	(4,522,532)
Pension provisions	17	0	25,319
Lease liabilities	18	129,746	218,421
Other non-current liabilities	18	930,901	4,887,989
Non-current liabilities		1,060,646	5,131,729
Trade payables	19	904,365	1,412,070
Liabilities arising from leases	19	210,501	251,625
Financial liabilities	19	2,637,500	10,548,169
Other current liabilities	19	12,987,053	7,993,400
Current liabilities		16,739,419	20,205,263
Total equity and liabilities		37,720,880	20,814,460

Rounding of exact figures may result in differences.

Consolidated statement of changes in equity (IFRS)

for the financial year from 1 December 2011 to 30 November 2012

Note	Shares	Subscribed capital €	Capital measures/ premium		Stock options	Currency translation differences €	Accumulated losses €	Total €
			Capital reserve €	€				
As of 1 December 2010	18,413,035	18,413,035	124,819,448	2,665,370				
Stock options	24			97,089				97,089
Net currency gain/loss from consolidation					(47,324)			(47,324)
Net loss for the period					(13,925,727)			(13,925,727)
Capital increase after accounting for capital procurement costs	3,200,000	3,200,000	7,448,523					10,648,523
Net change in equity								(3,227,440)
As of 30 November 2011	21,613,035	21,613,035	132,267,971	2,762,459				
Stock options	24			556,781				556,781
Net currency gain/loss from consolidation					(9,710)			(9,710)
Net loss for the period					(9,390,797)			(9,390,797)
Capital increase after accounting for capital procurement costs	9,662,472	9,662,472	23,624,600					33,287,072
Net change in equity								24,443,346
As of 30 November 2012	31,275,507	31,275,507	155,892,571	3,319,240				
					(47,637)	(170,518,867)		19,920,815

Rounding of exact figures may result in differences.

Consolidated cash flow statement (IFRS)

for the financial year from 1 December 2011 to 30 November 2012

	Note	2012 €	2011 €
Net loss for the year		(9,390,797)	(13,925,727)
Adjustment for items in the statement of comprehensive income			
Stock options	24	556,781	97,089
Depreciation/amortisation	23	671,864	524,153
Increase in pension obligations	17	0	909
Finance costs	26	947,118	547,318
Finance income	26	(468,726)	(6,582)
Tax expense	27	2,565	936
		1,709,602	1,163,824
Changes in net working capital			
Inventories		215,688	(228,583)
Trade receivables		(62,059)	55,169
Other receivables		1,940,744	(2,701,298)
Prepayments		219,421	172,568
Other non-current assets		22,762	(314,754)
Trade payables		(546,601)	(976,818)
Other liabilities		1,261,665	7,774,425
		3,051,619	3,780,708
Cash flow from operating activities		(4,629,575)	(8,981,195)
Finance costs paid		(508,503)	(24,408)
Finance income received		30,280	6,732
Net cash flow from operating activities		(5,107,798)	(8,998,871)
Cash flow from investing activities			
Purchase of property, plant and equipment	10	(201,633)	(280,988)
Purchase of intangible assets	9	(42,810)	(21,753)
Cash inflow from acquisition of Heidelberg Pharma		0	885,316
Net cash flow from investing activities		(244,443)	582,576
Cash flow from financing activities			
Proceeds from capital increases		33,829,993	0
Capital increase costs	16	(409,628)	(72,578)
Shareholder loan		(7,771,250)	10,000,000
Other financing activities		(39,835)	39,835
Repayment of finance leases		(266,556)	(146,117)
Net cash flow from financing activities		25,342,723	9,821,140
Influence of foreign exchange effects on cash and cash equivalents		(47,787)	72,644
Net change in cash and cash equivalents		19,942,695	1,477,489
Cash and cash equivalents			
at beginning of period		3,420,640	1,943,151
at end of period	15	23,363,335	3,420,640

Rounding of exact figures may result in differences.

Consolidated notes

1. Business and the company

WILEX was established in 1997 in Munich, Germany, as WILEX Biotechnology GmbH by a team of physicians and oncologists at the Technical University of Munich.

In accordance with the shareholders' resolution of 14 December 2000, amended on 28 February 2001, the company changed its legal form to become a stock corporation called WILEX AG. The change of name was entered into the commercial register at the district court in Munich on 9 April 2001, under registration number HRB 136670. The Company's registered office is Grillparzerstrasse 10, 81675 Munich, Germany. Since 13 November 2006, the shares of WILEX AG have been listed in the Regulated Market/Prime Standard of the Frankfurt/Main stock exchange using the symbol WL6, the securities identification number 661472 and ISIN DE0006614720.

"WILEX" will be used as a synonym for the Group hereinafter. Each entity's full corporate name is used whenever facts specific to WILEX AG as the parent company or the subsidiaries are reported.

WILEX is a biopharmaceutical company that focuses on the research, development, manufacturing, approval and marketing of drugs and diagnostic agents in oncology. The Company has a balanced portfolio of attractive product candidates that cover all stages, from research to advanced clinical trials. WILEX aims to market and sell the drugs and diagnostic agents after they have been approved.

1.1. Consolidated companies

1.1.1. WILEX Inc.

WILEX Inc., a wholly-owned subsidiary of WILEX AG that is domiciled in Cambridge, MA, USA, launched its operations on 17 November 2010. The staff of WILEX Inc. comprises eleven people in the fields of science, management and marketing, most of them previous employees of Oncogene Science. Oncogene Science is a former business unit of Siemens Healthcare Diagnostics Inc. WILEX Inc. focuses exclusively on the production, quality assurance, approval, marketing and sale of the developed diagnostic assays and sells them under the Oncogene Science brand to customers in the pharmaceutical industry and scientific institutions as well as to reference laboratories. WILEX Inc.'s financial year runs from 1 December of a given year to 30 November of the following year.

Because WILEX AG wholly owns its subsidiary, WILEX Inc., it is the latter's controlling shareholder and thus must fully consolidate it pursuant to IAS 27 in the Group's consolidated financial statements.

1.1.2. Heidelberg Pharma GmbH

On 3 November 2010, WILEX AG had signed an agreement, with the approval of the Supervisory Board, with all shareholders of Heidelberg Pharma AG (hereinafter also "Heidelberg Pharma") regarding the acquisition of all shares in Heidelberg Pharma in return for WILEX shares. Following the Extraordinary General Meeting's approval on 15 December 2010 and the recording of the capital increase in the Commercial Register on 17 March 2011, WILEX acquired all of the shares in Heidelberg Pharma AG by way of a non-cash capital increase in return for 3,200,000 new WILEX shares subject to the exclusion of shareholders' subscription rights.

Upon recording in the Commercial Register on 17 March 2011 ("acquisition date"), Heidelberg Pharma AG became a wholly-owned subsidiary of WILEX AG and thus an integral part of the WILEX Group. Heidelberg Pharma completed the change in its legal structure from an AG (German stock corporation) to a GmbH (German limited liability company) as of 1 December 2011.

2. Application of new and revised standards

2.1. New and revised standards and interpretations whose application has no effect or no material effect on the consolidated financial statements:

First-time application of the following standards and interpretations was mandatory in the past financial year beginning on 1 December 2011: None of the amendments listed affected the financial year just ended or the previous financial year.

IAS 24 (rev. 2009): Related party disclosures

IAS 24 (2009) changed the definition of a related party.

IAS 32: Classification of Rights Issues

The changes relate to the classification of certain rights issues denominated in foreign currencies either as equity instruments or financial liabilities.

IFRS 1: Severe Hyperinflation and Removal of Fixed Dates for First-time Adopters

This standard provides guidance and instructions for first-time adopters from countries with severe hyperinflation.

IFRS 1: Limited Exemption from Comparative IFRS 7 Disclosures for First-time Adopters

IFRS 7 disclosures with regard to the comparative period need not be made by first-time adopters.

IFRS 7: Disclosure requirements for the transfer of financial assets

The changes to IFRS 7 expand the disclosure obligations for transactions that involve the transfer of financial assets.

IFRIC 19: Extinguishing Financial Liabilities with Equity Instruments

IFRIC 19 explains how to account for the fulfilment of financial liabilities by issuing equity instruments.

IFRIC 14: Prepayments of a Minimum Funding Requirement

The changes to IFRIC 14 now permit prepayment of a minimum funding requirement to be recognised as an asset.

Miscellaneous amendments and clarifications to various IFRSs (2009 – 2010)

The application of the annual improvements of IFRSs 2009 – 2010 does not have a significant effect on the consolidated financial statements.

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

Application of the following interpretations and standards was voluntary or not yet required as of 1 December 2011. WILEX elected to refrain from early, voluntary application of the standards and interpretations adopted by the EU. Management does not expect the improvements and amendments listed below to materially affect measurement or accounting in future financial statements.

2.2.1. New and revised standards and interpretations adopted by the EU

IAS 19 (rev. 2011): Employee benefits

The revisions to IAS 19 change the treatment of defined-benefit retirement plans and termination benefits. WILEX has not instituted any defined-benefit retirement plans.

IAS 1: Presentation of Items in Other Comprehensive Income

The presentation of items in other comprehensive income will be adjusted accordingly when the changes are applied in future periods.

IFRS 10: Consolidated Financial Statements

This standard replaces the rules concerning consolidated financial statements in IAS 27 and SIC 12. Material changes relate to the control principle, which will have no effect whatsoever on the WILEX Group, because WILEX only has wholly-owned subsidiaries.

IFRS 11: Joint Arrangements

This standard replaces the rules in IAS 31 and SIC 13 and governs the classification of joint arrangements. A joint arrangement is a contractual agreement between two or more parties to exercise joint control over something.

IFRS 12: Disclosure of Interests in Other Entities

IFRS 12 is a standard concerning notes to the financial statements. It is applicable to companies that hold interests in subsidiaries, joint arrangements, associated companies and/or unconsolidated structured entities. The requirements of IFRS 12 are generally more far-reaching than those in the currently applicable standards.

IFRS 13: Fair Value Measurement

IFRS 13 specifies uniform guidelines for fair value measurement and the associated disclosures.

IAS 27: Separate Financial Statements

IAS 27 Separate Financial Statements (amended in 2011) describes the accounting and disclosure requirements for separate financial statements, which are those presented by a parent or an investor with joint control of, or significant influence over, an investee, in which the investments are accounted for at cost or in accordance with IAS 39 Financial Instruments: Recognition and Measurement or IFRS 9 Financial Instruments.

IAS 28: Investments in Associates

IAS 28 Investments in Associates and Joint Ventures (as amended in 2011) sets out the requirements for the application of the equity method when accounting for investments in associates and joint ventures, with a limited number of specific exceptions.

IAS 12: Deferred Tax – Recovery of Underlying Assets

The amendments to IAS 12 contain an exception to the basic principle behind IAS 12 which applies mainly to investment property in accordance with IAS 40 and will therefore be irrelevant for WILEX.

IFRS 7 and IAS 32: Amendments with respect to the offsetting of financial assets and financial liabilities and related disclosures

The amendments to IAS 32 provide clarification on application problems that exist with regard to the requirements for the offsetting of financial assets and financial liabilities.

The amendments to IFRS 7 require for financial instruments the disclosure of information about rights of set-off and associated agreements in an enforceable master netting arrangement or similar agreement.

IFRIC 20: Stripping Costs in the Production Phase of a Surface Mine

IFRIC 20 has no relevance for WILEX.

2.2.2. New and revised standards and interpretations that have been approved by the IASB, but have not yet been adopted by the EU

IFRS 9: Financial Instruments

According to IFRS 9, all financial assets currently covered by the scope of IAS 39 must be subsequently measured either at amortised cost or at fair value. Debt instruments held as part of a business model for the purpose of collecting contractual cash flows, and whose contractual cash flows solely constitute interest and principal payments on the outstanding capital, must be carried at amortised cost in subsequent periods. All other instruments must be measured at fair value through profit or loss.

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) as applicable in the European Union (EU).

3.2. Basis for preparation of the consolidated financial statements

As outlined below, the preparation of the consolidated financial statements is based on historical cost. Historical cost is in turn generally based on the fair value of the consideration paid in return for an asset.

In accordance with Section 325 (3) German Commercial Code, WILEX publishes these IFRS consolidated financial statements in the electronic Federal Gazette (Bundesanzeiger). These consolidated financial statements exempt the Company from preparing consolidated financial statements in accordance with the German Commercial Code.

The consolidated financial statements were prepared by the Executive Management Board on 7 February 2013 and released for publication in accordance with IAS 10. The Supervisory Board can decline to adopt the consolidated financial statements and Group management report released by the Executive Management Board, in which case the consolidated financial statements and Group management report would have to be adopted in the Annual General Meeting. The reporting period begins on 1 December 2011 and ends on 30 November 2012. It is referred to hereafter as the “2012 financial year” (“2011 financial year” for the previous period).

3.3. Basis of consolidation

The consolidated financial statements comprise the financial statements of the parent company WILEX AG and its controlled subsidiaries WILEX Inc. and Heidelberg Pharma GmbH. An entity is “controlled” when the Company has the power to govern the financial and operating policies of an entity so as to obtain benefits from its activities.

All intra-group transactions, balances and profits and losses are eliminated in full during consolidation. There is no direct comparability with previous year’s figures and no direct comparability can be presented due to the changes in the Group’s structure last year, because Heidelberg Pharma was not acquired until mid-second quarter of the previous year and was only included in the group of companies consolidated from this point onward.

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

3.4. Foreign currencies

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

The Group has one subsidiary domiciled outside of the euro zone. The functional currency of WILEX Inc. is the US dollar (USD) because the company is an independent foreign economic entity. Its financial statements are translated into euros for the purposes of the consolidated financial statements. They are translated based on the functional currency approach of IAS 21 "The Effects of Changes in Foreign Exchange Rates" using the modified closing rate method.

The translation of the annual financial statements prepared in the foreign currency is explained below.

Consequently, assets and liabilities are translated using the closing rate, equity is translated at the historical rate and both expenses and income are translated at the average annual exchange rate except where substantial fluctuations in exchange rates have occurred. Currency translation differences arising from consolidation are recognised in other comprehensive income as currency gains or losses. These foreign exchange differences are recognised in the income statement upon disposal of the subsidiary.

The translation of US dollar amounts within the Group was based on the following euro exchange rates:

- Closing rate: € 1 = USD 1.2996 (previous year: € 1 = USD 1.3336)
- Average exchange rate: € 1 = USD 1.2857 (previous year: € 1 = USD 1.3927)

Transactions settled in currencies other than the respective local currency are recognised in the separate financial statements at the foreign exchange rate on the transaction date. Monetary items in foreign currencies (cash and cash equivalents, receivables, liabilities) and non-monetary items in foreign currencies measured at historical cost are translated at the reporting date exchange rate. Non-monetary assets and liabilities in foreign currencies that are recognised at fair value are translated at the foreign exchange rates in effect on the date the fair value is determined. Gains and losses from foreign currency translation are recognised in the income statement.

WILEX also carries out transactions in US dollars, Swiss francs (CHF), British pound (GBP) and, to a smaller extent, in other foreign currencies as well.

Differences may result from commercial rounding of exact figures.

3.5. Property, plant and equipment

WILEX does not own plots of land or buildings. All office and laboratory premises used at present are rented. Property, plant and equipment consists mainly of laboratory and office equipment and is recognised at historical cost less accumulated depreciation and 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. Depreciation of property, plant and equipment is based on the following useful lives:

- Laboratory equipment 8 to 14 years
- Other office equipment 3 to 23 years

Expenses for repairs and maintenance and the replacement of subordinate items are recognised in income at the time they arise. Extensive replacements and new fixtures and fittings are capitalised 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 derecognised. Any gains or losses resulting from such disposal are recognised in profit or loss in the financial year.

WILEX has not pledged any property, plant or equipment as collateral for contingent liabilities.

See note 3.20 for information on the accounting treatment of finance leases recognised in property, plant and equipment.

 Page 96

3.6. Intangible assets

3.6.1. Separately acquired intangible assets

Intangible assets not acquired in a business combination with a determinable useful life are carried at cost less accumulated amortisation and impairment losses. The amortisation is on a straight-line basis over the expected useful life of the asset and is recognised as an expense. The expected useful life and the amortisation 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.

The following useful lives are assumed for intangible assets:

- Licenses und patents 12.5 to 20 years
- Software 3 years
- Acquired customer base 9 years

3.6.2. Intangible assets acquired from a business combination

Intangible assets acquired from a business combination are recognised separately from goodwill and measured at fair value, i.e., cost, as of the date of acquisition.

In subsequent periods, intangible assets with a definite useful life that were acquired in a business combination are measured in the same way as separately acquired intangible assets: at cost less accumulated amortisation and any accumulated impairment losses.

3.6.3. Research and development costs

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

Internally generated intangible assets resulting from development activities are recognised 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 not all of these requirements have been met at this time, a drug and a diagnostic agent under development could not yet be capitalised as an intangible asset.

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

3.7. Impairment of property, plant and equipment 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 estimated to determine the scope of a possible impairment loss. If the recoverable amount of the individual asset cannot be estimated, then the recoverable amount of the cash generating unit to which the asset belongs is estimated.

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 recognised 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 recognised in previous years. An impairment reversal is recognised immediately in profit or loss.

3.8. Goodwill

The goodwill resulting from a business combination is recognised at cost less impairment losses, as required, and is reported separately in the consolidated balance sheet.

For purposes of impairment testing, the goodwill must be distributed among each of the Group's cash generating units 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 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 recognised directly in profit or loss in the consolidated statement of comprehensive income. An impairment loss recognised on goodwill may not be reversed in future periods.

3.9. Other non-current assets

When leases for buildings and laboratory equipment are signed, rent security or security for leased equipment must 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.

3.10. Inventories

Inventories comprise raw materials, consumables and supplies, (contract) work in progress and finished products.

Inventories are measured at the lower of cost and net realisable value. The cost of sales for internally generated inventories contain all directly attributable costs as well as a reasonable percentage of the general overhead costs.

3.11. Trade receivables

Trade receivables belong to the category of loans and receivables (see note 3.14), which are measured at amortised cost. This means that they are recognised at the initial invoice amount net of any adjustments for doubtful accounts. Such adjustments are based on an assessment by management of the recoverability and aging structure of specific receivables.

 Page 92

3.12. Prepayments made

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

3.13. Other receivables

Receivables are initially recognised at fair value and subsequently at amortised cost, less any impairment losses. An impairment of other receivables is recognised if there is an objective, substantial indication that not all of the amounts due according to the original contractual terms and conditions are recoverable. The impairment is recognised in profit or loss.

3.14. Financial instruments

Disclosures under IAS 39/IFRS 7, financial instruments are classified according to type:

- Financial assets or financial liabilities at fair value through profit or loss. This category comprises two sub-categories:
 - Financial assets or liabilities held for trading (AFVPL-Tr.): This category comprises the financial assets and liabilities held for trading such as for instance interest-bearing securities, shares and borrower's note loans. In particular, the liabilities held for trading include derivative financial instruments with a negative fair value. Financial assets and liabilities held for trading are recognised at the fair value at every balance sheet date. The remeasurement gains or losses are recognised as the net profit/loss for the period. No such assets or liabilities were recognised in the period under review.

- Financial instruments designated at fair value through profit or loss (AFVPL-Des.): Under the fair value option, financial instruments may be subjected to a voluntary fair value, including recognition of remeasurement gains or losses in the net profit/loss for the period. The irrevocable decision to use the fair value option must be made on initial recognition of the financial instrument. The fair value option may be applied to a financial instrument for example if it eliminates or significantly reduces a measurement or recognition inconsistency. No such assets or liabilities were recognised in the period under review.
- Available-for-sale financial assets: Non-derivative financial assets that are designated as available for sale or are not classified as (a) loans and receivables, (b) held-to-maturity investments or (c) financial assets at fair value through profit or loss are allocated to this category. In particular, this concerns interest-bearing securities, shares and equity interests. They are measured at the fair value. Equity instruments shall be measured at amortised cost if their fair value cannot be reliably determined. No such assets or liabilities were recognised in the period under review.
- Financial assets held to maturity: Non-derivative financial assets with fixed or determinable payments and fixed maturity may be allocated to this category if an entity has the positive intention and ability to hold them to maturity. They are measured at amortised cost. The following are excluded from classification as held-to-maturity investments: (a) financial assets that the entity upon initial recognition designates as at fair value through profit or loss; (b) those that the entity designates as available for sale; and (c) those that meet the definition of loans and receivables.

WILEX currently does not recognise any of the financial instruments listed above.

- Loans and receivables: Non-derivative financial instruments with fixed or determinable payments for which there is no active market are allocated to this category. They are measured at amortised cost. Any impairment is recognised in profit or loss at the time the amortised cost is determined. A financial asset is impaired if there are objective indications of impairment which, in turn, arise from events that may have occurred after the initial measurement and have a negative effect on the value that was recognised on addition. Depending on the type and nature of the respective financial asset, the insolvency of a debtor for instance or even a reduction in the performance and fair value of an investment or other financial assets may constitute indications of and events leading to impairment. Premiums or discounts are recognised in net financial result over the relevant term. They are also measured at amortised cost.

Financial liabilities are initially measured at fair value. After initial recognition, all financial liabilities shall be measured at amortised cost using the effective interest method, except for:

- (a) Financial liabilities at fair value through profit or loss.
- (b) Financial liabilities that arise when a transfer of a financial asset does not qualify for derecognition or when the continuing involvement approach applies.
- (c) The financial guarantee contracts as defined in IAS 39.9.
- (d) Commitments to provide a loan at a below-market interest rate.

All financial liabilities of WILEX shall subsequently be measured at amortised cost using the effective interest method. These financial assets and financial liabilities are classified on initial recognition. WILEX reviews the carrying amounts of these financial assets 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.

In addition, financial instruments are divided into current or non-current assets or 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 recognised as non-current financial instruments while those with a remaining life of up to one year are recognised 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 WILEX 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.

WILEX does not utilise hedge accounting for hedging currency risks. Potential currency risks concern the US dollar in particular, which is the reporting currency of WILEX Inc. Some cash and cash equivalents are held in US dollars to minimise risk.

3.15. Equity and equity management

3.15.1. Composition of equity

The Company's equity consists of common bearer shares with a pro-rata interest in the company's share capital of € 1.00 each. Additional costs directly attributable to the issue of new shares and a capital measure are recognised under equity as a deduction from the issue proceeds.

The Company's capital comprises its share capital, capital reserves and loss carryforwards. In addition, foreign currency reserves from consolidation were recognised directly in equity under other comprehensive income because WILEX Inc. has a different functional currency.

3.15.2. Equity management

The equity management programme of WILEX serves to create a strong equity base and to strengthen it in a sustainable manner so as to be able to operate under the going-concern 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. Management regularly monitors the equity ratio and the sum of the items recognised in equity. There were no changes during the reporting year in the company's strategy or objectives as they relate to its capital management programme.

In principle, WILEX is interested in furthering its constructive, trustful and, in most cases, long-standing cooperation with its providers of equity. The company's goal is still to allow its employees and Executive Management Board a large share in the company's success as shareholders. To this end, Contingent Capital was created in connection with the issue of stock options (see note 3.19).

Preventing the share capital reported in the separate financial statements prepared under German commercial law from being halved is the primary quantitative control variable of equity management.

3.16. Liabilities and provisions

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

A liability for restructuring expenses is recognised if the Group has prepared a detailed formal restructuring plan which, in turn, has raised a valid expectation in those affected that it will carry out the restructuring by starting to implement that plan or announcing its main features to those affected by it. Solely the direct expenditures arising from the restructuring are considered in the measurement of a restructuring liability. Hence this only concerns amounts arising from the restructuring that are not associated with the Group's continuing operations.

Provisions are recognised 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 recognised is the best estimated amount as of the reporting date for the expenditure required to fulfil 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 recognised accordingly under other receivables.

3.17. Income taxes

Income tax expense is composed of the current tax expense and deferred taxes. The current tax expense item is insignificant due to the history of loss carryforwards.

Deferred income taxes are recognised 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 realised or a debt is settled. Deferred tax assets and deferred tax liabilities are not recognised 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 recognised 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 recognised to the extent it is probable that the benefit arising will be realised in future.

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

3.18. 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 used to calculate the effect of subscription rights. 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 3.19) could potentially dilute the diluted earnings per share in future. Because the stock options issued are currently not dilutive given WILEX AG's loss, the diluted and basic earnings per share are identical.

3.19. Employee benefits

3.19.1. Share-based payment

Equity-settled share-based payment provided to employees in the form of stock options is recognised 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 24.

 Page 122

The fair value calculated upon equity-settled share-based payment is recognised as an expense using the straight-line method 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 recognised 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.

3.19.2. Profit-sharing scheme

WILEX recognises both a liability and an expense for bonus entitlements of both Executive Management Board members and employees. A liability is recognised 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 compensation are contingent on the achievement of personal targets and the company's performance targets. The performance-based compensation 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 clinical development, the securing of the Company's further funding and the performance of WLEX's shares.

Since profit-sharing payments are made subsequently as of the reporting date, the Company recognises a corresponding provision that is measured using estimates and judgements based on previous payments.

3.19.3. Pension costs

Payments for defined-contribution pension plans for current and former Executive Management Board members and managing directors are recognised as expenses when the beneficiaries have performed the work that entitles them to the contributions. Currently there is a pension plan at Heidelberg Pharma into which contributions are still being paid. Regarding the WILEX AG pension plan, no additional contributions are expected due to a previous one-time payment.

The payments into a defined contribution plan as pledged in exchange for the work performed by the beneficiaries are expensed in the financial year in question.

3.20. Leases

The lease of equipment for which essentially all opportunities and risks associated with ownership are transferred to WILEX is deemed to represent a finance lease under IAS 17. Finance leases are recognised at the beginning of the lease at the lower of fair value or present value of the minimum lease payments. Each lease payment is split into an interest and repayment portion so as to produce a constant interest rate on the remaining balance of the liability. The relevant lease liabilities are contained in liabilities arising from leases. The interest portion of the financing costs is recognised in income over the term of the lease using the effective interest method. If there is sufficient certainty that ownership will transfer to the lessee at the end of the term of the lease, the asset acquired under a finance lease is depreciated over its expected useful life. Otherwise, the asset is depreciated over the shorter of its useful life or the term of the lease.

Leases, where the risks and benefits associated with ownership remain essentially with the lessor, are deemed to be operating leases. Any payments made under operating leases are recognised in income on a straight-line basis over the term of the lease.

3.21. Recognition of revenue and earnings

Sales revenue and other income are measured at the fair value of the consideration received or receivable.

WILEX's business activities are aimed at generating revenue from cooperation agreements and/or out-licensing agreements (depending on the design of the given contract in the form of upfront payments, milestone payments, cost reimbursements and royalties). WILEX also generates sales revenue from the provision of services as part of its customer specific contract research.

3.21.1. Sales revenue from cooperation and out-licensing agreements

Sales revenue from such agreements can consist of up-front payments, milestone payments or cost reimbursements for current project development and management.

Up-front payments are due as prepayments at the start of a given cooperation. Revenue recognition in connection with up-front payments requires a case-by-case analysis of the overall circumstances and is therefore contingent on the content of the relevant contract. Revenue is recognised upon receipt of the invoice providing all conditions in IAS 18.14 have been satisfied. Where individual conditions have not been met, the up-front payments received are recognised as deferred income and recognised on a pro-rata basis in profit or loss over the term of the defined work to be performed.

Milestone payments are contingent upon achievement of contractually stipulated targets. Milestones and the resulting sales revenue are not posted as such until the respective targets triggering the payments have been met in full.

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.

3.21.2. Sales revenue from the sale of goods

Sales revenue from the sale of goods is recognised when the goods have been delivered, legal transfer of ownership has taken place and the following conditions have been met at the time:

- The Group has transferred to the buyer the significant risks and rewards of ownership of the goods;
- The Group retains neither managerial involvement to the degree usually associated with ownership nor effective control over the goods sold;

- The amount of sales revenue can be estimated reliably;
- It is probable that the economic benefits associated with the transaction will flow to the Group;
- The costs incurred or to be incurred in respect of the transaction can be estimated reliably.

3.21.3. Sales revenue from the provision of services

Income from service contracts is recognised according to the percentage of completion. The percentage of completion is determined as follows:

- Income from customer-specific research is calculated on a time-and-materials basis and recognised at the contractually agreed hourly rates and directly incurred costs.

3.21.4. Other income

In addition to significant exchange rate gains in the financial year, other income relates mainly to government grants, such as those by the Federal Ministry of Education and Research (BMBF). These government grants are used to support certain projects by reimbursing research expenses from public funds. Reimbursement is based on the project costs incurred. The cash amounts received in advance are recognised according to the stage-of-completion method of the underlying service period.

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, amortisation and impairment losses, material and cost of sales, third party services, laboratory costs and fees for legal advice. They are recognised as expenses in the period in which they are incurred.

3.24. Interest income

Interest income is recognised in the statement of comprehensive income at the time it is generated, taking into account the effective yield on the asset.

3.25. Interest expense

Since the Group does not own qualifying assets, borrowing costs are recognised as an expense in the period in which they are incurred.

4. Segment reporting in accordance with IFRS 8

According to IFRS 8, an operating segment is a component of an entity whose business activities may generate sales revenue and incur expenses, whose operating results are regularly monitored by the entity's primary decision maker (the full Executive Management Board), and for which separate financial data are available.

Segmentation information is provided for the Group's operating segments based on the Group's management structure and the structure of its intragroup reporting. Segment results contain components that may be attributed directly to a single segment or, if possible, allocated to all segments on a reasonable basis. Intragroup pricing between segments is determined on an arm's length basis involving third parties.

In accordance with IFRS measurements and based on its internal management and organisational structure WILEX has been reporting on three operating segments since the previous financial year, all of which have materially different risk/reward profiles. The WILEX Group comprises three operating segments, each of which is explained below, along with its separate core business and core projects.

4.1. Therapeutics (Rx)

WILEX AG is a biopharmaceutical company focused on oncology. It develops therapeutic products for the targeted treatment and detection of various types of cancer. The compounds are based on antibodies and small molecules aimed at inhibiting tumour growth and preventing metastases while displaying a low side effect profile. Therapeutics in the 2012 financial year comprised the following product candidates: RENCAREX®, MESUPRON®, WX-554, WX-037 as well as all preclinical and research activities of WILEX AG.

4.2. Diagnostics (Dx)

WILEX Inc.'s acquisition of Oncogene Science added in vitro diagnostics to WILEX's portfolio. WILEX Inc. focuses on the production and marketing of a multitude of in biomarker tests related to oncology. It is the objective of WILEX to offer new approved tests for the clinical oncological immunodiagnostic market in order to improve treatment for cancer patients.

WILEX AG's imaging diagnostic candidate REDECTANE®, which has completed an initial Phase III trial, is also allocated to the Diagnostics segment.

4.3. Customer Specific Research (Cx)

For one, Heidelberg Pharma provides customer specific services in connection with a novel technology platform for therapeutic antibody drug conjugates (ADCs), which is still being developed. In that connection, Heidelberg Pharma aims at entering into collaborative partnerships with research institutes as well as pharmaceutical and biotechnology companies and performs contract work related to manufacturing, optimising and profiling new ADCs based on antibodies that are owned by the respective customers.

A possible ADC collaboration can be broken down into three steps:

- Material Transfer Agreements (MTA)
This phase concerns a non-exclusive agreement on testing a customer's antibodies.
- Technology Licence Agreements (TLA)
In this phase, the antibody that was tested during the MTA Phase I is further refined and tied to a toxin via a linker.
- Product Licence Agreement (PLA)
In this phase, the drug candidate defined in the PLA Phase I is subject to further research by the customer and refined in clinical trials. Heidelberg Pharma receives milestone and licence payments for achieving the individual trial phases as well as for commercialisation.

For another, Heidelberg Pharma performs work on drug metabolism, pharmacology and pharmacokinetics especially in oncology in its preclinical service business.

The two fee-for-service areas cannot be clearly separated from each other because they are interdependent.

At this time the business of Heidelberg Pharma is based solely on the fee-for-service model, which means that its services are billed individually.

4.4. Segment result

4.4.1. Segment result as of 30 November 2012

Segment results	Rx € '000	Dx € '000	Cx € '000	Not allocated € '000	Consoli- dation € '000	Group € '000
Sales revenue	13,873	353	2,064	0	(148)	16,142
External sales revenue	13,873	342	1,926	0	0	16,142
Intersegment sales revenue	0	11	137	0	0	148
Other income	388	9	245	1,064	(7)	1,700
Operating expenses	(18,346)	(3,837)	(4,724)	0	155	(26,751)
of which cost of sales	(3,163)	(1,711)	(1,872)	0	0	(6,746)
of which depreciation and amortisation	(192)	(65)	(415)	0	0	(672)
Finance income	0	0	1	249	(219)	30
Finance costs	0	(144)	(105)	(479)	219	(508)
Earnings before tax	(4,084)	(3,618)	(2,520)	834	0	(9,388)
Net loss for the year	(4,084)	(3,621)	(2,520)	834	0	(9,391)

The Group's intersegment sales revenue amounted to € 148 k. The Diagnostics (Dx) segment generated sales revenue of € 11 k with the Therapeutics (Rx) segment, and the Customer Specific Research (Cx) segment generated sales revenue of € 137 k with the Therapeutics (Rx) segment.

The Therapeutics segment accounted for most of the external sales revenue, all of which was generated through a single customer in connection with the out-licensing and cooperation agreement for RENCAREX® in the US market. Hence sales revenue of € 14,186 k (previous year: € 8,651 k) – which comprises all of the revenue from the Therapeutics segment as well as a large portion of external revenue from the Diagnostics segment – is allocated to the US market. The domestic market was the source of 75 % of the revenue of the Customer Specific Research (Cx) segment, while the US market accounted for 20 %. The remaining 5 % of segment revenue was generated by the European market; In the previous year all revenue still stemmed from the European market.

Key expense items in the 2012 financial year were restructuring expenses totalling € 350 k (previous year: € 0 k) and expenses for granting stock options amounting to € 557 k (previous year: € 97 k). Neither expense item can be clearly allocated to a specific segment.

4.4.2. Segment result as of 30 November 2011

Segment results	Rx € '000	Dx € '000	Cx ¹ € '000	Not allocated € '000	Consoli- dation € '000	Group € '000
Sales revenue	8,397	283	1,618	0	(422)	9,877
External sales revenue	8,397	260	1,220	0	0	9,877
Intersegment sales revenue	0	23	399	0	0	422
Other income	764	0	549	523	0	1,836
Operating expenses	(16,516)	(5,906)	(2,916)	(180)	422	(25,096)
of which cost of sales	(1,309)	(1,387)	(1,469)	0	0	(4,165)
of which depreciation and amortisation	0	(33)	(287)	(204)	0	(524)
Finance income	0	12	0	49	(54)	7
Finance costs	0	(161)	(23)	(418)	54	(548)
Earnings before tax	(7,355)	(5,772)	(771)	(26)	0	(13,924)
Net loss for the year	(7,357)	(5,772)	(771)	(26)	0	(13,926)

¹ Heidelberg Pharma was consolidated from 17 March 2011.

4.5. Segment assets

The assets shown on the consolidated balance sheet amount to €37,721 k (previous year: €20,814 k) and are allocable as follows among the various segments (taking into account consolidation effects):

- The Rx segment reported assets of €1,260 k (previous year: €3,725 k), €210 k (previous year: €232 k) of which were classified as non-current and €1,050 k (previous year: €3,493 k) of which were classified as current.
- The Dx segment recognised assets in the amount of €665 k (previous year: €1,064 k), €278 k (previous year: €779 k) of which were classified as non-current and €387 k (previous year: €285 k) of which were classified as current.
- The Cx segment reported assets of €10,878 k (previous year: €10,736 k), €10,457 k (previous year: €10,204 k) of which were classified as non-current and €421 k (previous year: €532 k) of which were classified as current.
- Non-current assets totalling €1,587 k (previous year: €1,603 k) and current assets amounting to €23,331 k (previous year: €3,686 k) cannot be allocated to a specific segment. The largest item here is cash and cash equivalents.

The Dx segment's assets are located exclusively in the United States, whereas the assets of the other two segments and the assets unallocable to a specific segment are situated in Germany.

Taking into account consolidation effects, investments in financial year 2012 amounted to € 244 k (previous year: € 11,100 k). The Cx segment accounts for € 37 k of this figure (previous year: € 10,910 k), while € 204 k (previous year: € 174 k) cannot be allocated to a specific segment. The major investments in the previous year are the result of the acquisition of Heidelberg Pharma.

Liabilities are not tracked by management at segment level. For this reason, no disclosure in accordance with IFRS 8.28(d) is made here.

5. Financial risk management

5.1. Financial risk factors

Given its business activities, WILEX is exposed to certain risks, in particular market risks (including currency risks, interest and price risks), liquidity risks, default risks and, to a smaller extent, credit risks. WILEX's risk management focuses on the unpredictability of the financial markets and aims to minimise any potential adverse effects on the company's ability to finance its business activities. WILEX 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 an effective groupwide risk management system throughout the entire WILEX 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 analyse risks to which WILEX 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 WILEX'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

WILEX has one subsidiary reporting in a foreign currency and the Group also cooperates with different service providers worldwide and is therefore exposed to currency risks in connection with currency positions, mainly in US dollars (USD), Swiss francs (CHF), British pound (GBP) 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 still limited overall, WILEX has not yet 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

WILEX is not exposed to risks from share price fluctuations related to equity securities, nor to risks from changes in the price of commodities.

5.1.2. Default, liquidity and interest risk

Mainly cash, cash equivalents and receivables constitute financial instruments that might expose WILEX to concentrations of default, liquidity and interest rate risks. WILEX has no obligations under long-term financial investments. WILEX has a detailed cash planning system, which is updated regularly, at least once a month. It serves to ensure that WILEX is aware of the available cash and cash equivalents and the due dates of its liabilities at all times in order to be able to pay liabilities as they fall due. The current financial liabilities shown on the balance sheet concern a shareholder loan from UCB Pharma S.A., Brussels, Belgium, (UCB).

Given the contractually fixed interest rates and short maturities, market-driven interest rate fluctuations do not have a direct effect on the financial assets and liabilities such that the interest rate risk plays a secondary role for WILEX.

5.1.3. Bad debt risk

WILEX is exposed to bad debt risks in connection with receivables. No material past due trade or other receivables were recognised as of the reporting date. Bad debt risks were perceived as a potential risk in the course of the WILEX's development and included in its risk management system.

The maximum default risk in connection with trade receivables is €270 k and corresponds to the trade receivables balance sheet item. The maximum default risk from other receivables is €563 k, of which €452 k are due to a claim being accrued based on costs incurred under the licence agreement with Prometheus. Another €57 k concern claims against tax authorities.

All financial assets are deemed to be fully recoverable and are neither past due nor impaired.

5.1.4. Cash flow and fair value interest rate risk from financial instruments

WILEX invests its liquid funds only in interest-bearing bank accounts or short-term fixed deposits. Market interest rate fluctuations may therefore affect the company's ability to generate sufficient interest income from these financial instruments. This conservative investment approach ensures that there is no nonpayment risk (see note 3.14).

Furthermore, WILEX maintains domestic credit balances only with major banks that belong to the German Deposit Insurance Fund and/or the German Savings Banks Organisation's deposit assurance fund. The credit balances of WILEX Inc. that are deposited with a US bank are also protected through a comparable deposit insurance system. The default risk in connection with these credit balances is therefore minimal.

5.2. Determination of fair value

The carrying amounts of financial assets and liabilities such as cash and cash equivalents as well as trade receivables and payables are more or less equal to their fair value on account of the short maturities.

6. Going concern risk

The carrying amount of cash and cash equivalents as of the 30 November 2012 reporting date exceeded the carrying amount of current liabilities (including accrued liabilities). The shareholder loan in the amount of €2,638 k recognised under current liabilities has an indefinite term. As far as the Company knows, the creditor UCB is not planning at this time to demand repayment on short notice. Whilst the WILEX Group substantially reduced its net loss in the 2012 financial year thanks to revenue from the licence agreement with Prometheus, it was still not in a position to close a year with positive earnings particularly because its necessary costs for clinical research and development are high. The rising revenue of the Company's subsidiaries, Heidelberg Pharma and WILEX Inc., is not yet sufficient to make a positive contribution to consolidated earnings either.

It is very important for WILEX to obtain liquid funds – preferably by commercialising other product candidates – particularly after failing to meet the primary endpoint in the Phase III registration trial for RENCAREX® for patients with clear cell renal cell cancer.

In 2013 WILEX will work on closing yet further commercialisation agreements for possible product candidates, which could significantly improve the company's financial position. Despite the failure to meet the primary trial endpoint, the Company is currently reviewing the possibilities for the commercial value of RENCAREX®. Talks with potential partners for MESUPRON® will be intensified after the announcement of positive data on progression-free survival from the breast cancer trial. The ADC technology offers options for a range of alliances in respect of customer specific research. However, the Executive Management Board cannot predict with any certainty from today's standpoint when and at what terms such an agreement might be made because the ongoing clinical development of the product candidate in question, the manufacturing terms and the marketing parameters must be negotiated along with the financial terms. The Executive Management Board aims to ensure that the product candidate generates the greatest possible return for WILEX.

These earnings are also to be improved through rising sales revenue from our subsidiaries' product sales (Dx) and customer specific research (Cx) business.

These steps would help ensure the Company's liquidity at least until the end of 2014.

However, it is possible that the time required for negotiations with a potential partner might exceed the Company's current cash reach. If WILEX is unable to raise additional funds, the Company is authorised to increase its share capital, with the approval of the Supervisory Board, by up to €5,946,937.00 by issuing up to 5,946,937 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 24 May 2017 (Authorised Capital 2012/I).

The existence as a going concern of WILEX AG, its subsidiaries and the WILEX Group would be at risk if the Executive Management Board, in contrast to its expectations, is unable to enter into a commercialisation agreement for a product candidate or raise additional capital via the capital market. In this case, WILEX might be unable to satisfy its payment obligations and/or become overindebted in the second quarter of the 2014 financial year.

7. Critical estimates and discretionary decisions

Application of the aforementioned accounting principles requires the Management Board 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 judgements are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable 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 financial 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 and other income are based on estimates by the Executive Management Board.

Determining the expense from the measurement of stock options and the parameters underlying the impairment test materially concern assumptions and judgements that are made by management and regularly reviewed.

7.1. Recognition of sales revenue

A material portion of WILEX's sales revenue (€ 16,142 k) arises from its cooperation and/or the licence agreement with Prometheus and the resulting accrual of payments that are recognised as other current or non-current liabilities. This requires forward-looking estimates especially in terms of winding up the development of RENCAREX® and the Phase III registration trial as well as its subsequent approval process in order to be able to accrue the payments received over the period of time work is performed. Because approval of RENCAREX® for the adjuvant treatment of clear cell renal cell cancer is no longer achievable since the failure to meet the primary endpoint in the ARISER trial in October 2012, adjustment of the parameters underlying the accruals, the accrual period and total costs was necessary.

7.2. Expense from the granting of stock options

WILEX recognises expenses in the amount of € 557 k from the granting of stock options under staff costs. 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, WILEX would need to change the relevant parameters and adjust its calculations and staff costs accordingly (see note 24).

 Page 121

 Glossary

7.3. Impairment test pursuant to IAS 36

The impairment tests of both goodwill (€ 6,111 k) and the technology asset In Process Research & Development (IP R&D) – which is not yet ready for use – (€ 2,493 k) require either estimating the value in use based on the cash generating unit's probable expected future cash flows and the reasonable weighted average cost of capital or estimating the fair value less costs to sell.

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.

8. Impairment testing pursuant to IAS 36

The following is a description of impairment testing of the goodwill and the intangible and not yet amortised technology asset acquired in the course of last year's business combination with Heidelberg Pharma.

For purposes of annual impairment testing, goodwill and the IP R&D technology asset are assigned to WILEX's lowest cash generating unit, which is monitored by the Executive Management Board and at the same time constitutes the Customer Specific Research (Cx) segment.

WILEX AG acquired Heidelberg Pharma in March 2011. This acquisition generated goodwill of € 6,111 k. Furthermore, an IP R&D asset consisting of the ADC technology with a net carrying amount of € 2,493 k was identified in the course of the purchase price allocation performed at the time. The carrying amounts as of 30 November 2012 correspond to the value at acquisition in each case.

Impairment tests are based on a discounted cash flow model using assumptions in respect of company planning and serve to determine an asset's value in use. Mid-term planning comprises a detailed five-year plan for the period from 2013 to 2017. Cash flow projections are based on model assumptions that are related to an internal customer analysis and apply probabilities concerning potential new contracts. The current customer base has been analysed as to its future contract potential and provides the basis for mid-term planning.

This is followed by a second, longer-term 15-year planning phase that is based on model assumptions and continues the first planning phase. Sales related to the ADC technology are adjusted using model assumptions rooted in probabilities. Starting with the last year of the detailed planning phase the operating expenses were reduced by 5% per year as development costs in particular are expected to decline once the technology has been developed. A steady growth rate of 1% was assumed for the sales from preclinical services.

The ADC technology platform is a cornerstone of Heidelberg Pharma's business model. The ADC technology is expected to be used to optimise antibodies for specific customers and manufacture corresponding anti-body-drug conjugates (ADC) to improve cancer treatments in the future. Heidelberg Pharma intends to market the ADC technology to third parties and plans to generate sales revenue in the form of milestone and licence payments. Particularly in the final phase of an ADC agreement (product licence 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 carrying amount of the cash generating unit analysed was € 10,901 k as of the reporting date (previous year: € 11,208 k).

Allowing for the risks and opportunities arising from the business activities, the weighted average cost of capital used for the impairment test was 14.9 % (previous year: 15.2 %) before taxes and 10.3 % (previous year: 11.3 %) after taxes.

The impairment test showed that there was no need to recognise impairment losses as of 30 November 2012. Not until a weighted average cost of capital of 19.0 % (after tax) (previous year: 13.5 %) is reached would the carrying amount of the cash generating unit equal the total present value calculated.

The underlying income tax rate is 28.43%, as in the previous year.

There were no events during the financial year just ended that would have indicated a need to conduct a specific impairment test.

9. Property, plant and equipment

As of 30 November 2012 and 2011, property, plant and equipment comprised the following:

	Laboratory equipment (owned) € '000	Laboratory equipment (leased) € '000	Other office equipment € '000	Total € '000
2011 financial year				
Opening carrying amount	641	169	54	864
Additions	100	312	60	472
Construction in progress	135	0	0	135
Acquisitions through a business combination	611	203	45	859
Depreciation	(145)	(42)	(69)	(256)
Net carrying amount as of 30.11.2011	1,342	642	90	2,074
As of 30.11.2011				
Cost	2,141	947	535	3,623
Accumulated depreciation	(997)	(107)	(444)	(1,548)
Reclassifications	199	(199)	0	0
Net carrying amount as of 30.11.2011	1,342	642	90	2,074
2012 financial year				
Opening carrying amount	1,342	642	90	2,074
Additions	271	137	69	477
Reclassifications	(135)	0	0	(135)
Depreciation	(223)	(49)	(57)	(329)
Net carrying amount as of 30.11.2012	1,256	729	102	2,087
As of 30.11.2012				
Cost	2,476	885	604	3,965
Accumulated depreciation	(1,220)	(156)	(502)	(1,878)
Net carrying amount as of 30.11.2012	1,256	729	102	2,087

Unless allocable to cost of sales, €329 k (previous year: €256 k) in depreciation were recognised in profit or loss as research and development costs and as general and administrative expenses. Laboratory equipment and devices under construction in connection with the expansion of the Munich laboratory, which were not made operational until after the reporting date, were capitalised.

WILEX renegotiated three finance leases pursuant to IAS 17 for one piece of laboratory equipment each (see note 3.20) in the financial year just ended. Finance lease assets are measured at fair value and amortised over their estimated useful life on a straight-line basis.

WILEX 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.

WILEX has not found any indication of impairment of property, plant and equipment.

10. Intangible assets

As of 30 November 2012 and 2011, intangible assets comprised the following:

	Software € '000	Licences € '000	Patents € '000	Other intangible assets € '000	Intangible assets not yet ready for use € '000	Goodwill € '000	Total € '000
2011 financial year							
Opening carrying amount	6	1,159	0	0	0	0	1,166
Additions	21	0	0	0	0	0	21
Acquisition through a business combination	246	1	457	320	2,493	6,111	9,628
Amortisation	(44)	(119)	(127)	(57)	0	0	(347)
Net carrying amount as of 30.11.2011	230	1,041	330	263	2,493	6,111	10,467
As of 30.11.2011							
Cost	402	1,796	457	320	2,493	6,111	11,579
Accumulated amortisation	(172)	(755)	(127)	(57)	0	0	(1,111)
Net carrying amount as of 30.11.2011	230	1,041	330	263	2,493	6,111	10,467
2012 financial year							
Opening carrying amount	230	1,041	330	263	2,493	6,111	10,467
Additions	48	0	46	0	0	0	93
Amortisation	(85)	(119)	(52)	(86)	0	0	(342)
Net carrying amount as of 30.11.2012	193	922	324	177	2,493	6,111	10,218
As of 30.11.2012							
Cost	686	1,796	502	320	2,493	6,111	11,907
Accumulated amortisation	(494)	(874)	(179)	(143)	0	0	(1,689)
Net carrying amount as of 30.11.2012	193	922	324	177	2,493	6,111	10,218

Unless allocable to cost of sales, €342 k (previous year: €347 k) in amortisation were recognised in profit or loss as research and development costs and as general and administrative expenses. Additions to this item relate exclusively to software. In addition, intangible assets identified in connection with a purchase price allocation, orders on hand and the acquired customer base were amortised.

WILEX 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 recognised arises from the business combination with Heidelberg Pharma. The assets and liabilities acquired as well as the deferred tax assets and liabilities are recognised separately as of the acquisition date.

Goodwill of €6.1 million was identified in connection with the acquisition of Heidelberg Pharma and the subsequent purchase price allocation; it will be tested for impairment annually in accordance with IAS 36 (see note 8).

 Page 104

10.2. Intangible assets not yet ready for use

In the purchase price allocation carried out last year, the novel technology platform for therapeutic antibody drug conjugates (hereinafter “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 k.

The Company believes that the ADC technology has the potential to enhance and improve the efficacy of many antibody-based therapies, including those marketed.

This technology will not be amortised 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 recognised through profit and loss as research and development expenses. They are not capitalised pursuant to IAS 38 in keeping with the treatment of other development costs and given WILEX’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 2012 during the impairment test carried out in November 2012. WILEX has not found any indication of impairment of this intangible asset.

10.3. Other intangible assets

Other intangible assets comprise a customer base acquired in the course of the business combination with Heidelberg Pharma in financial year 2011. In addition to regular amortisation, an impairment loss of €46 k was recognised for the customer base in the financial year just ended, which equalled around 20 % of the net carrying amount at the time of recognising the impairment loss. Despite growing sales, especially with new customers, this impairment loss was necessary because of the loss of one customer who was a key account at the acquisition date in March 2011.

10.4. Patents

WILEX AG signed a licence, sub-licence and option agreement in 2001 with Bayer Corporation Business Group Diagnostics, Tarrytown, NY, USA, for the acquisition of certain rights relating to the MN patent portfolio of Bayer. “MN” (also known as CAIX) is a tumour-associated antigen which is expressed in a large number of cancers, including virtually all clear cell renal cell carcinomas. The agreement grants WILEX specific property

rights for its Girentuximab antibody. WILEX capitalised the costs for acquiring the licence from Bayer Corporation and is amortising the licence over the period of use of the underlying MN patent.

In October 2004, WILEX AG capitalised the costs for acquiring an option agreement with Centocor Inc., Malvern, PA, USA. Under this option agreement, which WILEX may exercise until the date of filing for approval of a product candidate in the USA, WILEX acquired an option to the exclusive US marketing rights for the Girentuximab antibody. In 1999, WILEX acquired an exclusive licence for the Girentuximab antibody from Centocor for the worldwide development and marketing outside the USA. At that time, Centocor retained an option to the marketing rights in the USA, exercisable until the date of filing for approval of a product candidate based on the Girentuximab antibody in the USA. Under this option agreement, Centocor received an upfront payment and is entitled to future milestone payments and licence fees from the sale of the drug in the USA, should WILEX exercise the option. The option agreement is recognised at cost and will be amortised over the useful life of the underlying patent for the Girentuximab antibody.

A licence agreement was signed by WILEX and Genentech Inc., San Francisco, CA, USA, in June 2006. Genentech holds a patent protecting, along with other aspects, a process that is essential for the subsequent manufacturing of a product candidate based on the Girentuximab antibody. WILEX has therefore acquired a non-exclusive licence for the antibody relating to the Cabilly II Patent, together with the right to issue sub-licences. The licence fee was recognised at present value as an intangible asset in June 2006 and will be amortised on a straight-line basis until December 2018, which is when the underlying patent (US Patent No. 6,331,415, dated 18 December 2001) expires. The amortisation is included in research and development costs. The licence fee was payable in several tranches. A further obligation in the form of a milestone payment will arise once market approval for a product candidate in the USA has been granted by the FDA. This amount will increase the cost of the licence at the time of market approval and will then be amortised over the remaining useful life. In addition, there are agreements in place for royalty payments based on the annual net sales of a product. A patent dispute pending in the United States for years has since been resolved in favour of Genentech. As a result, these payments would have to be made in the future.

In February 2007, WILEX AG exercised the option regarding the acquisition of a patent portfolio from Dendreon Corporation, Seattle, WA, USA. The portfolio includes all of the patents and patent applications for uPA inhibitors owned by Dendreon. This enables WILEX to provide a more comprehensive framework for the subsequent clinical development of the second generation of uPA inhibitors, which are still being researched. The patent fee was recognised at present value as an intangible asset in February 2007 and will be amortised on a straight-line basis until December 2020, which is when the underlying patent expires. The amortisation is included in research and development costs. The licence fee was payable in two tranches. Further milestone payments will be due if the programmes enter the clinical development stage.

The capitalised licences are not in danger of impairment as of the reporting date despite the failure to meet the primary endpoint in the ARISER trial. For one, the patents apply to the Girentuximab antibody, which is also used in the REDECTANE® diagnostic agent. For another, there is a possibility that RENCAREX® could still be commercially marketable despite the failure to meet the primary endpoint of the trial.

11. Other non-current assets

The other non-current assets (2012: 228 k; previous year: € 277 k) mainly comprise rent security in the amount of € 148 k (previous year: € 148 k) and security for leased equipment in the amount of € 80 k (previous year: € 100 k) – all of which is deposited in bank accounts.

12. Inventories

The inventories (2012: € 258 k; previous year: € 515 k) mainly concern warehouse stock of marketable biomarker tests (€ 142 k) and materials for research and development (€ 116 k). A total of € 103 k were recognised as expenses in the statement of comprehensive income for the inventories during the reporting period.

No inventories were pledged as collateral for liabilities.

13. Other assets and prepayments

Other assets and prepayments are comprised as follows:

	30.11.2012 € '000	30.11.2011 € '000
Insurance	54	41
Prepayments to service providers	680	910
Other	1	1
Other assets and prepayments	735	952

Prepayments to service providers include, in particular, payments to service providers in clinical development and subcontractors.

14. Trade and other receivables

The business activities of all three subsidiaries generated € 270 k in trade receivables from a variety of sources (previous year: € 159 k).

	30.11.2012 € '000	30.11.2011 € '000
Trade receivables	270	159
Total	270	159

Other receivables are comprised as follows:

	30.11.2012 € '000	30.11.2011 € '000
VAT claim	48	132
Refund of withholding tax on capital gains	9	5
Receivables from other services (without current account)	28	9
Other receivables	23	0
Other receivables Prometheus	452	2,801
Other assets	3	3
Other receivables	563	2,950

Since the company has incurred only operating losses, the withholding tax on capital gains was refunded. Advance payments on travel costs (2012: €3 k; 2011: €3 k) are treated as other assets. Regardless of the failure to meet the primary endpoint of the Phase III ARISER trial, WILEX is entitled to the cost reimbursements from Prometheus. Accordingly, a receivable is recognised based on the actual costs incurred.

15. Cash and cash equivalents

	30.11.2012 € '000	30.11.2011 € '000
Cash and cash equivalents	23,363	3,421
Total	23,363	3,421

The increase in cash and cash equivalents compared to the previous year is due to the two capital increases and a payment received under the out-licensing agreement with Prometheus.

WILEX maintains domestic credit balances only with major banks that belong to the German Deposit Insurance Fund and/or the German Savings Banks Organisation's deposit assurance fund. The credit balances of WILEX Inc. that are deposited with a US bank are also protected through a comparable deposit insurance system. The default risks in respect of these credit balances are therefore minimal.

16. Equity

As of 30 November 2012, the share capital consisted of 31,275,507 (30 November 2011: 21,613,035) no par value bearer shares with a pro-rata interest in the share capital of € 1.00 per share. The arithmetical nominal amount and any premium on the issue of shares are reported under “subscribed capital” and “capital reserve” respectively.

The following shares have been issued since the company was established:

Issue date	Entry in the commercial register	Number of shares	€
On 30.11.2003¹		10,845,000	10,870,000
On 30.11.2004¹		10,845,000	10,870,000
29.04.2005	31.05.2005	6,521,598	6,521,598
08.09.2005	10.11.2005	—	(25,000)
08.09.2005	10.11.2005	51	51
08.09.2005	10.11.2005	(11,577,766)	(11,577,766)
On 30.11.2005		5,788,883	5,788,883
03.11.2005	21.12.2005	2,173,871	2,173,871
10.11.2006	10.11.2006	4,000,000	4,000,000
On 30.11.2006		11,962,754	11,962,754
On 30.11.2007		11,962,754	11,962,754
On 30.11.2008		11,962,754	11,962,754
18.02.2009	26.02.2009	1,818,181	1,818,181
On 30.11.2009		13,780,935	13,780,935
16.11.2009	04.12.2009	2,177,030	2,177,030
03.08.2010	05.08.2010	2,455,070	2,455,070
On 30.11.2010		18,413,035	18,413,035
17.03.2011	17.03.2011	3,200,000	3,200,000
On 30.11.2011		21,613,035	21,613,035
01.02.2012	03.02.2012	3,201,928	3,201,928
24.08.2012	27.08.2012	6,460,544	6,460,544
On 30.11.2012		31,275,507	31,275,507

¹ WILEX held an additional 25,000 no par value shares without voting rights as treasury shares.

The rights issue executed until 1 February 2012 was completed on 3 February 2012 when it was recorded in the appropriate Commercial Register. The Company's share capital was thus raised by €3,202 k to €24,815 k by issuing 3,201,928 new no par value bearer shares with pro-rata interest in the company's share capital of € 1.00.

The combined capital increase against cash and contributions in kind executed until 24 August was completed when it was recorded in the Commercial Register on 27 August 2012. This increased the capital of WILEX AG by €6,461 k to €31,276 k by issuing 6,460,544 new no par value bearer shares with pro-rata interest in the company's share capital of € 1.00.

Since the mandatory application of IFRS 2 in respect of the accounting for stock options, the value of the capital reserve is adjusted every quarter in line with the additional expenses resulting from the share-based model. A total of €557 k (previous year: €97 k) was recognised in this context in the period under review (see note 24).

 Page 121

The Company incurred €0.4 million in directly allocable transaction costs, which were charged against capital reserves, thus reducing equity.

On the whole the transaction costs mainly concerned fees for external legal advice. All acquisition-related costs incurred are contained in the consolidated statement of comprehensive income. As of the reporting date of 30 November 2012, the capital reserve amounted to €159,212 k (previous year: €135,030 k). The accumulated losses since the start of the Company's business activities in 1997 totalled €170,519 k as of the end of the financial year (previous year: €161,128 k).

17. Pension obligations

WILEX's pension plans are based solely on the defined-contribution model. The benefit obligations are covered by matching reinsurance (in terms of their amounts and maturity), and for this reason the fair value of the claims for reimbursement is reported in accordance with the associated obligations.

In 1999, WILEX granted a one-off pension commitment of €15 k to Professor Olaf G. Wilhelm, the current chairman of the Executive Management Board and Managing Director at the time, as part of a deferred benefit. The allocation to the pension provision totalled €1 k in the financial year just ended (previous year: €1 k).

An addition to Heidelberg Pharma's pension plan of €11 k was made in the reporting period (previous year: €34 k) and included in staff costs. Heidelberg Pharma has a pension commitment in respect of an employee who has since retired and in respect of Dr Jan Schmidt-Brand for which matching reinsurance was arranged.

The reinsurance cover matches because the payments under the reinsurance policy both in terms of their amount and the payments to the beneficiary are identical.

This is not shown in the balance sheet because the pension obligation is offset in each case against the asset value of the reinsurance policy.

18. Lease liabilities and other non-current liabilities

Lease liabilities of € 130 k (previous year: € 218 k) were recognised as of the reporting date because of finance leases for several items of laboratory equipment with a term of 36 months each.

Other non-current liabilities are comprised as follows:

	30.11.2012 € '000	30.11.2011 € '000
Accruals prepayment Prometheus (non-current)	784	4,780
Provision for rent	79	53
Provision for anniversary payment	68	55
Other non-current liabilities	931	4,888

The largest part relates to the non-current, accrued portion of prepayments from contractual partner Prometheus. Pursuant to the May 2011 licence agreement, Prometheus made a prepayment of USD 19.0 million when the contract was signed and an additional one-time payment of USD 17.5 million in July 2012 relating to the RENCAREX® project development to be performed. These prepayments by Prometheus must be accrued over the expected duration of the ARISER trial. The trial period also includes winding up the trial and trial follow-up costs. For this reason, despite the failure to meet the primary trial endpoint, the payments received must still be accrued until December 2013, the probable date of complete termination or winding-up of the trial. As a result, a non-current amount totalling € 784 k must still be reported.

The failure to meet the primary endpoint of the ARISER trial changes the course of the trial, which now provides for winding up the trial instead of continuing development. This affected the parameters for the accrual, the costs still expected and the period in which costs will still be incurred. In turn, this led to an additional reversal of the deferred income recognised in profit or loss, which is described in detail in the explanation of sales revenues (note 21).

One month's rent must be accrued under IFRS over the term of the lease because it is a graduated lease.

A service anniversary bonus was granted to all employees for WILEX's tenth anniversary. These staff costs were classified as current or non-current liabilities depending on the length of the given staff member's employment with the company. The actuarial report necessary for the measurement (IAS 19) is based on various assumptions, such as fluctuation and development of interest rates (2012: 1.43%; previous year: 4.21%) and must be adjusted to these parameters annually as of the reporting date. Based on the parameters stated above, the Company recognised an actuarial loss of € 8 k (previous year: gain of € 9 k) in 2012, which was recognised in the statement of comprehensive income.

19. Lease liabilities, trade payables, financial liabilities and other current liabilities

A current lease liability of € 211 k (previous year: € 252 k) was recognised as of the reporting date in connection with several leases in addition to the **non-current lease liability** described in note 18.

Current **trade payables** decreased from € 1,412 k in the 2011 financial year to € 904 k in the 2012 financial year. They were mainly incurred for services provided in connection with the clinical trials.

Financial liabilities in the amount of €2,638 k (previous year: € 10,548 k) concern the shareholder loan and, after contribution of the share of dievini Hopp BioTech holding GmbH & Co. KG, Walldorf, (dievini) in a combined cash/non-cash capital increase in August 2012, only include the loan disbursement from UCB and the resulting interest liability.

Other current liabilities are comprised as follows:

	30.11.2012 € '000	30.11.2011 € '000
Provisions for holidays not taken	383	409
Accruals Prometheus (current)	9,402	4,780
Social security and other taxes	207	241
Accrued liabilities	2,995	2,564
Other current liabilities	12,987	7,993

The portion of the prepayment and the one-time payment received during the year from Prometheus that has not yet been treated as income is shown under “Accruals Prometheus” (current). Regarding the current Prometheus accrual, see the information above regarding non-current accruals.

The **accrued liabilities** are composed as follows:

	30.11.2012 € '000	30.11.2011 € '000
Employee bonuses and profit-sharing bonuses	1,056	892
Costs for preparing the financial statements	93	135
Rent	35	16
Service anniversary payments	10	18
Deliveries/services	1,451	1,503
Restructuring measures	350	0
Total	2,995	2,546

WILEX recognises accruals for goods and services where it has a current obligation arising from the supply of goods and services received. Accruals were recognised in the amount of the best possible estimate of the payment outflow required to fulfil the current obligation. Most obligations in this category comprise external research and development costs of service providers in connection with preclinical and clinical work and trials, as well as the cost of production for the basic material.

Employee bonuses are granted depending on the performance of the company and of individual employees or members of the Executive Management Board, and are due for payment in the following financial year. The year-on-year rise is attributable to the increase in the number of employees.

The accrued liabilities include an obligation for restructuring expenses that had to be recognised for the first time and mainly includes termination benefits for business-related lay-offs.

20. Other disclosures on financial instruments

Carrying amounts and fair values follow from the table below. In addition, the financial instruments were broken down into categories pursuant to IAS 39 (see note 3.14):

	Measurement category according to IAS 39	Measurement as of 30.11.2012		Measurement as of 30.11.2011	
		Carrying amount € '000	Fair value € '000	Carrying amount € '000	Fair value € '000
Cash and cash equivalents	Loans and Receivables	23,363	23,363	3,421	3,421
Other non-current assets	Loans and Receivables	228	228	277	277
Trade receivables	Loans and Receivables	270	270	159	159
Other receivables	Loans and Receivables	563	563	2,950	2,950
Other non-current liabilities	Financial Liabilities Amortized Costs	(1,061)	(1,061)	(4,888)	(4,888)
Trade payables	Financial Liabilities Amortized Costs	(904)	(904)	(1,412)	(1,412)
Financial liabilities	Financial Liabilities Amortized Costs	(2,638)	(2,638)	(10,548)	(10,548)
Other current liabilities	Financial Liabilities Amortized Costs	(13,198)	(13,198)	0	0
Total		6,623	6,623	(10,041)	(10,041)
Aggregation after measurement criteria					
	Loans and Receivables	24,424	24,424	6,807	6,807
	Financial Liabilities Amortized Costs	(17,801)	(17,801)	(16,848)	(16,848)

The other receivables all have remaining maturities of substantially less than one year. There are no discernible default risks. The other non-current assets (see note 11) comprise an amount corresponding to the balance of the rent security accounts.

Most of the other current liabilities as well as trade payables have short remaining maturities, with the result that the carrying amounts also correspond to the fair value as of the reporting date. The other current and non-current liabilities include the respective current lease liabilities of €211 k (previous year: €252 k) and non-current lease liabilities of €130 k (previous year: €218 k). Lease liabilities are measured based on a payment plan.

The carrying amounts of financial assets and liabilities such as cash and cash equivalents as well as trade receivables and payables were more or less equal to their fair value on account of the short maturities.

No expense or income items were recognised through profit or loss for loans and receivables as well as financial liabilities carried at cost. A total of €475 k were recognised as interest expense related to financial liabilities.

The table below presents the reconciliation of the balance sheet items related to the classes of financial instruments broken down by carrying amount and fair value.

2012	Measured at amortised cost		Measured at fair value € '000	Not within the scope of IFRS 7 € '000	Balance sheet item as of 30.11.2012 € '000
	Carrying amount € '000	Fair value € '000			
Cash and cash equivalents	23,363	23,363	—	—	23,363
Non-current assets	228	228	—	12,304	12,532
Trade receivables	270	270	—	—	270
Other receivables	563	563	—	993	1,556
Non-current liabilities	(130)	(130)	—	(931)	(1,061)
Trade payables	(904)	(904)	—	—	(904)
Financial liabilities	(2,638)	(2,638)	—	—	(2,638)
Other current liabilities	(211)	(211)	—	(12,987)	(13,198)

The following figures apply to the previous year:

2011	Measured at amortised cost		Measured at fair value € '000	Not within the scope of IFRS 7 € '000	Balance sheet item as of 30.11.2011 € '000
	Carrying amount € '000	Fair value € '000			
Cash and cash equivalents	3,421	3,421	—	—	3,421
Non-current assets	277	277	—	12,541	12,818
Trade receivables	159	159	—	—	159
Other receivables	2,950	2,950	—	1,467	4,417
Non-current liabilities	(218)	(218)	—	(4,914)	(5,132)
Trade payables	(1,412)	(1,412)	—	—	(1,412)
Financial liabilities	(10,548)	(10,548)	—	—	(10,548)
Other current liabilities	(252)	(252)	—	(7,993)	(8,245)

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).

Financial instruments with an inherent default and liquidity risk mainly comprise cash and cash equivalents as well as other receivables. The carrying amounts of the financial assets generally reflect the maximum default risk.

Most of the cash and cash equivalents 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 Organisation. But WILEX 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.

There is no interest rate risk in the company's view because its cash and cash equivalents were invested exclusively in demand deposits as of the reporting date.

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. WILEX employs a rolling, monthly cash flow planning and age analysis in order to be able to recognise liquidity risks in due time. WILEX was able to meet its payment obligations at all times in the financial year just ended.

The trade receivables at the close of the financial year were attributable to business customers; they were invoiced as of the 30 November 2012 reporting date or immediately preceding it. No material trade receivables were past due as of the reporting date. No bad debt allowances are necessary in management's view because WILEX does not expect any default risks to arise.

WILEX 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. WILEX reviews the need for foreign currency hedges on an ongoing basis during the year but does not engage in any hedging. Instead, WILEX 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. Translated into the respective currency, as of 30 November 2012 foreign currency risks concerning trade receivables were € 133 k in USD, € 104 k in CHF, € 4 k in SEK, € 2 k in GBP and € 1 k in CAD.

Any increase or decrease in the euro by 10% compared to the given foreign currency would have had the following effect on earnings in the financial year just ended:

	Increase € '000	Decrease € '000
Euro (EUR) vs. Canadian dollar (CAD)	0	0
Euro vs. Swiss franc (CHF)	9	(12)
Euro vs. British pound (GBP)	0	0
Euro vs. Swedish Krona (SEK)	0	0
Euro vs. US dollar (USD)	12	(15)

A material portion of WILEX's sales revenue depends on the given USD/EUR foreign exchange rate. Both the up-front payments and the milestone payments are one-off cash transactions that are translated at the reporting date exchange rate and recognised as income or accrued. There are ongoing foreign currency risks in respect of the revenue from the cost reimbursements for services largely rendered in euros but passed on in US dollars. On the whole, € 14,463 k of all revenue was generated in USD, of which € 3,163 k concern cost reimbursements. Accordingly, an increase by 10% in the average exchange rate applied (i.e. the USD

appreciates vis-à-vis the euro) would have boosted revenue from the cost reimbursements by €224 k. Conversely, a decrease by 10% in the average foreign exchange rate (i.e. the USD weakens vis-à-vis the euro) would have lowered revenue by €273 k.

Given that both operating income and sales revenue from the upfront payment and milestone payment by Prometheus have already been collected and are limited to accrued items, the euro exchange rate relative to other currencies does not have any effect in this case. Solely the resulting cash and cash equivalents in USD are exposed to foreign currency risks. WILEX 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 and cash equivalents in USD as of the 30 November 2012 reporting date were €2,969 k.

Given the contractually fixed interest rates and short maturities, potential market-driven interest rate fluctuations do not have material effects on the financial assets and liabilities.

Non-derivative financial liabilities in the form of loan liabilities and trade payables must both be classified as current. As a rule, trade payables are due within one month. The same is true for liabilities from the shareholder loan, which can be called due or repaid within one month by either of the contractual parties.

21. Sales revenue

Sales revenue in the financial year just ended totalled €16,142 k (previous year: €9,877).

	2012 € '000	2011 € '000
Sales revenue from the sale of goods	284	260
Sales revenue from the provision of services	1,926	1,220
Sales revenue from royalties	13,932	8,397
Sales revenue	16,142	9,877

WILEX posted €13,874 k in sales revenue from the licence agreement with Prometheus (previous year: €8,397 k). These comprise cost reimbursements and elements of the up-front payment and the payment made in July 2012 that are recognised as revenue on a pro-rata basis.

In addition to sales recognised regularly and on a pro-rata basis according to the accrual principle, an additional effect associated with the recognition of sales revenue was noted in connection with the Prometheus prepayments. The missing of the primary endpoint of the ARISER trial did not lead to an abrupt end of the trial because contractually agreed and ethically imperative winding-up activities and follow-up examinations must be carried out. The costs yet to be incurred will, however, decline compared with the previously projected costs associated with meeting the trial targets. The winding-up of the trial also reduces the forecast period compared with a scenario in which the trial had continued. There is no obligation to repay the prepayments received from Prometheus. Nonetheless, the change in the accrual parameters regarding the Prometheus prepayments meant that, in addition to the regular reversal of the accrued prepayments, a further €1,132 k were recognised as revenue as of the balance sheet date.

The other sales revenue from usage fees is from the commercialisation of biomarker tests and customer specific services.

22. Other income

Other income comprises the following items:

	2012 € '000	2011 € '000
Income realisation licence agreements	0	64
Grant provided by the US Department of Defense	0	700
Other grants	642	549
Income from exchange rate differences	1,013	486
Other	45	36
Other income	1,700	1,836

The Federal Ministry of Education and Research (BMBF) has been promoting the Rhine-Neckar region – a biotech hub – as a leading-edge cluster for “Cell-based & Molecular Medicine in the Rhine-Neckar Metropolitan Area” and the Munich site as a leading-edge cluster “m4 – Personalised Medicine and Targeted Therapies”. The income item “other grants”, which is attributable to the Customer Specific Research (Cx) and Therapeutics (Rx) segments, stems from these public funds.

Other significant income from exchange rate differences – especially from the EUR/USD translation – was also generated in the 2012 financial year.

23. Types of expenses

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

	2012 € '000	2011 € '000
Staff costs	11,365	8,948
Travel costs	366	434
Rental expenses	1,561	1,588
Laboratory and other internal costs	3,255	2,104
External research and development costs	8,080	10,171
Legal and consulting costs	1,452	1,326
Depreciation/amortisation	672	524
Total	26,751	25,096

Staff costs rose firstly due to the inclusion of Heidelberg Pharma in the consolidated financial statements for the full year, and secondly because of the Group's larger headcount. Laboratory and other internal costs include expenses for raw materials, consumables and supplies as well as other purchased merchandise of € 1,000 k (previous year: € 561 k). External research and development costs comprise the cost of purchased services, especially from service providers in the area of clinical development. They fell year on year due to the progress of the clinical trials. Legal and consulting costs were up only slightly despite various financing and business development projects, as well as approval preparations and inclusion of Heidelberg Pharma in the consolidated financial statements for the full year. The expense item, legal and consulting costs, contains the cost of conventional legal representation as well as consulting costs related to business development, costs related to industrial property rights and patents and costs related to the development of ongoing research and development activities.

The expenses enumerated here contain € 6,746 k in costs of sales (previous year: € 4,165 k).

24. Staff costs

Staff costs are comprised as follows:

	2012 € '000	2011 € '000
Wages and salaries	8,276	7,035
Social security	1,167	968
Bonuses	1,087	738
Expense from the granting of stock options	557	97
Expense from the measurement of service anniversaries	5	(9)
Other staff costs	272	119
Total staff costs	11,365	8,948

The overall increase in staff costs results from an increase in the number of employees in the Group compared with 2011 due to inclusion of Heidelberg Pharma in the consolidated financial statements for the full year, as well as from salary rises and the promotion of employees. Furthermore, significantly higher expenses were associated with the granting of stock options.

In the comparative periods, WILEX employed the following number of staff on average:

	2012	2011
Administration	25	27
Production, service and sales	30	11
Research and development	72	69
Average number of employees¹	127	107

¹ Including the Executive Management Board

Since Heidelberg Pharma employees were included only from the date the company joined the Group (17 March 2011), the average number of employees in financial year 2011 was substantially lower.

The granting of stock options in accordance with IFRS 2 "Share-based Payments" pushed up staff costs considerably from the previous year's figure of €97 k to €557 k in 2012. On the one hand, this was mainly due to across-the-board adjustment of the exercise price to €3.10 as a result of the rights issue in February 2012. This reduction led to increased expenses for the 2005 Stock Option Plan in the 2012 financial year. On the other hand, options were issued for the first time from the new 2011 Stock Option Plan.

The following is a breakdown of stock option plan measurement in the reporting year:

2005 Stock Option Plan (2005 SOP)

Type of agreement	Share-based payment for the Executive Management Board, executives and employees							
	Tranche 1	Tranche 2	Tranche 3	Tranche 4	Tranche 5	Tranche 6	Tranche 7	Tranche 8
Grant date	30.12.2005	31.01.2006	28.02.2006	28.04.2006	30.09.2006	30.09.2007	31.10.2007	30.09.2010
Options outstanding at the beginning of the reporting period	318,388	167,343	85,078	3,040	148,635	27,000	152,000	76,516
Options granted during the reporting period	0	0	0	0	0	0	0	0
Options forfeited in the reporting period	0	0	0	0	0	0	0	4,500
Options exercised during the reporting period	0	0	0	0	0	0	0	0
Options expired in the reporting period	0	0	0	0	0	0	0	0
Options outstanding at the end of the reporting period	318,388	167,343	85,078	3,040	148,635	27,000	152,000	72,016
Options exercisable as of 30.11.2012	318,388	167,343	85,078	3,040	148,635	27,000	123,500	43,854
Maximum term	10 years	10 years	10 years	10 years	10 years	10 years	10 years	10 years

The options defined as vested in the table above cannot be exercised until the next exercise window, according to the option terms. At that point, they can be exercised provided that WILEX AG's share price then is still 10 % higher than the relevant reference price.

The fair value of stock options has been calculated on the basis of a binomial model. The fair values are illustrated in the following. Settlement is carried out in equity securities.

	Issue date	Expected term (months)	Share price on issue date €	Total term	Exercise price (on issue date) €	Volatility	Risk-free interest rate	Option value (rounded) €
Tranche 1	30.12.2005	24	6.90	10 years	5.52	42.54 %	2.86 %	2.42
Tranche 2	31.01.2006	24	6.90	10 years	5.52	40.40 %	2.97 %	2.36
Tranche 3	28.02.2006	25	6.90	10 years	5.52	41.69 %	3.06 %	2.44
Tranche 4	28.04.2006	24	6.90	10 years	5.52	40.61 %	3.44 %	2.40
Tranche 5	30.09.2006	24	6.90	10 years	5.52	43.25 %	3.56 %	2.48
Tranche 6	30.09.2007	24 – 48	9.84	10 years	9.73	45.3 % – 47.4 %	4.06 % – 4.15 %	2.92 – 4.08
Tranche 7	31.10.2007	24 – 47	9.02	10 years	9.62	47.4 % – 50.1 %	4.06 % – 4.08 %	2.55 – 3.57
Tranche 8	30.09.2010	24 – 48	4.70	10 years	4.34	61.7 % – 72.0 %	0.72 % – 1.20 %	1.96 – 2.33

An expected dividend yield of 0 % was assumed for all eight tranches as of the measurement date. The stock options had the following maximum terms as of the reporting date:

	Issue date	30.11.2012 years	30.11.2011 years
Tranche 1	30.12.2005	3.08	4.08
Tranche 2	31.01.2006	3.17	4.17
Tranche 3	28.02.2006	3.24	4.24
Tranche 4	28.04.2006	3.41	4.41
Tranche 5	30.09.2006	3.83	4.83
Tranche 6	30.09.2007	4.83	5.83
Tranche 7	31.10.2007	4.92	5.92
Tranche 8	30.09.2010	7.83	8.83

The exercise price for all stock options issued until the reporting date was reduced to € 4.10 (the subscription price fixed for the capital increase) across the board in accordance with Article 7 (1i) of the 2005 Stock Option Plan once the rights issue had been recorded in the Commercial Register on 4 December 2009 (2009 Repricing). Furthermore, the subscription price in connection with the rights issue was reduced to € 3.10 per option on 3 February 2012 (2012 Repricing). If, as in this case, the fair value of the stock options rises in connection with such an amendment of the option terms, the additional fair value granted must be recognised pursuant to IFRS 2 either over the remaining vesting period of the stock options or if the vesting period has already ended, immediately and in full as of the date of the amendment. The additional fair value was determined on the basis of a binomial model. In this connection, the additional fair value was determined based on the

difference between the fair value of the changed stock options and that of the initial stock options, both of which were estimated as of the modification date. The additional fair value granted per tranche and option, as determined by means of a binomial model, was measured as follows:

	Additional fair value per option (2012 repricing) €	Additional fair value per option (2009 repricing) €
Tranche 1 – 5	0.48	0.37
Tranche 6	0.48	0.67 – 0.89
Tranche 7	0.48	0.67 – 0.88
Tranche 8	0.34 – 0.45	n.a.

The following parameters were utilised in the determination of the fair values as of 4 December 2009:

Model parameter	Repricing 2012	Repricing 2009
Share price on the issue date	€3.65	€3.91
Expected term of the options in months	5 – 32	7 – 22
Exercise price at expected exercise date (changed options)	€3.10	€4.10
Exercise price at expected exercise date (initial options)	€4.10	€5.52 – €9.73
Expected dividend yield	0 %	0 %
Risk-free interest rate for the term	0.09 % – 0.34 %	0.56 % – 1.26 %
Expected volatility for the term	36.59 % – 53.97 %	63.83 % – 70.18 %

The additional fair value calculated based on repricing in 2009 amounts to €399 k for all options as of 4 December 2009; the figure based on repricing in 2012 is €464 k for all options as of 3 February 2012. At the time of the respective change in exercise price, the majority of the stock options had already vested, so most of the amount for repricing in 2009 (€336 k) as of 4 December 2009 and repricing in 2012 (€436 k) was already recognised. The additional fair value of the stock options that had not yet vested will be recognised on a straight-line basis over the remaining vesting period.

WILEX incurred the following costs under the 2005 Stock Option Plan, taking the repricing into account:

	2012 € '000	2011 € '000
Expenses for the period from stock option plan	482	97

In the meanwhile, the authorisation to grant stock options from the 2005 SOP expired. New options can now only be issued from the new plan described below.

2011 Stock Option Plan (2011 SOP)

The Annual General Meeting resolved on 18 May 2011 to authorise WILEX AG to issue a total of 809,488 stock options as part of the 2011 Stock Option Plan to employees of WILEX AG and its affiliates. The objective of the plan is to acknowledge and reward the commitment of employees going forward and their future contributions to the Company's value.

A stock option entitles the holder to subscribe for one no par value bearer share of WILEX AG. 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 WILEX's share price during the ten trading days preceding the start of the relevant exercise period ("reference price") exceeds the issuing 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). The payout amount per employee for the exercised stock options continues to be limited to three times the annual gross compensation (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 (cap agreement).

The stock options granted under the 2011 SOP developed as follows in the financial year just ended:

Tranche 1	
Grant date	30.03.2012
Options outstanding at the beginning of the reporting period	0
Options granted during the reporting period	270,500
Options forfeited during the reporting period	17,713
Options exercised during the reporting period	0
Options expired during the reporting period	0
Options outstanding at the end of the reporting period	252,787
Options exercisable as of 30.11.2012	0
Maximum term	10 years

The 2011 SOP was classified and measured as an equity-settled share-based payment. The fair value of the capital reserves to be recognised as a liability due to the stock option plan was calculated based on a Monte Carlo model. In the financial year just ended, there was no change to the plan, and it was not revoked.

A capital reserve in the amount of €75 k (30 November 2011: €0 k) was recognised as a liability as of 30 November 2012 for the stock options granted as part of the 2011 SOP.

	2012 € '000	2011 € '000
Expenses for the period from 2011 Stock Option Plan	75	0

Measurement is based on the following parameters:

	Tranche 1
Measurement date	30.03.2012
Exercise price	€ 3.53
Price of the WILEX share as of the measurement date	€ 3.82
Expected remaining term until the measurement date	4.81 years
Expected volatility of the WILEX share	57.83 %
Expected dividend yield of the WILEX share	0.00 %
Risk-free interest rate	0.61 %
Maximum term	10 years

The expected volatility was calculated based on the historical volatility of the WILEX share over the past five years.

The fair value of the stock options granted in the 2012 financial year as part of the 2011 SOP amounted to € 2.13 per option as of the measurement date.

The total expense for the granting of stock options for the period thus amounted to € 557 k (previous year: € 97 k).

During the financial year just ended, 270,500 new stock options were issued to members of the Company's Executive Management Board, executives of affiliates and non-executive employees of the Company or affiliates.

In the financial year just ended, 22,213 stock options were returned. This means that 1,226,287 options – 833,335 for current or former members of the Executive management Board and 392,952 for current or former employees – had been issued as of the end of the financial year.

25. Net currency gains/losses

WILEX posted a currency gain of € 320 k (previous year: € 307 k) in the 2012 financial year.

The consolidation of WILEX Inc. led to an unrealised currency loss of € 10 k that was recognised directly in equity (previous year: unrealised currency loss of € 47 k).

The balance of the exchange differences, which were recognised in other income and accumulated as a separate component of equity, is – € 48 k as of the end of the 2012 financial year (previous year: – € 38 k).

26. Financial result

	2012 € '000	2011 € '000
Interest income from bank accounts/Other	30	7
Finance income	30	7
Interest expense from leasing and current liabilities to banks	(33)	(30)
Interest income from shareholder loans	(475)	(518)
Finance costs	(508)	(548)
Financial result	(478)	(541)

The year-on-year improvement of the financial result is due to the contribution of the dievini shareholder loan as part of the mixed cash and non-cash capital increase in August 2012.

27. Income taxes

Due to operating losses, no significant income tax was payable in the 2012 and 2011 financial years. Neither expenses nor income from deferred taxes were included in tax expenses in the 2011 and 2012 financial years.

Deferred tax assets or liabilities were determined using the tax rates in effect in the respective country (Germany, United States). A composite tax rate of 32.98% (previous year: 32.98%) was applied to the parent company, WILEX AG, which is comprised of a corporation tax rate of 15% (previous year: 15%), solidarity surcharge of 5.5% (previous year: 5.5%) and municipal trade tax of 17.15% (previous year: 17.15%).

Tax rates of 28.43% (Heidelberg Pharma; as in the previous year) and 42.25% (WILEX Inc.; previous year: 35%) were applied to the subsidiaries.

The reported current tax expense deviates from the expected tax income. The nominal tax rate of 32.98% (previous year: 32.98%) must be applied to income in accordance with IFRS. Reconciliation of the differences is shown in the following table.

	2012 € '000	2011 € '000
Earnings before tax	(9,388)	(13,924)
Tax rate	32.98%	32.98%
Expected tax income	3,096	4,592
Non-capitalisable losses carried forward for the period	(3,135)	(4,651)
Change in non-capitalised temporary differences	43	35
Effect from different tax rate	(12)	(21)
Non-deductible operating expenses/Other	5	43
Reported tax expense	(3)	(2)

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

	2012 € '000	2011 € '000
Deferred tax assets		
Other assets	275	261
Equity investments	109	0
Due to loss carryforwards	790	922
	1,174	1,183
Deferred tax liabilities		
Intangible assets	825	854
Property, plant and equipment	152	107
Other provisions	195	220
Other	2	1
	1,174	1,183

Of the deferred tax assets, a total of € 109 k resulted from outside basis differences in respect of different measurements of the equity investments.

Applying IAS 12.74, deferred tax assets and liabilities have been offset, since they exist vis-à-vis the same taxation authority and arise in the same periods.

As further losses can be expected in the foreseeable future, no deferred tax assets were recognised regarding the following:

	30.11.2012 € '000	30.11.2011 € '000
Losses carried forward		
for corporation tax	210,247	201,207
for trade tax	207,581	198,718
Deductible temporary differences	0	0

The tax loss carryforwards shown are mainly attributable to WILEX AG (corporation tax loss carryforward of € 166,229 k; municipal trade tax loss carryforward of € 163,563 k) and may be carried forward indefinitely. Other tax loss carryforwards concern the subsidiaries WILEX Inc. and Heidelberg Pharma. Heidelberg Pharma has € 42,927 k in losses carried forward for corporation tax and municipal trade tax purposes. WILEX Inc. in turn has € 3,881 k in losses carried forward for corporation tax and municipal trade tax purposes. Deferred tax assets (amounting to € 790 k) were recognised in the financial year just ended for € 2,791 k in tax loss carryforwards.

Note the following in regards to the tax loss carryforwards available to WILEX AG and Heidelberg Pharma: 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 municipal trade tax. The Company has not been subject to a tax audit since it was established. Regarding WILEX AG, it has to be noted that due to the capital increases as part of the fourth financing round in April 2005 and the IPO in November 2006, the company may have lost its losses carried forward accumulated until the end of 2006, which amount to € 67.24 million (corporation tax) and € 64.95 million (municipal trade tax). Effective 1 January 2008, under amended Section 8c German Corporation Tax Act (Körperschaftsteuergesetz) the acquisition by an acquirer or parties related to it of 25 % to 50 % of the subscribed capital of a loss corporation results in the pro-rated elimination of its tax loss carryforwards whilst the acquisition of more than 50 % of the subscribed capital results in the complete elimination thereof. Because capital increases also cause shifts in shareholdings and thus adverse acquisitions of equity as defined in Section 8c German Corporation Tax Act, the capital increases carried out since 2008 might possibly have led to the pro-rated elimination of the tax loss carryforwards.

Tax loss carryforwards in the amount of € 40,286 k that Heidelberg Pharma accumulated up to the acquisition date are at risk because WILEX AG acquired all shares in Heidelberg Pharma. The only thing that is not in doubt is 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 under German tax law; they amount to € 12,808 k.

As already described in the Notes, WILEX AG acquired 100 % of the shares in Heidelberg Pharma. 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 k; they were offset in the same amount by deferred tax assets from tax loss carryforwards taken over. As of 30 November 2012, deferred taxes on these amounted to € 759 thousand (previous year: € 784 thousand); the Company continues to make use of the option to offset deferred taxes in accordance with IAS 12.74.

28. Earnings per share

28.1. Basic

Basic earnings per share are calculated by dividing the net profit for the year available to shareholders by the average number of shares issued during the financial year.

	2012	2011
Net loss for the year available to shareholders (in € '000)	(9,391)	(13,926)
Weighted average number of shares issued (in thousands)	25,932	20,684
Basic earnings per share (in € per share)	(0.36)	(0.67)

To the extent that reference is made to the shares outstanding as of the reporting date, basic earnings per share as of 30 November 2012 change to - € 0.30 per share (based on 31,275,507 shares). In the previous year therefore, basic earnings per share were - € 0.64 (based on 21,613,035 shares).

28.2. Diluted

Basic and diluted earnings per share of WILEX are calculated based on the same number of shares because the conversion of common stock equivalents would be anti-dilutive.

29. Leases, guarantees and obligations

29.1. Finance leases

In 2012 laboratory equipment was purchased by means of finance leases with terms of 36 months in each case subject to capitalisation and depreciation of the purchase cost in property, plant and equipment (see note 9). The total of €33 k in paid interest is shown in the statement of comprehensive income under "Finance costs" (previous year: €30 k). A total of €80 k in security were made available for leases (previous year: €100 k).

The net carrying amount of all finance leases as of the reporting date was €563 k (previous year: €642 k). These leases do not stipulate contingent lease payments, nor do they impose restrictions in respect of dividends, additional liabilities or other leases. Whilst price adjustment clauses were not stipulated, there is the option to purchase the leased equipment once the given lease expires.

WILEX will incur the following minimum obligations in the next reporting periods under finance leases:

	up to 1 year € '000	1 – 5 years € '000	after 5 years € '000	Total € '000
Obligations under finance leases (laboratory equipment)				
30.11.2012	210	148	–	358
30.11.2011	258	246	–	504
Discount effect				
30.11.2012	–	18	–	18
30.11.2011	–	30	–	30
Present value of minimum lease payments				
30.11.2012	210	130	–	340
30.11.2011	258	216	–	474

The interest rates applicable to the liabilities from finance leases were determined on the date the lease was signed in each case and range from 7.0% to 8.5%. The current lease liabilities correspond to the respective present values.

29.2. Operating leases, guarantees and obligations

WILEX has also leased laboratory and office equipment under operating leases, which will expire at different times until 2016. All of the parent company's office and laboratory premises used at present are rented under leases expiring at the end of December 2016. The leases for the premises of the subsidiaries are also scheduled to expire in 2016 (WILEX Inc.) or may be terminated on short notice (Heidelberg Pharma). The cost of office and laboratory equipment as well as office and laboratory premises under the operating leases are reported as other expenses in the statement of comprehensive income, together with the obligations under lease agreements for company cars:

Expenses from operating leases and tenancy agreements	€ '000
2012	1,236
2011	1,204

WILEX has pledged bank accounts with a balance of € 148 k as deposit for the landlord. No other guarantees exist.

The future minimum annual payments under tenancy agreements and leases are comprised as follows:

Obligations as of 30.11.2012	up to 1 year € '000	1 – 5 years € '000	after 5 years € '000	Total € '000
Rental obligations for laboratory and office premises	1,147	2,983	0	4,130
Obligations under operating leases (laboratory and other office equipment, vehicles)	57	57	0	114
	1,204	3,040	0	4,244

Also as in the previous year, there are royalty claims under licences that are contingent on revenue and become due and payable once products are sold upon approval.

Below are previous year's figures:

Obligations as of 30.11.2011	up to 1 year € '000	1 – 5 years € '000	after 5 years € '000	Total € '000
Rental obligations for laboratory and office premises	1,068	4,054	50	5,172
Obligations under operating leases (laboratory and other office equipment, vehicles)	54	73	0	127
	1,122	4,127	50	5,299

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.

There is a contingent liability in that WILEX may have the obligation under the existing lease to return the laboratory to its original condition if the lessor so desires at the end of the lease. But WILEX does not believe in the likelihood of such an outcome.

30. Corporate bodies and compensation

30.1. Executive Management Board

The current Executive Management Board members of WILEX AG are:

Professor Olaf G. Wilhelm, Chairman of the Executive Management Board

Dr Paul Bevan, Head of Research and Development

Dr Thomas Borcholte, Chief Business Officer

Dr Jan Schmidt-Brand, Chief Financial Officer (since 1 September 2012)

The previous CFO, Peter Llewellyn-Davies, stepped down from the Executive Management Board of WILEX AG effective at the end of 31 August 2012. Dr Jan Schmidt-Brand continues to serve as Managing Director of Heidelberg Pharma (since 2004).

30.2. Supervisory Board

The Supervisory Board members of WILEX AG as of 30 November 2012 were:

- Professor Christof Hettich, lawyer and partner, RITTERSHAUS Rechtsanwälte, and Managing Director, dievini Verwaltungs GmbH (Chairman of the Supervisory Board)
- Dr Georg F. Baur, Entrepreneur (Deputy Chairman of the Supervisory Board)
- Professor Friedrich von Bohlen und Halbach, Managing Director, dievini Verwaltungs GmbH
- Professor Iris Löw-Friedrich, Chief Medical Officer and Executive Vice President Development, UCB S.A.
- Andreas R. Krebs, Managing Partner, ColognelInvest GmbH
- Dr Birgit Kudlek, Global Head, Sandoz Development Center Network, Sandoz International GmbH (since 25 May 2012)

The former member, Dr Alexandra Goll, General Partner, TVM Capital GmbH, stepped down from the Supervisory Board of WILEX AG effective at the end of 14 December 2011.

30.2.1. 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 compensation 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. Professor Christof Hettich is the Chairman; Andreas R. Krebs is a member of this committee.

A Research and Development Committee tasked with issues related to WILEX's oncological product candidates was established in September 2010. This committee is chaired by Professor Friedrich von Bohlen and Halbach; Professor Iris Löw-Friedrich and Andreas R. Krebs are additional members.

The Supervisory Board also established an Audit Committee, whose tasks include the discussion and preparatory examination of consolidated financial statements and quarterly reports of the Group as well as the preselection of the auditor of the financial statements. The Audit Committee is chaired by Dr Georg F. Baur. Its further members are Professor Friedrich von Bohlen und Halbach and Dr Birgit Kudlek.

30.2.2. Other appointments of the Supervisory Board members

In addition to being a member of the Supervisory Board of WILEX, **Professor Hettich** is also the Chairman or a member of the following bodies:

Company	Position
Agennix AG, Heidelberg	Chairman of the Supervisory Board
InterComponentWare AG, Walldorf	Chairman of the Supervisory Board
LTS Lohmann Therapie-Systeme AG, Andernach	Member of the Supervisory Board
SYGNIS Pharma AG, Heidelberg	Deputy Chairman of the Supervisory Board
Cytonet GmbH & Co. KG, Weinheim	Chairman of the Advisory Board
febit Holding GmbH, Heidelberg	Chairman of the Advisory Board
febit Inc., Massachusetts, USA	Non-executive Chairman of the Board of Directors
immatics biotechnologies GmbH, Tübingen	Member of the Advisory Board
SRH Holding SdbR, Heidelberg	Member of the Foundation Council
Companies of the Vetter Group:	Member of the Advisory Boards
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	
AC Immune SA, Lausanne (Switzerland)	Member of the Board of Directors
CureVac GmbH, Tübingen	Member of the Advisory Board

In addition to being a member of the Supervisory Board of WILEX, **Dr Baur** is also the Chairman or a member of the following bodies:

Company	Position
Franz Haniel & Cie. GmbH, Duisburg	Vice Chairman of the Supervisory Board
J.F. Müller & Sohn AG, Hamburg	Chairman of the Supervisory Board
LR HEALTH & BEAUTY SYSTEMS	Chairman of the Advisory Board
HOLDING GmbH, Ahlen	
TAKKO Fashion GmbH, Telgte	Chairman of the Advisory Board

In addition to being a member of the Supervisory Board of WILEX, **Professor von Bohlen und Halbach** is also the Chairman or a member of the following bodies:

Company	Position
Apogenix GmbH, Heidelberg	Chairman of the Advisory Board
Cosmo S.p.A., Milan, Italy	Non-executive member of the Board of Directors
Curacyte AG, Munich	Member of the Supervisory Board
CureVac GmbH, Tübingen	Chairman of the Advisory Board
Cytonet GmbH & Co. KG, Weinheim	Member of the Advisory Board
febit Holding GmbH, Heidelberg	Member of the Advisory Board
Immatics GmbH, Tübingen	Member of the Advisory Board
Molecular Health AG, Basel, Switzerland	Chairman of the Board of Directors
SYGNIS Pharma AG, Heidelberg	Chairman of the Supervisory Board

In addition to being a member of the Supervisory Board of WILEX, Mr **Krebs** is also the Chairman or a member of the following bodies:

Company	Position
Max Planck Institut, Münster	Member of the Board of Trustees
Paul-Ehrlich-Stiftung, Frankfurt am Main	Member of the Board of Trustees
Merz GmbH & Co. KGaA, Frankfurt am Main	Chairman of the Supervisory Board
Merz GmbH & Co. KGaA, Frankfurt am Main	Chairman of the Shareholders' Council
Merz KGaA, Frankfurt am Main	Chairman of the Advisory Board
Senator GmbH & Co KGaA, Groß-Bieberau	Member of the Supervisory Board

Professor Löw-Friedrich and **Dr Kudlek** are neither the Chairwoman nor a member of other control bodies as defined by Section 125 (1) sentence 5 German Stock Corporation Act.

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.

30.3. Compensation of corporate bodies

A detailed description of the compensation model and the information on compensation of each Executive Management Board and Supervisory Board member are included in the compensation report, which is part of the combined management report. These disclosures were subject to the audit of the annual financial statements and consolidated financial statements. The compensation report is included in chapter 6, "Corporate governance", of the combined management report.

Page 44

30.3.1. Executive Management Board

Page 48

Compensation consists of a salary (fixed compensation), other benefits (non-cash compensation), a variable compensation component and a stock option programme with a long-term incentive and a risk element.

The members of the Executive Management Board received total compensation of € 1,426 k (previous year: € 1,248 k) in financial year 2012, € 1,097 k (previous year: € 1,018 k) of which was fixed compensation, € 276 k (previous year: € 194 k) was variable compensation and € 53 k (previous year: € 36 k) was paid in the form of other benefits or non-cash compensation.

The Executive Management Board received a total of 823,335 stock options as of 30 November 2012 (30 November 2011: 719,335) from the stock option programme with a long-term incentive and a risk element. The cumulative fair value of all stock options granted to the Executive Management Board was € 1,967 k as of the end of the reporting period (previous year: € 1,802 k). The expenses incurred in connection with the share-based compensation in the financial year just ended totalled € 371 k (previous year: € 22 k).

30.3.2. Supervisory Board

Page 52

In accordance with the Company's Articles of Association, the members of the Supervisory Board receive a fixed compensation for each full financial year of service on the Supervisory Board. Members of a Supervisory Board committee are paid a flat fee per financial year and committee. The Supervisory Board members do not receive variable compensation, nor are they granted options or similar rights. Supervisory Board members are not entitled to a settlement if their membership ends.

The total compensation paid by WILEX to the Supervisory Board for the 2012 financial year amounted to € 208 k plus expenses (previous year: € 219 k).

31. Related party transactions

Balances and transactions between the Company and its subsidiaries which are related parties were eliminated in consolidation and are not outlined in this note. Details concerning transactions between the Group and other related parties are listed below.

31.1. Shares held by the Management Board and the Supervisory Board

As of 30 November 2012, the Executive Management Board held 242,717 shares (representing 0.78% of the company's share capital of 31,275,507 shares). The Supervisory Board for its part held 258,023 shares directly and 9,976,358 shares indirectly (representing 32.72% of the company's share capital). Chapter 6.2.3, Shares held by the Supervisory Board and the Executive Management Board, contains a disclosure of the shareholdings of the individual Board members.

 Page 45

31.2. Directors' dealings

In the 2012 financial year, the Company's executives reported 15 transactions subject to disclosure in accordance with Section 15a German Securities Trading Act (Wertpapierhandelsgesetz) (Directors' dealings), which are described individually and in detail in the Corporate Governance Report, Chapter 6.2.2 Directors' Dealings, in the combined management report. All directors' dealings were also posted immediately after publication on [WILEX's website](#) under the tab "Press + Investors > Announcements > Directors' Dealings".

 Page 44

 @ www.wilex.com

31.3. Other transactions

In 1999, WILEX granted a pension commitment to a managing director (the current Chairman of the Executive Management Board) as part of a deferred benefit. WILEX assumes that no additional payments to the plan will be necessary. No retirements are expected in the next five years either.

Furthermore, Heidelberg Pharma granted Dr Schmidt-Brand a pension commitment in his capacity as an executive of the Company for which matching reinsurance was arranged.

WILEX signed a loan agreement for up to € 10 million with its two main shareholders, dievini Hopp BioTech holding GmbH & Co. KG, Walldorf, ("dievini") and UCB Pharma S.A., Brussels, Belgium, ("UCB") on 17 December 2010 subject to subordination and payable in two instalments. The share of dievini in this loan is € 7.5 million, and that of UCB € 2.5 million. Both lenders are paid interest of 6 % p. a. During the cash/non-cash capital increase in August 2012, the loan by shareholder dievini was converted into 2,100,337 new shares as part of a contribution in kind with the existing repayment claim, including interest, amounting to approximately € 7.8 million. The only outstanding loan as of the 30 November 2012 reporting date is the loan from UCB.

The remaining loan is unsecured and is not limited in time. The lender is entitled to terminate the loan. In that case, it would have to be repaid within one month. In lieu of asking for repayment of the loan, the lender may also contribute their claims to repayment as an in-kind contribution in connection with a rights issue or convert it into shares subject to a convertible bond programme yet to be resolved. These two repayment options are subject to the proviso, for one, that the rights issue or the convertible bond programme are adopted and carried out and, for another, that an external assessor confirms the value of the respective claim to repayment.

A total of 52,000 stock options were issued to members of the Executive Management Board in the 2012 financial year under the 2011 Stock Option Plan. Of these, 8,000 options were returned by Mr Peter Llewellyn-Davies effective 31 August 2012. In his capacity as Managing Director of Heidelberg Pharma, Dr Jan Schmidt-Brand was awarded 60,000 stock options (see note 30.1). No stock options have been exercised to date. Furthermore, no stock options under this Plan have expired or were forfeited.

 Page 132

A total of 19,500 options held by the Executive Management Board from the 2011 SOP have vested as of the reporting date. All of the Executive Management Board's options from the 2005 Stock Option Plan already vested in the previous financial year.

WILEX made payments of € 12 k to Rittershaus law firm for legal consulting services in the first quarter of 2012. Rittershaus is a related party because the chairman of the Supervisory Board, Professor Christof Hettich, is a partner in this law firm. Furthermore, Rittershaus provided consulting services in connection with the capital increase and the directors' contracts for a fee of € 24 k in the second half of 2012.

No other relationships to related parties exist.

32. Expenses for the auditors

Deloitte & Touche GmbH Wirtschaftsprüfungsgesellschaft was appointed the auditor of the company's consolidated financial statements at its Annual General meeting on 25 May 2012. The following fees for services were recorded as expenses in the periods reviewed:

	2012 € '000	2011 ¹ € '000
Audit of the annual financial statements	88	125
Other assurance services	74	76
Total expenses for auditors	162	201

¹ KPMG AG Wirtschaftsprüfungsgesellschaft was the auditor of the 2011 consolidated financial statements.

Audit fees (€ 88 k) solely concern the statutory audit of the consolidated financial statements pursuant to IFRS and the audit of the annual financial statements pursuant to HGB.

33. Declaration of Conformity with the German Corporate Governance Code in accordance with Section 161 German Stock Corporation Act

The Declaration of Conformity to be submitted annually in accordance with Section 161 of the German Stock Corporation Act was submitted by the Executive Management Board and the Supervisory Board in February 2013. It has been made permanently available to all shareholders and interested parties on the company's website.

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34. Events after the reporting period

The restructuring measures announced on 4 December 2012 are being implemented according to plan. No labour tribunal proceedings are pending in connection with the business-related lay-offs. The restructuring will not have a financial effect until the second quarter of 2013.

After the end of the reporting period, no other significant events occurred which had a direct influence on the business performance of the WILEX Group.

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 WILEX Group, and the combined management report includes a fair review of the development and performance of the business and the position of the WILEX Group and of WILEX AG, together with a description of the material opportunities and risks associated with their expected development.”

Munich, 7 February 2013

Executive Management Board



Professor Olaf G. Wilhelm

Dr Jan Schmidt-Brand

Dr Paul Bevan

Dr Thomas Borcholte

Auditors' report

We have audited the consolidated financial statements prepared by WILEX AG, Munich, comprising the balance sheet, statement of comprehensive income, statement of changes in equity, cash flow statement and notes, together with the Group management report, which was combined with the management report, for the financial year from 1 December 2011 to 30 November 2012. The preparation of the consolidated financial statements and Group management report in accordance with International Financial Reporting Standards (IFRSs), as adopted by the EU, and the additional requirements of German commercial law pursuant to section 315a (1) HGB [Handelsgesetzbuch: German Commercial Code] are the responsibility of the Company's Executive Management Board. Our responsibility is to express an opinion on the consolidated financial statements and on the Group management report based on our audit.

We conducted our audit of the consolidated financial statements in accordance with Section 317 HGB [Handelsgesetzbuch "German Commercial Code"] and German generally accepted standards for the audit of financial statements promulgated by the Institut der Wirtschaftsprüfer [Institute of Public Auditors in Germany]. Those standards require that we plan and perform the audit such that misstatements materially affecting the presentation of the net assets, financial position and results of operations in the consolidated financial statements in accordance with the applicable financial reporting framework and in the Group management report are detected with reasonable assurance. Knowledge of the business activities and the economic and legal environment of the Group and expectations as to possible misstatements are taken into account in the determination of audit procedures. The effectiveness of the accounting-related internal control system and the evidence supporting the disclosures in the consolidated financial statements and the management report of the Group are examined primarily on a test basis within the framework of the audit. The audit includes assessing the annual financial statements of those entities included in consolidation, the determination of entities to be included in consolidation, the accounting and consolidation principles used and significant estimates made by the Executive Management Board, as well as evaluating the overall presentation of the consolidated financial statements and the Group management report. We believe that our audit provides a reasonable basis for our opinion.

Our audit has not led to any reservations.

In our opinion, based on the findings of our audit, the consolidated financial statements of WILEX AG, Munich, comply with IFRSs, as adopted by the EU, the additional requirements of German commercial law pursuant to Section 315a (1) HGB and give a true and fair view of the net assets, financial position and results of operations of the Group in accordance with these requirements. The Group management report is consistent with the consolidated financial statements and as a whole provides a suitable view of the Group's position and suitably presents the opportunities and risks of future development.

Without qualifying this opinion we refer to the discussion in sections 7 "Report on risks and opportunities", sub-sections "Financing risk", "Going concern risks" and "Overall assessment of the risk situation", and 9 "Anticipated developments" in the management report for the parent company and the Group. Therein it is disclosed that the existence as a going concern of the Company, its subsidiaries and the Group is at risk if the Company is unable either to enter into a commercialisation agreement for a product candidate or significantly improve the subsidiaries' results of operations or raise additional capital via the capital market.

Mannheim, 13 February 2013

Deloitte & Touche GmbH
Wirtschaftsprüfungsgesellschaft

Schmidt
Wirtschaftsprüfer
[German Public Auditor]

Dr von Pock
Wirtschaftsprüfer
[German Public Auditor]

Glossary

Adjuvant therapy: Supportive therapy after surgery

Antibodies: Proteins which are produced by the immune system with the aim of identifying and destroying foreign substances that cause disease, such as viruses and bacteria

Antibody Drug Conjugate (ADC) technology: Antibody drug conjugates are monoclonal antibodies attached to biologically active drugs by chemical linkers. Combining the specific targeting of antibodies with cancer-killing cytotoxic drugs enables ADCs to discriminate between healthy and tumour tissue. This combination enhances the control of drug pharmacokinetics and significantly improves delivery to target tissue.

Antigen: Structure onto which an antibody specifically binds

ARISER: Adjuvant RENCAREX® Immunotherapy Phase III trial to Study Efficacy in non-metastatic RCC. ARISER is a double-blind, placebo-controlled Phase III study to assess the effect of adjuvant treatment with RENCAREX® on disease-free survival and overall survival in RCC patients with a high risk of recurrence following surgery (nephrectomy).

Assay: Test procedure

Biomarker test: Biomarkers are indicators of objectively measurable biological processes. Pathological changes of biological processes can be detected early using biomarker tests.

Biopharmacy: The use of biological research methods to develop drugs

BMBF: Bundesministerium für Bildung und Forschung (Federal Ministry of Education and Research)

CAIX: Antigen that binds to the antibody Girentuximab

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

Chimeric: Genetically composed from different species

Clinical Trial Application (CTA): Approval of clinical trials in the EU

Combination therapy: Therapy with two or more substances

Companion diagnostics: Therapy selection can be improved through diagnostic tests, e.g. biomarker tests. Companion diagnostics are integral to personalised medicine.

Cytotoxic: Poisonous to cells

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

diebini: diebini Hopp BioTech holding GmbH & Co. KG, Walldorf

Double-blind trial: Neither doctor nor patient knows whether the patient is receiving the new drug candidate or a placebo during a clinical trial.

EGFR: Epidermal Growth Factor Receptor is a protein found in cell membranes

ELISA: An Enzyme Linked ImmunoSorbent Assay is an immunological test procedure (assay) based on an enzymatic colour reaction.

EMA: European medicines Agency

Enzymes: Proteins that act as catalysts to facilitate or accelerate chemical reactions

Esteve: Laboratorios del Dr. Esteve S.A., Barcelona, Spain

Expression: The use of genetic information to synthesise the corresponding protein

FDA: Food and Drug Administration – regulatory authority in the USA

Gemcitabine: A specific chemotherapeutic agent (Gemzar®)

Girentuximab: INN (International Nonproprietary Name) for RENCAREX®. RENCAREX® is the development name for the therapeutic antibody WX-G250, which is based on the chimeric antibody cG250. The INN for the radio labelled antibody, which is developed under the name REDECTANE®, is 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

HER2: Human Epidermal Growth Factor Receptor Type 2 (HER2) is a protein that occurs on the surface of cells of numerous organs in the human body. In about 20% – 30% of women with breast cancer, the HER2 receptor is over-expressed (HER2-receptor positive), i.e. there are approximately 10 to 100 times as many of these receptors on the cell surface. Overexpression of the receptors means that signal transduction is enhanced, which results in accelerated tumour cell division. If there is no overexpression of HER2 receptors, this is referred to as HER2-receptor negative.

Hypoxia: Lack of oxygen in tissue

IBA: IBA Pharma S.A., Louvain-la-Neuve, Belgium, IBA Pharma SPRL, IBA Molecular North America Inc., IBA Molecular Compounds Development SARL, IBA Molecular Holding SA, and Rose Holdings SARL

IDMC: Independent Data Monitoring Committee – a body that monitors clinical trials in terms of drug safety, tolerance and efficacy

IHC test: Immunohistochemical test with which antibodies can be used to make proteins visible in tissue

Inhibitor: Substance which reduces or inhibits specific biological activities

INN: International Nonproprietary Name

Intravenous (IV): Administration via a vein

Investigational Medicinal Product Dossier (IMPD): Application for the implementation of clinical trials in the European Union

Investigational New Drug (IND) Application: Application for the implementation of clinical trials in the USA

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

IP R&D: In Process Research & Development acquired under a business combination

Kinase: A type of enzyme that phosphorylates proteins

Level of Evidence I: The highest prognosis factor or quality estimate for establishing scientific proof; it is issued and may also be incorporated into evidence-based medical guidelines

Linker: Bridging molecule, used e.g. to connect a toxin to an antibody

Malignant cells: Cells or tumours that damage the host body

MEK: The mitogen-activated protein kinase has been shown to play a central role in signal transduction. MEK has been linked to a multitude of biological processes such as cell division, cell differentiation and cell death.

MESUPRON®: Name under which the oral uPA inhibitor is being developed (formerly WX-671)

Metastases: The spread of malignant tumour cells in the body and the formation of secondary tumours

Metastasis: Malignant spread of a tumour in an organism

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

Monoclonal antibodies: Monoclonal antibodies are produced by cells created when an antibody producing cell (such as a B lymphocyte) fuses with an immortalised cancer cell. This procedure is carried out in the laboratory and produces a hybrid cell (hybridoma) possessing the properties of both cells. Since these cells originate from the same cell, they are all identical and are therefore described as "monoclonal". They produce large amounts of a specific antibody, which binds to a specific antigen.

Oncology: Research field which focuses on cancer studies

Oral: Administration via the mouth

Overexpressed: Too many copies of a substance, e.g. a protein

PAI-1: Plasminogen activator inhibitor 1

PET/CT: PET/CT is a combination of two imaging procedures. Whereas PET (positron emission tomography) is a radionuclide imaging procedure that can visualise biochemical and physiological processes, CT (computer tomography) is a radiological method which shows the anatomic structures that are necessary to localise the PET signal.

Pharmacodynamics: Explores and describes the physiological effects of drugs on the body or on micro organisms within the body, i.e. the mechanisms of drug action and adverse effects.

Pharmacokinetics: Describes all processes of the action of drugs in the body, examining absorption, distribution, metabolism, and excretion.

Pharmacology: A scientific discipline investigating the characterisation, effect and application of drugs and their interaction with the organism

Phenotype: Physical appearance or outwardly observable characteristics of an organism

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

PI3K: The phosphatidylinositol-3-kinase-B signalling pathway sends a “growth” signal to the nucleus of a tumour cell.

Placebo: Dummy drug with no active ingredients

Plasminogen: Precursor of plasmin, an enzyme that dissolves blood clots

Positron emission tomography (PET): A radio nuclide imaging procedure, which can visualise 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.

Primary tumour: A tumour that triggers a malignant disease

Prometheus: Prometheus Laboratories Inc., San Diego, CA, USA

Protease: An enzyme that splits proteins, subdividing them into smaller parts

R&D: Research and development

Randomised trial: Clinical trial for which the subjects are divided into several groups according to the principle of random selection (randomised)

Receptor: A protein usually found on the surface of cells to which a specific chemical messenger, for example a hormone, binds

REDECT: Renal Masses: Pivotal Trial To **Detect** clear-cell RCC with pre-surgical PET/CT. REDECT is a Phase III registration trial, which will evaluate whether imaging with REDECTANE® can improve the diagnosis in comparison to the current standard (CT).

REDECTANE®: Development name for the antibody Girentuximab radioactively labelled with iodine-124 (INN Iodine (124I) Girentuximab), formerly CA9-SCAN

RENCAREX®: Development name for the therapeutic antibody Girentuximab (formerly WX-G250)

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

Solid tumours: Solid growth of tissue

Special Protocol Assessment (SPA): The SPA documents that the FDA confirms that the design and planned analysis of a clinical trial adequately address the requirements for a regulatory submission.

Therapeutic agent: Drug applied for the treatment of illnesses

Thrombin: Enzyme that enables blood to coagulate

Toxicology: Scientific discipline investigating the effects of poisonous substances (toxins) or investigating substances for poisonous effects

UCB: UCB Pharma S.A., Brussels, Belgium

uPA: Urokinase-type plasminogen activator

uPA system: Urokinase-specific plasminogen activator (uPA) system. A protein lysing enzyme system which plays an important role in the growth, spread and metastasis of different malignant tumours

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