

6th Annual International Partnering Conference

**BIO-EUROPE**  
**SPRING<sup>®</sup> 2012**

MARCH 19-21, 2012  
AMSTERDAM, THE NETHERLANDS

Amsterdam RAI Convention Center



Producer  
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GROUP

# **Woulgan<sup>®</sup> biogel**

## **An advanced wound healing product**

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# Agenda

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- **The company and the product**
- **The market**
- **Our product documentation**
- **Regulatory classification, label claims and health economics**
- **Launch plan**
- **Summary**

# Biotec Pharmacon

## Business areas and core expertise

Tromsø



### Beta-Glucan (SBG) technology

- Well documented effect in wound care - diabetic ulcer but also projects in cancer, oral mucositis, and IBD
- Company focus on class III/rule 13 medical device for topical ulcers/wounds (Woulgan<sup>®</sup> biogel)
- Highly documented and patent-protected platform technology
- Already significant partner interest to take such a product to market

### Enzymes – ArcticZymes

- Business based on marine biochemicals
- Core role in PCR contamination control
- Strong IP position for marketed products
- Large unexploited market
- Strong pipeline secured through strategic alliances and acquisition

**Over 20 years of research in key areas – strong IP based science**

# Woulgan<sup>®</sup> biogel – the product

Woulgan<sup>®</sup> biogel is a sterile, non-preserved amorphous and thixotrope wound filling gel formulation based on water, glycerol and water soluble polymer chains (Carboxymethyl-Cellulose (CMC) and beta-glucan (SBG)).

Woulgan<sup>®</sup> biogel is intended for dry to moderate exuding partial and full thickness wounds such as:

- diabetic ulcers
- pressure ulcers
- leg ulcers
- graft and donor sites
- post-operative surgical wounds
- trauma wounds
- 1<sup>st</sup> and 2<sup>nd</sup> degree burns
- Abrasions and lacerations

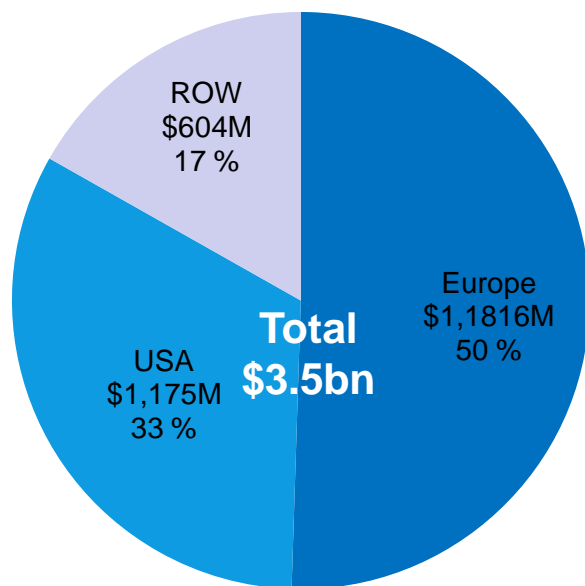


*Woulgan<sup>®</sup> biogel can be applied to the wound every second day until complete wound healing or for a maximum of 12 weeks unless improvements are seen at that stage.*

# Woulgan<sup>®</sup> biogel – the market

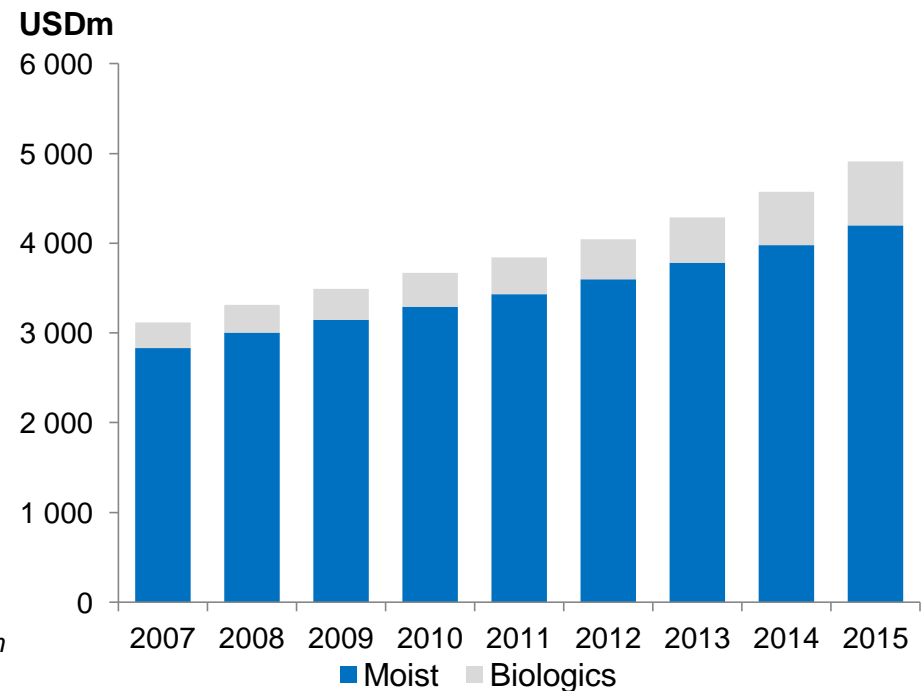
## Addressing the advanced wound care market

**Moist and Biologics market  
by regions**



Source: Espicom

**Moist and Biologics market  
Growth projections**



# Diabetic ulcer – the market

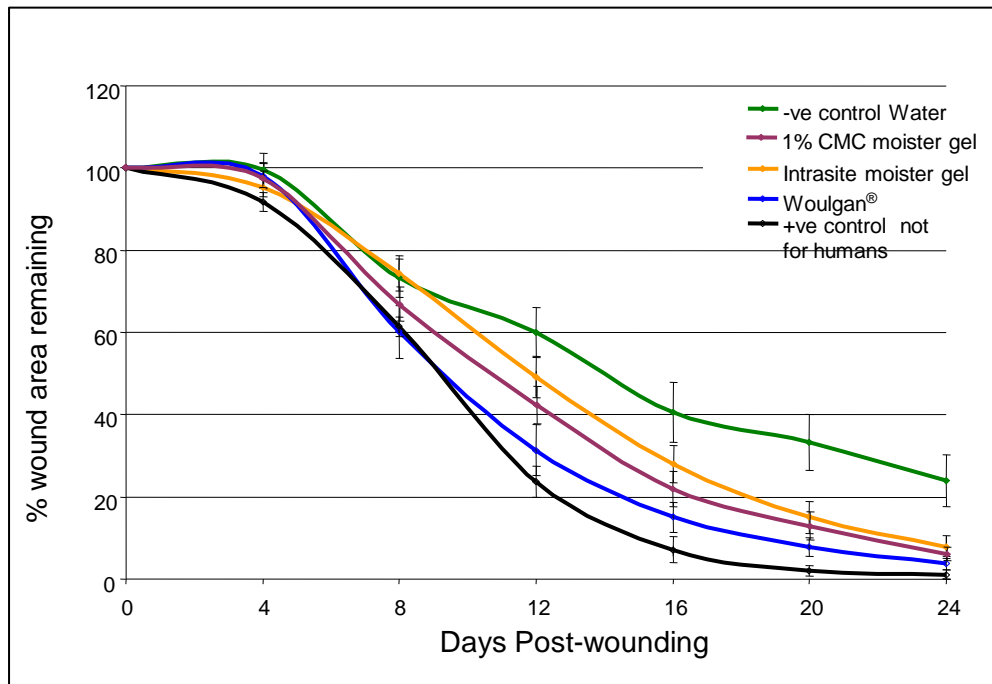
- More than 50 million people have diabetes in Europe, US and Japan – and the disease is rapidly increasing
- 15% of diabetics will ultimately develop diabetic foot ulcers;
  - Representing about 8 million ulcers in the Western World
  - Annual incidence of at least 1.2 million new ulcers
  - 71,000 amputations in people with diabetes in the US alone
- US medical expenses of USD 27 billion for diabetes care



**Improved diabetic ulcer treatment needed to  
reduce amputation rates and cut costs**

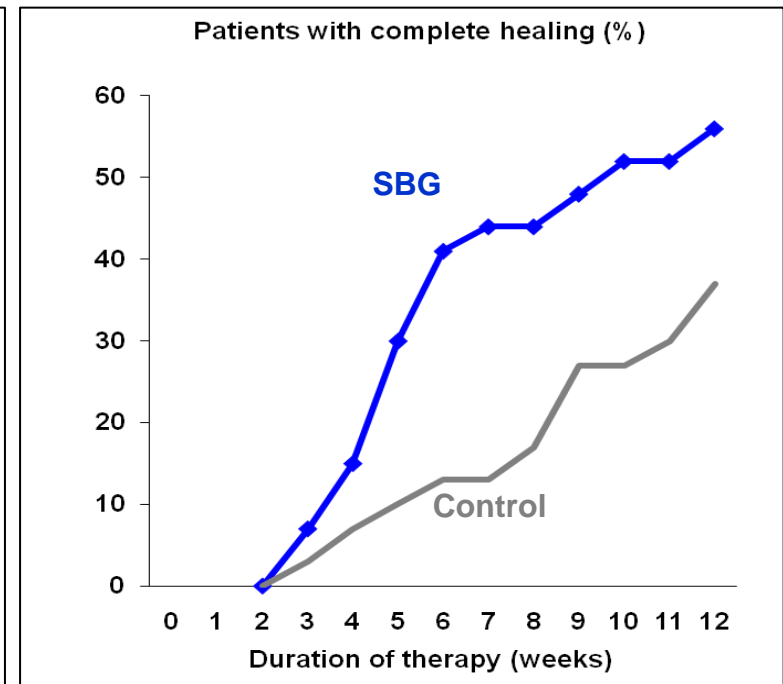
# We have an outstanding product -with a lot of documentation

## Successful animal study for reformulated product



*The animal study in diabetic mice shows that the performance of the reformulated SBG product (Woulgan®) with proven stability is close to the positive control and well above typical moistur gels used for wound healing*

## Successful phase 2 study in diabetic ulcer



*Placebo controlled double blinded study of 60 patients  
Statistical significant after 8 weeks*

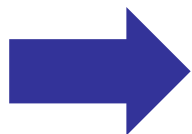


# SBG and Woulgan® biogel documentation

- 2002-2011: Pre-clinical toxicology and pharmacology studies using soluble beta glucan in animal models and in *in vitro* models. All studies have confirmed a very good safety profile of the product.
- 2003-2010: Six phase I/II safety studies in volunteers or in patients (cancer & and burns), all confirming the excellent safety profile.
- 2003-2007: One double blinded placebo controlled phase II study for prevention and treatment of diabetic ulcers. With statistical significant outcome.
- 2007-2010: Two double blinded placebo controlled phase III studies for prevention and treatment of diabetic ulcers.
- 2010-2011: Three animal studies with a new medical device composition.
- 2010-2011: Several stability studies with a new medical device composition.

## Cost for a user

- 10 weeks – 1 dose every 3<sup>rd</sup> day ~ 23 doses
- Price indication of ~USD 20 per dose, depending on partner preferences
- 23 doses at USD 20 per dose  
=USD 460/treatment
- 8 weeks healing ~ 53% against placebo 33%
- Average shorter healing time was 20 days



This gives the following health economics.....

# Strong Health Economics

1. Clinical cost savings - USD 460 for 20 days saved healing time. 1-2 clinic visits per week means at least 5 visits saved, plus ....
2. Patient convenience and increased healing ratio:  
8 weeks = 20%, 12 weeks = 15%, plus ....
3. Reduced amputations (based on phase II study):  
Placebo = 3 amputations, and  
Product = 1 amputation  
Total 4 out of 60 patients (7%)

# Decided on advanced classification for Woulgan® biogel

- Have decided to go to class III rule 13 to ensure product uniqueness, sufficient strong label claims, and the opportunity to communicate the efficacy
- In general, claims will be as follows:
  - Primary claims related to physical characteristics, like moist, autolytic debridement, protective, etc
  - Secondary (ancillary) claims, related to the beta-glucan effect as a medicinal product improving specific wound healing mechanisms

# Upcoming milestones for launch of Woulgan<sup>®</sup> as Class III, rule 13 medical device



# What are we looking for at the Bio-Europe?

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1. We like to have one or several strong commercial partner(s) that can be active in the final product development process and/or the launch of the product in their core markets
  - We are open for discussions with potential global, regional or local partners
  - No specific funding requirements needed from the partner
2. We are presently further evaluating partnerships with potential CMOs that are able to fill our Woulgan<sup>®</sup> biogel

# Summary

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- We will launch a class III, rule 13 wound healing product in 2013
- Large market potential; few direct competitors
- Strong documentation and health economics
- First prototype is available; large scale batch tested
- We are looking for partners to launch the product in their core markets and CMOs for filling of the product
- The SBG-technology is a platform technology which can be applied in different product settings and indications



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