



## Q3 Results and Update on R&D Progress

NOVEMBER 9, 2010

*Intercell* develops *vaccines*   
for the  *prevention and treatment*  
of *infectious diseases* .

For more information be invited to: [www.intercell.com](http://www.intercell.com)



## Forward-looking statements

These materials contain certain forward-looking statements relating to the business of Intercell AG (the “Company”), including with respect to the progress, timing and completion of the Company's research, development and clinical trials for product candidates, the Company's ability to manufacture, market, commercialize and achieve market acceptance for product candidates, its ability to protect its intellectual property and operate its business without infringing on the intellectual property rights of others, the Company's estimates for future performance and its estimates regarding anticipated operating losses, future revenues, capital requirements and its needs for additional financing. In addition, even if the Company's actual results or development are consistent with the forward-looking statements contained in this presentation, those results or developments may not be indicative of the Company's results or developments in the future. In some cases, you can identify forward-looking statements by words such as “could,” “should,” “may,” “expects,” “anticipates,” “believes,” “intends,” “estimates,” or similar words. These forward-looking statements are based largely on the Company's current expectations as of the date of this presentation and are subject to a number of known and unknown risks and uncertainties and other factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievement expressed or implied by these forward-looking statements. In particular, the Company's expectations could be affected by, among other things, uncertainties involved in the development and manufacture of vaccines, unexpected clinical trial results, unexpected regulatory actions or delays, competition in general, the impact of the global credit crisis, and the Company's ability to obtain or maintain patent or other proprietary intellectual property protection. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements made during this presentation will in fact be realized. The Company is providing the information in these materials as of this date, and we disclaim any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

» **Introduction & Strategy**

*Gerd Zettlmeissl, CEO*

» Progress in Japanese Encephalitis

*Staph Bakali, CBO*

» Nosocomial vaccines

*Thomas Lingelbach, COO*

» Additional key pipeline programs

*Thomas Lingelbach, COO*

» Financial performance & Outlook

*Reinhard Kandra, CFO*

## MANAGEMENT BOARD



**Gerd Zettlmeissl,  
CEO**

Former CEO of  
Chiron Behring, co-  
inventor of Enbrel



**Staph Leaven-  
worth Bakali, CBO**

Appointed CBO in  
October 2010,  
former CEO of  
Genocea  
Biosciences



**Thomas  
Lingelbach, COO**

Former Vice  
President Industrial  
Operations Chiron  
Vaccines, Managing  
Director for Novartis  
Vaccines Germany



**Reinhard Kandra,  
CFO**

Appointed CFO in  
March 2009, more  
than 8 years with  
Intercell,  
formerly Deutsche  
Bank

Today's focus!

## DRIVING VACCINE INNOVATION

### 1 New travelers' vaccines

- » Japanese Encephalitis vaccine – approved and launched in U.S., EU\*, Canada and Australia – long term U.S.-military contract signed
- » Travelers' Diarrhea vaccine patch – in pivotal Phase III

### 2 Nosocomial vaccines

- » S. aureus prophylactic vaccine against hospital-acquired infections – in Phase II/III\*\*
- » **Pseudomonas prophylactic vaccine for ICU patients – in Phase II**
- » Clostridium difficile vaccine against hospital-acquired Diarrhea – Phase I start in 2010 **New**

### 3 Leading product technologies and strong pipeline

- » AIP® – generating novel vaccine and antibody product candidates
- » IC31® – new vaccine adjuvant
- » Vaccine patch – highly efficient vaccine delivery
- » Additional clinical pipeline products: Flu vaccines (pandemic & seasonal), Pneumococcus vaccine, Tuberculosis vaccine, therapeutic Hepatitis C vaccine

### 4 Strong alliances and excellent strategic position

- » Strategic alliances with Novartis, GSK, Merck & Co, sanofi pasteur, Pfizer
- » Facilities in Austria (headquarters), Scotland, USA; more than 400 employees
- » Strong financial position – growing revenue base, significant R&D investments and strong cash position\*\*\*
- » Listing: VSE (ATX)

\* Key countries

\*\* Sequential design, conducted by Merck & Co., Inc.

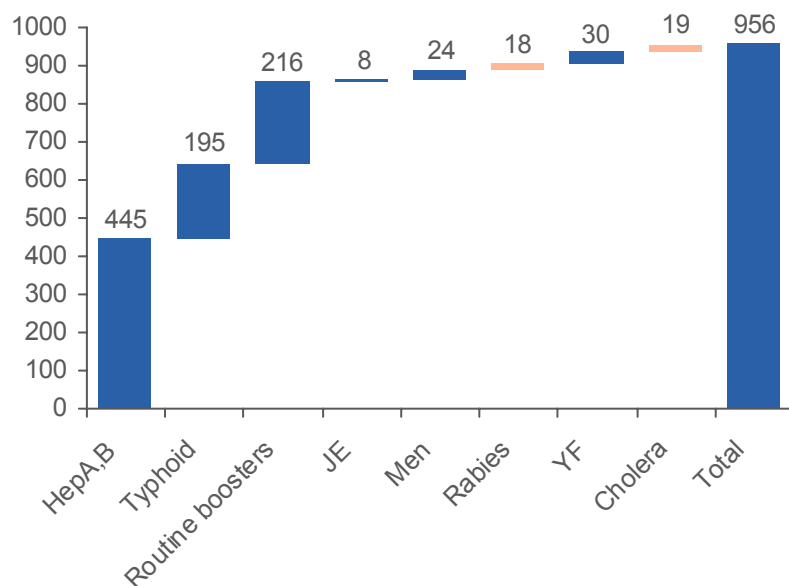
\*\*\* ~EUR 107m by end Q3 2010

- » Introduction & Strategy  
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# Travel vaccine market estimated to be ~USD 1bn globally – taken ~10 years to build

## OVERVIEW

Travel vaccine market (2007)  
in USD m



### Travel Market has unique characteristics

- » Predominantly a private market, based on individual traveler choice
- » Requires investment to increase awareness of risk with health care providers and travelers
- » Development of a travel franchise to deliver cross sales opportunity and service offering

### JE-specific characteristics

- » No previously licensed product in EU
- » Limited disease awareness amongst travelers and HCPs due to minimal promotion of former mouse-brain derived vaccines
- » High impact, low incidence profile

### Launch Years

- » **Havrix** (GSK) 1992 (EU), 1995 (US)
- » **Twinrix** (GSK) 1997 (EU), 2001 (US)
- » **Typhim Vi** (sanofi) 1998 (US)

# The positive sales trend continues

## IXIARO®/JESPECT® SALES IN THE FIRST 9 MONTHS 2010

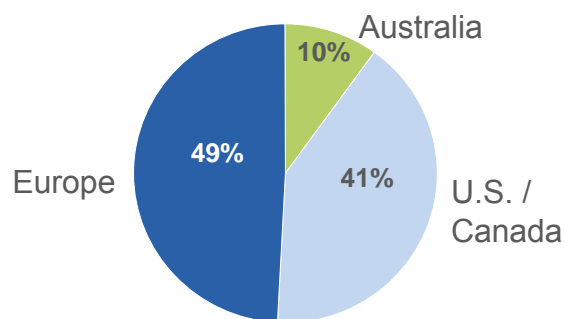
### Growth Momentum

- » Strong Year on Year growth (68%)
- » Increased penetration in key markets
- » Growth momentum expected to increase in 2011

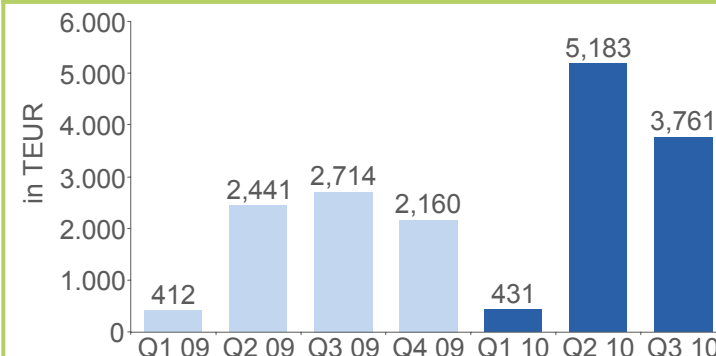
### Growth Drivers

- » Full year of sales and marketing efforts
- » Increased disease and brand awareness
- » Increased penetration in key markets
- » Increased usage by military
- » Broader recommendations

### Total Sales Q3 YTD: EUR 9.4m



### Revenue Growth



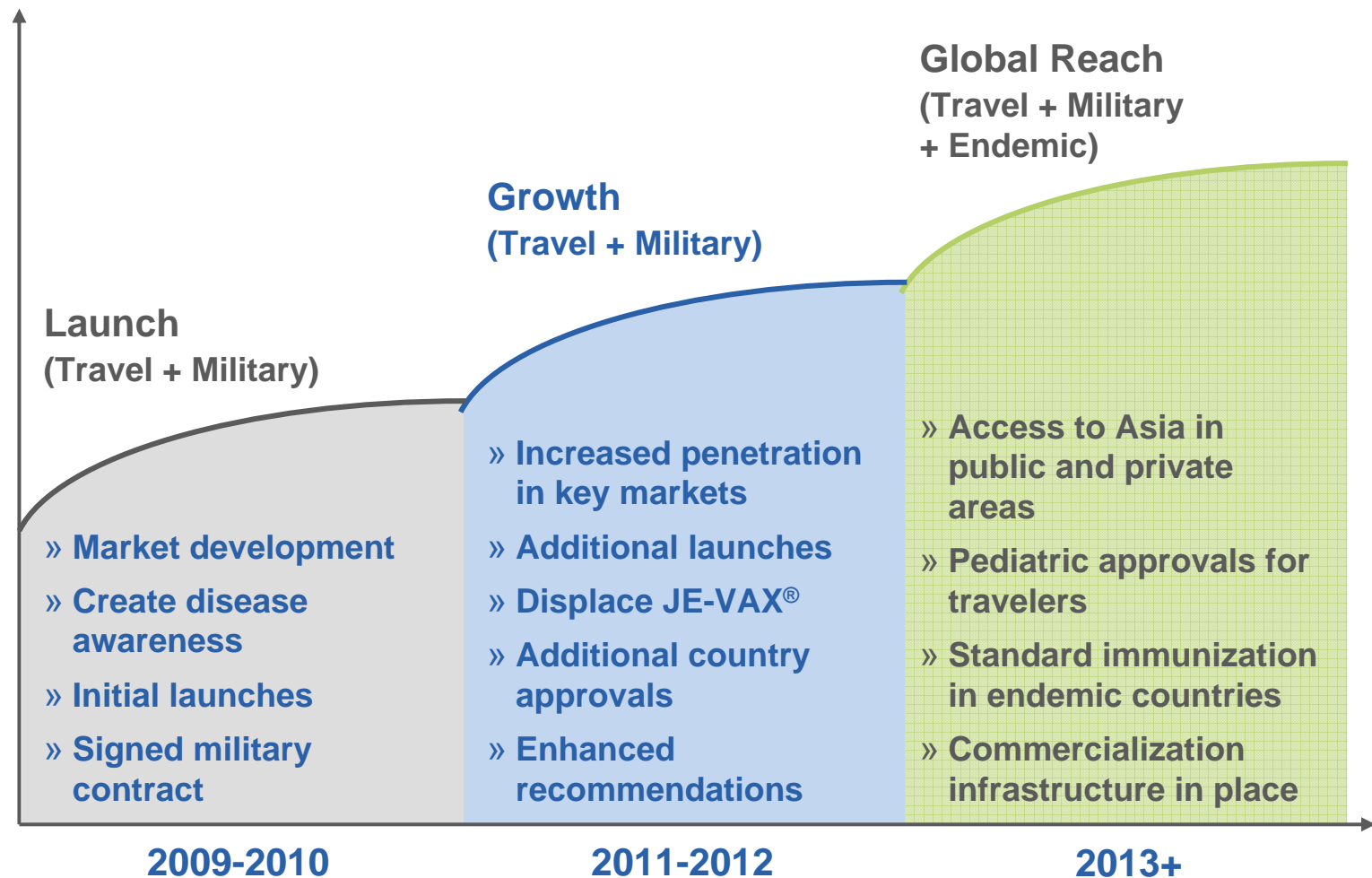
## A lot of progress for U.S. Military business

### Q3 SUMMARY

- » While JE-VAX<sup>®</sup> supplies still exist in the DoD, IXIARO<sup>®</sup> now has become the only JEV vaccine used outside continental U.S. (OCONUS)
- » The Defense Logistic Agency increased frequency of re-ordering IXIARO<sup>®</sup> to meet military treatment facility demands
- » Current stockpile of JE-VAX<sup>®</sup> expected to be exhausted in H1 2011
- » JE policy meetings ongoing to evaluate new risk/benefit profile for increasing vaccination coverage levels in at risk populations (military personnel and dependents)

# We have a strong growth strategy

## STRATEGIC POSITIONING



- » Introduction & Strategy  
*Gerd Zettlmeissl, CEO*
- » Progress in Japanese Encephalitis  
*Staph Bakali, CBO*
- » **Nosocomial vaccines**  
*Thomas Lingelbach, COO*
- » Additional key pipeline programs  
*Thomas Lingelbach, COO*
- » Financial performance & Outlook  
*Reinhard Kandra, CFO*

# Hospital-acquired infections – a major threat for global health

Today's focus!

## OVERVIEW

### Bacteria involved

- » *Staphylococcus* incl. MRSA (~40%)
- » *Pseudomonas* (~20%)
- » Other, i.e. *Clostridium*, *Enterococcus*, *Klebsiella*, ... (~40%)

➔ Intercell R&D vaccine programs in relevant indications

### Medical need – Economic impact

- » ~ 6 million infections per year
- » ~ 200,000 deaths per year
- » Long hospital stays – up to EUR 50,000 extra costs per case
- » High cost impact on social/health systems

➔ A huge health problem and economic burden

### Treatment limitations

- » Increasing antibiotic resistance (e.g. MRSA)
- » High costs of new antibiotics
- » No vaccination available

➔ Prophylactic vaccines urgently needed

# Staphylococcus aureus – the leading cause of nosocomial infections

## KEY FACTS

» Leading cause of hospital-acquired infections

» *S. aureus* infections result in USD 14.5bn in excess charges and 2.7 million days in excess length of hospital stay in the U.S.

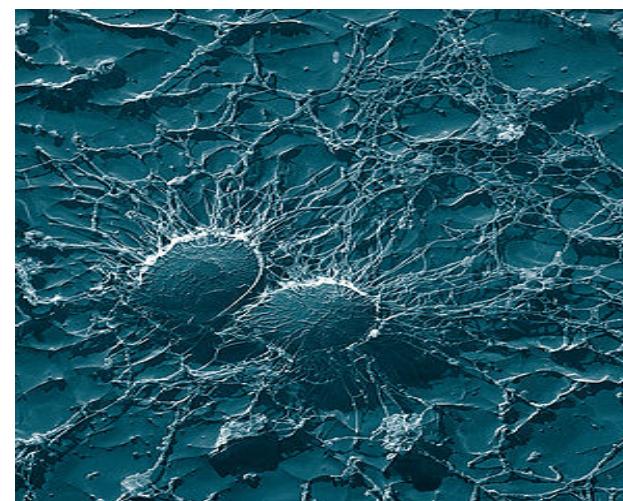
» ~20,000 deaths attributed to MRSA in the U.S. per year

» In 2007, over 60% of staphylococcal infections were MRSA, up from 2% in 1974

» Increases in community-associated MRSA (CAMRSA) infections

### V 710 vaccine candidate, partnered with Merck

- » Recombinant protein of iron surface determinant B (IsdB)
- » Unadjuvanted lyophilized formulation
- » Identified through Intercell's AIP\*



\* Antigen Identification Program

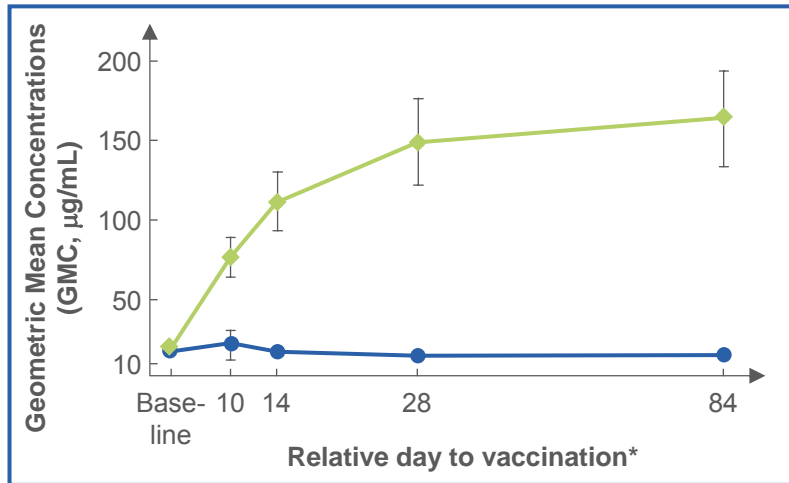
# Fast and sustained IsdB-specific immune response



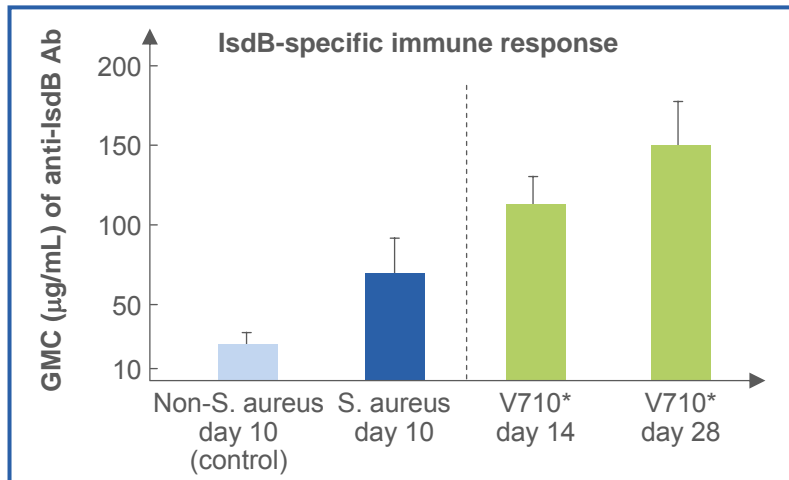
◆ V710 60 µg  
(n = 41)

● Placebo  
(n = 10)

## SELECTED CLINICAL DATA



- » Anamnestic response detected as early as 10 days
- » Sustained response over at least 84 days



- » Epidemiology studies show that IsdB antibody titers are elevated during acute S. aureus infections
- » Vaccine does not use any adjuvant

\* Harro et al.  
Inter. Sym.  
Staph & Staph  
Infect (ISSSI),  
Sep 2008

Source:  
Merck & Co



# Broad Phase II/III efficacy clinical program is ongoing



## S. AUREUS VACCINE STATUS

### Cardiothoracic surgery (Phase II/III)\*

- » **Primary Outcome:**  
Prevention of serious *S. aureus* infections for 90 days following cardiothoracic surgery
- » First efficacy data expected for 2011\*\*

### End-stage kidney disease / dialysis (Phase II)

- » **Primary Outcome:**  
Safety and immunogenicity in patients with end-stage kidney disease and hemodialysis
- » Data expected for 2010

\* Sequential design

\*\* Slower than anticipated enrollment and accrual of *S. aureus* infections

# *Pseudomonas aeruginosa* infections – a high unmet medical need

## KEY FACTS


- » Causes ~20% of nosocomial infections
- » No.1 cause of ICU-related pneumonia
- » No.2 cause of all nosocomial pneumonia
- » *Pseudomonas aeruginosa* colonization of ventilated patients is associated with increased mortality rate

### **Our investigational vaccine**

- » Recombinant OMP F/I fusion produced in *E. coli*
- » No preservatives
- » Pre-filled syringes
- » 2 injections (days 0 and 7)



# A straight forward Phase II study design

 Primary endpoints

## STUDY DESIGN



**IC43 100 mcg with Alum, 100 patients**

**IC43 200 mcg with Alum, 100 patients**

**IC43 100 mcg w/o Alum, 100 patients**

**Placebo, 100 patients**

- » Randomized, placebo-controlled, Phase II study
- » 30 centers in 8 countries\*
- » 400 ICU-patients with mechanical ventilation

|                        | <br><i>Day 0</i> | <br><i>Day 7</i> | <i>Day 14*</i> | <i>Biweekly visits</i> | <i>ICU discharge</i> | <i>Day 90</i> |
|------------------------|---|---|----------------|------------------------|----------------------|---------------|
| <b>Safety</b>          | X   | X   | X              | X                      | X                    | X             |
| <b>Immuno-genicity</b> | X   | X   | X              | X                      | X                    | X             |
| <b>Infection</b>       | X   | X   | X              | X                      | X                    |               |
| <b>Mortality</b>       | X   | X   | X              | X                      | X                    | X             |

\* Countries:  
Argentina,  
Austria,  
Belgium, Chile,  
Hungary,  
Romania,  
Spain, Turkey

# Primary endpoints on immunogenicity met

Primary endpoints

100mcg with Alum

100mcg w/o Alum

200mcg with Alum

Placebo

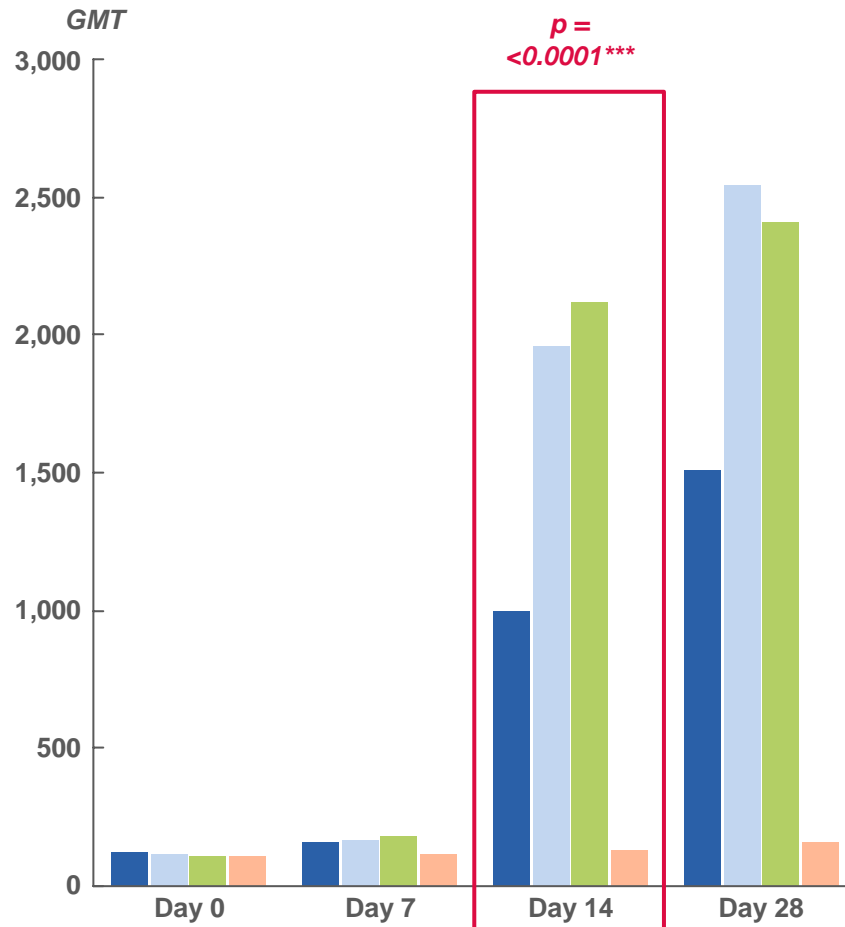
\* OprF/I Elisa

\*\* 4-fold increase vs. day 0-baseline

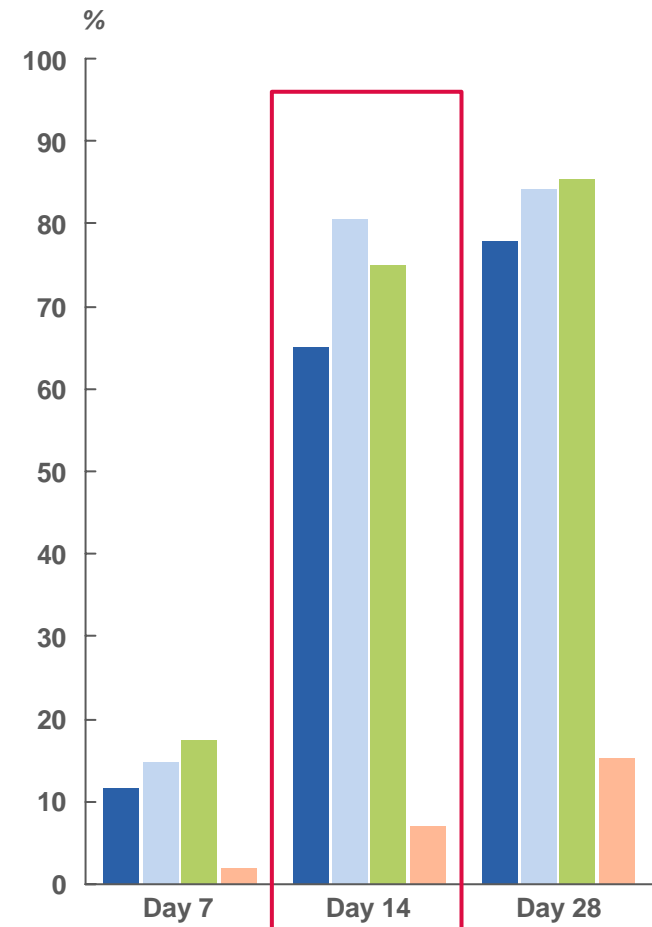
\*\*\* Group vs. placebo

## SUMMARY IMMUNOGENICITY

GMTs\*



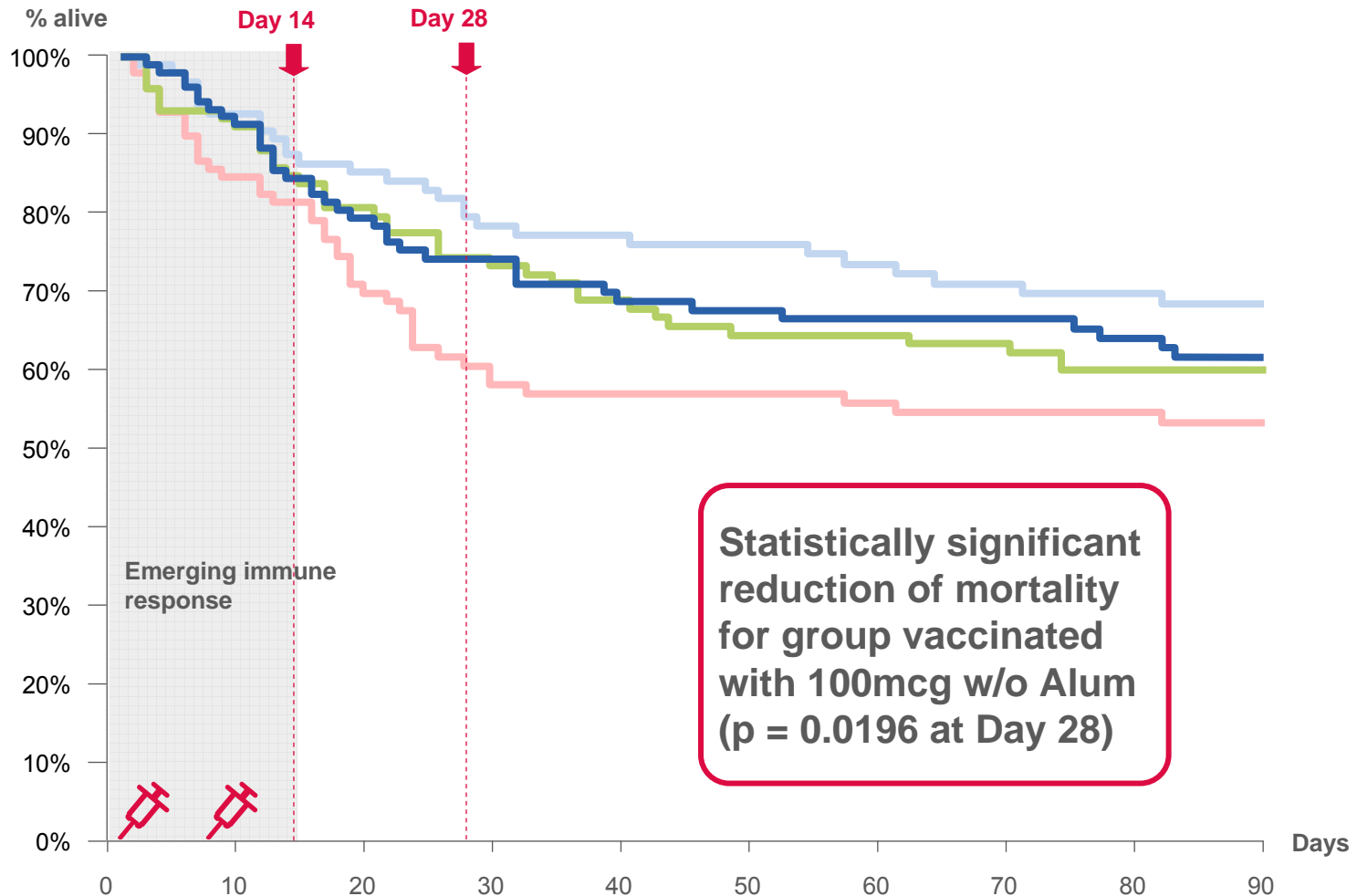
Seroconversion rates\*,\*\*



# Reduction in mortality vs. placebo in all vaccine groups

## SURVIVAL RATES

- 100mcg w/o Alum
- 100mcg with Alum
- 200mcg with Alum
- Placebo



### CONCLUSIONS INFECTION RATES

» Invasive disease infection rate\* of 6-14% within expectations from feasibility studies

» No significant differences of infection rates\* between vaccine and placebo groups observed

#### **Potential explanations:**

» Mismatch between infection incidence (~70% of cases prior day 14) and induction of immune response (emerging between days 7 and 14)

- Low number of preventable cases
- Potential vaccine effects more likely on virulence than on clearance

» Study not powered for infection rates

\*Clinical  
Endpoint  
Committee  
confirmed



# Phase II study results open up future development strategies

## CONCLUSIONS AND NEXT STEPS

### Conclusions

- » All endpoints on immunogenicity and safety met
- » Lower mortality rate in all vaccine groups versus placebo\*
- » Larger sufficiently powered studies required to validate and verify vaccine effects on mortality and infection rates

### Next steps

- » Complementary data analysis and tests to identify potential modes of action
- » Data evaluation with Novartis to define potential next development steps

\* Statistically significant for 100mcg (w/o Alum) group

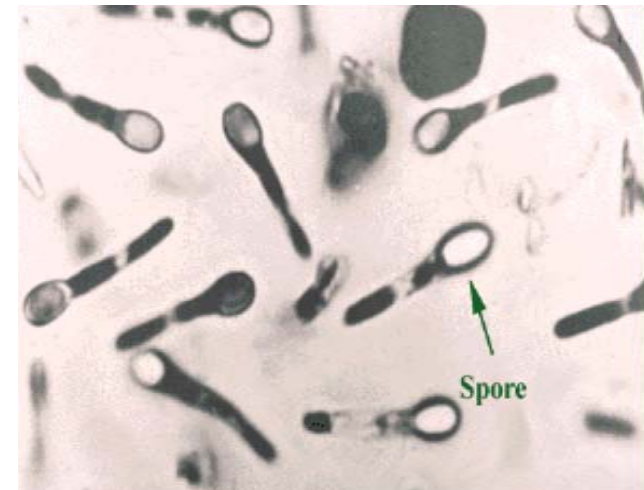
# *Clostridium difficile* – the leading cause of nosocomial Diarrhea

## KEY FACTS

- » Leading cause of nosocomial diarrhea in the U.S. and Europe
- » Estimated 0.5-3 million cases annually in the U.S.
- » Commensal bacterium of the healthy adult human intestine in 2-5% of the population
- » Up to 60% of healthy neonates and infants are colonized without clinical symptoms
- » Toxin mediated disease where anti-toxin immunity can be protective

### Our investigational vaccine

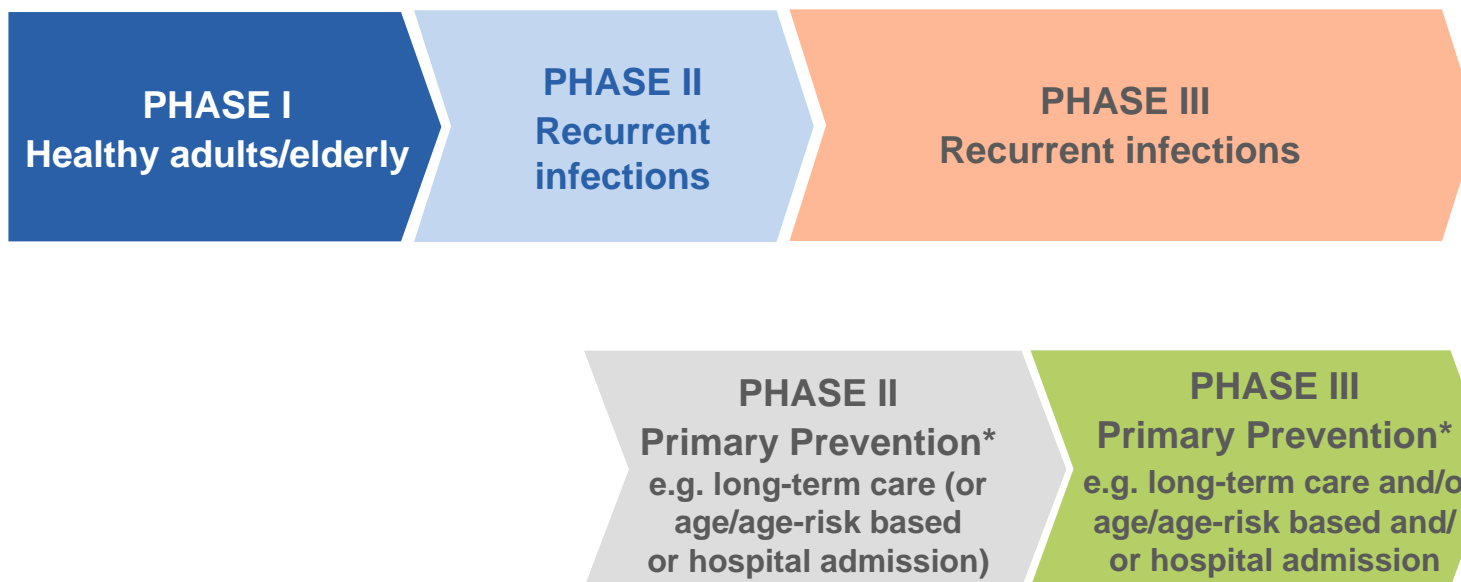
- » Recombinant fusion protein of relevant parts of toxins A and B
- » Alum adjuvanted
- » 3 injections on days 0, 7 and 21



Picture:  
[www.amozeshonline.com/bacteriology](http://www.amozeshonline.com/bacteriology)

# Development plan towards primary prevention

## OVERVIEW CLINICAL STRATEGY



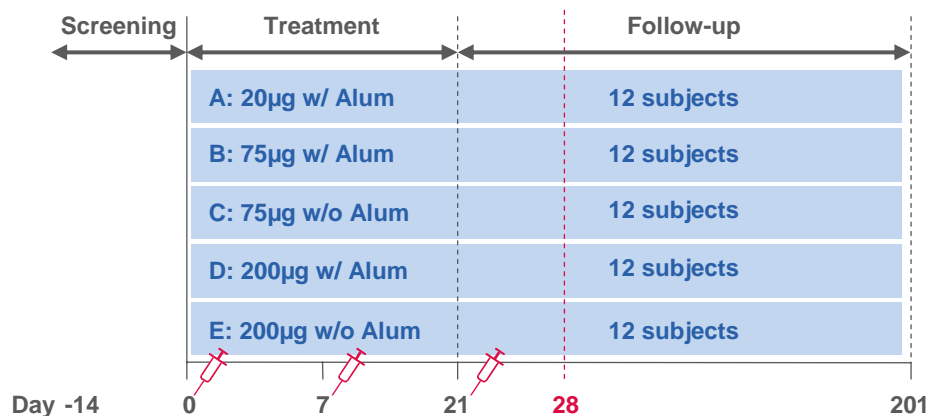
\* age or age-risk based / booster at hospital admission

- » Process for production of Phase I material established
- » Toxicology study completed
- » Phase I start planned still in 2010

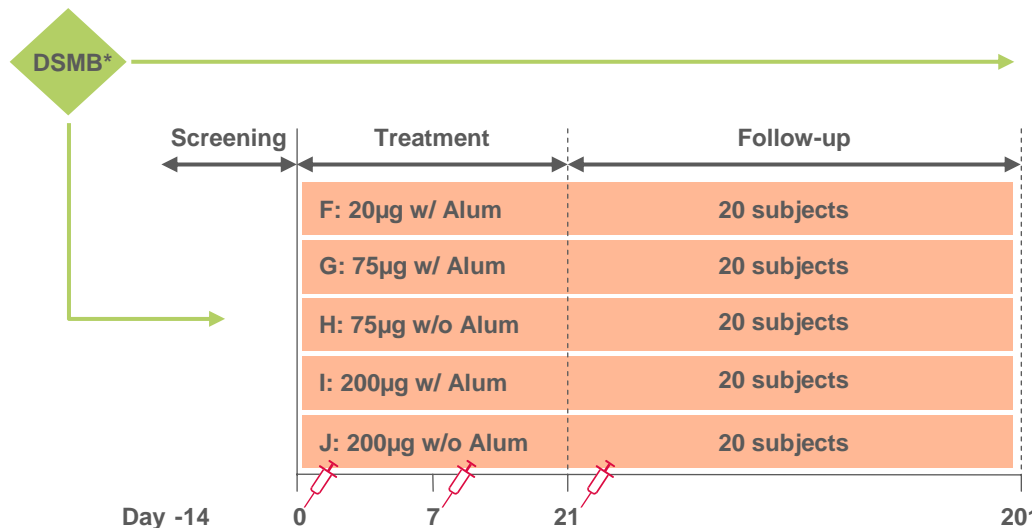
# A Phase I designed towards quick access to target group (elderly)

- ≥18 years to <65 years
- ≥65 years

## STUDY DESIGN PHASE I IC84



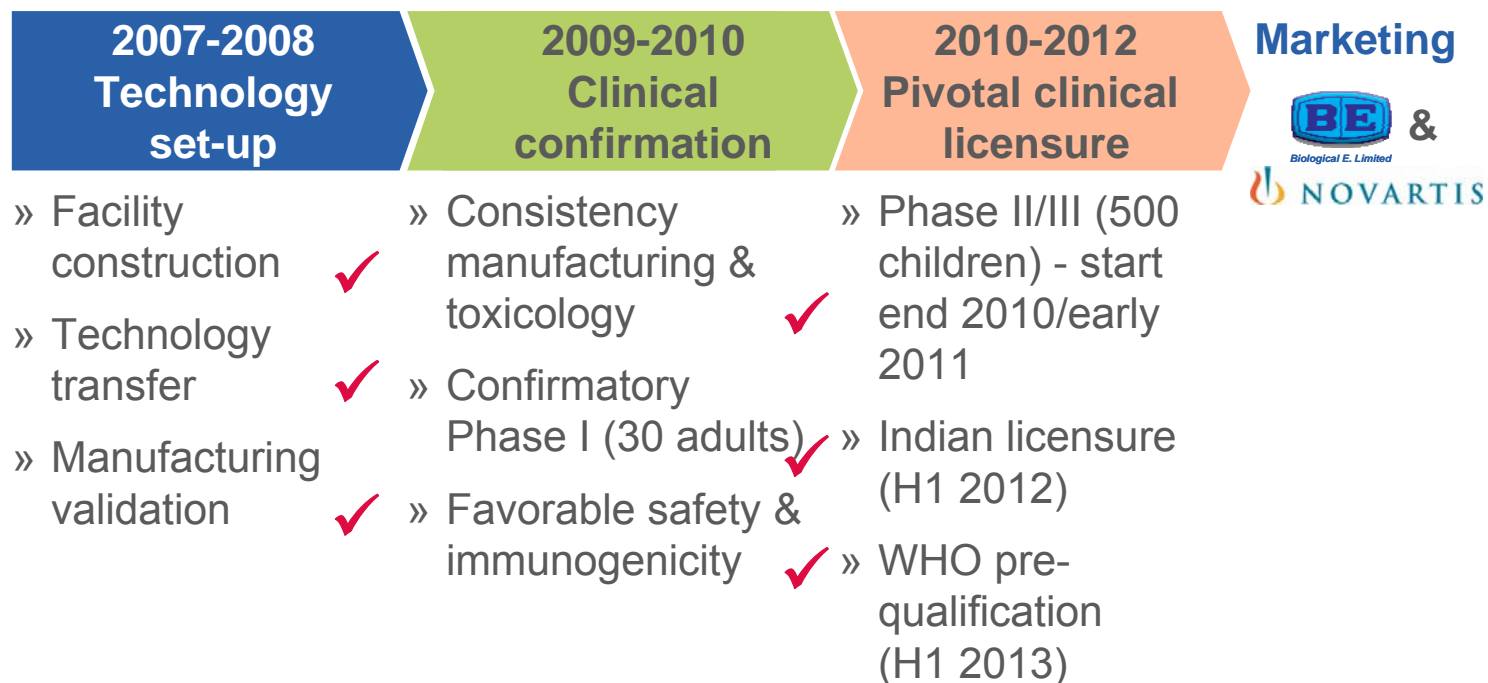
- » Open label
- » Randomized and dose-escalating
- » Study sites in Austria & Hungary



\* Drug Safety Monitoring Board

- » Introduction & Strategy  
*Gerd Zettlmeissl, CEO*
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- » **Additional key pipeline programs**  
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*Reinhard Kandra, CFO*

## PLAN FOR DEVELOPING COUNTRIES



\* Distinct product based on Intercell's manufacturing technology



# Progressing towards pediatric licensure for travelers

## PLAN FOR TRAVELING CHILDREN



- |  |   |   |
|--|---|---|
| <ul style="list-style-type: none"> <li>» Dose confirmation (60 children 1-3 years) ✓</li> <li>» Half-dose confirmation ✓</li> <li>» Favorable safety &amp; immunogenicity ✓</li> </ul> | <ul style="list-style-type: none"> <li>» Phase III – non-endemic (100 children, 2 months - ≤18 years) (✓)</li> <li>» Phase III – endemic* (1,900 children, 2 months - ≤18 years) (✓)</li> </ul> | <ul style="list-style-type: none"> <li>» Phase III – non-endemic, long-term immunity</li> <li>» Phase III – endemic, long-term immunity &amp; booster</li> <li>» Label extension (2012/2013)</li> </ul> |
|--|---|---|

\* Interim readout confirmed favorable safety & immunogenicity and half-dose ≤ 3 years of age (DSMB, Nov 2010)

# TD vaccine – First vaccine candidate delivered with patch heading towards Phase III data

## SUMMARY

### Pivotal Phase III

- » Started in October 2009
- » Travelers to Mexico & Guatemala
- » Recruitment completed
- » First data expected for late 2010 / early 2011



### Asian pilot efficacy Phase II

- » Started in January 2010
- » Travelers to India
- » Recruitment completed
- » First data expected for Q4 2010

**In an earlier Phase II field trial, the vaccine showed immunogenicity and reduced the risk of clinically significant diarrheal episodes**



# Potential of VEP to improve existing and new injectable vaccines\* will be further investigated

## PATH FORWARD

### Key results of Phase I

- » 1 dose H5N1 vaccine\*\* (1x45mcg) **with patch protects 73%** of subjects (vs. 49% without patch)
- » Meets FDA guideline of >70% protection rate for Pandemic Flu vaccine
- » Excellent local and systemic safety profile

### Key results of Phase II

- » No statistically significant difference observed across study groups with and without VEP
- » Endpoints
  - Dose-dependent response to H5N1 antigen observed (**not met**)
  - Safety (✓)
  - LT uptake dose dependent (✓)
- » Good safety profile (✓)
- » VEP consistently delivers vaccine adjuvant (✓)

**Next steps:** Start clinical study by end 2010/early 2011 investigating GSK's egg-based H5N1 vaccine in combination with Intercell's VEP

\* Program funded (USD 128m) and supported by United States Department of Health & Human Services

\*\* injected, from Solvay

# Leading therapeutic vaccine approach

## HEPATITIS C THERAPEUTIC VACCINE

### Substantial unmet medical need

- » Viral infection with often chronic outcome
- » 170 m chronically infected worldwide
- » Leads to liver cirrhosis, carcinoma, transplantation
- » 8,000 - 10,000 deaths per year in United States alone

### Competitive Environment

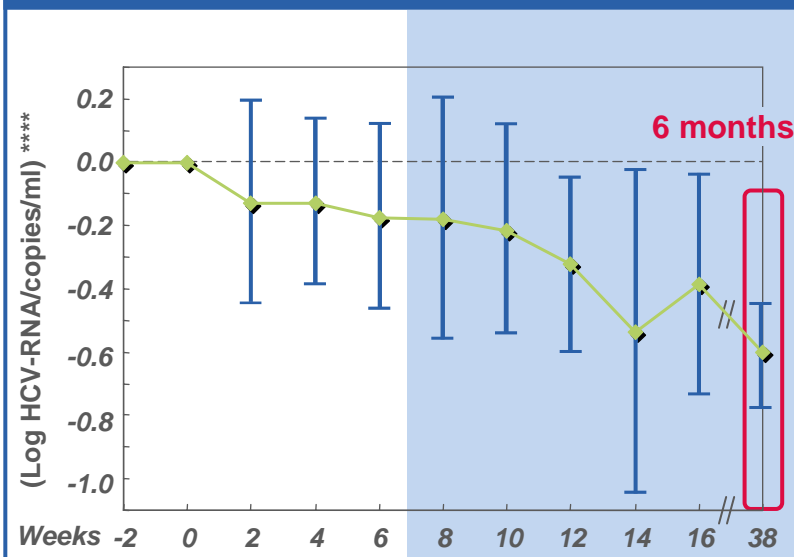
- » Current products (Interferon/Ribavirin)
  - Limited efficacy
  - Severe side effects
  - Very expensive treatment
- » Other new treatment approaches
  - Protease inhibitors\*\*\*\*\* most advanced
  - Still dependent on interferon/ribavirin
  - Additional side effects

**Market size: >EUR 3.0bn\***

### Our product

- » T-cell vaccine: 5 peptides plus Poly-Arginine (IC30)\*\*
- » Good safety profile (Phase I and Phase II)
- » Competitive costs of goods

### Statistically significant 6 months viral-load reduction\*\*\*



\* Source: BioSeeker Group 2005

\*\* Plus TLR-agonist (Imiquimod)

\*\*\* Change from baseline in 25 high viral load patients (>2 mio copies/ml)

\*\*\*\* 95% confidence intervals

\*\*\*\*\* i.e. from Merck, Vertex

# Nitazoxanide (NTZ) from Romark – a promising combination candidate for IC41

## OVERVIEW

### About NTZ

- » FDA approved for treatment of parasite infections\* in children and adults
- » Excellent safety track record
- » Strong in-vitro antiviral activity\*\*
- » Excellent data from HCV Phase II in combination with Interferon
  - Improved SVR by 20-30% vs. SOC
  - Reduced relapse rate
  - No added toxicity
- » Acting at virus cell cycle ⇒ low risk of viral resistance

\* Giardia lamblia, Cryptosporidium parvum

\*\* incl. HCV, Korba et al. 2007

### Combination rationale

- » Provide a potential Hepatitis C therapy without Interferon / Ribavirin
  - » Low side effect profile expected (based on clinical experience with IC41 and NTZ)
    - Earlier treatment
    - Better compliance
- ➔ **The next generation of Hepatitis C treatment?**

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## Solid financial position

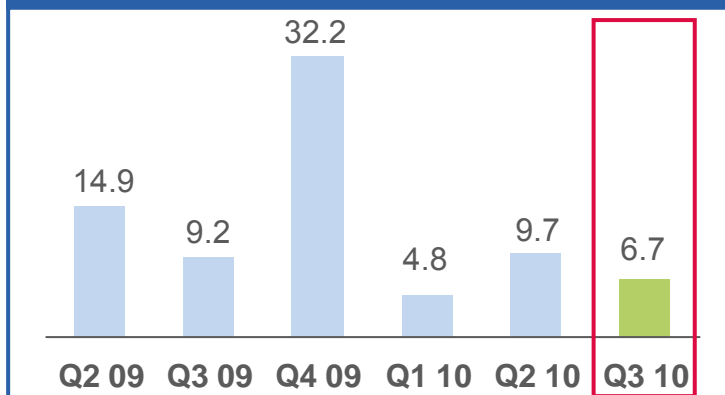
### KEY FINANCIAL FIGURES Q3 AND FIRST 9 MONTHS 2010

|   | 3 months ended |                | 9 months ended |                | Year ended   |
|---|----------------|----------------|----------------|----------------|--------------|
|   | Sept 30, 2010* | Sept 30, 2009* | Sept 30, 2010* | Sept 30, 2009* | Dec 31, 2009 |
| <i>EUR in thousands</i>                         |                |                |                |                |              |
| » Revenues                                      | 6,704          | 9,159          | 21,118         | 29,480         | 61,681       |
| » R&D Expenses                                  | (19,694)       | (17,005)       | (54,555)       | (45,713)       | (62,539)     |
| » Net loss                                      | (27,844)       | (14,671)       | (50,892)       | (25,925)       | (18,375)     |
| » Net operating cash flow                       | (22,724)       | (14,753)       | (49,218)       | (43,322)       | (25,995)     |
| » Cash and marketable securities, end of period | 107,141        | 139,746        | 107,141        | 139,746        | 180,019      |

\* unaudited

# Quarterly overview Q3 2010<sup>\*,\*\*</sup>

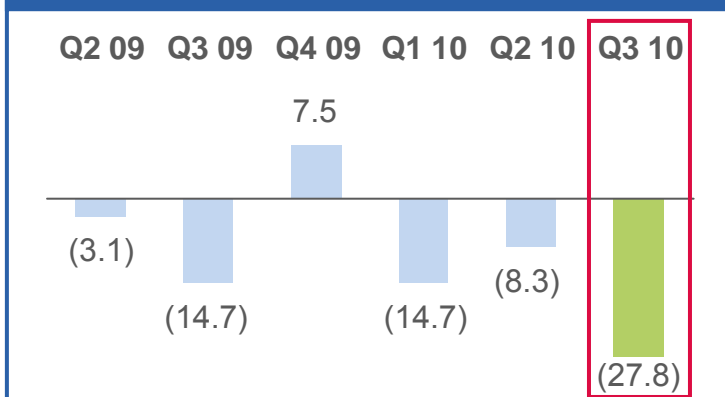
## Revenues, in EUR m



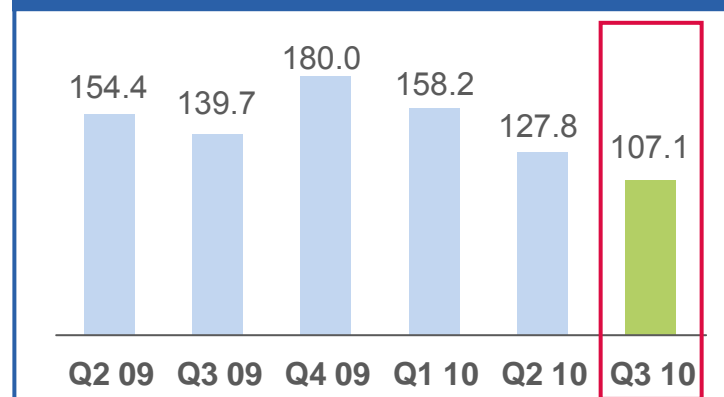
## R&D spending, in EUR m



## Net profit/(loss), in EUR m



## Cash, in EUR m



\* Reporting under IFRS  
\*\* unaudited

## Financial highlights

### Q3 ANALYSIS AND FY 2010 OUTLOOK

- » **Revenues:** EUR 6.7m\* revenues in Q3 2010 – decrease from EUR 9.2\* in Q3 2009 due to absence of milestone events and declining recognition of deferred prior year revenues – strong Q4 revenues expected
- » **Product sales:** IXIARO®/JESPECT® sales revenues of EUR 3.8m\* in Q3 2010 – further y-o-y increase expected for Q4
- » **COGS:** COGS of EUR 3.0m\* in Q3 2010 led to a positive gross margin from JEV product sales
- » **R&D expenses:** Spending of EUR 19.7m\* in Q3 2010 was mainly driven by late-stage development projects, especially our clinical Phase III TD Vaccine Patch program
- » **S,G&A expenses:** SG&A costs were EUR 4.8m\* in Q3 2010
- » **Other operating expense, net:** EUR 7.4m\* expense in Q3 2010 mainly resulted from non-cash EUR/USD currency effects
- » **Net loss** of EUR 27.8m\* in Q3 2010 and EUR 50.9\* in the first 9 months of 2010; Net loss for FY 2010 expected to reach approximately EUR 40.0m assuming positive outcome of upcoming milestone events

\* unaudited

# Important growth steps well under way

## SELECTED NEXT MILESTONES\*

### JE vaccine

- » First Phase III data from children for travelers' market
- » Start of Phase III in children in endemic countries
- » First approval in endemic countries

### TD vaccine

- » Phase II data (India)
- » Phase III efficacy data (Mexico/Guatemala)

### S. aureus, Pseudomonas & Pneumococcus vaccines

- » Phase II/III efficacy data in S. aureus
- » Pseudomonas evaluation with Novartis
- » Phase I studies in Pneumococcus in target population

### Other vaccines

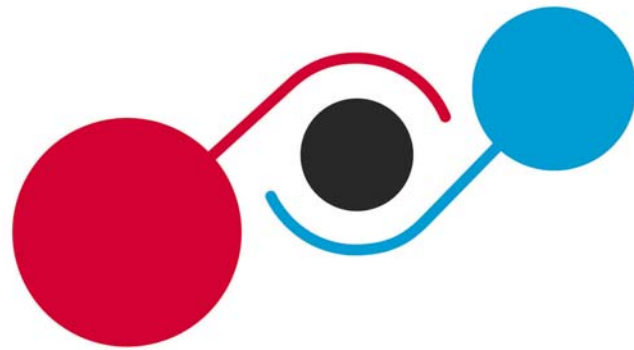
- » Initiation of pandemic Flu study combining VEP\*\* and GSK's H5N1 vaccine
- » Multiple clinical data points within partnerships (e.g. Tuberculosis, Flu)
- » Start of clinical combination study for Hepatitis C vaccine

### AIP®, IC31® Vaccine Patch, Antibodies

- » Further out-licensing of vaccine patch (delivery and VEP\*\*)
- » IC31® in new vaccine indications (including allergy and cancer vaccines)
- » Antibody products – definition of lead candidates

\* 2010/2011

\*\* Vaccine Enhancement Patch



intercell  
SMART VACCINES

For more information be invited to: [www.intercell.com](http://www.intercell.com)