WILEX

Focused Cancer Therapies

Company update

January 2015

WILEX
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Company Overview

WILEX antibody portfolio

Development of the ADC technology platform

Financials and Outlook

Company overview

Oncology-focused biopharmaceutical company

- Founded 1997 by a team of clinical oncologists from the Technical University of Munich
- Listed on the Frankfurt Stock Exchange (Regulated Market, Prime Standard) since 2006

Repositioning of the Company and restructuring implemented in 2014

- to cut costs and expand cash reach
- to focus on ADC technology and service business

R&D activities focused on ADC technology platform

Excellent know-how in antibody drug conjugates and development of first candidates

ADC activities at Heidelberg Pharma GmbH in Ladenburg

- 100% subsidiary which was acquired by WILEX in 2011 (44 FTE)

Headquarters WILEX AG in Munich

- with a holding function only (5 FTE)

WILEX at a glance

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Subsidiary Heidelberg Pharma:

ADC technology platform for oncology

Further development of the technology platform for Antibody Targeted Amanitin Conjugates (ATAC) and commercialisation to partner

Roche: Licence agreement

Further research programmes under MTA with big Pharma or Biotech started or completed

WILEX AG: No R&D activities, but asset and administration holding

Retain value participation of assets by back loaded licence agreements

REDECTANE®

Diagnostic imaging agent to detect clear cell renal cell carcinoma, positive Phase III data, further Phase III required

to be partnered

RENCAREX®

Therapeutic antibody for adjuvant treatment of clear cell renal cell carcinoma, further Phase III in subgroup required

to be partnered

MESUPRON®

uPA inhibitor with positive Phase II data in breast, pancreatic cancer

Further development through Link Health in Greater China and RedHill Biopharmaceutical in the rest of the world

partnered

Review 2014

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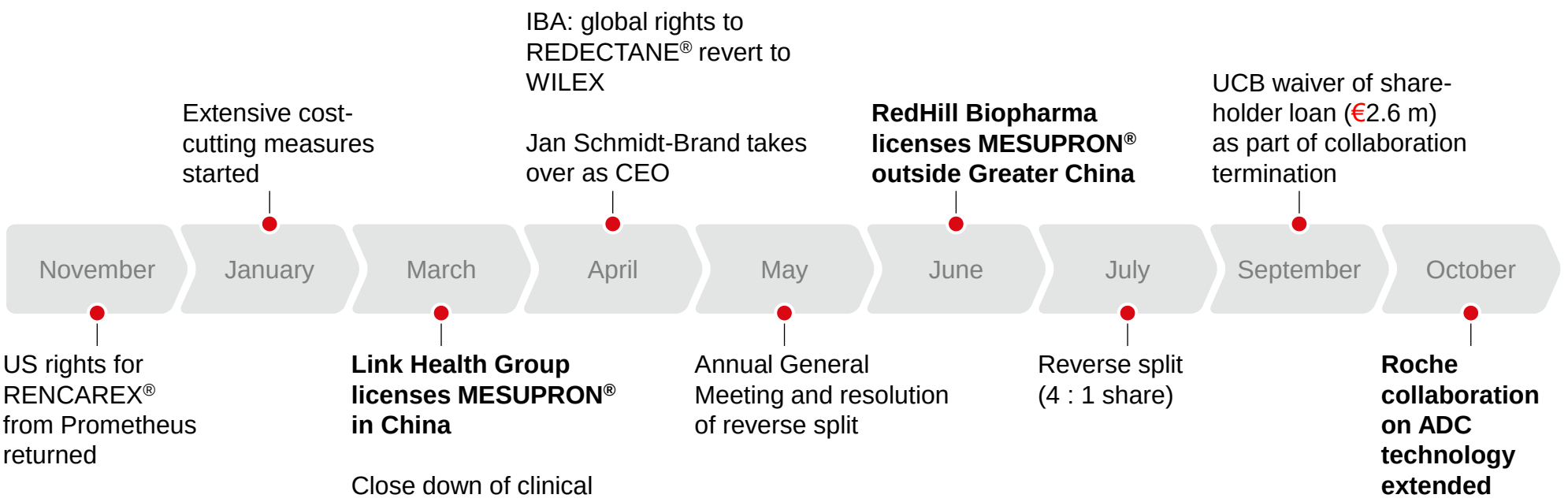
Focus on consolidation and realignment, close down of R&D activities and reduction of workforce in Munich, renting out around a quarter of our premises to other companies



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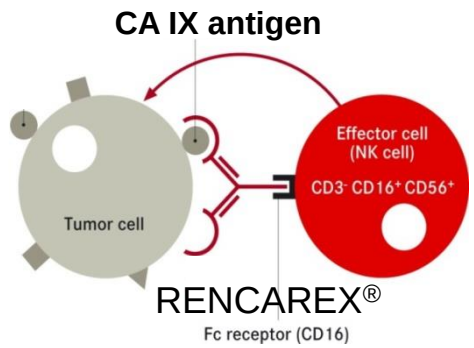
RENCAREX® – Therapeutic antibody Development rationale

Chimeric monoclonal antibody Girentuximab

- Targets CAIX antigen (Carbonic Anhydrase IX) which is abundantly expressed in clear cell renal cell carcinoma (ccRCC), bladder, head & neck and colon cancers
- Cell killing via Antibody-Dependent-Cellular-Cytotoxicity (ADCC)
- Cell growth inhibition as additional mechanism of Girentuximab action independent of ADCC



NK=Nature Killer

Three Phase I studies

- Total of 41 patients
- Safety

Three Phase II studies

- Total of 104 metastatic stage IV renal cell carcinoma patients
- Efficacy as monotherapy and in combination; Safe and well tolerated

Phase III ARISER trial with non-metastatic ccRCC patients did not meet the primary endpoint

- Double-blind, placebo-controlled study, adjuvant setting
- 864 patients142 sites in America and Europe
- Median DFS was unexpectedly long at 72 months
- No difference between RENCAREX® and placebo

Retrospective subgroup analysis of the ARISER trial show statistical significance and efficacy

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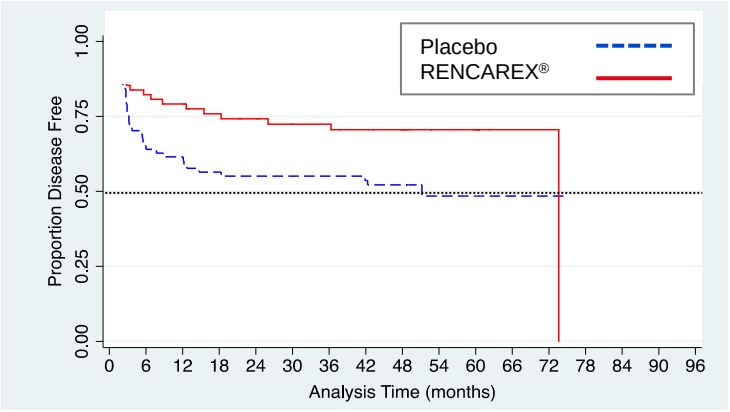
ARISER
Adjuvant Rencarex® Immunotherapy Phase III trial to Study Efficacy in non-metastatic Renal cell carcinoma

ITT* (151 patients): high CAIX score ≥ 2.6

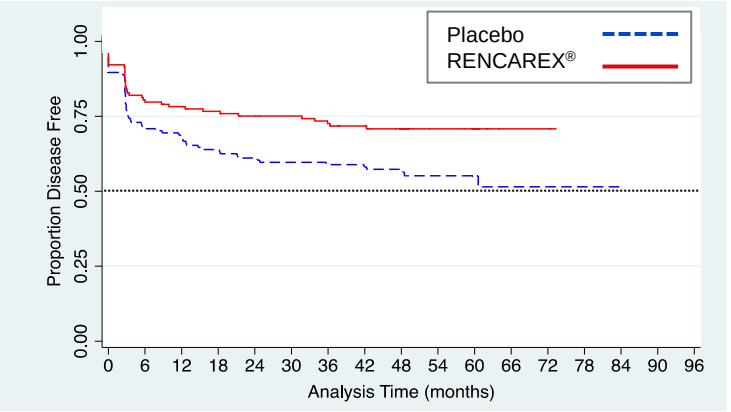
- Median DFS by over 22 months (= 44%)
- HR=0.54; p=0.02



* Intent to treat (ITT) approach includes all patients of the trial

ITT (286 pts): < 65 years & CAIX score ≥ 2.0

- Median DFS not reached
- Impressive HR=0.60; p=0.01



→ **Patients stratified by CAIX score may benefit from RENCAREX® adjuvant therapy**

Next Step:

- Partnering and financing of prospective study to confirm predictive value in high CAIX score patients and to further develop RENCAREX® as immunotherapy
- Attractive peak sale potential, CAIX plays an important role in other cancer indications
- CAIX CDx (IHC) for patient stratification will be developed by Nuclea Diagnostics

REDECTANE® – Diagnostic Antibody Development rationale

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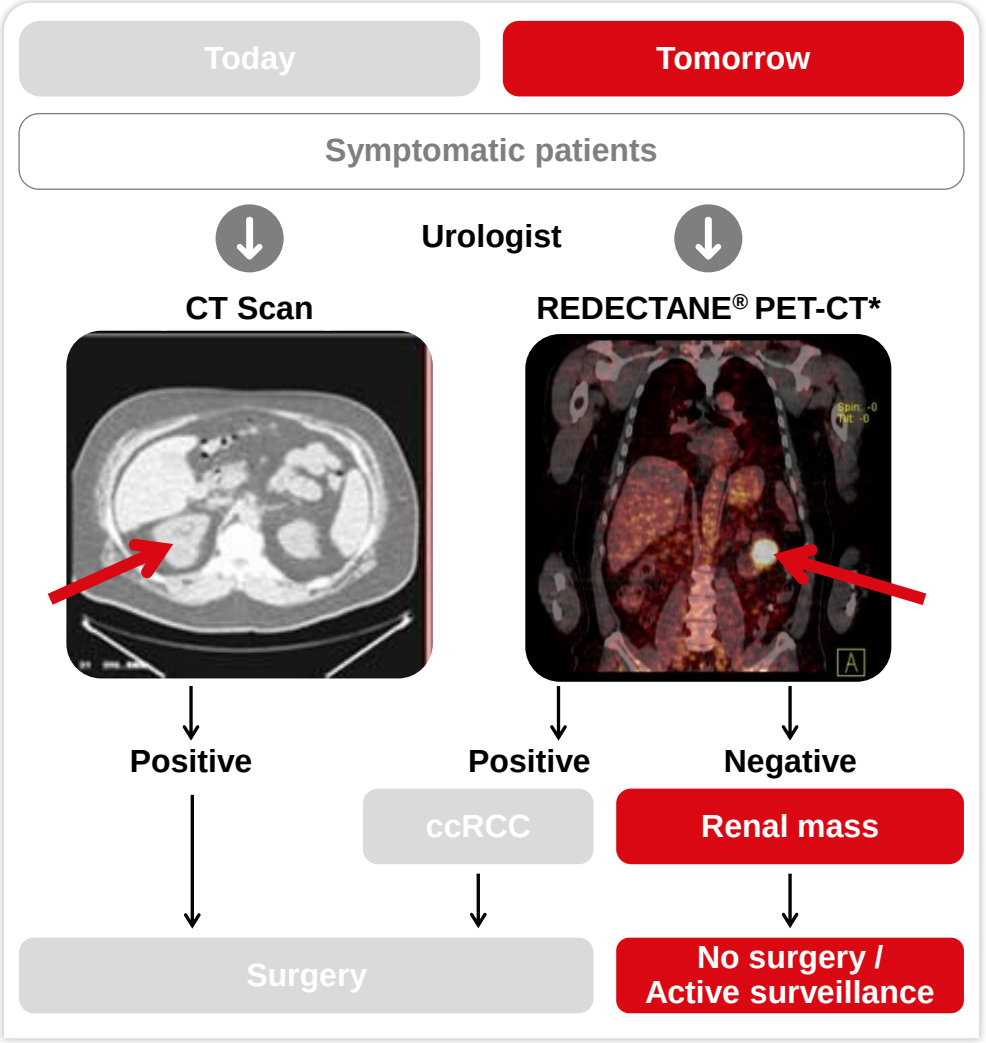
Antibody Girentuximab radio-labelled with 124I for PET-CT*

- Antibody targets CAIX antigen
- First in class imaging agent for ccRCC



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

REDECTANE® with PET/CT proved to be superior to CT in a Phase III study

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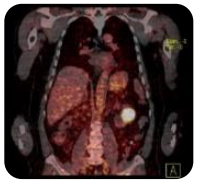
Positive data from US Phase III REDECT 1 trial (224 patients) in 2010



REDECTANE® in comparison to CT

- Specificity (p=0.001)
- Sensitivity (p≤0.016)

REDECTANE® in comparison to an arbitrary value of 75% for specificity and sensitivity

- Specificity of 87% (p=0.057)
- Sensitivity of 86% (p≤0.002)

Regulatory path

- FDA Oncologic Drugs Advisory Committee (ODAC) in 2012: Positive vote by 16 to 0 (1 abstention) in favour of diagnostic performance and clinical usefulness
- REDECT 2: FDA granted SPA on design of a confirmatory diagnostic performance trial

WILEX regained worldwide commercialisation rights from IBA Pharma in 2014

Next Step:

- Partnering and financing of the REDECT 2 trial
- Peak sale potential: USD 100 million in diagnosis of ccRCC

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Principle of anti-cancer Antibody Drug Conjugates

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Combining specificity & efficacy

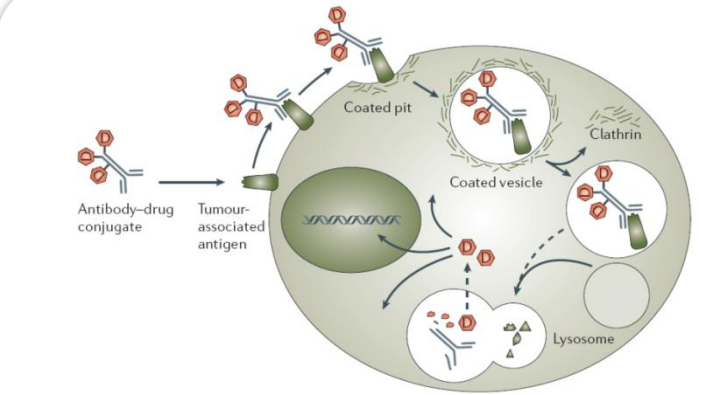
- The antibody ‘guides’ the toxin to the tumour cell
- The linker provides cleavage and release of the toxin within the targeted tumour cell
- The toxin kills the tumour cell

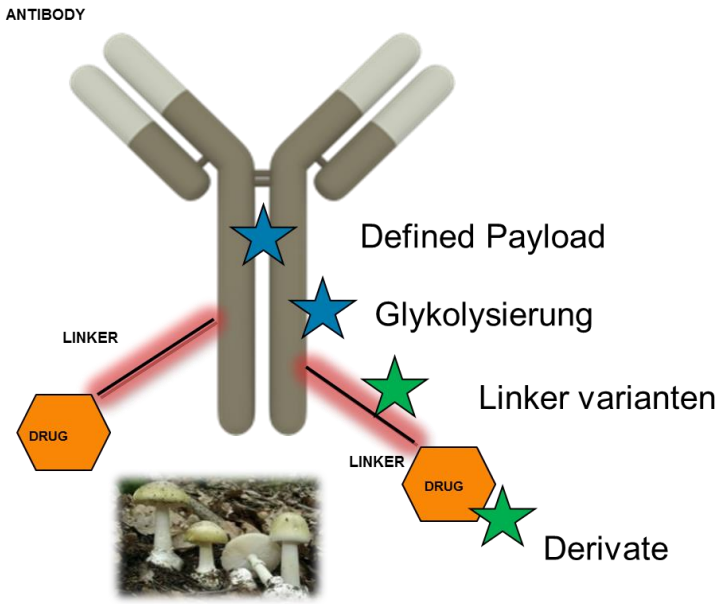
Unique mode of action

- Major toxic mechanism of Amanitin is the inhibition of RNA polymerase II (RNA pol II)
- Acting on ‘dormant’ tumour cells causing metastasis & tumour relapse; breaking of resistance
- Shows superior pre-clinical anti-tumour efficacy

What are the regulating screws to improve the therapeutic window?

- Site-specific conjugation, linker optimization and derivates





Curative potential of Amanitin-ADC superior to Roche‘s T-DM1 (FDA approved Kadcyla®)

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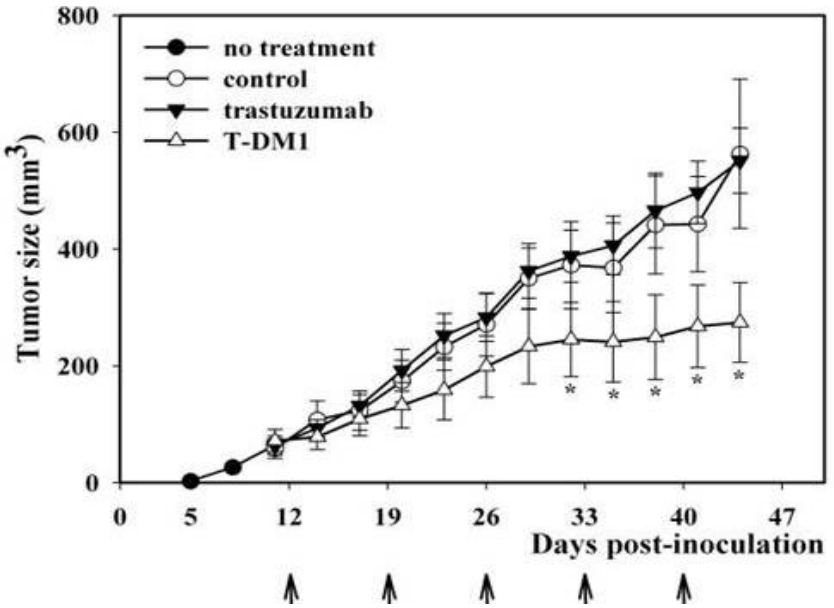
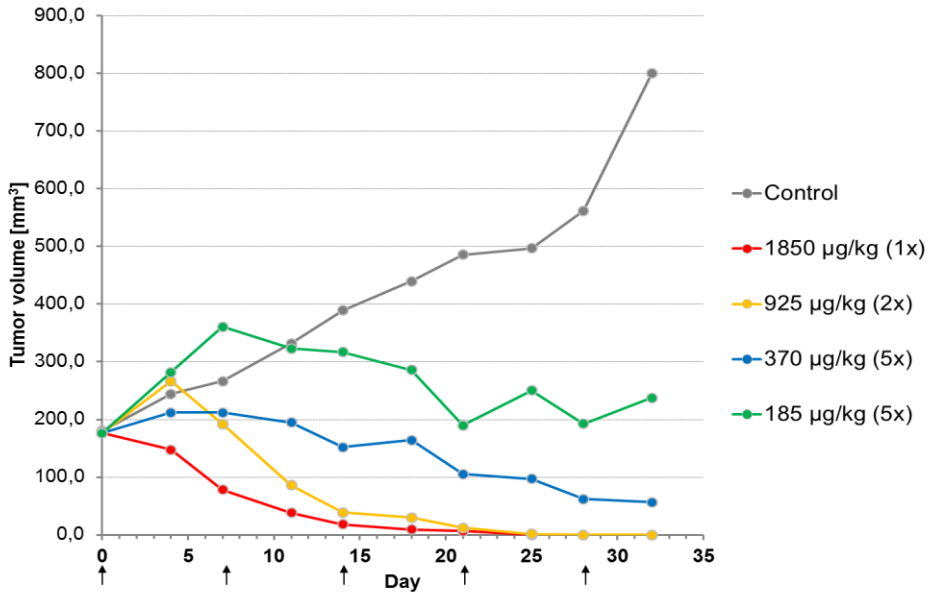
Historical data of T-DM1 in Herceptin-resistant mouse xenograft model JIMT-1



Test with Amanitin-ADC (ATAC) in Herceptin-resistant mouse xenograft model JIMT-1



1850 µg/kg of Amanitin-ADC shows higher activity than 15.000 µg/kg Trastuzumab-DM1

Roche dedicated to collaborate with WILEX

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Ongoing collaboration on Roche targets (antibodies)

Licence Agreement signed in July 2013

- MS I (off target toxicity in rodents / cynomolgus) achieved
- Targeted programme started
- Several targets blocked, number increased since start of the research programme
- Several Roche teams in Penzberg and Basel committed to intensive research with ATACs
- Undisclosed upfront and milestone payments plus royalties

One of Heidelberg Pharma's proprietary ATAC transferred to Roche

Licence Agreement ATAC with Roche signed in October 2014

- Target specific antibody licensed-in from DKFZ
- Upfront and milestone payments: € 52 million plus royalties

Outcome expectations: First ATAC supposed to reach clinic by 2017

Additional ADC activities

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Further cooperations

Big Pharma #1

- Research programmes in rodents under MTA concluded
- High gap between therapeutically effective and toxic doses: confirmation of therapeutic window
- Confirmed interest in moving to cynomolgus program

Big Pharma #2

- Research programmes in rodents under MTA started

Stock-listed, clinical stage biotech

- License Agreement in preparation

'Capstem' approaches

Joint venture with biotech

- Rodent programmes with ATACs against two tumour targets successfully finished
- Cynomolgus programs in preparation

PSMA-ATAC project for prostate tumour therapy

- BMBF grant for KMU innovative project, excellent feedback on the PSMA-ATAC approach
- Cost of € 1.8 m, 50% funded by the BMBF, 30 months
- Preclinical development strategy:
  - Manufacturing of therapeutic human PSMA antibody
  - Combination with the toxin Amanitin to PSMA-ATAC
  - Preclinical trials to determine safety, tolerability, first efficacy and dose scheme in animal models

CapStem© – project financing

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Amanitin- and linker technology

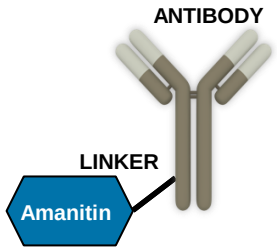
Heidelberg Pharma

Licences from academic and biotech partners

- Old and new antibodies for high unmet medical need

CAPSTEM©

2nd Generation ADCs



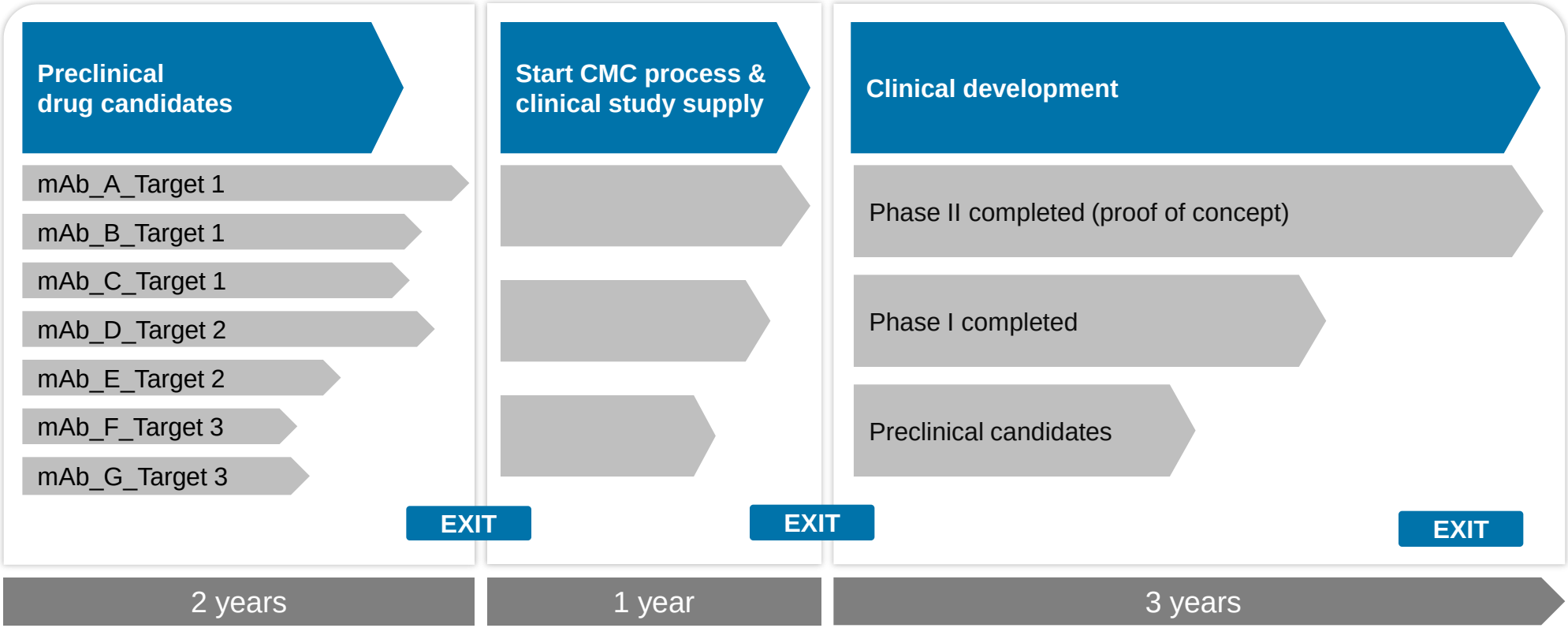
Support for medical and regulatory affairs

Support from CRO and CMO specialists

Venture Capital Funds

Financing, know-how, partner network

Capstem approach: Developing ADC candidates in a scalable business model



Status quo: 3 targets identified, access to Abs with therapeutic potential in various indications

Next step: Develop preclinical ADC candidates, selection of potentially successful ADCs

Goal: Achieve clinical proof of concept and demonstrate safety, tolerability and efficacy

Challenges in the ATAC development

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Safety & tolerability

- Recent data indicate reasonable therapeutic window in non-human primates

Antibody search

- Find the right antibody with good internalisation and tumour specificity

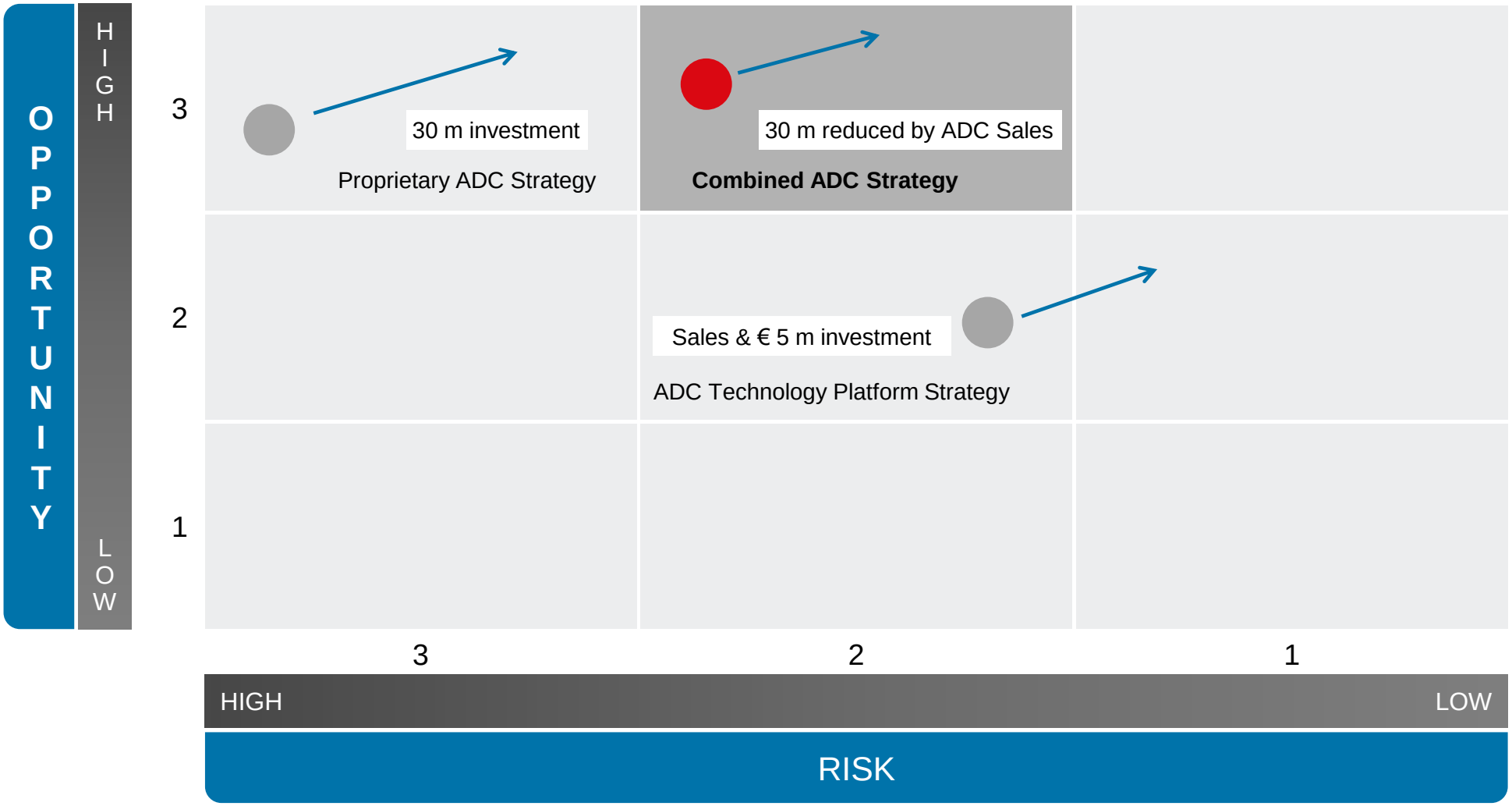
Manufacturing

- Optimization of established fermentation process
- Variation of the toxin (derivates)

Supply

- GMP supply chain for Amanitin prepared but not yet established
- Process requires approx. 12 months and € 1m of investment

ATAC – Strategic Options



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Profit and loss 9M 2014

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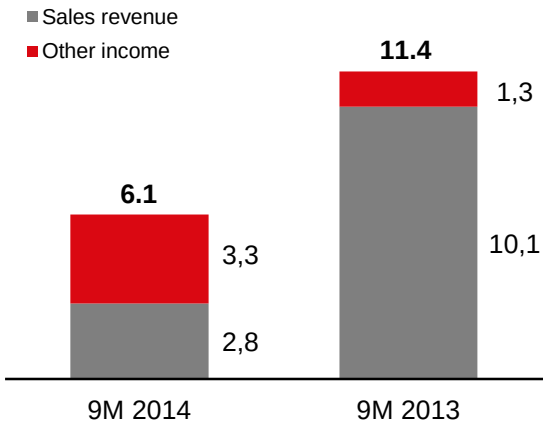
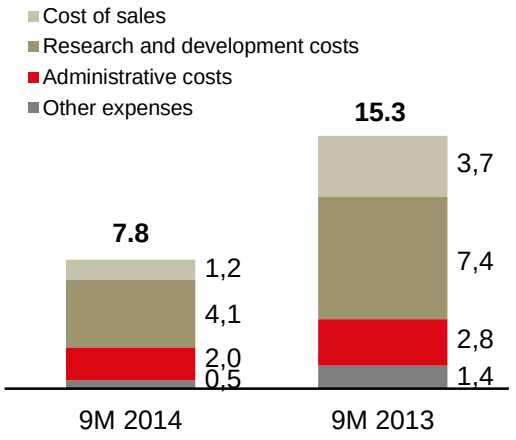
Income

€ m; rounded



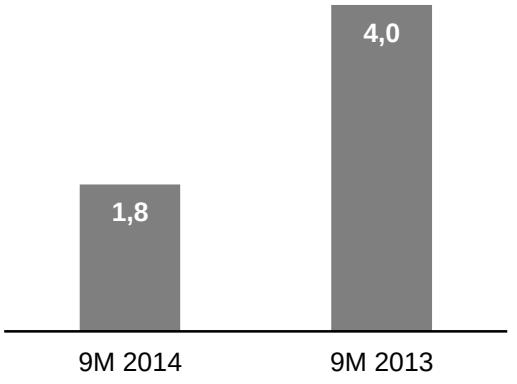
Operating expenses

€ m; rounded



Net loss for the period

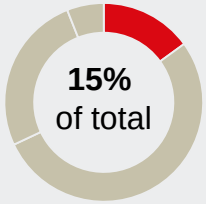
€ m; rounded



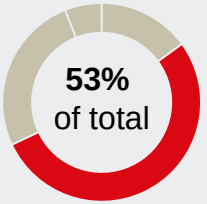
- **Sales revenue and other income decreased considerably by 46%**

- **Operating expenses significantly were lower than previous year**

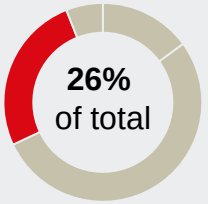
Cost of sales
68% lower



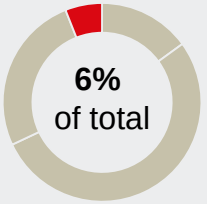
R&D costs
45% lower



Administration
29% lower



Other expenses
64% lower



- **Net loss decreased by 55% due to reduced costs, EPS improved to - € 0.07 (2013: - € 0.13)**

WILEX Group Financials 2014

in € m	Guidance 10/2014	Actual 2013
Sales revenue and other income	6.0 – 7.5	19.1
Operating expenses	8.0 – 11.0	24.1
Operating result (EBIT)	(2.0) – (3.5)	(5.0)
Total funding requirement	6.0 – 8.0	14.4
Funds required per month	0.5 – 0.7	1.2

- Income boosted by disclosure of extraordinary income by € 2.6 m from the waiver
- Funding requirements higher than anticipated, but cash burn is now € 0.3 m per month
- WILEX' cash reach is secured into Q2 2015

Shareholders

dievini Biotech: ~ 47%

UCB: ~ 14%

Freefloat: ~ 38%

Corporate bodies: ~ 1%

Shares

Share capital: 7.8 m shares

ISIN: DE000A11QVV0, WL6

Market cap: € 14 m

Analyst coverage

EDISON: target € 5.89 per share

Equinet: target € 5.52 per share

Challenges WILEX

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ADC strategy	• Mature ADC technology • Sign multiple partnering deals • Create proprietary candidate pipeline (antibody + toxin)
REDECTANE®	• Negotiate Partnering Agreement • Release Testing / Manufacturing of Antibody (ex WILEX)
RENCAREX®	• From retrospective to prospective data • CAIX companion diagnostic test development • Release Testing / Manufacturing of Antibody (ex WILEX)
MESUPRON®	• Support Link Health and RedHill • Push development activities of partners

partnered

Safe harbour

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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.

Such factors include, among others, the following: uncertainties related to results of our clinical trials, the uncertainty of regulatory approval and commercial uncertainty, reimbursement and drug price uncertainty, the absence of sales and marketing experience and limited manufacturing capabilities, attraction and retention of technologically skilled employees, dependence on licenses, patents and proprietary technology, dependence upon collaborators, future capital needs and the uncertainty of additional funding, risks of product liability and limitations of insurance, limitations of supplies, competition from other biopharmaceutical, chemical and pharmaceutical companies, environmental, health and safety matters, availability of licensing arrangements, currency fluctuations, adverse changes in governmental rules and fiscal policies, civil unrest, acts of God, acts of war, and other factors referenced in this communication.

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.

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Ticker data

ISIN:	DE000A11QVV0
Symbol:	WL6
Reuters:	WL6G.DE
Bloomberg:	WL6.GR