



BioEquity Europe 2009

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## Forward-looking statements

This presentation includes forward-looking statements based on the beliefs and expectations of the Company. These statements are based on the Company's current plans, estimates and projections, as well as of expectations of external conditions and events. All such forward-looking statements involve inherent risks and uncertainties. Hence actual results could differ materially from those discussed in, or implied by, these statements.

# BioInvent in summary

- Focus on therapeutic antibodies - the fastest growing segment in the pharmaceutical industry.
- An exciting pipeline of Product Candidates addressing large market segments.
- Strong discovery & development engine feeds the product portfolio.
- Business model and technology platform validated through numerous partnerships.
- Supporting cash generating service business
- Capitalised value as of today: ~1500 MSEK
- Located on the Ideon Science Park in Lund, Sweden
- 100 employees












## Product pipeline overview

Project	Indication	Research	Preclinical Development	Clinical Phase I	Clinical Phase II	Clinical Phase III	Partner
TB-402	Deep vein thrombosis Atrial fibrillation						
TB-403	Cancer						
BI-204	Secondary prevention of cardiac events in high-risk patients						
BI-505	Cancer						
Internal research programs	Cancer						
	Macular degeneration						
	Anti-inflammation						

# Commercial achievements to date

## Selected partners

Internal Portfolio	BI-204 US License & Co-Development		<ul style="list-style-type: none"><li>➤ 320 MSEK received so far</li><li>➤ Up to 3300 MSEK in future milestone payments</li><li>➤ Royalty on Product sales</li><li>➤ Value from retained rights</li></ul>
	TB-403 Global License & Co-Promotion		
Technology Provider	Discovery of Product Candidates	   "Undisclosed Japanese pharma"	<ul style="list-style-type: none"><li>➤ Potentially more than 20 programs</li><li>➤ Up to ~100 MSEK in future milestone payments per program</li><li>➤ Royalty on Product sales</li><li>➤ Cost of program fully funded by partner</li></ul>
	Process Development & Clinical Supply	   	<ul style="list-style-type: none"><li>➤ Average annual turnover of ~ 50 MSEK recent years</li></ul>

• • • • • TB-402: Novel anti-coagulant therapy

	Patient numbers (000s)						
	2005	2007	2009	2011	2013	2015	CAGR
Atrial Fibrillation Chronic therapy	8492	8800	9106	9401	9721	10041	1,55 %
Venous Thromboembolism ≥3-6 months of therapy	976	1008	1040	1069	1100	1131	1,35 %
Total Hip Replacement ≥1 month of therapy	896	988	1072	1140	1230	1312	3,85 %
Total Knee Replacement ≥ 10-14 days of therapy	958	1136	1306	1443	1599	1766	7,05 %

## TB-402: Novel anti-coagulant therapy

### Mode of action

- Human Ig4 antibody against Factor VIII
- Partial, well controlled inhibition of Factor VIII
  - Factor VIII activity reduced to levels found in mild haemophilia A patients
  - Plateau inhibition

### Product Advantages

- Long acting plateau effect
  - Single injections for acute indications, monthly for chronic conditions
  - No need for routine monitoring
  - Low risk of overdosing
- Antidote available
  - Factor VIII concentrates
- Fully human
- Low risk of drug interaction

## TB-402: Phase I studies

### Phase I Studies

- A randomised, placebo-controlled, dose escalation study of a single I.V. administration of TB-402 in 56 healthy male volunteers
- Double-blind, placebo-controlled, single dose TB-402 in 12 male HV Randomised to treatment with rFVIII
- Double-blind, placebo-controlled, single dose TB-402 in 12 male HV. Randomised to treatment with warfarin or low LMWH

### Phase I results

- TB-402 was safe and well-tolerated
  - No serious treatment-emergent adverse events possibly related to TB-402
  - Bleeding complications
    - No major or clinically significant bleeding
- Half-life: 21 Days
- Anticoagulant effect demonstrated > 4weeks
- Targeted “plateau effect” demonstrated
- Activity reversed by recombinant factor VIII
- No safety issues in combination with LMWH and warfarin

## TB-402: Post surgical thromboprophylaxis following knee surgery

Ongoing  
Phase II  
“proof of  
concept”

- Open dose escalation study
- Three dose levels of TB-402
  - Single injection
- Active control (enoxaparin)
  - >10 days
- 36 centers mainly Central Europe
- 300 patients
- Primary outcome measurements
  - Composite of the occurrence of asymptomatic DVT as detected by bilateral venography and symptomatic VTE, i.e. DVT or fatal or non-fatal PE
  - Occurrence of total bleeding defined as major and/or clinically relevant non-major bleeding events, from randomisation until end of study

## TB-403: Novel angiogenesis inhibitor for the treatment of cancer

### Markets

- Anti-angiogenesis proven commercially: Avastin (anti-VEGF) > 4 billion US \$ in annual revenues 2008

### Mode of action

- Inhibits PlGF – a homologue of VEGF.
- PlGF is overexpressed in several tumours
- PlGF upregulated during Avastin therapy of colon cancer
- Low side effects: Targets only pathogenic angiogenesis
- Less likely development of resistance

### Status

- Phase Ia completed
- Phase Ib ongoing
- Partnered with Roche

### Opportunity

- Combination with chemotherapy in major markets
- Combination with chemotherapy and Avastin in major markets
- Treatment of patients who progress during Avastin therapy

## TB-403: Phase I studies

### Design of single dose trial

- Double-blind and within-group randomised trial testing single-doses of TB-403 or placebo at three escalating levels in 16 healthy male subjects

### Results

- TB-403 was safe and well tolerated

### Design of repeat-dose trial

- Open, dose escalation study
- Tolerability, pharmacokinetics and pharmacodynamics in patients with advanced cancer having failed prior therapy
- Objective tumour response
- Set the dosage of for future Phase II trials

## BI-204: Secondary prevention of acute coronary syndromes

### Markets

- Positioning: Secondary prevention of cardiac events in high-risk patients
- The post-myocardial infarction population accounts for 15.4 million patients in five major markets
- First in class addressing the underlying cause of plaque build up
- Currently no efficient treatment for this group on market / in pipeline

### Mode of action

- BI-204 binds a specific peptide from oxidized Apo-B100
- Reduces the inflammatory process
- Reduces the size of pre-existing plaque and the plaque build up

### Status

- Phase I successfully concluded. Decision to move to phase II expected in Q2-2009.

### Rights

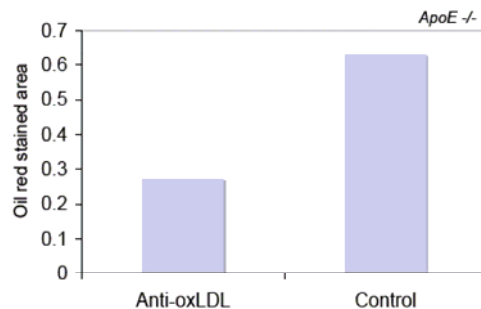
- Rights: North America licensed to Genentech, BioInvent retained RoW

## BI-204 characteristics

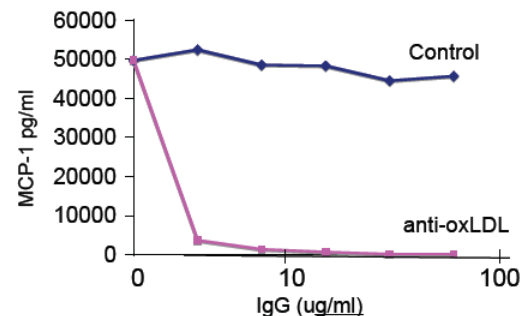
- BI-204 is an n-CoDeR-derived fully human antibody targeting oxidized LDL
- Targets what is believed to be a primary cause of atherosclerotic disease: vascular inflammation
- Reduces the size of pre-existing plaque
- Inhibits induction of MCP-1 by lipoproteins present in human serum

### **BI-204 (anti-oxLDL) reduces plaque build up and blocks MCP-1 secretion in vitro\***

Reduces median plaque build up with > 50% during a 4 week treatment period

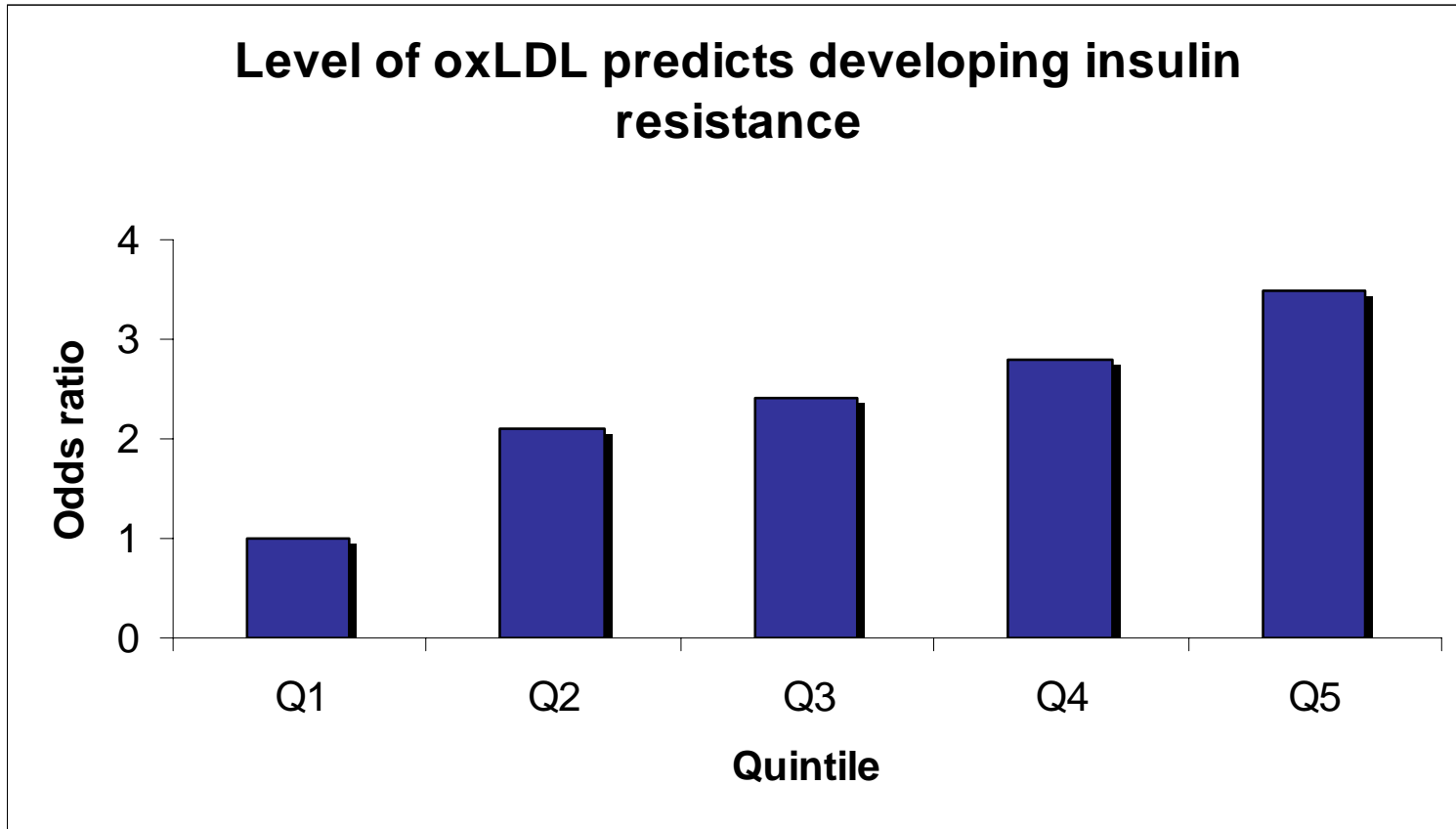


Efficiently blocks MCP-1 secretion in vitro from macrophages



\* Efficacy data from mouse models; source: BioInvent

# Oxidized LDL May Play a Role in Insulin Resistance



JAMA. 2008; 299 (19) 2287-2293

## BI-204: Phase I

### Study Design

- Double blind, placebo controlled, dose escalation study
- Single and multiple doses administered intravenously and subcutaneously
- 80 healthy volunteers with elevated levels of LDL

### Results

- BI-204 was safe and well tolerated
- Half-life: As expected for human antibodies

## BI-505: New candidate to treat certain hematological malignancy and cancer

### Markets

- 200 000 patients diagnosed with blood cancer per year

### Mode of action

- Fully human high affinity IgG1 antibody
- Targets ICAM-1
- Over expressed in tumours and restricted expression in normal tissue
- Induces apoptosis and triggers immune effector functions that helps to kill tumour cells

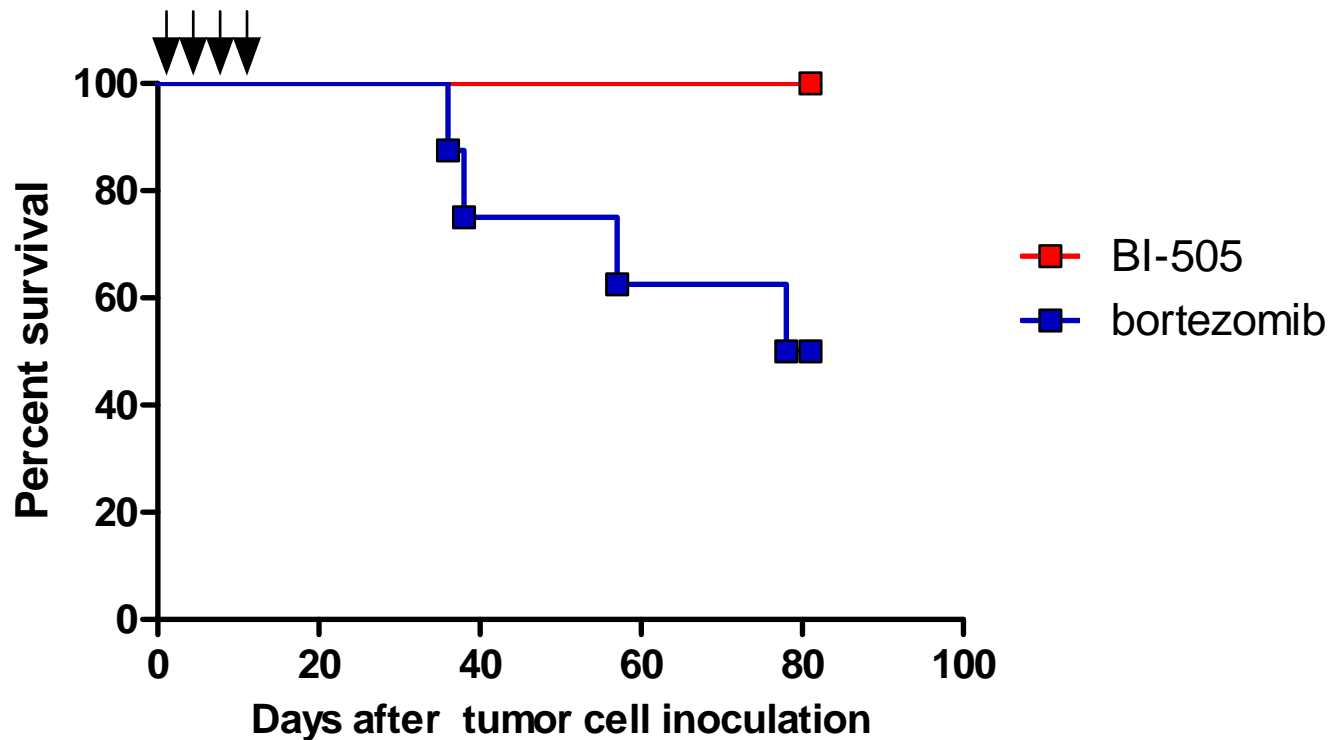
### Status

- Preclinical data demonstrating highly efficacious and potent anti-tumour activity
- Strong IP position and Orphan Drug Designation in Europe and US
- Phase I expected to start Q3

### Rights

- 100% BioInvent

## BI-505 has competitive anti-myeloma activity *in vivo*



**Experimental Design:**

Irradiated Female Fox Chase *scid* mice were injected IV with  $1 \times 10^6$  ARH-77 myeloma cells, 2mg/kg Ab was administered i.v for 4 times, d1, d3, d7, d110, as indicated by arrows. There were 8 animals per group.

## Key Financials

<b>SEK million</b>	<u>Annual accounts</u>		<u>Jan. - March</u>	
	<b>2008</b>	<b>2007</b>	<b>2009</b>	<b>2008</b>
Net revenues	252.1	143.4	36.8	16.2
Sales and administrative costs	-30.9	-28.7	-8.7	-6.9
Research and development costs	-214.6	-138.2	-64.4	-51.0
<b>Operating profit/loss</b>	<b>6.6</b>	<b>- 23.4</b>	<b>-36.3</b>	<b>-41.7</b>
Profit/loss from financial investments	9.7	7,4	1.6	1.8
<b>Profit/loss for the year</b>	<b>16.3</b>	<b>- 16.1</b>	<b>-34.7</b>	<b>-39.9</b>
<b>Cash and cash equivalents</b>	<b>212.5</b>	<b>216.9</b>	<b>192.3</b>	<b>157.7</b>

## Forthcoming project milestones



### Drug Candidate/Event

### Timing

➤ **BI-204**

- Decision to start phase II

Q2-2009

➤ **TB-403**

- Phase Ib results expected

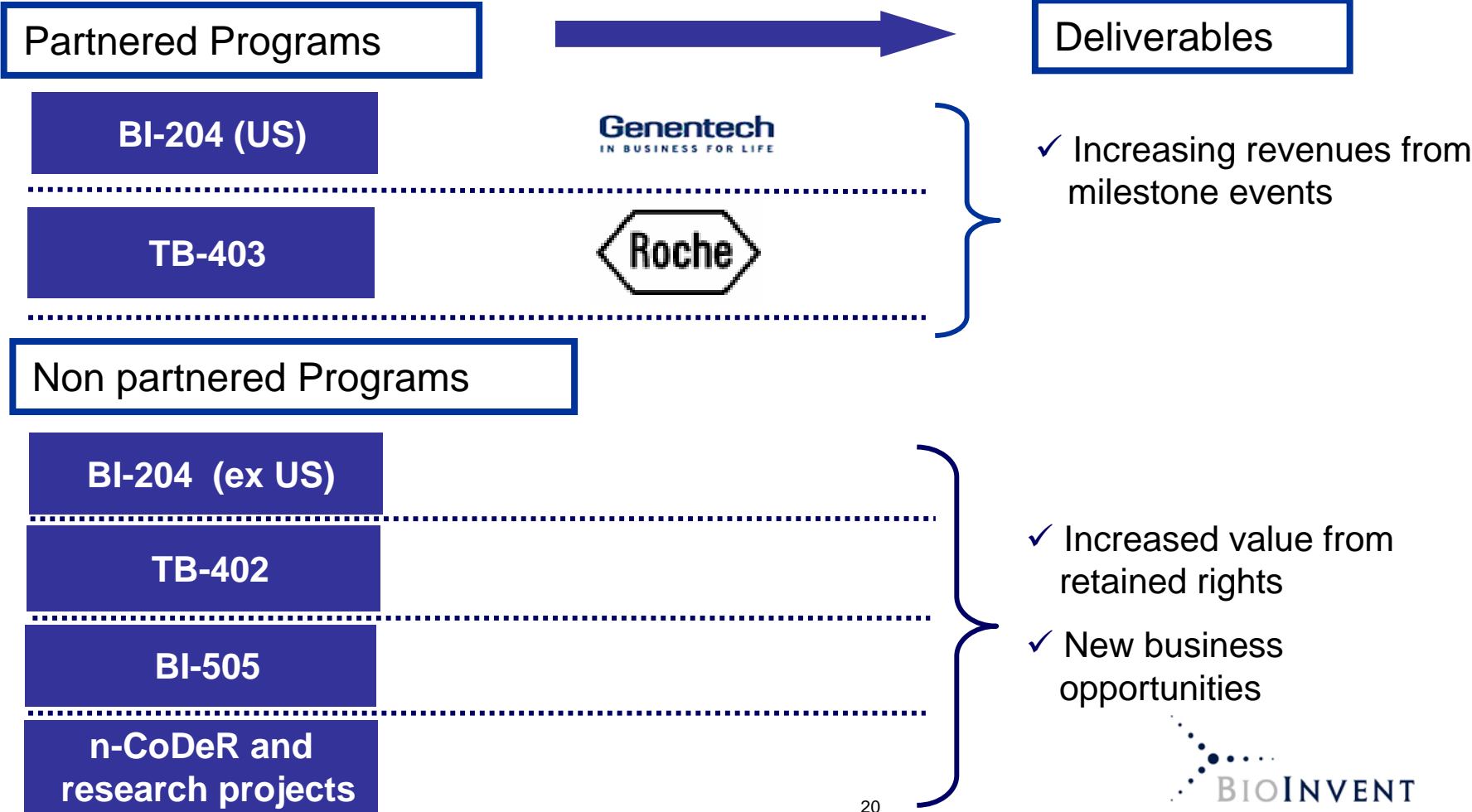
Q3-2009

➤ **BI-505**

- Start phase I

Q3-2009

# Partnered and non partnered programs





Thank You.