



**2010 Financial Year**  
**Press and analyst presentation**  
22 February 2011

- Oncology-focused biopharmaceutical company
- Transition from R&D to commercially driven business
- Product candidates close to market
  - First-in-class
  - Strong competitive profile

## Development success

Phase I II III

REDECTANE®

RENCAREX®

MESUPRON®

WX-554

## Significant sales potential

- REDECTANE® (diagnostic MAb\*):  
~ \$100m
- RENCAREX® (therapeutic MAb\*):  
~ \$500m
- MESUPRON® (small molecule):  
~ \$1bn

\* Monoclonal antibody

## Deals



## Products & Technologies

OncogeneScience



- Multiple value inflection points in the next months

## R & D

- ✓ REDECTANE®: Final Phase III data and report
- ✓ RENCAREX – 343 events (Jan. 2011)
- ✓ MESUPRON®: Final Phase II data in pancreatic cancer
- ✓ WX-554: Phase I data healthy volunteer study

## Corporate

### Financing:

- ✓ 2 rights issues: €18.5m raised
- ✓ SEDA signed: equity line over 36 months
- ✓ Shareholder loans to secure financing

### Acquisitions:

- ✓ Oncogene Science
- ✓ Heidelberg Pharma

# Strategic fit: The new WILEX

	Heidelberg Pharma AG	WILEX AG	WILEX Inc./ Oncogene Science
Indication	Oncology		
Profile	Platform technology and contract research	Therapeutics and diagnostics	Companion diagnostics
Products	Antibody drug conjugates	Antibodies and small molecules	Diagnostic tests for biomarkers
Activities	Discovery / research	Clinical development and commercialisation	Manufacturing, marketing and sales
Status	Research / preclinical	Marketing application, Phase III, II, I	On the market



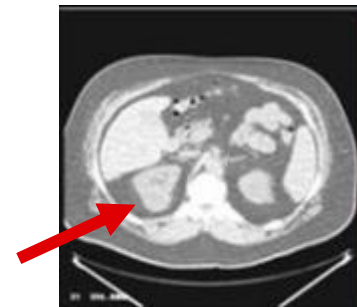
## Pipeline status

# REDECTANE®: First-in-class diagnostic imaging agent for kidney cancer

- Radiolabelled antibody for diagnostic use targets CA IX antigen
  - INN:  $^{124}\text{I}$ -Girentuximab
- High medical benefit
  - Could avoid surgery
- Strong worldwide commercial partnership with Ion Beam Applications (IBA)
- Expected to be the first commercial product
- Peak sales potential > \$100m in kidney cancer only
  - Market expansion through other indications possible

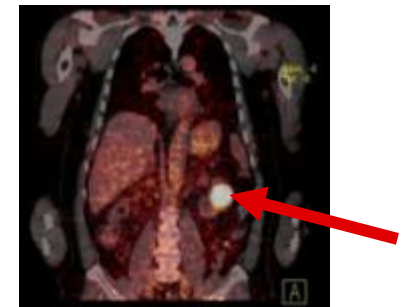
Today

CT Scan



Tomorrow

REDECTANE®  
PET-CT\*



\*PET-CT: Positron-Emission Tomography – Computerised Tomography

# REDECTANE®: WILEX's first product soon in approval process

- **US pivotal Phase III trial (SPA) with 226 patients in 14 centres**
  - Completed in May 2010
- **REDECTANE® with PET/CT proves to be superior to CT**
  - Specificity: highly statistical value  $p < 0.001$
  - Sensitivity: statistical significance with  $p \leq 0.016$
- **REDECTANE® with PET/CT in comparison to an arbitrary value of 75% for specificity and sensitivity**
  - Specificity of 87% ( $p = 0.057$ )
  - Sensitivity of 86% ( $p \leq 0.002$ )
- **Process**
  - Application for Pre BLA Meeting, as soon as the product manufacturing sections have been received from partner IBA
  - Pre BLA Meeting
  - FDA filing

# RENCAREX<sup>®</sup>: First-in-class therapy for adjuvant treatment of clear cell Renal Cell Carcinoma (ccRCC)

- **Monoclonal antibody for therapeutic use**
  - INN: Girentuximab
  - Specifically binds to the antigen CA IX on tumour cells
  - Validated mechanism of action (ADCC\*)
- **High medical benefit**
  - Targets micro-metastases to delay onset of metastatic disease
- **No drug approved by FDA / EMA in non-metastatic ccRCC**
- **Marketing and co-development deal with Esteve for Southern Europe (2004)**
- **Peak sales potential of ~ \$500m in ccRCC only**
- **Market expansion through other indications possible**



\* Antibody Dependant Cellular Cytotoxicity

# RENCAREX®: Data of interim analysis for efficacy expected soon

→ **Phase II studies confirm biological activity**

→ Increased survival of RCC patients with late stage metastatic disease

→ **Phase III trial: 864 renal cancer patients enrolled**

→ Non-metastatic RCC patients post nephrectomy (adjuvant setting)

→ Double-blind, placebo-controlled study in 142 sites in the Americas and Europe

→ **343 events triggered Interim Analysis in Q1 2011**

→ Interim data of Phase III study and IDMC recommendation expected H2 2011

→ Could be basis for EMA filing

# MESUPRON®: First-in-class therapy targeting primary and metastatic tumour growth

- **Oral small molecule targeted therapy**
  - INN: Upamostat
  - Inhibits primary tumour growth and metastases
- **World leader in uPA inhibitors**
  - Strong IP position and high entry barrier
- **Extensive Phase I programme to determine safety, tolerance and Phase II dose rationale**
- **Peak sales potential of ~ \$ 1 bn for various indications**
- **Worldwide partnership planned**



# MESUPRON®: Encouraging Phase II clinical proof-of-concept data

- **Pancreatic cancer:** Phase II randomised trial of 95 patients successfully completed and data published in June 2010
  - Tumour response rate more than doubled
  - One year progression free survival rate improved by 66%
  - One year overall survival rate increased by 49%
  - Median overall survival in months improved by 26%
  
- **Breast cancer:** Phase II trial ongoing
  - First line therapy for HER2 receptor negative metastatic breast cancer
  - Combination therapy with Capecitabine, double-blind design
  - 121 patients recruited at the end of January 2011 in 21 centres (Europe, USA, Brazil)
  - Completion of recruitment (131 patients) expected Q1 2011
  - Study data (PFS) expected 2012



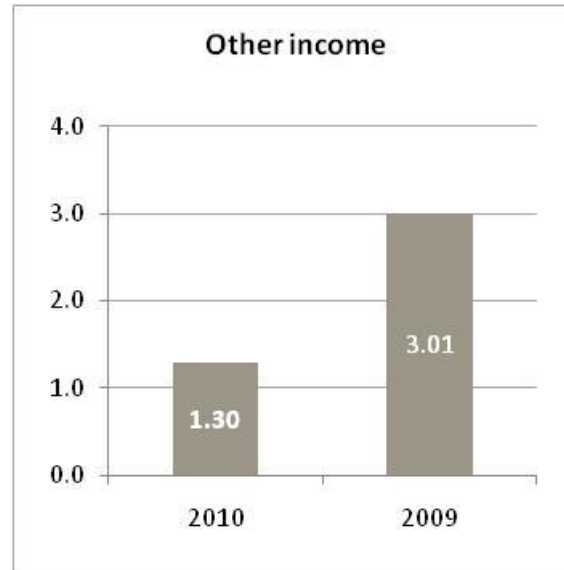
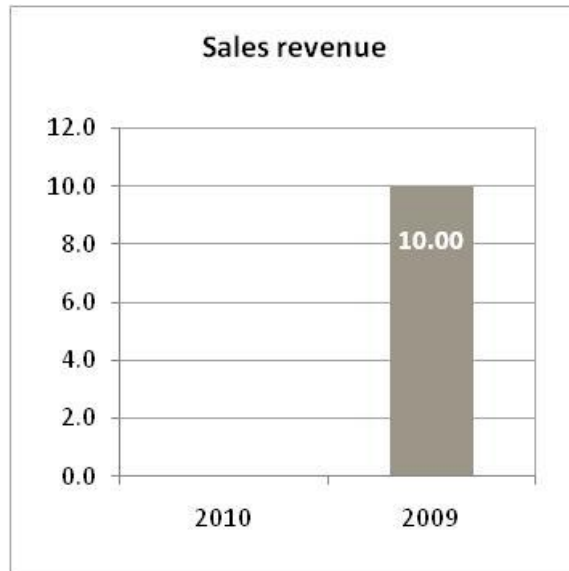
## Financial review 2010

in € m	Guidance 2010	Revised Guidance	2010 reported
Sales revenue	In connection with a licence agreement	n/a	0
Other income	1.5 – 2.0	1.3 – 1.6	1.3
Operating expenses	26.0 – 30.0	24 – 26	24.4
Of which: R&D costs	22.0 – 26.0	20 – 23	19.7
Funding requirement	14 - 18	6 – 8	18.5 raised

- **Other income slightly lower than forecast**
- **Operating expenses lower than expected**
  - Lower R&D costs and cost-cutting measures implemented in 2010
- **Funding requirement achieved**

# Sales revenue and other income 2010

\*€ m; rounded



## → No sales revenue 2010

→ 2009 includes € 10 m milestone revenue from UCB

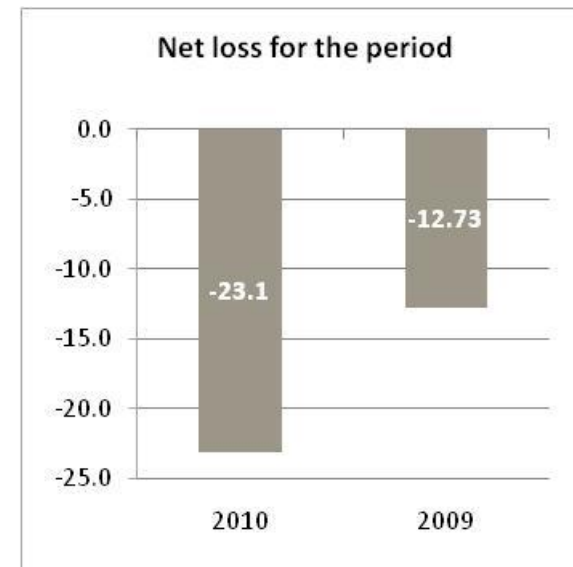
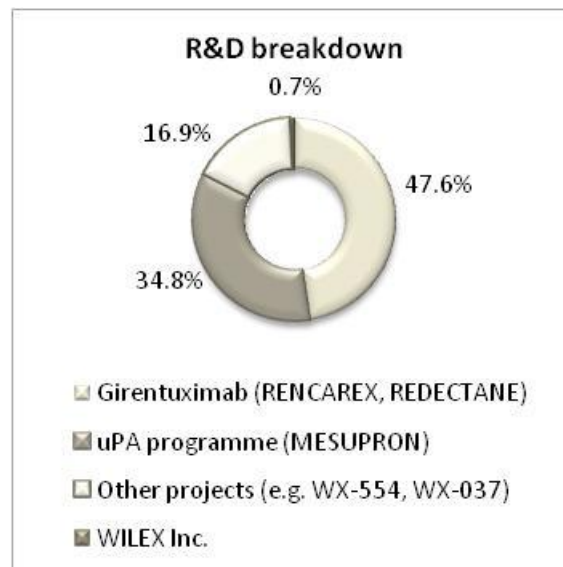
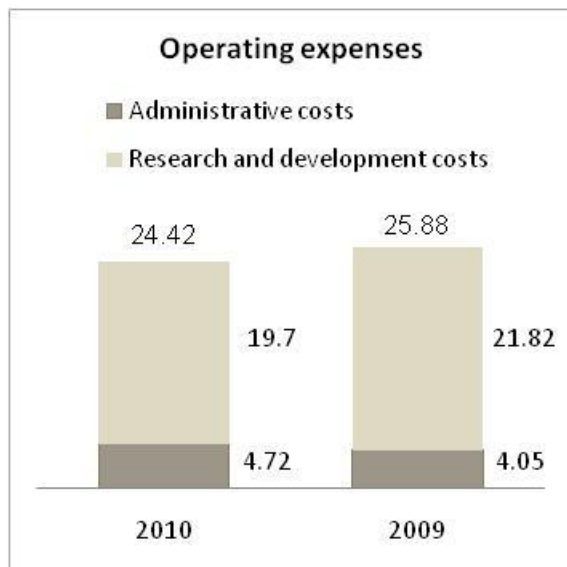
## → Other income

→ Other income related to project progress

## → Number of employees increased from 71 to 80 (incl. WILEX Inc.)

# Operating expenses 2010

\*€ m; rounded



→ Operating expenses 5.6% lower than previous year

→ R&D expenses over 80 % of total costs

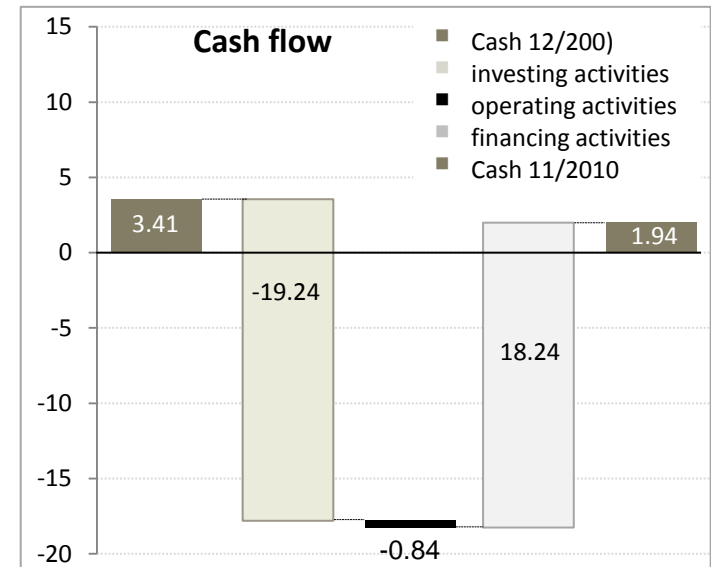
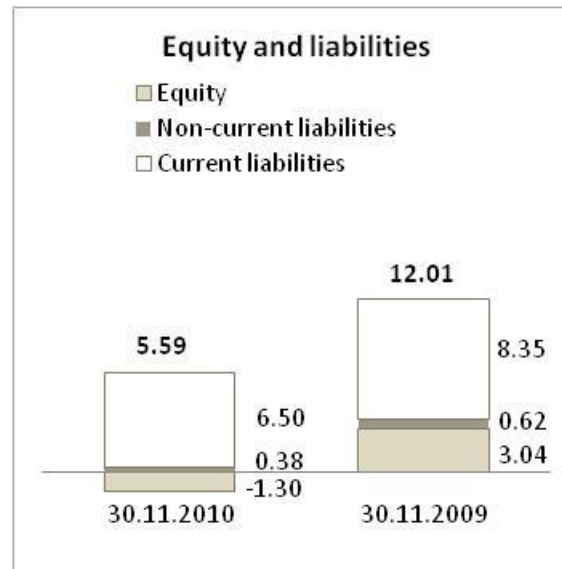
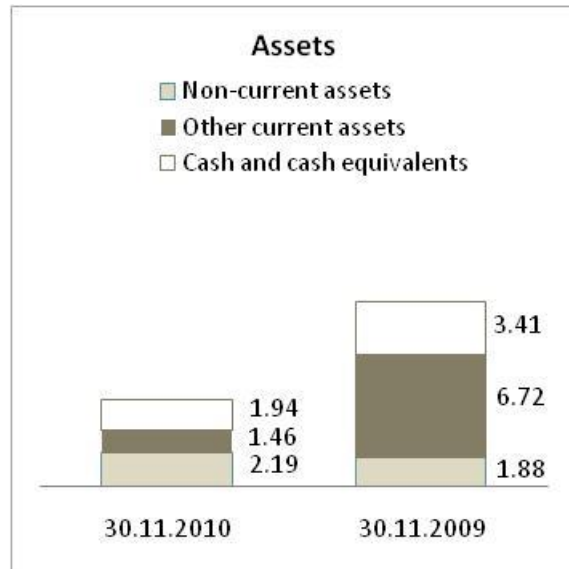
→ Administrative costs

→ higher due to transaction costs and expenses for revaluation of stock options

→ Net loss of € 23.10 m, EPS of € -1.38 (2009: € -0.95)

# Balance sheet as at 30 November 2010

\*€ m; rounded



→ **€ 18.5 m total capital increases**

→ Cash balance as at 30.11.2010 € 1.94 m

→ **Average cash usage per month € 2.06 m (2009: € 1.96 m)**

→ **€ 10.0 m shareholder loan (post reporting period)**



## Guidance 2011

In € m	Guidance 2011	2010
Sales and other income	3.0 – 4.5	1.3
Operating expenses	28.0 – 33.0	24.4
- Of which R&D	22.0 – 27.0	19.7
Net loss	24.0 – 29.0	23.1
- Of which WILEX Inc. and Heidelberg Pharma	2.0 – 3.0	n/a
Usage of cash and cash equivalents	26.0 – 29.0	25.5
Monthly use of cash	2.2 – 2.5	2.06

Corporate  
&  
Commercial

- **Integration of WILEX Inc. into the WILEX Group**
  - Achieve positive cash flow in 2012
- **Complete acquisition of Heidelberg Pharma**
  - ADC technology licensing deal
- **Licensing deal for WILEX's product candidates**
- **Secure additional financing**

**REDECTANE®**

- Application for Pre-BLA Meeting
- Pre-BLA Meeting
- Filing with FDA

**RENCAREX®**

- Data Interim analysis for efficacy
  - Could be basis for filing with EMA

**MESUPRON®**

- Completion of patient recruitment Phase II breast cancer trial

**WX-554**

- Start Phase Ib study

## **Forward looking statements**

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 general discussion of strategy, plans or intentions of the Company. Such forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause our actual results of operations, financial condition, performance, or achievements, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements.

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## → Financial Calendar 2011

- 13 April            3-month Financial Report 2011
- 18 May            Annual General Meeting 2011
- 14 July            Half-yearly Financial Report 2011
- 13 October        9-month Financial Report 2011

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