

PRESS RELEASE

WILEX publishes 9-month Financial Report 2013

- **UCB acquires rights to an antibody programme for non-oncology indications**
- **Cooperation and licence agreement for ADC signed with Roche**
- **Nuclea acquires WILEX Inc. and will develop CAIX companion diagnostic**
- **Improved financial guidance for 2013**

Munich, Germany, 10 October 2013. WILEX AG (ISIN DE0006614720 / WL6 / FSE) today published its financial figures for the first nine months of the 2013 financial year and reported on the progress of its projects.

Dr Jan Schmidt-Brand, Chief Financial Officer of WILEX AG, commented: "Having made good progress in the third quarter in implementing our business strategy comprising the three elements partnerships, financing and cost management, we have raised our earnings forecast for the year as a whole, thus extending our cash reach into the third quarter of 2014."

Activities and outlook of the operating segments

Therapeutics (Rx)

RENCAREX[®] (INN: Girentuximab): All work concerning the Phase III ARISER trial was duly completed as planned in accordance with "Good Clinical Practice" in the third quarter of 2013. The antibody was tested in the double-blind, placebo-controlled Phase III ARISER trial for adjuvant therapy of clear cell renal cell carcinoma (ccRCC). While the final analysis performed in October 2012 showed no improvement in median disease-free survival following treatment with RENCAREX[®] compared to placebo, positive subgroup data were presented at the Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago in June 2013.

The retrospective subgroup analysis showed that RENCAREX[®] could deliver a well-tolerated and effective therapy for ccRCC patients with a high CAIX antigen score. WILEX has held initial talks with regulatory authorities (the FDA and European agencies) and reached agreement on plans for a confirmatory prospective Phase III trial with RENCAREX[®] in the defined subgroup using the biomarker CAIX for stratification.

WILEX is in discussions with Prometheus about the termination of the existing licence agreement for the US commercial rights to RENCAREX[®].

MESUPRON[®] (INN: Upamostat): Based on the positive Phase II data (proof-of-concept) in the pancreatic cancer (2010) and breast cancer (2012) indications, the partnering process for this uPA inhibitor was advanced further.

WILEX aims to sign a licensing deal with a partner for the further development of MESUPRON[®].

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 serves to confirm the biologically effective dose by way of a dose escalation. The second part, which began in August 2013, is designed to obtain initial data on clinical activity and on pharmacodynamics in tumour tissue.

The plan is to complete patient recruitment by the end of 2013 and to present data in the second half of 2014.

WX-037: Clinical development of the PI3K inhibitor WX-037 began in the third quarter, and the first patient has been included in the study. The open-label, dose-escalation study is being conducted in patients with solid tumours in three study centres in the UK. The purpose of the trial is to investigate the safety, pharmacokinetics, pharmacodynamics and clinical activity of the PI3K inhibitor.

The MEK and PI3K programmes, as well as three antibody programmes, were acquired from UCB for further development as part of a strategic alliance. WILEX identified a lead candidate for one of the antibody programmes and generated preclinical data, which prompted UCB in July 2013 to acquire the rights outside oncology to develop the antibody further in non-oncology indications. However, WILEX keeps the rights to the antibody's further development in oncology and will be reimbursed for the development costs incurred to date. WILEX is also eligible for development, regulatory and commercial milestone payments as well as royalties.

Diagnostics (Dx)

REDECTANE[®] (INN: Iodine (124I) Girentuximab): The radiolabelled form of the antibody Girentuximab is being developed as an imaging diagnostic agent for the detection clear cell renal cell carcinomas. A Phase III trial already showed that REDECTANE[®] with PET/CT is clearly superior to CT alone in diagnosing clear cell renal cell carcinomas.

In the third quarter, WILEX received written notification from the FDA confirming agreement on the development strategy and study design for the confirmatory Phase III diagnostic performance clinical trial with REDECTANE[®] (REDECT 2).

In parallel to the finalisation of the study protocol as part of a Special Protocol Assessment (SPA), financing options are being investigated to enable the implementation of the trial.

In vitro diagnostic tests: The subsidiary WILEX Inc. was acquired by the US company Nuclea Biotechnologies Inc., at the beginning of September. Under the terms of the deal, Nuclea will also assume responsibility for repayment of USD 2.5 million which is a part of an intercompany loan from WILEX AG to WILEX Inc. In addition, WILEX AG is eligible for single-digit royalties on net sales of the HER2/neu and CAIX assays.

Concurrently, and as an essential part of the overall deal, WILEX AG and Nuclea entered into a development agreement under which Nuclea will develop an automated CAIX IVD IHC assay ("CAIX Dx") to be submitted for FDA approval under the investigational device exemption ("IDE"). This CAIX Dx is intended to be used for patient stratification in a planned pivotal study with RENCAREX[®] and as a potential future companion diagnostic in the adjuvant treatment of clear cell renal cell carcinoma. Nuclea will bear the costs for the development of this CAIX Dx as a contribution in kind which will lead to savings of at least USD 2.5 million for WILEX AG.

Customer Specific Research (Cx)

The subsidiary Heidelberg Pharma GmbH offers customer specific preclinical contract research related to cancers and inflammatory and autoimmune diseases and possesses a technology platform for therapeutic 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 GmbH signed a licence agreement with Roche at the beginning of September. One component of this agreement is the joint development of a novel class of antibody drug conjugates on the basis of Heidelberg Pharma's patented technology to couple α -

Amanitin to antibodies (Antibody Targeted Amanitin Conjugates, ATACs). Heidelberg Pharma will receive regular payments for granting access to its technology and providing research services and at a later time will be eligible for customary upfront payments, milestone payments and royalties as a percentage of net sales for each development candidate selected by Roche.

A project (CapStem[®]) has also been developed in recent months to refine this innovative ADC technology as an independent business model. This opens the opportunity not only to license the toxin linker technology but also to develop complete ADC molecules with in-licensed antibodies. This will enable the Company to exploit the attractive market potential and to use project finance to support development.

Financial results for the first nine months of 2013

In the first nine months of the 2013 financial year, the WILEX Group generated income of EUR 11.4 million (previous year: EUR 12.8 million). This figure includes sales revenue of EUR 10.1 million (previous year: EUR 11.3 million) and other income of EUR 1.3 million (previous year: EUR 1.5 million). Most of the sales revenue is attributable to the license agreement concluded with Prometheus for RENCAREX[®], whereby 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 15.3 million in the reporting period, down substantially from the previous year (EUR 19.8 million). Cost of sales fell to EUR 3.7 million (previous year: EUR 4.9 million) due to lower expenses for RENCAREX[®] in the Rx segment. Research and development costs, which were EUR 9.7 million the previous year, fell to EUR 7.4 million and administrative costs were trimmed from EUR 3.4 million to EUR 2.8 million due to the cost-cutting following the restructuring programme. Other expenses, comprising the costs for activities in the areas of business development, marketing and commercial market supply, were EUR 1.4 million (previous year: EUR 1.8 million).

The WILEX Group reported an improved financial result of EUR -62 k (previous year: EUR -451 k). The net loss for the period was EUR 4.0 million, which represents an improvement of 47% on the loss in the same period of the previous year (EUR 7.4 million) and is solely attributable to lower costs. Earnings per share improved by 59% to EUR -0.13 (previous year: EUR -0.31), which is also due to the higher number of shares in circulation compared with the first nine months of 2012.

The three segments of the WILEX Group achieved the following results in the reporting period: Therapeutics (Rx) posted sales revenue of EUR 8.8 million and a profit for the period of EUR 0.5 million. The Diagnostics (Dx) segment recorded sales revenue of EUR 0.2 million and a net loss of EUR 3.1 million. Customer Specific Research generated sales revenue of EUR 1.1 million and a net loss for the period of EUR 2.2 million.

In the interests of continuous reporting, the Dx segment, to which WILEX Inc. was allocated during the reporting period, will be maintained as this segment also reports activities relating to REDECTANE[®]. In accordance with IFRS 5, the assets and liabilities of WILEX Inc., which was sold after the reporting date in early September 2013, are classified as a disposal group and shown as a separate balance sheet item as of the reporting date. These assets amounted to EUR 0.5 million and included current assets, non-current assets and cash.

Total assets as of 31 August 2013 amounted to EUR 24.9 million (30 November 2012: EUR 37.7 million). The WILEX Group had cash and cash equivalents of EUR 9.9 million

(30 November 2012: EUR 23.4 million). Equity at the end of the reporting period was EUR 16.0 million (30 November 2012: EUR 19.9 million) and the equity ratio was 64.4%.

As a result of the implementation of our strategy, the guidance for the WILEX Group for the current financial year issued in February 2013 is revised as follows:

	Guidance 10/2013 EUR million	Guidance 02/2013 EUR million	Actual 2012 EUR million
Sales revenue and other income	14.0 – 17.0	15.0 – 19.0	17.8
Operating expenses	18.0 – 22.0	22.0 – 27.0	26.8
Operating result	(2.0) – (6.0)	(5.0) – (9.0)	(8.9)
Total funding requirement	14.0 – 17.0	16.0 – 20.0	20.0
Funds required per month	1.2 – 1.4	1.3 – 1.7	1.7

Key figures for the WILEX Group

Key figures	9M 2013¹	9M 2012¹
Earnings	EUR '000	EUR '000
Sales revenue	10,090	11,359
Other income	1,295	1,472
Operating expenses	(15,278)	(19,799)
of which research and development costs	(7,355)	(9,735)
Operating result	(3,893)	(6,968)
Earnings before tax	(3,956)	(7,418)
Net loss for the period	(3,956)	(7,420)
Earnings per share in EUR	(0.13)	(0.31)
Balance sheet as of end of period		
Total assets	24,917	43,174
Cash and cash equivalents	9,876	28,677
Equity	16,043	21,449
Equity ratio ² in %	64.4	49.7
Cash flow		
from operating activities	(13,499)	111
from investing activities	(111)	(268)
from financing activities	(160)	25,440
Employees (number)		
Employees as of the end of the period ³	110	127
Employees as of the end of the period (full-time equivalents) ³	101	118

¹ The reporting period begins on 1 December and ends on 31 August.

² Equity/total assets

³ Including members of the Executive Management Board

Rounding of exact figures may result in differences.

The entire 9-month Financial Report 2013 including the consolidated financial statements prepared in accordance with International Financial Reporting Standards (IFRS) was published at 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 10 October 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 from 02:30 p.m. CEST.

About WILEX

WILEX AG is a biopharmaceutical company based in Munich, Germany. Focused on oncology, the Company develops diagnostic and therapeutic product candidates for the specific detection and targeted treatment of various types of cancer based on antibodies and small molecules. The subsidiary Heidelberg Pharma GmbH offers preclinical contract research services and an antibody drug conjugate (ADC) technology platform. The business model comprises research and product development as well as the commercialisation of its activities. Our customers and partners include leading international pharmaceutical companies. WILEX AG is listed at the Frankfurt Stock Exchange. ISIN DE0006614720 / WKN 661472 / Symbol WL6. More information is available at www.wilex.com.

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