



## Second Quarter 2015

13<sup>th</sup> August 2015

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# Agenda

- **Highlights**
- **Q2 financials**
- **Beta-Glucans**
  - advanced wound care
- **Enzymes**
  - molecular testing
- **Outlook**



## Highlights Q2 2015

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- Q2 revenues NOK 11.5 million (9,3 million). H1 2015 revenues 23.8 million (13.4 million)
- Continued positive development in ArcticZymes with quarterly sales at NOK 7.3 million (5.3 million)
- Improved EBIT to minus NOK 1.7 million in the quarter (NOK -2.9 million)
- Decided to end the commercial discussions for the Woulgan<sup>®</sup> distribution with Smith & Nephew and accelerate on-going processes with alternative distribution partners

- Highlights
- **Q2 financials**
- Beta-Glucans
  - advanced wound care
- Enzymes
  - molecular testing
- Outlook



# Financial highlights Q2

NOK million	Q2 2015	Q2 2014	6M 2015	6M 2014	2014
Enzymes	7.3	4.0	14.9	8.6	16.3
Beta-Glucans	4.2	5.3	8.9	4.8	16.8
<b>Sales revenues</b>	<b>11.5</b>	<b>9.3</b>	<b>23.8</b>	<b>13.4</b>	<b>33.0</b>
Enzymes	3.2	0.9	5.1	-0.5	-3.8
Beta-Glucans	-4.2	-3.3	-8.9	-8.8	-17.4
<b>EBITDA</b>	<b>-1.0</b>	<b>-2.3</b>	<b>-3.8</b>	<b>-9.4</b>	<b>-21.2</b>
<b>Profit before tax</b>	<b>-1.3</b>	<b>-2.5</b>	<b>-4.5</b>	<b>-10.0</b>	<b>-22.0</b>

\* The segment figures reflect that all costs are allocated to the two operating units

# Cash flow and cash position Q2

NOK million	Q2 2015	Q2 2014	6M 2015	6M 2014	2014
Operating activities	-4.8	-7.7	-14.0	-18.3	-21.2
Investing activities	-0.5	-0.3	-0.5	-2.2	-1.9
Financing activities	4.5	75.2	4.5	75.9	77.7
<b>Changes in cash and cash equivalent</b>	<b>-0.8</b>	<b>67.2</b>	<b>-10.0</b>	<b>55.3</b>	<b>54.6</b>
Cash and cash equivalents at the beginning of period	79.1	21.8	88.3	33.7	33.7
<b>Cash and cash equivalents at the end of period</b>	<b>78.3</b>	<b>89.0</b>	<b>78.3</b>	<b>89.0</b>	<b>88.3</b>

# Biotec BetaGlucans

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- Highlights

- Q2 financials

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- **Beta-Glucans**
  - advanced wound care



- Enzymes

  - molecular testing

- Outlook

# Biotech BetaGlucans (segment numbers)

NOK million	Q2 2015	Q2 2014	6M 2015	6M 2014	2014
Sales Revenue	4.2	4.0	8.9	4.8	16.8
Gross profit	<b>2.2</b>	<b>2.1</b>	<b>4.2</b>	<b>2.5</b>	<b>6.7</b>
Other income	0.5	0	1.0	0	1.6
Personnel expenses	-2.9	-2.4	-7.5	-6.1	-15.2
Operating expenses	-3.7	-3.0	-6.7	-5.3	-10.5
EBITDA	<b>-4.2</b>	<b>-3.3</b>	<b>-8.9</b>	<b>-8.8</b>	<b>-17.4</b>
Depreciation & Amortization	-0.4	-0.4	-0.9	-0.8	-1.5
EBIT	<b>-4.6</b>	<b>-3.7</b>	<b>-9.8</b>	<b>-9.6</b>	<b>-18.9</b>

\* The segment figures reflect that all costs are allocated to the two operating units

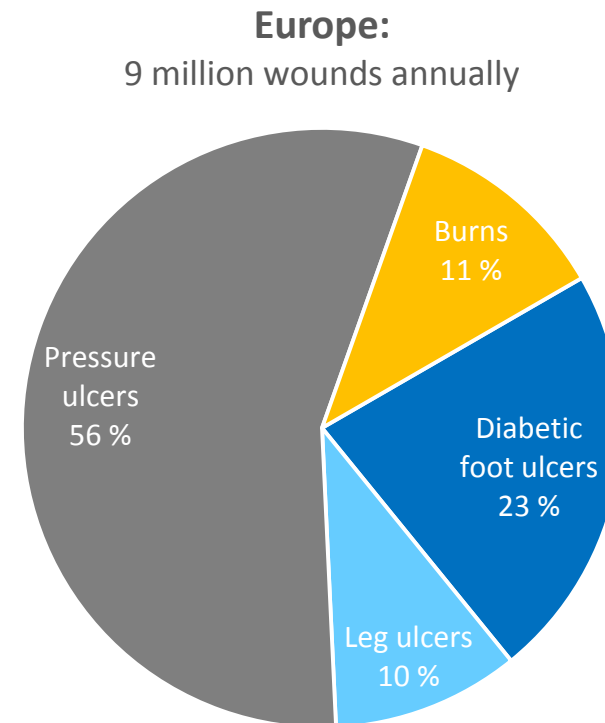
# Advanced wound healing: Major market opportunity

- The European market counts ~9 million wounds in the initial indication areas

Diabetic ulcers, leg ulcers, pressure ulcers, burns

- Approved also for other major wound areas

Post-surgery wounds, trauma wounds, lacerations, and abrasions



➔ Europe represents ~1/3 of the total available global wound market

# Background and summary of the S&N process

- The process between S&N and Biotec started in the middle of 2010 when the company started working with the major wound care companies following the phase 3 failure. The reason for this early contact was the experience that new products are best developed together with demanding customers
- When the Evaluation agreement was signed by the end of 2012 it was uncertainties related to whether the Woulgan® product could be approved, with what claims and how good it was
- For Biotec, it was very important to structure a relationship such a way that if the company was able to get the product approved with strong claims, and the product also performed well, this value creation should be to the benefit of Biotec's shareholders
- This meant that Biotec should not make a long term agreement and should have escapes. This led to the process where S&N should evaluate the product in the market after the product was approved. Both parties recognized that Woulgan® would need a lot of efforts to succeed being substantially different from most existing advanced wound care products
- What S&N wanted in return was time to test out the product and run the process with us on an exclusive basis
- The product approval process was very complicated and took more time than expected. Also the Evaluation Study was 3 months delayed due to slow recruitments of patients
- Following the conclusion of the study, it became difficult to get a number of the sites to report study outcome details but S&N got enough information to make their internal assessment and business case
- For Biotec it has all the time been clear that a successful global S&N agreement would be a good solution, but also potentially the worst position for the company if S&N should reduce the attention to the product. For a product with no commercial track record it is very difficult to get sufficient long term protection in a commercial agreement
- The combination of Woulgan® being a unique product that requires special attention to be successful, but with no commercial track record, made Biotec and S&N to conclude that the company is better off outside S&N

# Significant achievements during partner process

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- Biotec is a scientific company and when the process started in 2010, it had limited competence in wound healing
- In the period from 2010 to 2014 Biotec was able to develop a promising product and get it approved with very strong claims. In addition, the company learned a lot about the commercial opportunity in wound healing
- Much of the commercial guidance during this period was related to regulatory positioning and product performance that came from the discussions with potential partners. After the end of 2012 this was solely S&N
- This time was by no mean wasted. The company has achieved a lot during this period in term of early processes towards KOL's in UK, Germany and Norway, and parallel partner processes. However, Biotec are now looking forward to start executing on the commercial pathway for Woulgan®

## About the Evaluation Study:

- The aim of the study was to investigate the users perception of the product in a clinical setting
- S&N used mostly verbal conclusions and interviews with the sites in their assessment of the product
- As of today, Biotec has received all details S&N has from the study, but these are not complete
- Biotec will now work with the testing sites to get the remaining details and to urge them to publish

# Evaluation study - Recruitment

	No. of centres	DFU/FU	VLU/LU	PU	Other	Total
UK – target	5	50	40	0	0	90
UK - actual	6	44	35	1	0	80
Germany - target	5	50	0	0	0	50
Germany - actual	6	46	17	4	3	70
<b>Totals - actual</b>	<b>12</b>	<b>90</b>	<b>52</b>	<b>5</b>	<b>3</b>	<b>150</b>

Patients withdrawn\*

5                      5                      0                      1

\* Clinicians attributed withdrawals to non-Woulgan related issues e.g. infection.

# Evaluation study - Key themes

	UK	Germany
<b>Target wounds</b>	DFU, FU, VLU, LU, PU	DFU, FU, VLU, LU, PU
<b>Tubes per application</b>	DFU – less than 1 VLU – 1 or more	DFU – less than 1 VLU – 1 or more
<b>Applications per week</b>	DFU – 1 to 3 per week VLU – 1 to 2 per week	DFU – 1 to 3 per week VLU – 1 to 2 per week
<b>Application</b>	Very easy to use. Patients have applied it themselves at home.	Very easy to use. Patients have applied it themselves at home. The size keeps the price down.
<b>Tube size</b>	About right. Sometimes need more, sometimes need less.	About right, but keep the price down.
<b>Gel</b>	Really nice consistency. Stays in place.	Really like the way it stays in place once applied. Better than other gels.
<b>Wound response</b>	Varies from neutral to improvement seen. Most centres have at least one good example of progress, but mixed with others that are slow or no response.	Some clear responders, majority show slight progression, others remain static.
<b>Pain</b>	Some anecdotal reports of reduced pain	Occasional reports of pain reduction

# Evaluation study – Leg Ulcer UK

<b>Recruitment</b>	
Patients recruited	20
Patients completed	18
Patients stopped	2
(2 stopped: compliance, infection)	

<b>Aetiology</b>	
Venous	10
Arterial	2
ischaemic	2
trauma	4
pressure	2
	<b>20</b>
(2 stopped: Venous)	

<b>Treatment frequency</b>	
Weekly	3
Biweekly	11
Triweekly	4
New patient	2
	<b>20</b>

- 50% of leg ulcer were venous
- 100% easy to apply
- 50% led to reduce exudate
- 90% of wounds improved or better

<b>Easy to apply</b>	
Yes	20
No	0

<b>Change in exudate</b>	
Improved	10
No change	8
Deterioration	0
Stopped	2

<b>Change in surrounding skin</b>	
Improved	7
No change	11
Deterioration	1
Stopped	1

<b>Clinician view of wound</b>		
Healed	2	10%
Much improved	8	40%
Improved	8	40%
Same	0	0%
Worse	1	5%
Much worse	0	0%
Stopped	1	5%
	<b>20</b>	

# Clinical Impact

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- **Venous Leg Ulcers** (CHCP, Hull)
  - “Wow!!”
  - “Patients like it. Staff like it”.
  - “Has reduced pain of the wound in several instances”.
  - “Reduced exudate and maceration”.
  - Has progressed many wounds that have been stuck.
- **Selected numbers** (CHCP only = 18 leg ulcers (10 venous))
  - 80% improved or much improved. 10% to full healing
  - 50% of wounds had reduced exudate, 40% had no change. Others withdrew.

# Results from UK, site 2 (18 patients with foot ulcers assessed over 12 weeks)

Patient	Wound type	Infected (Y/N) start vs end		Pain (0-10) start vs end		Comfort (0-10) start vs end		Wound healing progress
1	FU	Yes	No	0	0	8	10	NA
2	FU	Yes	No	0	0	9	7	Improved
3	DFU	Yes	No	0	0	9	10	Improved
4	FU	No	No	0	0	10	10	Improved
5	DFU	No	No	5	0	5	10	Much improved
6	DFU	Yes	No	0	0	10	10	Much improved
7	FU	No	No	0	0	8	9	Much improved
8	FU	No	No	0	0	9	10	Much improved
9	DFU	Yes	No	0	0	8	10	Improved
10	DFU	Yes	No	0	0	9	10	Improved
11	FU	No	No	3	0	9	10	Improved
12	DFU	Yes	No	0	0	6	10	Much improved
13	DFU	No	No	0	0	8	9	Much improved
14	FU	Yes	No	0	0	9	10	Improved
15	DFU	Yes	No	1	0	10	10	Improved
16	FU	No	No	3	0	6	10	Much improved
17	FU	Yes	No	2	0	7	10	Much improved
18	DFU	No	No	0	0	10	10	Improved

# Clinical Impact

- **Diabetic Foot Ulcers** (UK feedback - Croydon Hosp, CHCP, Humber NHS Trust)
  - Wound improvement in some but not all. “I’m neutral”, “not been set on fire”.
  - But... “in one case its been a limb-saver” (UK and Germany example)
  - “Reduced exudate and maceration”.
  - Has progressed several wounds that have been stuck. “Pain and peri-wound itching reduced.”
  - “It seems to work better on non-diabetic foot ulcers”.
- **Selected numbers** (CHCP only = 9 diabetic, 11 non-diabetic)
  - 56% infected. 100% resolved in 12 weeks. 70% of infected didn’t require A/B
  - 94% either improved or much improved in wound size/condition. None healed in 12 weeks
  - Average pain during wear score = 0
  - Resolution of pain in the 5 patients who reported pain = 100%

# Results from Germany, site 1 (10 patients with mainly foot ulcers assessed up to 16 weeks)

Patient	Wound type	Infection	Ease of use	Pain	Comfort	Wound healing progress
1	DFU	Yes	Yes	Much improved	9 (only average given)	Much improved
2	DFU	-	Yes	0		Much improved
3	DFU	Yes	Yes	0		Much improved
4	PU	Yes	Yes	Improved		Improved
5	DFU	-	Yes	0		Worse; non-compliant
6	DFU	-	Yes	0		Much improved
7	PU	Improved	Yes	0		Improved
8	Dehiscence	-	Yes	Worse		Withdrawn
9	Leg ulcer	-	Yes	0		Improved
10	Abcess	-	Yes	Worse		The same

# Results from Germany, site 4 (15 patients with diabetic foot ulcers assessed up to 16 weeks)

Patient	Wound type	Infected (Y/N) start vs end		Ease of use	Pain (0-10)	Comfort (0-10)	Wound healing progress
1	DFU	Yes	No	Yes	0	9 (only average given)	Improved
2	DFU	No	No	Yes	0		The same
3	DFU	No	No	Yes	0		Improved
4	DFU	No	No	Yes	0		Improved
5	DFU	No	No	Yes	0		Improved
6	DFU	No	No	Yes	0		Improved
7	DFU	No	No	Yes	0		Much improved
8	DFU	No	No	Yes	0		The same
9	DFU	No	No	Yes	0		Worse (not related to Woulgan treatment)
10	DFU	No	No	Yes	0		Improved
11	DFU	No	No	Yes	0		Improved
12	DFU	No	No	Yes	0		The same
13	DFU	No	No	Yes	0		Much worse (not related to Woulgan)
14	DFU	No	No	Yes	0		Improved
15	DFU	No	No	Yes	0		Much improved

## Process going forward

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- Since beginning of this year the company has worked with alternative partners in particular in Europe with main focus towards Germany, UK and Scandinavia where the Product already has been tested
- During spring, Biotec had a shortlist of companies in both markets, but learned they were difficult to commit while the S&N process was running
- Following the conclusion of the S&N process in July these alternative processes are now moving forward and Biotec is currently discussing agreements with potential regional partners in Europe
- In particular some of the German alternatives cover other European countries as well, so Biotec will keep these on hold until Germany is decided

## Other areas Woulgan<sup>®</sup>

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- **US**
  - Reimbursement positioning strategy being developed
  - This work is also key to potential US partners
- **Strengthening the commercial organization:**
  - Conducting search for an experienced wound care specialist as International Marketing Director Woulgan
  - Will over time build a commercial organization of 6-8 marketing/product managers working in the local markets
- **Health Economics**
  - Building the documentation for DFU based on published clinical evidence and supporting documentation
  - Will represent an important basis for marketing

# Health Economic – Patient outcomes (DFU)

(Based on published phase 2 data)

	SBG/Woulgan	Std. care	Difference (Woulgan-std.care)
Percent of ulcers healed			
8 weeks	44%	19%	+25%
12 weeks	56%	37%	+19%
26 weeks*	83%	56%	+27%
52 weeks*	97%	82%	+15%
Mean healed weeks per patient			
12 weeks	4	2	+2
52 weeks*	38	26	+12
Mean weeks of treatment per patient			
12 weeks	8	10	-2
52 weeks*	14	26	-12

\*Extrapolated data

## Other beta-glucan opportunities:

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- Pursuing additional opportunities in the Animal Health sector
- Working on clarifying the strategic options for the Nutrition market for decision later this year. Exclusivity is expiring January 2016
- The study using Biotec's SBG as an adjuvant in treatment of Neuroblastoma conducted by Memorial Sloan Kettering Cancer Center in New York are encouraging and is expanded into a phase II aiming to recruit a total of 115 patients

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- Outlook

# Enzymes (segment numbers)

NOK million	Q2 2015	Q2 2014	6M 2015	6M 2014	2014
Sales Revenue	7.3	5.3	14.9	8.6	16.3
Gross profit	<b>7.0</b>	<b>5.0</b>	<b>14.4</b>	<b>8.0</b>	<b>15.3</b>
Other income	1.5	1.0	2.8	2.2	4.0
Personnel expenses	-3.2	-2.3	-7.6	-6.0	-13.9
Other Operating expenses	-2.2	-2.8	-4.4	-4.7	-9.3
EBITDA	<b>3.2</b>	<b>0.9</b>	<b>5.1</b>	<b>-0.5</b>	<b>-3.8</b>
Depreciation & Amortization	-0.2	-0.2	-0.5	-0.5	-1.0
EBIT	<b>2.9</b>	<b>0.7</b>	<b>4.6</b>	<b>-1.0</b>	<b>-4.8</b>

\* The segment figures reflect that all costs are allocated to the two operating units

## ArcticZymes highlights Q2 2015

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- ArcticZymes continued to maintain momentum by driving sales with its key customers
- Three top products; rSAP, Cod UNG, and the DNase product portfolio (stand-alone enzymes and finished kits) continue to drive the sales figures
- The pipeline of B2B (business to business) customer prospects for the PCR Cleanup and DNase portfolio, as well as Cod UNG and early prototypes are progressing to the next stage of commercial development

## New business & developing the pipeline

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- ArcticZymes plans to commercialize a synergetic mix of new enzymes and applications primarily targeted towards the PCR, Sequencing and Molecular Diagnostics markets
- Close contact with customer (B2B partners) to understand future direction and opportunities
- Use this “wish list” working with bioprospecting outcome and prospects in libraries combined with ArcticZymes’ in house expertise for genetic modification and synthesis
- Will lead to a number of new products with interesting commercial potential

## New branding

- ArcticZymes has revamped its brand via its new booth and updated website to be positioned more towards B2B and OEM relationships
- The new booth was exhibited for the first time at Front Line Genomics 2015 in Boston



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# Outlook

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- The primary focus of Biotec currently is to enter into agreement(s) which will best possibly secure the full commercial potential of Woulgan<sup>®</sup>
- Biotec is currently discussing agreements with potential regional partners in Europe.
- The short term focus are on UK, Germany and Scandinavia
- Will work to have more data from the Woulgan<sup>®</sup> evaluation published and to finalize health economic data model which also will influence the pricing
- Keeping up the momentum on ArcticZymes to secure continuous growth

# New product offer of Woulgan<sup>®</sup> to shareholders

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- We will send out an offer to all shareholders that are registered in the shareholder register as off 13<sup>th</sup> August to purchase 10 tubes of Woulgan<sup>®</sup> for NOK 350 plus shipment
- This time we can ship to all European shareholders

# Q&A

**WOULGAN<sup>®</sup> BIOGEL**  
is now available via our web store

[BUY NOW](#)



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