



Immunity for Life ™

# Presentation Fourth quarter 2005 Preliminary results 2005

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# **Highlights - operations**

- Finished patient treatment in the phase II clinical trial for the prevention of oral mucositis in London
- ➤ Good progress in the phase II clinical trial for treatment of diabetic ulcers in Russia, with 70% of patients randomized to date.
- ➤ Additional diabetic ulcers studies in the U.K. in the pipeline
- > Treatment of patients with burn wounds has started at Haukeland University Hospital in Bergen
- Clinical phase I/II trial at Memorial Sloan-Kettering Cancer Center in New York is progressing according to plans
- ➤ Clinical trials with SBG and mAbs being planned at Ullevaal University Hospital and Rikshospitalet-Radiumhospitalet in Oslo
- ➤ The Norwegian Medicines Agency has made a resolution which allows sales of consumer health products in Norway



## **Highlights - financials**

- ➤ Sales income of non-pharmaceutical products in the fourth quarter of NOK 17 million (NOK 15.2 million in Q4-2004), and NOK 70.3 million in 2005 (NOK 70.2 million in 2004)
- ➤ Gross R&D-expenses of NOK 8.4 million in the fourth quarter (NOK 6.7 million in Q4-2004) and NOK 29.1 million in 2005 (NOK 23.4 million in 2004)
- ➤ After tax loss of NOK 4.6 million in the fourth quarter (NOK 2.7 million in Q4-2004), and preliminary 2005 after tax loss of NOK 11.8 million (NOK 6.4 million in 2004)
- ➤ Liquidity reserve of NOK 104.8 million
- > Equity ratio of 90.9%

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### **Current activities - overview**

### Pharmaceutical development

- Main priority projects:
  - Treatment of diabetic ulcers
  - Immunotherapy of cancer
- Other projects:
  - Prevention of oral mucositis
  - Treatment of burn wounds

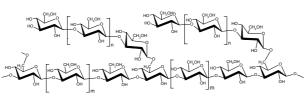
### Sales of non-pharmaceuticals

- Consumer health products
  - NBG®
  - Immutol®
  - Immuderm®
- · Animal health products
  - MacroGard®
- Biochemicals
  - DNA modifying marine enzymes



### The pharmaceutical product candidate SBG - Soluble Beta-Glucan

- Beta-glucans: a diverse group of natural polysaccharides found in the cell wall of yeast, fungi and certain bacteria
- <u>SBG</u>: a unique soluble yeast-derived beta-1,3/1,6-glucan with high bioactivity and a well-documented safety profile

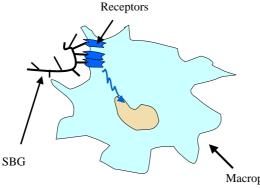




# BIOTEC PHARMACON

### The pharmaceutical product candidate SBG - Soluble Beta-Glucan

SBG binds to specific receptors on macrophages and other white blood cells in the body's innate front-line defence



Effect of SBG activated macrophages in...

#### Cancer:

Induce enhanced antibodydependent tumour regression and enhance the activity of vaccines

#### Ulcers:

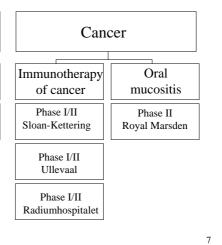
Become more effective in repairing damaged tissue, particularly in diabetics

Macrophage



## Overview of clinical trials with SBG

Ulcers an	d wounds
Diabetic ulcers	Burns
Phase II Archangelsk/ St. Petersburg	Phase I/II Haukeland
Phase II Nottingham	



# **Diabetic ulcers: POP-study**

- An <u>open</u> proof-of-principle study was carried out with 20 diabetic patients suffering from severe foot and leg ulcers
  - The results showed extraordinary good effect of SBG compared to best available alternative treatment (control group)
  - Most of the ulcers treated with SBG had healed in 35 days, and all of them in 100 days, compared to only two in the control group







(Dr. T. Zykova, University Hospital, Archangelsk)



### **Diabetic ulcers: Market**

- Chronic ulcers are painful and disabling
- About 10% of diabetes patients will develop chronic ulcers (6-15%)
- Currently at least 3 million diabetic ulcers patients in North America, Europe and Japan (approximately 50 million diabetes patients)
- The number of patients will grow due to demographic developments and the general increase in the incidence of diabetes
- >Several treatments per patient may be required
- ➤ No efficient treatment exists today for complicated ulcers, and the cost of treatment is high (overall 5-7 billion US\$ per year in USA)
- Most likely partners for Biotec Pharmacon include the major players in this therapeutic area, which is dominated by a handful companies with pharmaceuticals and devices (e.g. dressings)

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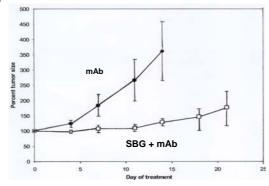
# Diabetic ulcers: Fourth quarter update

- ➤ Good progress in the double-blinded Phase II (therapeutic exploratory) study with diabetic ulcer patients in Russia, with 70% (42 of 60) patients randomized to date
- Second site (St. Petersburg) was added to Archangelsk
- ➤ Patient inclusion scheduled to be completed by Q2, patient treatment scheduled to be finished by Q3, and reporting of results tentatively during Q4
- Arrangements have been made with Nottingham City Hospital to conduct a second phase II trial in the UK



# Immunotherapy of cancer: POP-studies

Effect of a monoclonal antibody (mAb) alone and in combination with oral SBG on tumour development in SCID-mice inoculated with human cancer cells



(Dr. N.K. Cheung, Memorial Sloan-Kettering Cancer Center, New York)

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# Immunotherapy of cancer: Market for monoclonal antibodies (mAbs)

- Despite the fact that cost of treatment is very high, and therapeutic effects are modest, sales of mAbs have skyrocketed in recent years
- Total mAbs sales in 2004 exceeded USD 10 billion, of which about half for cancer treatment, and the market is forecasted to triple within 2010 (Source: Datamonitor, 04/2005)
- Almost 5 million new cancer incidents each year in North-America, Europe and Japan. The number of patients treated with mAbs is still low, but will increase sharply with the approval of new products
- It is believed that SBG will be proven effective in combination with certain mAbs, but not with all, depending on specificity and/or mode of action
- New developments in the mAbs market are driven by biotechnology companies; most likely partners are either big pharma with prominent market positions or biotech companies with mAb pipelines



# Immunotherapy of cancer: Fourth quarter update

- ➤ In the phase I/II trial with neuroblasoma-patients receiving oral treatment with SBG in combination with injected mAbs, 5 patients (of 15) have been included and no dose limiting toxicities related to study drugs have been observed so far
- ➤ Additional studies at Sloan-Kettering is being discussed in line with the existing agreement, but no firm decisions have been made
- ➤ Clinical trials with SBG in combination with Herceptin (Ullevaal University Hospital) and Rituxan (Rikshospitalet-Radiumhospitalet) are being planned with the objective to begin patient treatment in 2006
- ➤ Discussions ongoing with other hospitals (Europe) to conduct additional studies in cancer patients

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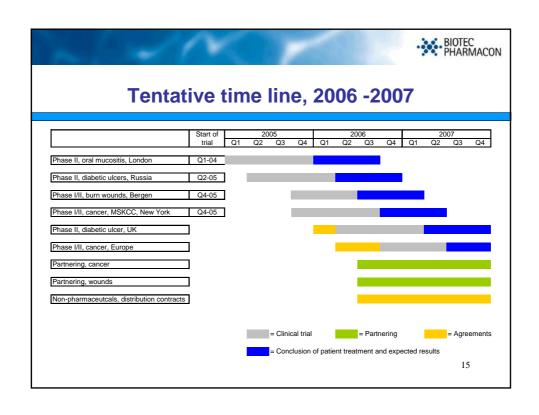
# Other ongoing clinical trials Fourth quarter update

### > Oral mucositis

- ☐ Patient treatment has been completed in the clinical phase II trial at the Royal Marsden Hospital in London. Results to be obtained in the next three months.
- □ EMEA has granted Orphan drug designation for SBG used in the prevention of oral mucositis. Possible partners for further development have been identified.

#### Burn wounds

☐ An open clinical phase I/II trial on patients with burn wounds has been initiated at Haukeland University Hospital in Bergen. Results from the first patients will be obtained in the next few months.





# **Business model – pharmaceuticals**

- Complete phase II clinical studies (human proof-of-principle), and retain ownership and strategic flexibility until such studies are completed
- ➤ Partner with suitable international pharmaceutical or biotechnology companies with capabilities in late stage clinical development, regulatory compliance, marketing and sales
- ➤ Income stream through up-front licence fees, milestone fees, royalty and product sales



### Non-pharmaceutical products

High-margin products with good growth potentials, based on immune modulating compounds and DNA-modifying enzymes

Consumer Health



Animal Health & Nutrition







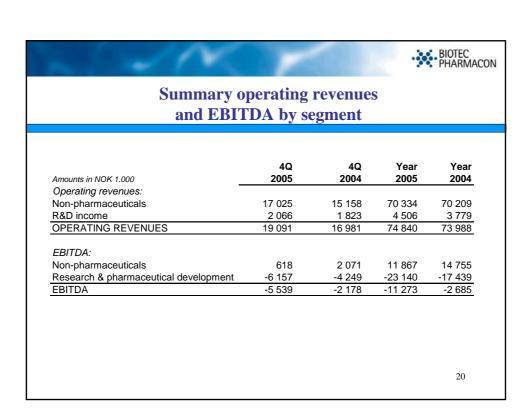
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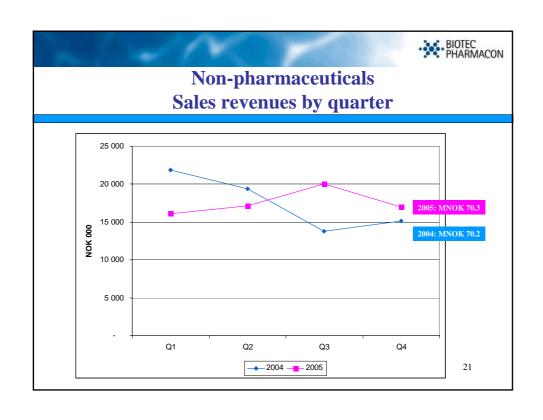


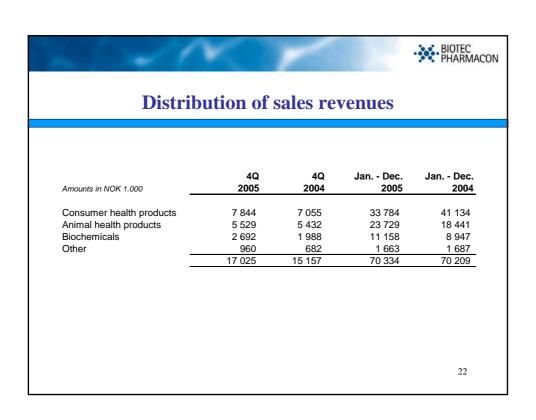
# Non-pharmaceutical products Fourth quarter update

- > The sales organization has been strengthened
- ➤ Other steps to launch consumer health products in Norway and internationally are being taken
- ➤ The Norwegian Medicines Agency (SLV) in December made a resolution which allows sales of consumer health products
- ➤ Increased marketing efforts to benefit from the prohibition of feed antibiotics in the EU
- Expect sales and profit contribution to fluctuate from quarter to quarter due to inventory levels at distributors, sales mix and marketing campaigns











# Non-pharmaceuticals

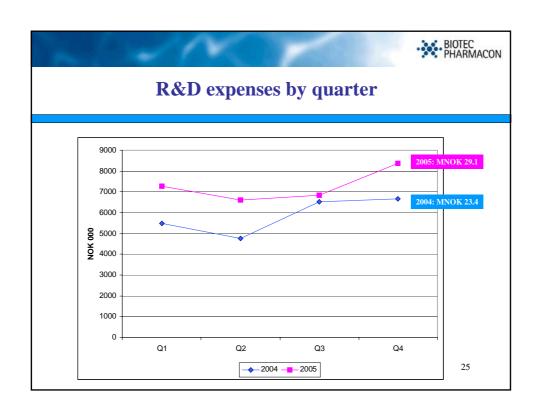
Amounts in NOK 1.000	4Q 2005	4Q 2004	Year 2005	Year 2004
Operating revenues	17 025	15 158	70 334	70 209
Cost of goods sold	3 447	1 922	14 242	12 107
Gross profit	13 577	13 235	56 092	58 102
Gross margin	79,8 %	87,3 %	79,8 %	82,8 %
Other operating expenses	12 959	11 165	44 225	43 347
EBITDA	618	2 071	11 867	14 755
Depreciation	684	1 122	3 560	4 243
EBIT	-66	948	8 307	10 511

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# Research and pharmaceutical development

Amounts in NOK 1.000	4Q 2005	4Q 2004	Year 2005	Year 2004
R&D income	2 066	1 823	4 506	3 779
R&D expenses	8 358	6 650	29 078	23 404
Net R&D	-6 292	-4 827	-24 572	-19 625
R&D exp. in % of op. income	43,8%	39,2%	38,9%	31,6%



#### BIOTEC **Consolidated income statement Summary** 4Q 4Q Year Year 2005 2004 2005 2004 Amounts in NOK 1.000 74 840 73 988 Operating revenue 19 091 16 981 Operating expenses 25 449 20 859 91 105 83 102 Operating profit -6 358 -3 879 -16 265 -9 114 Net financial items 636 -187 819 196 Profit before tax -5 721 -4 065 -15 446 -8 918 -1 133 -1 384 -3 635 -2 562 Net income -4 588 -2 682 -11 811 -6 357 26



# Consolidated balance sheet Summary

Amounts in NOK 1.000	31/12/2005	31/12/2004
Non-current assets	30 056	26 833
Cash and cash equivalents	94 884	20 141
Other current assets	15 654	13 674
Total current assets	110 537	33 815
Total assets	140 593	60 648
Equity	127 758	51 253
Liabilities	12 835	9 395
Total equity and liabilities	140 593	60 648

Liquidity reserve per 31/12/2005: NOK 104.8 million Equity ratio per 31/12/2005: 90.9%

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# **Share information**



Number of shares outstanding: 21.489.010 Own shares: 432.000 Number of shareholders: 380 Market cap (27.02.06): MNOK 816

### 20 largest shareholders:

Piro AS	17.84%
Four Seasons Private Equity AS	10.25%
Ludwig Mack AS	8.92%
Odin Norge	8.89%
Nordea Bank Denmark AS	3.79%
Gunnar Rørstad	3.75%
Hartvig Wennberg AS	3.41%
Jan Raa	2.83%
Knut Eirik Andersen	2.16%
Biotec Pharmacon ASA	2.01%
NorgesInvestor Proto AS	1.99%
Anchor Secondary 2 Holding AS	1.97%
B Skaugen AS	1.86%
Richard Waggoner	1.86%
MP Pensjon	1.63%
VPF Avanse Norden	1.09%
Arne Handeland	0.94%
Hilde Raa	0.86%
Selvaag Invest AS	0.76%
Telespar A/L	0.75%