

**PRESS RELEASE**

**WILEX publishes half-yearly financial report 2013**

- **Positive subgroup data for RENCAREX<sup>®</sup> presented at the ASCO Annual Meeting**
- **Agreement reached with the FDA on the trial design for REDECTANE<sup>®</sup>**
- **Financial figures in line with guidance**
- **Invitation to the conference call**

**Munich, Germany, 11 July 2013.** WILEX AG (ISIN DE0006614720 / WL6 / FSE) published today its financial report for the first six months of the 2013 financial year (1 December 2012 – 31 May 2013). The WILEX Group, comprising WILEX AG and the subsidiaries WILEX Inc. and Heidelberg Pharma GmbH, reports consolidated figures and on three operating segments.

Dr Jan Schmidt-Brand, Chief Financial Officer of WILEX AG, commented: “The second quarter of the year saw extensive preparations for the ASCO Annual Meeting to present data on MESUPRON<sup>®</sup> and from the ARISER study with the new, encouraging findings from the retrospective subgroup analysis. We are working hard to bring all of our projects to the next stage of development and to secure financing for them.”

WILEX presented its financing plans at the Annual General Meeting on 14 June 2013 on the basis of a three-pillar strategy: the search for licensing and development partners for MESUPRON<sup>®</sup>, RENCAREX<sup>®</sup> and for the ADC technology remains the main economic objective. Parallel to the endeavours with potential licensing partners from industry, WILEX will work together with financial investors on ensuring financing of projects or of the entire portfolio, whereby the classic rights issue has the lowest priority in this context. The investment bank Burrill Securities LLC has been engaged as an advisor to assist in finding project financing. In addition to possible financing options, WILEX will continue with cost saving measures introduced at the beginning of the financial year. Vacant positions have not been filled with tasks re-assigned within the team instead. Management functions within the Executive Management Board and the executive management of the subsidiaries were consolidated. The Executive Management Board was effectively reduced from 4 to 3 full-time equivalents.

**Activities and outlook of the operating segments**

***Therapeutics (Rx)***

**RENCAREX<sup>®</sup>** (INN: Girentuximab): Over the last few months the data of the ARISER trial in the adjuvant therapy of clear cell renal cell carcinoma were analysed intensively with respect to biomarkers and subgroups. Retrospective analysis revealed that as the score of the antigen CAIX increases, the more pronounced the RENCAREX<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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).

This indicates that RENCAREX<sup>®</sup> could deliver a well-tolerated and effective therapy for ccRCC patients with a high CAIX score. The relevance of CAIX as a prognostic biomarker was

introduced to leading urologists at the AUA Annual Meeting in May 2013 in San Diego, and the detailed data from the ARISER trial were presented at the ASCO Annual Meeting in Chicago at the beginning of June 2013.

Based on the promising subgroup data, initial talks with the regulatory authorities (the FDA and European agencies) on a confirmatory prospective Phase III trial with RENCAREX<sup>®</sup> in the stratified subgroup using the biomarker CAIX are planned for the second half of 2013. The Company plans to further develop the CAIX in vitro diagnostic test as a companion diagnostic, which may be helpful in identifying and stratifying patients who might benefit from RENCAREX<sup>®</sup> therapy.

WILEX is currently in discussion with Prometheus about the termination of the existing licence agreement for the US commercial rights to RENCAREX<sup>®</sup>. Following termination, WILEX will regain the global rights with the exception of Southern Europe and could 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<sup>®</sup> 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.

**MESUPRON<sup>®</sup>** (INN: Upamostat): The partnering process for the uPA inhibitor is progressing based on the positive Phase II data (proof-of-concept) in the pancreatic cancer (2010) and breast cancer (2012) indications. WILEX aims to sign a licence agreement for MESUPRON<sup>®</sup> and decide together with the partner the further development strategy for a Phase IIb/III programme. WILEX is currently holding in-depth direct discussions with several parties with oncology expertise.

**WX-554:** A Phase Ib/II trial with the small molecule MEK inhibitor WX-554 was started in April 2012 to analyse the safety, pharmacokinetics, pharmacodynamics and efficacy of WX-554 in patients with solid tumours. The first part of the study (a dose escalation) serves to confirm the biologically effective dose. This is followed by a second part in which this dose is administered to patients with MEK pathway relevant mutations to obtain initial data on clinical activity and on pharmacodynamics within the tumour tissue.

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.

**WX-037:** The small molecule PI3K inhibitor is under development supported by the “m4 Personalised Medicine and Targeted Therapies” initiative of the Munich-based m4 Biotech Cluster and will receive grants of up to EUR 2.6 million from the Federal Ministry of Education and Research (BMBF) for preclinical and clinical development. Preclinical work has been completed and clinical development began in July 2013. A Phase I trial will examine the safety and tolerability of WX-037 in patients first as monotherapy and then in combination with the MEK inhibitor WX-554.

The MEK and PI3K programmes together with several antibody programmes were acquired from the biopharmaceutical company UCB in 2009. 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 in July 2013. WILEX will be reimbursed an undisclosed

amount for its development to date and is eligible for future, undisclosed development, regulatory and commercial milestone payments and royalties whilst keeping all rights in oncology. UCB will work on these antibodies in immunology/inflammatory diseases and, as part of the strategic partnership between the two companies, will make available data to WILEX relevant for oncology.

### ***Diagnostics (Dx)***

**REDECTANE<sup>®</sup>** (INN: 124I-Girentuximab): The radiolabelled form of the antibody Girentuximab is being developed as an imaging agent for the diagnosis of clear cell renal cell carcinoma. Data of a Phase III trial showed that REDECTANE<sup>®</sup> with PET/CT is clearly superior to CT alone in diagnosing clear cell renal cell carcinomas. WILEX AG is currently developing the protocol for a confirmatory Phase III trial (REDECT 2) together with the FDA under a Special Protocol Assessment (SPA). 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<sup>®</sup>. WILEX AG will now prepare and submit full documentation for REDECT 2 to the FDA under the SPA procedure for formal approval. Details will be disclosed at the start of the study, which is planned when WILEX has secured financing for the entire study.

**In vitro diagnostic tests:** The US subsidiary WILEX Inc. produces and markets ELISA and immunohistochemical tests under the brand name Oncogene Science for various biomarkers (e.g. HER2/neu and CAIX). In addition to manufacturing the biomarker tests, WILEX Inc. offers a range of contract manufacturing services for third parties.

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 subsidiary Heidelberg Pharma GmbH offers customer specific preclinical contract research related to cancers and inflammatory and autoimmune diseases and also possesses a technology 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.

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 and performs contract work for customers related to designing, optimising, profiling and manufacturing new ADCs. Important scientific findings and data have been recorded that could form the basis for continuing the collaboration.

A project (CapStem<sup>®</sup>) 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 also 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.

**Key financial figures for the first half year of 2013**

In the first six months of the 2013 financial year, the WILEX Group generated income of EUR 7.6 million (previous year: EUR 8.3 million). This includes sales revenue of EUR 6.6 million (previous year: EUR 7.2 million) and other income of EUR 1.0 million (previous year: EUR 1.1 million). Most of this is attributable to sales revenue from the license agreement concluded with Prometheus for RENCAREX<sup>®</sup>; payments received were recognised as deferred income and will be reversed through profit or loss on a pro rata basis.

Operating expenses including depreciation and amortisation amounted to EUR 11.1 million in the reporting period, down from the previous year (EUR 13.5 million). The cost of sales amounted to EUR 2.7 million, down on the prior-year figure of EUR 3.3 million as a result of lower expenses in the Cx segment for the provision of services in the services business. Research and development costs, which were EUR 6.9 million the previous year, fell to EUR 5.4 million and also administrative costs were trimmed to EUR 1.9 million in the first half of the year due to the cost cutting following the restructuring programme (previous year: EUR 2.2 million). Other expenses for activities in the areas of business development, marketing and commercial market supply amounted to EUR 1.1 million in the reporting period (previous year: EUR 1.2 million).

The Therapeutics segment (Rx) posted sales revenue of EUR 5.8 million and a net loss of EUR 0.5 million in the first six months of the financial year. The Diagnostics segment (Dx) generated sales revenue of EUR 0.1 million and a net loss for the period of EUR 2.1 million. Customer Specific Research (Cx) generated sales revenue of EUR 0.6 million and a net loss for the period of EUR 1.6 million.

The WILEX Group reported an improved financial result of EUR -50 k (H1 2012: EUR -320 k). The net loss for the period amounted to EUR 3.5 million. This represents an improvement of 37% on the loss in the same period of the previous year (EUR 5.6 million) and is solely attributable to lower costs. Earnings per share improved by 53% to EUR -0.11 (H1 2012: EUR -0.24), also due to the higher number of shares in circulation compared with H1 2012.

Total assets as of 31 May 2013 amounted to EUR 28.0 million (30 November 2012: EUR 37.7 million). The WILEX Group had cash and cash equivalents of EUR 12.9 million (30 November 2012: EUR 23.4 million). Equity as of the end of the reporting period was EUR 16.4 million (30 November 2012: EUR 19.9 million) with an equity ratio of 58.7% (30 November 2012: 52.8%).

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

## Key figures for the WILEX Group

<b>Key figures</b>	<b>H1 2013 <sup>1)</sup></b>	<b>H1 2012 <sup>1)</sup></b>
<b>Earnings</b>	<b>EUR'000</b>	<b>EUR'000</b>
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 EUR	(0.11)	(0.24)
<b>Balance sheet as of end of period</b>		
Total assets	27,983	22,414
Cash and cash equivalents	12,894	2,920
Equity	16,439	(281)
Equity ratio in %	58.7	(1.3)
<b>Cash flow</b>		
from operating activities	(10,504)	(9,906)
from investing activities	(43)	(140)
from financing activities	(115)	9,639
<b>Employees (number)</b>		
Employees as of the end of the period <sup>2)</sup>	111	126
Full-time equivalents as of the end of the period <sup>2)</sup>	104	116

<sup>1</sup> The reporting period begins on 1 December and ends on 31 May.

<sup>2</sup> Including members of the Executive Management Board

Rounding of exact figures may result in differences.

The entire half-yearly Financial Report 2013 including the consolidated financial statements prepared in accordance with International Financial Reporting Standards (IFRS) was published at [www.wilex.com](http://www.wilex.com).

### Invitation to the conference call

WILEX will hold a public conference call for media, analysts and investors in English at 03:00 p.m. CEST on 11 July 2013. Please dial in ten minutes before the conference call using the following dial-in numbers:

1. Germany: +49 69 71044 5598
2. UK: +44 20 3003 2666
3. USA: +1 212 999 6659
4. USA Freephone: +1 866 966 5335

You will be welcomed by an operator who will ask for the password (WILEX) and take your name and company. The presentation for the conference will be available for download from [www.wilex.com](http://www.wilex.com) from 02:30 p.m. CEST.

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**About WILEX**

WILEX AG is a biopharmaceutical company based in Munich, Germany. Focused on oncology, the Company has a broad portfolio of diagnostic and therapeutic products for the specific detection and targeted treatment of various types of cancer. WILEX's therapeutic product candidates are based on antibodies (RENCAREX<sup>®</sup> in Phase III) and small molecules (MESUPRON<sup>®</sup> two Phase IIa trials completed, WX-554 in Phase Ib/II and WX-037 in preclinical development). In the field of diagnostics, REDECTANE<sup>®</sup> is an antibody-based, imaging diagnostic agent that is currently in a Phase III programme. WILEX's US subsidiary WILEX Inc. in Cambridge, MA, markets a portfolio of research use only tests and in vitro diagnostic agents under the brand Oncogene Science. The subsidiary Heidelberg Pharma GmbH offers an attractive and highly promising antibody drug conjugate technology platform and preclinical contract research services. The business model of WILEX comprises research, technology, product development and commercialisation. WILEX's customers and partners include leading international pharmaceutical companies.

Website: <http://www.WILEX.com>, ISIN DE0006614720 / WKN 661472 / Symbol WL6

This communication contains certain forward-looking statements relating to the Company's business, which can be identified by the use of forward-looking terminology such as "estimates", "believes", "expects", "may", "will", "should", "future", "potential" or similar expressions or by a general discussion of the Company's strategy, plans or intentions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause our actual results of operations, financial position, earnings, achievements, or industry results, to be materially different from any future results, earnings or achievements expressed or implied by such forward-looking statements. Given these uncertainties, prospective investors and partners are cautioned not to place undue reliance on such forward-looking statements. We disclaim any obligation to update any such forward-looking statements to reflect future events or developments.