

# HALF-YEARLY FINANCIAL REPORT 2013

- → Positive subgroup data for RENCAREX® presented at the ASCO Annual Meeting
- → Agreement reached with the FDA on the trial design for REDECTANE®
- → Financial figures in line with guidance

# **Key Group figures**

	H1 2013¹ €'000	H1 2012¹ € '000
Earnings		
Sales revenue	6,595	7,214
Other income	1,038	1,039
Operating expenses	(11,123)	(13,541)
of which research and development costs	(5,415)	(6,906)
Operating result	(3,490)	(5,289)
Earnings before tax	(3,540)	(5,608)
Net loss for the period	(3,540)	(5,609)
Earnings per share in €	(0.11)	(0.24)
Balance sheet as of the end of the period		
Total assets	27,983	22,414
Cash and cash equivalents	12,894	2,920
Equity	16,439	(281)
Equity ratio <sup>2</sup> in%	58.7	(1.3)
Cash flow statement		
Cash flow from operating activities	(10,504)	(9,906)
Cash flow from investing activities	(43)	(140)
Cash flow from financing activities	(115)	9,639
Employees (number)		
Employees as of the end of the period <sup>3</sup>	111	126
Employees as of the end of the period (full-time equivalents) <sup>3</sup>	104	116

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

<sup>&</sup>lt;sup>2</sup> Equity/total assets

 $<sup>^{\</sup>scriptscriptstyle 3}$  Including members of the Executive Management Board

The second quarter of the year saw extensive preparations for the Annual Meetings of the American Urological Association (AUA) and the American Society of Clinical Oncology (ASCO). We had the opportunity to present data from two of our biomarker tests and the breast cancer trial with MESUPRON®. Of particular importance to us was the presentation of data from the ARISER study in adjuvant therapy of clear cell renal cell carcinoma and the new, encouraging findings of the retrospective subgroup analysis. We were able to show that RENCAREX® is not only well tolerated but could also be an effective therapy for patients with ccRCC and a high CAIX score. We will capitalise on the keen interest from science and industry to engage in deeper discussions in the coming weeks.

We are working hard to bring all of our therapeutic and diagnostic projects, and also the ADC technology, to the next stage of development. Our deliberations about financing were presented at our Annual General Meeting in June on the basis of a three-pillar strategy:

- 1. Partnerships search for licensing and development partners: WILEX's economic objective is to find licensing partners for each of its advanced clinical projects who will licence the projects and pursue their development. If we are successful, these partner companies would take over the further development of a project and pay WILEX a lump sum for the research and development work already done when they acquire the product plus milestone payments when further development targets have been reached. Later, WILEX would receive a percentage of the sales revenue, as is usual under licence agreements.
- 2. Financing search for project-oriented financing or overall financing of the portfolio through financial investors: In parallel to our endeavours with potential licensing partners from the biotechnology and pharmaceutical industries, we will work together with financial investors on ensuring financing of our portfolio projects. Given the low price of our shares at present, we are mainly looking at options for project-oriented financing, though we are also open to financing through a strategic investor. We are exploring ways to develop the assets in the portfolio in the best possible manner in the interests of our shareholders. This currently does not exclude any form of financing, though the classic rights issue has the lowest priority in this context.

We have therefore engaged the investment bank Burrill Securities LLC as an advisor to assist us in finding project financing partners (see "Events after the reporting period").

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3. Cost management – implementing cost savings: In addition to our other endeavours, we will strive to maximise the use of the available cash reserves and leverage all possible cost savings potential. We started this last year with significant workforce reductions and have continued this process by not filling vacant positions, but re-assigning the tasks within the team instead. The management functions in the Executive Management Board and the executive management of the subsidiaries were also consolidated and de facto reduced. I serve both as a member of the Executive Management Board and as Managing Director of Heidelberg Pharma. Also Dr Bevan has reduced his work time to 50% in agreement with WILEX.

Our efforts are reflected in the figures for the first half-year, when the net loss was reduced once again. All the same, sales revenue in the Diagnostics and Customer Specific Research segments fell short of projections. Given our current situation, however, we assume that we can maintain our overall guidance for the 2013 financial year as a whole and that our funding is secured into the second quarter of 2014.

Munich, 11 July 2013

Dr Jan Schmidt-Brand Chief Financial Officer

Mich Land

# Interim management report Reporting period from 1 December 2012 to 31 May 2013

#### Introduction

WILEX AG is a biopharmaceutical company focused on oncology. It has 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. They are designed to have a low side effect profile, inhibit tumour growth and prevent metastases. The Company's US subsidiary, WILEX Inc., produces and markets biomarker tests related to oncology. The second subsidiary, Heidelberg Pharma GmbH, offers an innovative platform technology for therapeutic antibody drug conjugates (ADCs) and operates a preclinical service business within the scope of Customer Specific Research.

#### Business performance and research and development activities

The WILEX Group's business activities are subdivided into three segments: Therapeutics (Rx), Diagnostics (Dx) and Customer Specific Research (Cx).

#### Therapeutics (= Rx)

#### **RENCAREX®**

The antibody RENCAREX® (INN: Girentuximab) was tested in the double-blind, placebo-controlled Phase III ARISER trial for adjuvant therapy of clear cell renal cell carcinoma (ccRCC). The final analysis performed in October 2012 showed no improvement in median disease-free survival following treatment with RENCAREX® compared to placebo.

In February 2013, WILEX announced that the results of a retrospective subgroup analysis showed that RENCAREX® has a therapeutic effect in the subgroup of patients with a high score of the antigen CAIX. The relevance of CAIX as a prognostic biomarker was explained to leading urologists by the team of Professor Arie Belldegrun, Principal Investigator of the trial in the USA, at the AUA Annual Meeting in May 2013 in San Diego. At the beginning of June 2013, Professor Belldegrun presented the detailed data from the ARISER trial including the positive subgroup analysis at the Annual Meeting of the American Society of Clinical Oncology in Chicago.

The data confirmed that CAIX expression is a characteristic of ccRCC. A surprising outcome was that the antigen density, as determined by the CAIX score, varies from patient to patient and evidently plays a key role in the efficacy of RENCAREX®. Analysis of all CAIX scores revealed that as the CAIX score increases, the more pronounced the RENCAREX® treatment effect becomes. A CAIX score of  $\geq 2.6$  resulted in a clinically and statistically significant treatment effect with median DFS increasing from 51.2 months in the placebo arm to 73.6 months in RENCAREX® patients (N=151; HR=0.54; p=0.02).

Further analyses of the subgroup population underpinned this effect. In patients under the age of 65 years RENCAREX® showed a clinically and statistically significant DFS with a CAIX score as low as  $\geq$  2.0 (N = 286; HR = 0.60; p = 0.01).

The retrospective subgroup analysis indicates that RENCAREX® could deliver a well-tolerated and effective therapy for ccRCC patients with a high CAIX score. WILEX plans to hold talks with regulatory authorities (the FDA and European agencies) on a confirmatory prospective Phase III trial with RENCAREX® in the adjuvant therapy of ccRCC in the defined subgroup using the biomarker CAIX for stratification. The Company plans to develop the CAIX in-vitro diagnostic test further as a companion diagnostic, which may be helpful in identifying and stratifying patients who might benefit from RENCAREX® therapy.

#### **MESUPRON®**

MESUPRON® (INN: Upamostat) is a small molecule drug 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 the growth of solid primary tumours. Data from two Phase IIa trials (proof of concept) in locally advanced pancreatic cancer (2010) and metastatic breast cancer (2012) indications show the safety and activity of the drug candidate in combination with chemotherapeutic agents. Data from the breast cancer trial were also presented at this year's ASCO Annual Meeting.

WILEX aims to sign a licence agreement with a partner for MESUPRON® and together decide the further development strategy for a Phase IIb/III programme. The partnering process was initiated in the fourth quarter of 2012 and some 50 potential candidates worldwide who meet the necessary requirements, such as oncology expertise, were identified for a development and marketing partnership. WILEX is currently holding in-depth direct discussions with several parties.

#### WX-554

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 tumour cell growth.

WX-554 has been tested in a Phase Ib/II dose escalation study in cancer patients in the UK since April 2012. 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 a second part in which this dose is administered primarily to patients with MEK pathway relevant mutations to obtain initial data on clinical activity and on pharmacodynamics within the tumour tissue. Contrary to the original plans, dose escalation was not completed in the second quarter of 2013 because of a good tolerability profile. However, WILEX still expects to start the second part of the study and to complete patient recruitment by the end of 2013.

#### WX-037

The small molecule agent WX-037 inhibits the phosphatidylinositol-3-kinase pathway (PI3K) which sends a "growth" signal to the nucleus of a tumour cell. It has been shown that mutations of the PI3K signalling pathway are present in most types of cancer. Identifying an inhibitor for the PI3K signalling pathway is thus of therapeutic interest.

With this WX-037 project WILEX AG participates 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 will receive funding of up to € 2.6 million from the BMBF for the preclinical and clinical development. Preclinical work on WX-037 has been completed and clinical development has now started (see "Events after the reporting period").

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The MEK and PI3K programmes were both acquired from UCB Pharma S.A., Brussels, Belgium, as part of a strategic alliance.

#### Research

Antibody-based projects acquired from UCB are currently in the research phase. WILEX identified a lead candidate for one of these antibody programmes and generated preclinical data, which prompted UCB to acquire the rights for indications outside oncology (see "Events after the reporting period").

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#### **REDECTANE®**

REDECTANE® (INN: 124I-Girentuximab) is a radiolabelled form of the antibody Girentuximab, which binds to the antigen CAIX on clear cell renal cell carcinoma. The radiopharmaceutical REDECTANE® is designed to support physicians in diagnosing renal cancers and determine whether or not clear cell renal cell carcinoma is present. 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 2010 the Phase III REDECT trial was completed and data were published which showed that REDECTANE® with PET/CT is clearly superior to CT alone in diagnosing clear cell renal cell carcinomas. Following extensive talks with the FDA, agreement was reached to conduct a confirmatory diagnostic performance study instead of an outcomes-based study.

WILEX has now reached agreement with the FDA on the development strategy and study design for a confirmatory Phase III diagnostic performance clinical trial (REDECT 2).

#### In vitro diagnostic tests (WILEX Inc./Oncogene Science)

The subsidiary WILEX Inc. produces and markets biomarker tests in oncology under the brand name Oncogene Science with the aim of supporting treatment regimens for cancer patients. ELISA assays are used to detect antigens or proteins for instance in the blood. Measuring proteins in the blood and using the respective bioanalytical methods is aimed at predicting 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.

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" and may be used in patients to measure the CAIX level in tumour tissue. In the "Research Use Only" (RUO) field, ELISA assays are available for the CAIX, uPA, PAI-1, EGFR and TIMP-1 biomarkers.

Since WILEX Inc. does not have a distribution structure of its own, several partnerships have been concluded in recent months with established distribution companies (Immundiagnostik AG for the German-speaking region, GeneDiagnostics for China plus IBL-America Inc. and Nuclea Inc. for the United States) to step up the marketing of the tests and extend their scope of application.

#### Customer Specific Research (= Cx)

The Customer Specific Research segment comprises the services offered by the subsidiary Heidelberg Pharma GmbH.

The service business includes customer specific preclinical contract research related to cancers and inflammatory and autoimmune diseases. Heidelberg Pharma also possesses a platform for therapeutic antibodies (antibody drug conjugates, ADCs). This ADC technology has the potential to enhance and improve the efficacy of many antibody-based therapies, including those on the market. What makes this technology unique is that it links the antibody's specificity with the efficiency of the toxin amanitin, which is found in the green Death Cap mushroom.

In experimental testing this second generation of ADCs shows clear advantages over established ADC technologies due to its mode of action. These ADCs are highly effective and may break through frequent resistance mechanisms. They target slow-growing tumours regardless of whether the tumour cell is dividing or not and can also eliminate "dormant" tumour cells. As a result, they have the potential to prevent tumour recurrence.

Heidelberg Pharma has entered into several partnerships with research institutions as well as pharmaceutical and biotechnology companies to examine the applicability of this ADC technology to its partners' specific, proprietary antibodies. Important scientific findings and data have been recorded that could form the basis for continuing the collaboration.

A project (CapStem®) has also been developed in recent months to refine this innovative ADC technology as an independent business model. This presents the opportunity to market not only the toxin linker technology but to create complete ADC molecules with licensed antibodies. With this model Heidelberg Pharma is able to harness the attractive market potential better and finance development on a project basis.

## Market environment

See pages 16 to 20 of the 2012 annual report for further information on the market environment for WILEX's products and product candidates. In the Company's view there have been no significant changes since then.

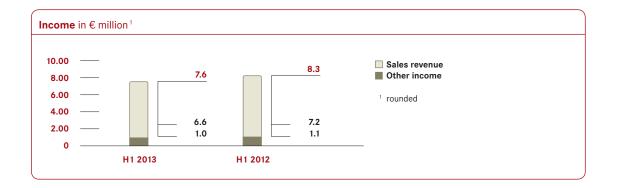
#### Earnings, financial position and net assets

The WILEX Group, comprising WILEX AG and the subsidiaries WILEX Inc. and Heidelberg Pharma GmbH, reports consolidated figures. The reporting period referred to below concerns the period from 1 December 2012 to 31 May 2013 (H1 2013). Due to rounding, it is possible that individual figures in this half-yearly financial 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 WILEX Group reports on three operating segments: The Therapeutics (Rx) segment comprises RENCAREX®, MESUPRON®, WX-554, WX-037 as well as all preclinical research activities of WILEX AG. The Diagnostics (Dx) segment includes WILEX AG's imaging diagnostic candidate REDECTANE® and the in vitro diagnostics of WILEX Inc. The Customer Specific Research (Cx) segment comprises the service business based on the ADC platform technology and the preclinical service business of Heidelberg Pharma.

#### Sales revenue and other income

In the first six months of the 2013 financial year, the WILEX Group generated sales revenue of  $\in$  6.6 million (previous year:  $\in$  7.2 million), excluding intersegment sales revenue. Most of this ( $\in$  5.8 million; previous year:  $\in$  5.9 million) is attributable to sales revenue from the Rx segment generated from the individual components of the license agreement concluded with Prometheus for RENCAREX®; payments received were recognised as deferred income and will be reversed through profit or loss on a pro rata basis. The Dx segment generated sales revenue of  $\in$  0.1 million (previous year:  $\in$  0.2 million), thus continuing to fall short of expectations. The Cx segment recorded sales revenue of  $\in$  0.6 million, significantly down from the previous year ( $\in$  1.2 million). The figure for the previous year had included the final work on a major contract that was completed in the first quarter of 2012.

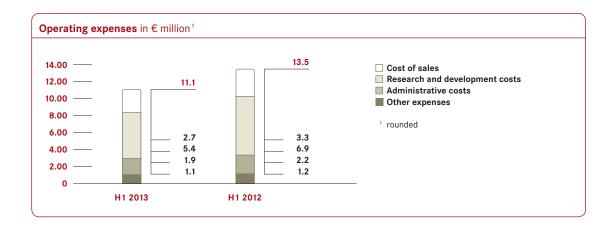


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At €1.0 million, other income was comparable with the prior-year figure and mainly stems from the reversal through profit or loss of provisions for bonuses and restructuring measures that were not required in the amounts planned. Both the Rx segment and the Cx segment recognised grants from the Federal Ministry of Education and Research (BMBF) for research projects.

#### Operating expenses

Operating expenses including depreciation and amortisation amounted to  $\in$  11.1 million in the reporting period, down from the previous year ( $\in$  13.5 million). They are distributed as follows across the three segments: Therapeutics  $\in$  6.8 million (previous year:  $\in$  9.2 million), Diagnostics  $\in$  2.2 million (previous year:  $\in$  1.8 million) and Customer Specific Research  $\in$  2.2 million (previous year:  $\in$  2.6 million).



The **cost of sales** concerns costs directly related to sale revenue of the Group's respective segments. This item amounted to  $\in$  2.7 million in the reporting period, down on the prior-year figure of  $\in$  3.3 million as a result of lower expenses in the Cx segment for the provision of services in the services business. The Rx segment predominantly reports expenses for RENCAREX®, for which it receives cost reimbursements from Prometheus that are reported in sales revenue. The Dx segment generates this cost type through the production of biomarker tests as tradable products.

Research and development costs, which were €6.9 million the previous year, fell to €5.4 million. This reduction is due exclusively to the Rx segment. While the previous year had included costs for the breast cancer trial with MESUPRON® that was concluded in the second quarter of 2012, these costs were no longer incurred in the current reporting period. R&D expenses in the Dx segment were higher than in the previous year, reflecting the preparations for the next Phase III trial with REDECTANE®. R&D costs in the Cx segment remained at the prior-year level.

Administrative costs were trimmed to € 1.9 million in the first half of the year due to the cost cutting following the restructuring programme (previous year: €2.2 million).

Other expenses comprise the costs for activities in the areas of business development, marketing and commercial market supply. These amounted to € 1.1 million in the reporting period (previous year: € 1.2 million).

#### Financial result

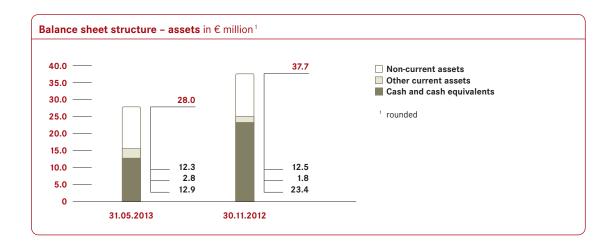
The WILEX Group reported an improved financial result of  $-€50 \, k$  (previous year:  $-€320 \, k$ ). While finance income rose to  $€36 \, k$  (previous year:  $-€331 \, k$ ), finance costs were substantially reduced to  $€86 \, k$  (previous year:  $€320 \, k$ ). The prior-year reporting period had included the dievini shareholder loan including interest that was converted into shares in the third quarter of 2012. This item now primarily comprises the interest expense on the UCB loan.

#### Profit/loss for the period

The WILEX Group posted a loss of €3.5 million for the first six months of the current financial year. This represents an improvement of 37% on the loss in the same period of the previous year (€5.6 million) and is solely attributable to lower costs. Earnings per share improved by 53% to -€0.11 (previous year: -€0.24), also due to the higher number of shares in circulation compared with H1 2012.

#### Assets

Total assets as of 31 May 2013 amounted to €28.0 million (30 November 2012: €37.7 million).

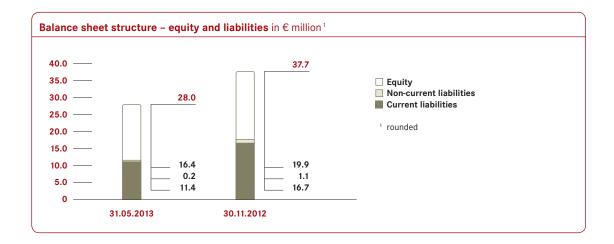


Non-current assets amounted to €12.3 million (30 November 2012: €12.5 million). Of that amount, property, plant and equipment (mainly laboratory and office equipment) were €1.9 million and thus below the level recorded at the end of the 2012 financial year (€2.1 million). Intangible assets were €4.0 million (30 November 2012: €4.1 million). At the reporting date, non-current assets continue to include the goodwill of Heidelberg Pharma amounting to €6.1 million – the same as at the end of the previous financial year – as well as rent security of €0.2 million (30 November 2012: €0.2 million).

Current assets amounted to €15.7 million (30 November 2012: €25.2 million). The decline is due to the use of cash and cash equivalents for the Company's operations, amounting to €12.9 million as of 31 May 2013 (30 November 2012: €23.4 million). Final invoicing with a service provider in the ARISER trial reduced the prepayments made. In contrast, trade receivables rose to €1.7 million (30 November 2012: €0.3 million), with the lion's share (€1.5 million) relating to a receivable from Prometheus arising from the obligation to assume a portion of the costs for the ARISER trial. An audit that has been contractually agreed is currently being conducted by an independent audit firm. This audit, which serves to review the type and amount of the ARISER costs, is an important prerequisite for the planned termination of the agreement with Prometheus.

Equity as of the end of the reporting period was €16.4 million (30 November 2012: €19.9 million). The equity ratio was 58.7% (30 November 2012: 52.8%; 31 May 2012: -1.3%). Further information regarding the development of equity can be found in the notes.

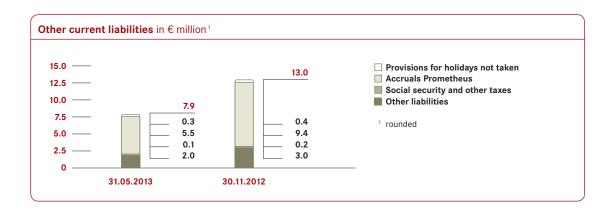




#### Liabilities

Non-current liabilities were reduced to €0.2 million (30 November 2012: €1.1 million). They include necessary deferrals from a staggered lease for rented offices, liabilities for service anniversaries and leasing liabilities. These are mainly attributable to expired leases and the exclusive accrual of payments received in the context of the Prometheus transaction reported under current liabilities.

Current liabilities decreased to €11.4 million as of the end of the period (30 November 2012: €16.7 million). While liabilities arising from lease agreements (€0.2 million; 30 November 2012: €0.2 million) and financial liabilities (€2.6 million; 30 November 2012: €2.6 million) remained constant, trade payables (€0.7 million; 30 November 2012: €0.9 million) and other current liabilities (€7.9 million; 30 November 2012: €13.0 million) were reduced further.



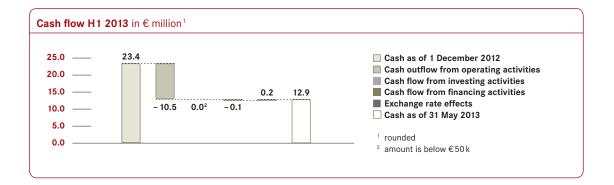
#### Cash flow statement

At  $\in$  10.5 million, the net cash outflow from operating activities during the first half of 2013 was higher than in the same period of 2012 ( $\in$  9.9 million) in spite of the lower net loss for the period. This higher cash outflow is attributable to the outstanding receivable from Prometheus.

The outflow of funds for investing activities was €43 k (previous year: €140 k).

A cash outflow from financing activities of €115k that was used to repay finance leases was recorded in the reporting period. This contrasts with the same period of the previous year, which had seen a substantial inflow of funds of €9.6 million from the capital increase implemented in the first quarter of 2012.

In spite of a positive influence from exchange rate effects of  $\in$  193 k on cash (previous year: negative effect of  $- \in$  94 k), the net change in cash and cash equivalents amounted to  $- \in$  10.5 million (previous year:  $- \in$  0.5 million).



# **Employees and compensation system**

Including the members of its Executive Management Board, WILEX had 111 employees (104 FTEs) at the close of the reporting period (30 November 2012: 128 employees/120 FTEs). The reduction of the workforce is to a large extent a result of the restructuring programme at the headquarters in Munich.

The Company has developed a performance-related compensation system for its employees comprising a fixed annual salary and a variable salary component. In addition, the 2005 and 2011 stock option programmes give employees a stake in the Company's performance. For more information, see section "D. Issue and measurement of stock options" of the notes.

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## Report on risks and opportunities

WILEX is exposed to risks typical for the industry, namely those arising from the development and production of drug candidates used in cancer therapies. The time between the commencement of drug development and marketing approval usually spans many years. Even though the portfolio has matured, further studies have to be carried out and funded. There is a continued risk that not all or none of the drug and diagnostic candidates in our current portfolio will receive marketing approval. Risks and opportunities in connection with the WILEX Group's business are described in detail on pages 56 to 69 of the 2012 annual report. They remain unchanged unless noted otherwise.

## **Events after the reporting period**

After the end of the reporting period, WILEX engaged the investment bank Burrill Securities LLC as an advisor to assist WILEX in selecting partners for the financing of its projects. Burrill Securities provides life sciences companies with access to financial resources through global capital and a complementary blend of financial advisory services on public and private financings and cross-border transactions, including M&A, strategic partnerships, spin-outs, and public and private capital raising. The aim is to ensure financing for the planned Phase III trials by exploring all possible alternatives so as to enhance the enterprise value and serve the interests of shareholders.

In July 2013, UCB acquired an antibody programme from WILEX's preclinical portfolio with the objective of developing the antibody further in an indication outside the field of oncology. WILEX keeps the rights to the antibody's further development in oncology. WILEX will be reimbursed an undisclosed amount for its development to date and is eligible for future, undisclosed development, regulatory and commercial milestone payments as well as royalties. UCB will be working on these antibodies in immunology/inflammatory and, and as part of the strategic partnership between the two companies, will make available the data relevant to WILEX in oncology.

At the beginning of July, WILEX received written notification from the FDA confirming agreement on the development strategy and study design for a confirmatory Phase III diagnostic performance clinical trial with REDECTANE®.

Clinical development of the PI3K inhibitor WX-037 began in July 2012. The safety and tolerability of WX-037 will be tested in patients in a Phase I trial, initially as monotherapy and subsequently in combination with the MEK inhibitor WX-554.

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

#### Outlook

WILEX reaffirms its guidance for the current financial year issued in February 2013.

## Therapeutics (Rx)

All work concerning the ARISER trial with RENCAREX® are scheduled to be duly completed in accordance with "Good Clinical Practice" in the third quarter of 2013. Based on of the promising subgroup data, initial talks with the regulatory authorities (the FDA and European agencies) on a confirmatory prospective Phase III trial with RENCAREX® in the subgroup are planned for the second half of 2013.

WILEX is currently in discussion with Prometheus about the termination of the existing licence agreement for the US commercial rights to RENCAREX®. Following termination, WILEX could regain the global rights except Southern Europe and offer these to a new partner. Talks are being held in parallel with several parties for out-licensing the rights for Europe and the rest of the world with a possible option for the United States. WILEX's goal is to find a partner that will participate in financing, development and commercialisation. If RENCAREX® receives regulatory approval, the definition of the subgroup for a further Phase III trial could mean adjusted peak sale potential of over USD 300 million in adjuvant therapy of ccRCC.

The partnering process for the drug candidate MESUPRON® with the goal of finding a licensing and development partner is under way. The Company's aim is to finalise a partnership agreement in the 2013 financial year.

Data from the dose escalation in the ongoing Phase Ib/II trial with the MEK inhibitor WX-554 will become available in the coming weeks. The aim is to define the dosage scheme so that the safety, tolerability, pharmacokinetics and pharmacodynamics of the chosen dosages as well as their potential efficacy in patients with specific tumours (such as melanoma) can be analysed in the second part of the trial. Patient recruitment is expected to be completed by the end of 2013, with data becoming available in the second half of 2014.

#### Diagnostics (= Dx)

WILEX AG will prepare and submit full documentation for REDECT 2 to the FDA under the SPA procedure for formal approval. The start of the trial is not planned until WILEX has secured the financing for the entire study.

WILEX Inc. and its partners plan to significantly step up the marketing of the biomarker tests in the coming months.

#### Customer Specific Research (= Cx)

WILEX plans to further increase sales revenue from the services business and acquire new customers for this service by expanding its offering for inflammatory diseases, oncology and bioanalytics.

Additional partnerships planned for the ADC technology shall provide the basis for successfully commercialising this platform. Furthermore, the necessary activities for establishing and funding the CapStem® project shall be advanced. Going forward, all ADC activities are intended to tap into short-term and long-term future potential for generating sales revenue and creating added value through licence agreements. Despite the good opportunities, expenses are likely to remain higher than income because the business activities related to the ADC technology are still in an early stage.

# Consolidated statement of comprehensive income (IFRS) Reporting period from 1 December 2012 to 31 May 2013

	H1 2013 €	H1 2012 €
Revenue	6,594,817	7,214,097
Other income	1,038,004	1,038,652
Income	7,632,822	8,252,749
Cost of sales	(2,688,072)	(3,297,450)
Research and development costs	(5,414,630)	(6,906,449)
Administrative costs	(1,882,602)	(2,159,844)
Other expenses	(1,137,536)	(1,177,582)
Operating expenses	(11,122,841)	(13,541,325)
Operating result	(3,490,019)	(5,288,576)
Finance income	35,970	11,295
Finance costs	(85,739)	(330,957)
Financial result	(49,769)	(319,663)
Earnings before tax	(3,539,789)	(5,608,239)
Income tax	(121)	(1,260)
Net loss for the period	(3,539,910)	(5,609,499)
Net currency gain/loss from consolidation	(1,291)	(102,353)
Comprehensive income	(3,541,201)	(5,711,852)
Earnings per share		
Basic and diluted earnings per share	(0.11)	(0.24)
Average number of shares issued	31,275,507	23,695,163

Rounding of exact figures may result in differences.

Quarterly comparison	Q2 2013 € '000	Q1 2013 € '000	Q4 2012 € '000	Q3 2012 € '000	Q2 2012 € '000
Revenue	3,272	3,323	4,783	4,145	3,503
Other income	473	565	228	433	809
Operating expenses	(5,288)	(5,834)	(6,953)	(6,257)	(7,224)
Operating result	(1,543)	(1,947)	(1,942)	(1,679)	(2,912)
Earnings before tax	(1,562)	(1,978)	(1,970)	(1,810)	(3,054)
Net loss for the period	(1,562)	(1,978)	(1,971)	(1,810)	(3,054)
Net currency gain/loss from consolidation	4	(5)	88	4	(119)
Comprehensive income	(1,558)	(1,983)	(1,883)	(1,806)	(3,174)
Basic and diluted earnings per share in €	(0.05)	(0.06)	(0.05)	(0.07)	(0.13)
Average number of shares issued	31,275,507	31,275,507	31,275,507	25,095,856	24,814,963

# Consolidated balance sheet (IFRS)

as of 31 May 2013 and as of 30 November 2012

Assets	31.05.2013 €	30.11.2012 €
Property, plant and equipment	1,945,023	2,086,534
Intangible assets	4,001,424	4,106,758
Goodwill	6,111,166	6,111,166
Other non-current assets	227,719	227,674
Non-current assets	12,285,332	12,532,132
Inventories	233,055	258,210
Prepayments	353,907	734,759
Trade receivables	1,668,431	269,550
Other receivables	548,300	562,894
Cash and cash equivalents	12,893,767	23,363,335
Current assets	15,697,461	25,188,748
Total assets	27,982,793	37,720,880

Equity and liabilities	31.05.2013 €	30.11.2012 €
Subscribed capital	31,275,507	31,275,507
Capital reserve	159,271,676	159,211,811
Accumulated losses	(174,058,777)	(170,518,867)
Net currency gain/loss from consolidation	(48,928)	(47,637)
Equity	16,439,478	19,920,815
Lease liabilities	53,427	129,746
Other non-current liabilities	139,372	930,901
Non-current liabilities	192,798	1,060,646
Trade payables	713,529	904,365
Liabilities arising from leases	171,917	210,501
Financial liabilities	2,562,500	2,637,500
Other current liabilities	7,902,571	12,987,053
Current liabilities	11,350,516	16,739,419
Total equity and liabilities	27,982,793	37,720,880

# Consolidated cash flow statement (IFRS)

Reporting period from 1 December 2012 to 31 May 2013

	H1 2013 €	H1 2012 €
Net loss for the period	(3,539,910)	(5,609,499)
Adjustment for items in the statement of comprehensive income		
Measurement of stock options	59,865	171,712
Depreciation/amortisation	288,152	327,514
Finance costs	85,739	489,164
Finance income	(35,921)	(169,502)
Tax expense	0	1,260
	397,835	820,149
Changes in net working capital		
Inventories	25,053	164,922
Trade receivables	(1,387,657)	57,524
Other receivables	(525,363)	(2,371,847)
Prepayments	381,302	28,021
Other non-current assets	(518)	(11,171)
Trade payables	(201,824)	124,141
Other liabilities	(5,528,537)	(2,593,353)
	(7,237,545)	(4,601,764)
Cash flow from operating activities	(10,379,620)	(9,391,114)
Finance costs paid	(160,918)	(526,264)
Finance income received	36,093	11,295
Net cash flow from operating activities	(10,504,445)	(9,906,084)
Cash flow from investing activities		
Purchase of property, plant and equipment	(18,559)	(135,034)
Purchase of intangible assets	(24,361)	(5,383)
Net cash flow from investing activities	(42,920)	(140,417)
Cash flow from financing activities		
Proceeds from capital increase	0	9,925,977
Capital increase costs	0	(144,031)
Other financing activities	0	(20,039)
Repayment of finance leases	(114,903)	(122,536)
Net cash flow from financing activities	(114,903)	9,639,370
Influence of foreign exchange effects on cash and cash equivalents	192,699	(93,565)
Net change in cash and cash equivalents	(10,469,568)	(500,695)
Cash and cash equivalents		
at beginning of period	23,363,335	3,420,639
at end of period	12,893,767	2,919,944

# Consolidated statement of changes in equity (IFRS) Reporting period from 1 December 2012 to 31 May 2013

			Capital measures/	Measure- ment of stock options	Currency		
	Shares	Subscribed capital €	Capital €	reserve	translation differences	Accumulated losses €	Total €
As of			132,267,971	2,762,459			
1 December 2011	21,613,035	21,613,035	135,0	30,430	(37,926)	(161,128,070)	(4,522,532)
Measurement of stock options				171,712			171,712
Net currency gain/loss from consolidation					(102,353)		(102,353)
Net loss for the period						(5,609,499)	(5,609,499)
Capital increase after accounting for capital pro- curement costs	3,201,928	3,201,928	6,580,018				9,781,946
Net change in equity						-	4,241,805
A			138,847,989	2,934,171		-	
As of 31 May 2012	24,814,963	24,814,963	141,7	82,160	(140,279)	(166,737,570)	(280,726)
			155,892,571	3,319,240			
As of 1 December 2012	31,275,507	31,275,507	159,2	11,811	(47,637)	(170,518,867)	(280,726)
Measurement of stock options				59,865			59,865
Net currency gain/loss from consolidation					(1,291)		(1,291)
Net loss for the period						(3,539,910)	(3,539,910)
Capital increase after accounting for capital pro- curement costs							0
Net change in equity				-			3,481,336
A	·		155,892,571	3,379,105			
As of 31 May 2013	31,275,507	31,275,507	159,2	71,676	(48,928)	(174,058,777)	16,439,478

# Selected notes

#### A. General disclosures

This half-yearly financial report as of 31 May 2013 was prepared in accordance with the same accounting policies as the consolidated financial statements as of 30 November 2012. The interim consolidated financial statements as of 31 May 2013 include the Group's parent, WILEX AG, Munich, Germany, as well as its subsidiaries WILEX Inc., Cambridge, MA, USA, and Heidelberg Pharma GmbH, Ladenburg, Germany – jointly the "Group".

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

The interim consolidated financial statements reproduced in this report were generally prepared in accordance with the International Financial Reporting Standards (IFRS) endorsed by the European Union, specifically in accordance with IAS 34 "Interim Financial Reporting" issued by the International Accounting Standards Board (IASB) and in compliance with the Interpretations of the Standing Interpretations Committee (SIC) and the International Financial Reporting Interpretations Committee (IFRIC). These interim financial statements must be read in the context of the IFRS consolidated financial statements as of 30 November 2012 published for the 2012 financial year.

The interim consolidated financial statements were not subjected to a review by an auditor. Pursuant to our Declaration of Conformity issued in February 2013 concerning Section 7.1.2 of the German Corporate Governance Code, both the interim consolidated financial statements and the interim management report for the Group were discussed with the Supervisory Board's Audit Committee before being published. This interim report was approved for publication by the Executive Management Board on 11 July 2013.

## **B. Segment reporting**

The WILEX Group comprises three operating segments, each of which is explained below, along with its separate core business and core projects. There has been no change in the segmentation of WILEX compared to the financial statements as of 30 November 2012 and compared to 31 May 2012, the closing date of the previous year's comparative period.

#### Therapeutics (Rx)

The Therapeutics segment posted sales revenue of €5.8 million and a net loss of €0.5 million in the first half of 2013 financial year. WILEX AG develops drug candidates in its Rx segment for the targeted treatment 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. The Therapeutics segment comprises the following programmes: RENCAREX®, MESUPRON®, WX-554, WX-037 as well as all preclinical and research activities of WILEX AG.

## Diagnostics (Dx)

The Diagnostics segment generated sales revenue of €0.1 million and a net loss for the period of €2.1 million. WILEX AG develops the imaging diagnostic candidate REDECTANE®, which is allocated to the Diagnostics segment. WILEX Inc. produces and markets a multitude of biomarker tests related to oncology under the Oncogene Science brand. It is the objective of WILEX to offer approved in vitro diagnostics for the clinical, oncological and immunodiagnostic market in order to improve treatment for cancer patients worldwide.

## **Customer Specific Research (Cx)**

Customer Specific Research generated sales revenue of €0.6 million and a net loss for the period of €1.6 million. 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. These services are being provided in collaboration with pharmaceutical and biotech companies. For another, Heidelberg Pharma performs work for businesses and research institutes on drug metabolism, pharmacology and pharmacokinetics especially in oncology in its preclinical service business. At this time Heidelberg Pharma's business is based mainly on fee for service.

#### Intersegment sales revenue

Intersegment sales revenue in the first half year of 2013 totalled €9 k, all of which was generated by the Cx segment in transactions with the Rx segment.

The segment results were as follows:

Segment results H1 2013 <sup>1</sup>	Rx € '000	Dx €'000	Cx € '000	Not allocated € '000	Consoli- dation € '000	Group €'000
Sales revenue	5,848	117	639	0	(9)	6,595
External sales revenue	5,848	117	630	0	0	6,595
Intersegment sales revenue	0	0	9	0	0	9
Other income	384	85	67	507	(6)	1,038
Operating expenses	(6,755)	(2,209)	(2,174)	0	15	(11,123)
Operating result	(522)	(2,007)	(1,469)	507	0	(3,490)
Financial result	0	(107)	(98)	155	0	(50)
Profit/loss for the period	(522)	(2,114)	(1,567)	662	0	(3,540)
Total assets	2,183	3,759	16,285	14,875	(9,119)	27,983

<sup>1</sup> rounded

The breakdown of segment assets for purposes of interim reporting pursuant to IAS 34 has not changed; it continues to concern the intangible assets of Heidelberg Pharma that were identified and taken over as well as its goodwill. The non-allocated portion of total assets largely represents the cash and cash equivalents not attributable to a specific segment.

# C. Change in equity

As of the reporting date, the total number of WILEX shares issued (subscribed capital) remained at 31,275,507.

The equity of the WILEX Group at the end of the reporting period was €16.4 million (30 November 2012: €19.9 million). The capital reserve was €159.3 million (30 November 2012: €159.2 million) and the losses accumulated since WILEX's foundation totalled €174.1 million (30 November 2012: €170.5 million). The Company recognised a currency loss of €49 k in equity in connection with the consolidation of its US subsidiary (30 November 2012: currency loss of €48 k). The equity ratio of the WILEX Group was 58.7% (30 November 2012: 52.8%).

## D. Issue and measurement of stock options

On 18 May 2011 the Company's Annual General Meeting resolved the WILEX Stock Option Plan 2011. This resolution authorises the Company to issue a total of up to 1,156,412 stock options, of which up to 346,924 stock options (approx. 30%) may be issued to members of the Company's Executive Management Board, up to 173,462 stock options (approx. 15%) to executives of affiliated companies, up to 346,923 stock options (approx. 30%) to employees of the Company and up to 289,103 stock options (approx. 25%) to employees of the Company's affiliates. In the first half of the 2013 financial year, no stock options were issued under the 2011 Stock Option Plan.

Similar to the approach described in the annual report as of 30 November 2012, WILEX's liabilities to employees resulting from the issue of stock options were reported pursuant to IFRS 2 in the reporting period just ended. These liabilities are calculated using a binomial model at the time the options are granted. The fair value of the work provided by the employees in return for the options granted to them is charged against the capital reserve, i. e. recognised in equity. The total expense to be recognised until the time at which the options become vested is determined by the fair value of the options granted, excluding effects of exercise thresholds that are not based on capital market parameters (e. g. profit and sales growth targets). Such non-capital-market exercise thresholds are considered in the assumptions regarding the number of options that are expected to become exercisable. Settlement is carried out in equity securities. The estimate of the number of options expected to become exercisable is reviewed on every reporting date. The effects of any adjustments that have to be considered with regard to initial estimates are recognised in the statement of comprehensive income as well as by adjusting equity accordingly.

The measurement of the stock options in the first six months of the 2013 financial year entailed staff costs of €60 k, of which €49 k was attributable to the measurement of the stock options issued in 2012 under the 2011 Stock Option Plan. The remaining €11 k relates to the 2005 Stock Option Plan, under which no more new options can be issued; not all of the issued options have vested, however.

No stock options were issued or exercised in the first half of the 2013 financial year. A total of 4,800 stock options were returned because employees left the Company. Furthermore, no options held by employees or members of the Executive Management Board under the relevant plans have expired or were forfeited for other reasons. This means that 1,221,487 options – 833,335 for current or former members of the Executive management Board and 388,152 for current or former employees – had been issued as of the end of the reporting period.

A total of 6,500 options of the Executive Management Board and 13,192 options of employees have vested as of the reporting date.

# E. Related party transactions

In the reporting period, the Company's executives reported the following transactions subject to disclosure in accordance with Section 15a German Securities Trading Act (Wertpapierhandelsgesetz) (Directors' dealings):

Name	Date	Trans- action	Market- place	Price €	Number	Volume €
Dr Georg Baur <sup>1</sup>	01.03.2013	Sale	XETRA	1.6962	50,000	84,808.45
Dr Georg Baur	28.02.2013	Sale	XETRA	1.7046	50,000	85,229.42

<sup>&</sup>lt;sup>1</sup> Dr Georg Baur is Deputy Chairman of the Supervisory Board of WILEX AG.

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

## F. Key events after the interim reporting period

All significant events that occurred after the end of the reporting period are explained in the report on events after the reporting period that is part of the interim management report.



# Responsibility statement of the Executive Management Board

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

Munich, 11 July 2013

The Executive Management Board

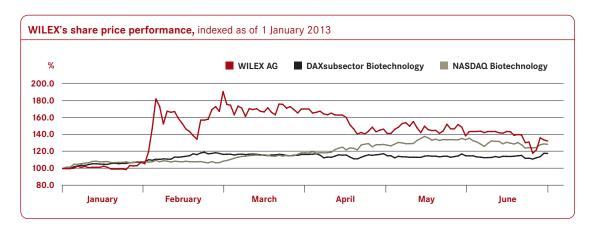
Professor Olaf G. Wilhelm

Dr Jan Schmidt-Brand

Dr Paul Bevan

Dr Thomas Borcholte

# WILEX's shares



WILEX's shares started the 2013 trading year at €0.976 and closed at €1.291 on 30 June 2013, posting a gain of around 32%. The DAXsubsector Biotechnology Index and the NASDAQ Biotechnology Index both continued the positive trend witnessed in the previous year, gaining 18 % and 29 %, respectively.

Key share figures as of the end of the reporting period		H1 2013	H1 2012
Shares issued	Number	31,275,507	24,814,963
Market capitalisation	€ million	43.79	90.33
Closing price (XETRA)	€	1.400	3.640
High <sup>1</sup>	€	2.299 (27.02.13)	4.679 (07.12.11)
Low <sup>1</sup>	€	0.830 (11.12.12)	2.874 (10.01.12)
Volatility (260 days, XETRA)	%	115.941	59.827
Average daily trading volume 1	Shares	151,369	24,091
Average daily trading volume <sup>1</sup>	€	228,064	89,266
Earnings per share	€	(0.11)	(0.24)

Source: Bloomberg; <sup>1</sup> All stock exchanges

#### Investor relations

WILEX AG's Annual General Meeting was held in Munich on 14 June 2013. A total of 21,177,730 shares (67.7%) of the share capital of 31,275,507 no par value bearer shares were present at the voting. The approval of the actions of the Executive Management Board and Supervisory Board members and the election of Deloitte & Touche GmbH Wirtschaftsprüfungsgesellschaft, Mannheim, as the Company's auditors for the current fiscal year were put to the vote. All proposed resolutions were adopted by majorities of 99.9%.

On 17 June 2013, TVM V Life Science Ventures GmbH & Co. KG notified us that it had reduced its share in WILEX AG to 2.57%, thus falling below the voting rights threshold of 3%. These shares are now shown as being held in free float.

Shareholder structure of WILEX AG	
dievini Hopp BioTech holding GmbH & Co. KG, Curacyte AG and DH-Holding Verwaltungs GmbH (formerly: Verwaltungsgesellschaft Golf Club St. Leon-Rot mbH)	≈47 %
UCB	≈14 %
Corporate bodies	≈2%
Free float less than 3%	≈37%

# Financial calendar

Financial calendar 2013	
10 October 2013	9-month Financial Report 2013

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# **Publishing information**

Published by: WILEX AG, Grillparzerstr. 10, 81675 Munich, Germany

Responsible for the project: Katja Arnold, WILEX AG

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

Director Corporate Communications & IR

As of: 11 July 2013

