WILEX

Focused Cancer Therapies

Company update

January 2011

At a glance

WILEX
Focused Cancer Therapies

- 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 peak sales potential

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

* Monoclonal antibody

Commercial deals

iba

ESTEVE closer to you

ucb

- Multiple value inflexion points in the next months

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Balanced portfolio

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Product	Indication	Pre-clinical	Phase I	Phase II	Phase III	Market	Partner
REDECTANE® (antibody for diagnostic use)	Renal mass						iba (ww**)
RENCAREX® (antibody for therapeutic use)	ccRCC*						ESTEVE closer to you (Southern Europe)
MESUPRON® (small molecule uPA inhibitor)	Pancreatic cancer						
	Breast cancer						
WX-554 (small molecule, MEK inhibitor)	Cancer						ucb (ww)
WX-037 (small molecule, PI3K inhibitor)	Cancer						ucb (ww)
3 antibody programmes	Cancer						ucb (ww)

*clear cell Renal Cell Carcinoma, non-metastatic, ** worldwide

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REDECTANE®: First-in-class diagnostic imaging agent

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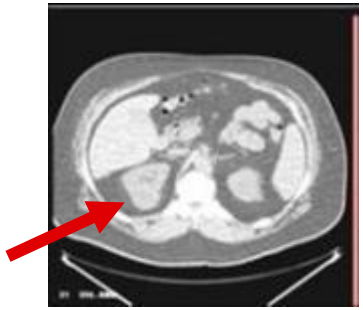
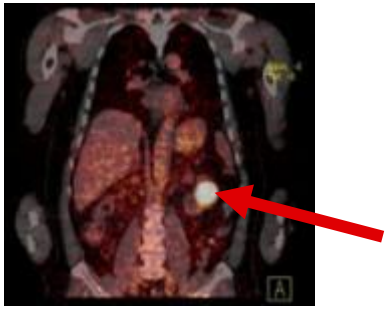
- **Radiolabelled antibody ^{124}I-Girentuximab for diagnostic use targets CA IX* antigen**
- **High medical benefit**
  - Could avoid surgery
- **Impressive proof of concept data 2006**
  - 100% specificity, 94% sensitivity
- **Strong worldwide commercial partnership with Ion Beam Applications**
  - Excellent deal terms
  - 45% royalties on ex-factory sales
  - World-wide co-promotion rights
- **Expected to be the first commercial product**
- **Peak sales potential > USD100m in kidney cancer only**
- **Market expansion through other indications possible**

Today	Tomorrow
CT Scan	REDECTANE® PET-CT**





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

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REDECTANE®: Phase III Final Study results

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- **US pivotal trial (SPA) with 226 patients in 14 centres**

- **REDECTANE® with PET/CT proves to be superior to CT**
  - Specificity: confirmed with a highly statistical value $p<0.001$
  - Sensitivity: also achieved statistical significance with $p\leq0.016$

- **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% ($p\leq0.002$)

- **FDA filing in preparation**
- **Pre BLA meeting in Q1 2011**

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RENCAREX®: First-in-class therapy for adjuvant treatment of clear cell RCC

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- **High medical benefit**
  - Targets micro-metastases to delay onset of metastatic disease
- **No drug approved by FDA / EMEA in non-metastatic ccRCC**
- **Marketing and co-development deal with Esteve for Southern Europe (2004)**
- **Peak sales potential of ~ USD500m in the indication of ccRCC**
- **Market expansion through other indications possible**

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RENCAREX®: (INN: girentuximab)
Antibody for therapeutic use

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- **Monoclonal antibody**
  - Specifically binds to the antigen CA IX on tumour cells
  - Validated mechanism of action (ADCC*)
- **Phase II studies confirm biological activity**
  - Increased survival of RCC patients with late stage metastatic disease
- **Pivotal 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
- **Potential filing for approval at EMA in 2011**
  - 343 relapses expected in Q1/2011 (338 relapses in December 2010)
  - IDMC recommendation 6 months later

* Antibody Dependant Cellular Cytotoxicity

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

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- **Oral small molecule targeted therapy**
  - 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**
- **Worldwide partnership planned**
- **Peak sales potential of ~ USD 1 billion for various indications**

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MESUPRON®: Phase II
Encouraging clinical proof of concept data

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→ **Phase II randomised trial of 95 pancreatic cancer patients successfully completed**

Final data	Gemcitabine alone	Gemcitabine & MESUPRON® (200 mg)	Gemcitabine & MESUPRON® (400 mg)	Improvement***
Tumour response*	15.4%	21.4%	35.5%	doubled
PFS rate at 12 months	16.2%	22.5%	26.9%	66%
Median OS (months)**	9.9	9.7	12.5	26%
1 year survival	33.9%	40.7%	50.6%	49%

* Partial response (All CTs were assessed by central independent radiology. Responses were assessed from Waterfall plots using RECIST cut-off criteria.)
*** Poplin et al JCO Aug 2009: 9.2 months for Gemcitabine*
**** Improvement between Gemcitabine alone and Gemcitabine & MESUPRON 400mg*
PFS /progression free survival , OS / overall survival

→ **Phase II trial of 114 breast cancer patients ongoing**

- → First line therapy for HER2 receptor negative metastatic breast cancer
- → Combination therapy with Capecitabine, double-blind design
- → 103 patients recruited at the end of 09 2010 in 21 centres (Europe, USA, Brazil)
- → Completion of recruitment expected Q1 2011, study data (PFS) expected in 2012

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Heidelberg Pharma at a glance
www.heidelberg-pharma.com

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Profile	→ Focused on novel cancer therapies
Business model	→ ADC technology platform business → Preclinical contract research business
Capabilities	→ Proprietary antibody drug technology → Preclinical: Bioanalytics, Cell Biology, Pharmacology
Structure	→ Privately held company → Investments of approximately € 41 million since 2004
Organisation	→ Founded in 2004 → Located in Ladenburg, Germany → 34 Employees
Financials	→ Revenues through preclinical contract research business

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Heidelberg Pharma – ADC technology

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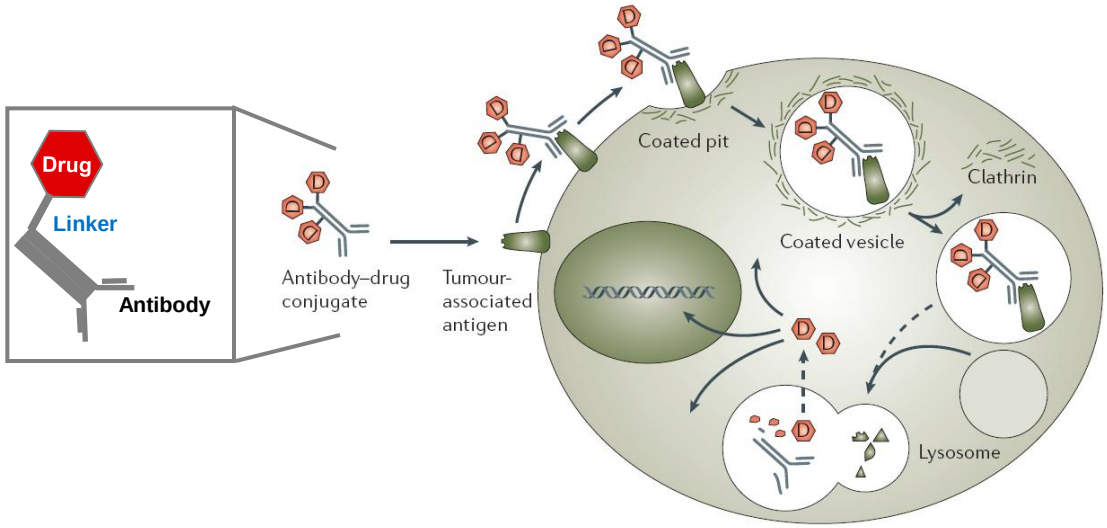
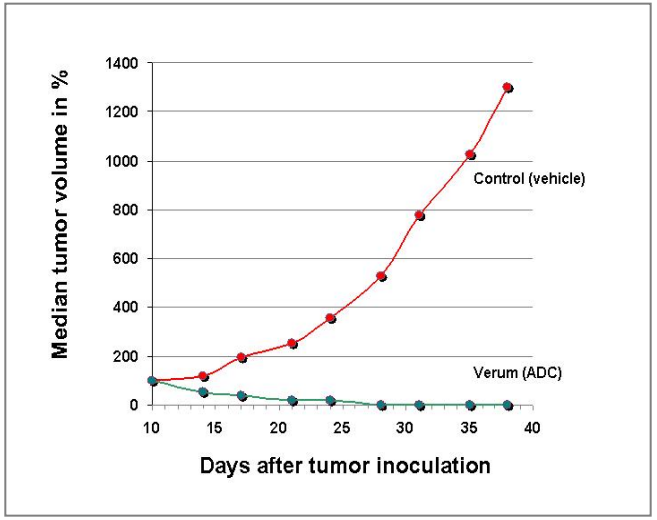


Tumor cell



- → Mode of action: The antibody guides the toxin high selectively to the tumour cell, the linker provides cleavage and release of the toxin within the targeted tumour cell ONLY, the toxin kills the tumour cell
- → Combining specificity & efficacy
- → Proof of concept in vivo tumour model showed impressive results

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Heidelberg Pharma – deal rationale

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WILEX	Heidelberg Pharma
Oncology focused drug development	Oncology focused research and technologies
Therapeutic and diagnostic antibodies	Antibody drug conjugates
Late stage clinical pipeline	Preclinical research expertise, facilities and contract research business with revenues
Proven clinical development expertise	

→ **Access to novel platform technology and instant revenues from services**

- → Provides novel preclinical candidates for the WILEX therapeutic antibody pipeline
- → Significant revenue potential from ADC platform and research alliances

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Heidelberg Pharma – deal structure

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- **WILEX acquires 100 % ownership**
  - by issuing 3,200,000 new WILEX shares
  - by a non-cash capital increase excluding shareholders' subscription rights
- **Transaction volume**
  - Equates EUR 19.2 million for Heidelberg Pharma
  - EUR 6.00 for each newly issued WILEX share
  - Ratio WILEX to Heidelberg Pharma : 5.75 to 1
- **EGM on 15 December 2010**
  - WILEX shareholders' approval and issuance of 3,200,000 new WILEX shares to shareholders of Heidelberg Pharma
  - Create new authorised capital (approximately 50% of the current share capital; up to 9,206,517 new WILEX shares)

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Oncogene Science at a Glance
www.oncogene.com

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Profile	→ Strategic IP and commercial products in Companion diagnostics
Business Model	→ Manufacturing and commercialisation of oncology biomarker assays
Products	→ Biomarker diagnostics (ELISA and IHC): HER-2, CA IX, uPA, PAI-1, EGFr, TIMP
Capabilities	→ GMP manufacturing facility → State of the art facilities and equipment
Structure	→ Former Companion diagnostics business unit of Siemens Healthcare → Now a business unit and brand of WILEX Inc.
Organization	→ Founded 1983 → Located in Cambridge, MA/USA → 10 Employees
Financials	→ Cash flows from product sales to existing customers (US)

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Oncogene Science – Companion diagnostics

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Positioning

- IP and test for companion diagnostics to provide tools for targeted therapies

Advantages

- Measuring proteins in blood with ELISA tests
- Bioanalytical methods designed to select patients for therapy
- Assessment how patients will respond to a specific medical treatment
- Monitoring of patient's treatment and outcome

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Oncogene Science – deal rationale

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WILEX	Oncogene Science
Therapeutic and diagnostic products	Biomarkers, assays in Companion Diagnostics
RENCAREX and REDECTANE (CA IX)	CA IX/MN ELISA and IHC
MESUPRON (uPA)	uPA ELISA, PAI ELISA
	HER-2 ELISA (only one FDA approved)

→ **Strong product synergies to WILEX' therapeutics**
→ **Sales revenues in companion diagnostics**

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Oncogene Science – deal structure

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- **WILEX Inc., Cambridge, MA, USA founded**
- **Acquisition of core assets for approx. € 500 k**
  - Access to Oncogene's IP via licenses
  - Inventory, equipment and stock of marketable products
- **Siemens receives low single to mid digit royalties on product sales**
- **Siemens retains the right to use Oncogene Science products on their automated platforms**
- **Lease contract for existing facilities transferred**
- **Experienced management and staff retained**
- **Oncogene Science is a business unit and brand of WILEX Inc.**

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Strategic Fit

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	Heidelberg Pharma	WILEX AG	WILEX Inc./Oncogene
Profile	Platform technology	Therapeutics and diagnostics	Companion diagnostics
Indications	Oncology	Oncology	Oncology
Activities	Discovery /research	Clinical development and commercialisation	Manufacturing, marketing and sales
Products	Antibody drug conjugates	Antibodies and small molecules	Diagnostic assays and biomarkers
Time to market	Research / preclinical	Filing for approval , Phase III	On the market

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Structure of the new WILEX

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→ **Fully integrated biopharmaceutical company focussed on oncology**

Clinical Product Development

Companion Diagnostics

Preclinical Services

ADC Platform Technology

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Professor Olaf G. Wilhelm;
Dr Paul Bevan,
Dr Thomas Borcholte,
Peter Llewellyn-Davies

WILEX Inc.

Professor Olaf G. Wilhelm;
Peter Llewellyn-Davies

Heidelberg Pharma AG

Dr. Jan Schmidt-Brand

→ **Transition from R&D to commercially driven business**

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Financials: Q3 2010

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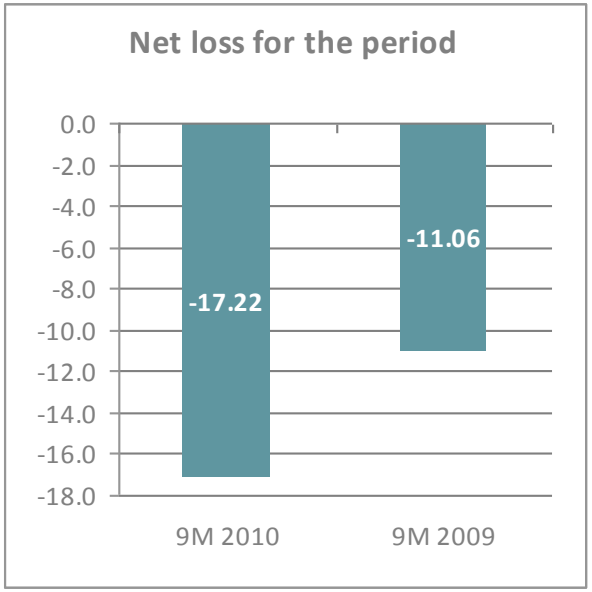
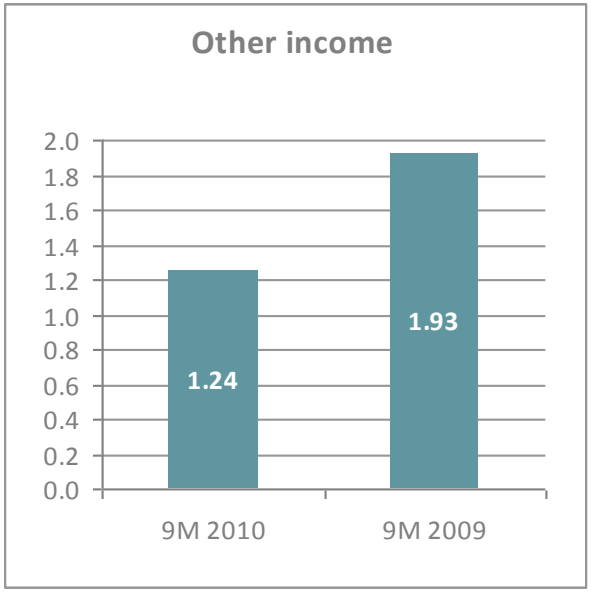
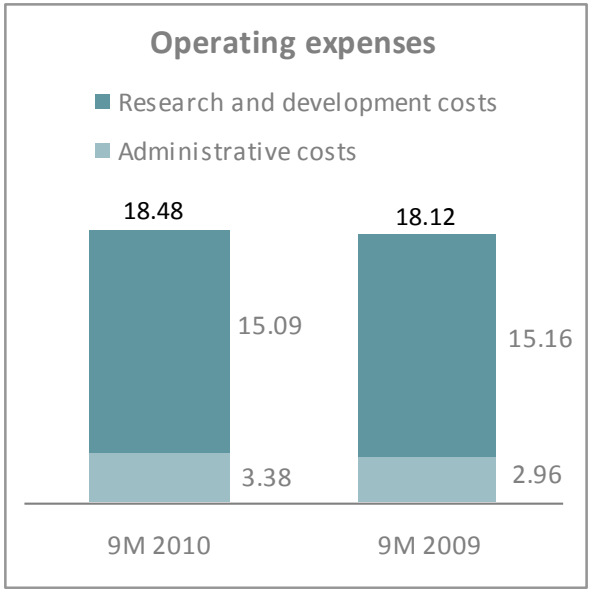
*€ m; rounded







- → Net loss for the period € 17.22 m, 55.7% above 9M 2009
- → Other income at € 1.24 m, 35.4% below 9M 2009
- → Operating expenses up 2.0%, R&D costs are 81.7% of total
- → Cash balance as at 31.08.10 € 7.76 m
- → Average cash usage per month € 2.11 m (9M 2009: € 2.01 m per month)

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Implications on Financial Guidance

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→ **Adjustment of financial guidance 2010 (provided in February 2010)**

In € mill	Guidance 02/2010	Update Guidance 11/2010	Implication
Sales	n/a	n/a	
Other income	1.5-3.0	1.3 – 1.6	Lower deferred accruals
Operating expenses	26 – 30	24 – 26	Lower R&D costs
Of which R&D	22 –26	20 – 23	Lower costs in the ARISER and REDECT trials
Cash reach	Q2 2010	Q1 2011	Longer due to cost reduction and capital increase

→ **Further financing secured with shareholder loan of up to € 10m**

→ **Cash reach Q2 2011**

→ **Guidance 2011**

- → will be published at the Press and Analyst Conference in February 2011

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Shareholders and Equity

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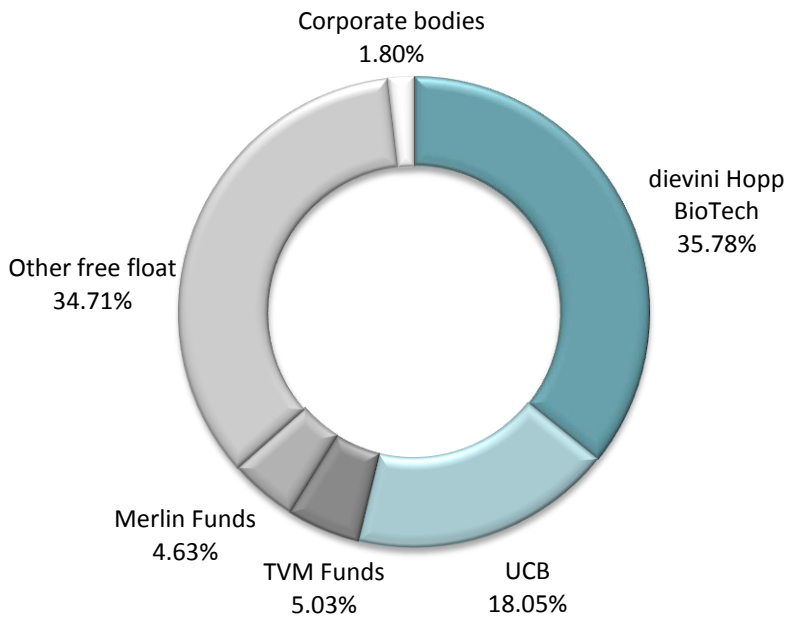
→ Shareholder structure



→ Capital raised

- → €68m private funding
- → €55m IPO in 11/2006
- → €10m UCB transaction in 02/2009
- → €8.5m net capital increase in 12/2009
- → €10m rights issue in 08/2010

→ Stock Exchange data

- → FSE Prime Standard (Ticker symbol: WL6)
- → 18,413,035 shares (€1.00/per share)

→ Financial calendar

- → 22 Feb. 2011 Annual Report 2010
- → 13 April 2011 3-month Financial Report 2011
- → 18 May 2011 Annual General Meeting 2011
- → 14 July 2011 Half-yearly Financial Report 2011
- → 13 Oct. 2011 9-month Financial Report 2011

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News flow 2010 / upcoming months

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Corporate

- ✓ SEDA signed; Equity line over 36 months
- ✓ Rights issue: €10m raised in August 2010
- ✓ Take over bid from dievini
- ✓ Acquisition of Oncogene Science
- → Acquisition of Heidelberg Pharma AG, formal share transfer
- → Commercialisation

REDECTANE®

- ✓ Final Phase III data and report
- → Application for approval in preparation, Pre BLA meeting

RENCAREX®

- → Announcement of 343 relapses in ARISER trial followed by interim analysis for efficacy 6 months later

MESUPRON®

- ✓ Final Phase II data in pancreatic cancer
- → Completion of patient recruitment in Phase II breast cancer trial

WX-554

- ✓ Complete Phase I healthy volunteer study

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Forward looking statements

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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.

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Bloomberg: WL6G.GR

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