Opening up the world of sound with hearing implants

Jes Olsen
President, Oticon Medical
Jes Olsen

President, Oticon Medical

Curriculum

• Born in 1960
• B.Sc. in electronic engineering and electroacoustics
• Employed with Group since 1986
• General Manager, Oticon AB, Stockholm 1993-1996
• Various senior management roles in Oticon, including Vice President of R&D 1997-2008
• President, Oticon Medical since 2008
Agenda

Hearing implants market
Oticon Medical
The Neuro System: Scientific-based outcomes
Prof. Prof. h.c. Dr. med. Thomas Lenarz, Hannover Medical School
The Neuro system: Status
The Ponto system: Innovation fuelling better outcomes
Q&A
The market for hearing implants
Primary technologies within hearing implants

Cochlear implants (CI)

A cochlear implant makes sense of sound for people with severe to profound sensorineural hearing loss

Bone anchored hearing systems (BAHS)

A bone-conducting hearing system is suited for people with conductive hearing loss, unilateral hearing loss or single-sided deafness
Cochlear implant (CI) market

- Significant variations between markets
- Given our small market share, we are focused on current addressable market

Growth drivers:
- Education, reimbursement, new indications, new markets, innovation, ageing population
- 40/60 split between paediatric/adult in a market of ~65,000 implantations a year

Total market size of approx. EUR 1.3 billion

- 2.5% of all aged 75+ have a hearing loss that qualifies them for a CI
- 130,000+ new CI candidates a year with severe/profound hearing loss

Note: Company estimates
Where does CI market growth come from?

<table>
<thead>
<tr>
<th>Emerging markets</th>
<th>Developed markets</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Strong growth</strong></td>
<td><strong>Moderate growth</strong></td>
</tr>
<tr>
<td>• Improved newborn hearing screening</td>
<td>• Mandatory newborn hearing screening</td>
</tr>
<tr>
<td>• Reimbursement in most countries</td>
<td>• Increased indications</td>
</tr>
<tr>
<td><strong>Limited growth</strong></td>
<td>• Mature market</td>
</tr>
<tr>
<td>• Generally limited focus</td>
<td>• Increased indications</td>
</tr>
<tr>
<td>• No reimbursement in place</td>
<td>• Improved reimbursement and awareness</td>
</tr>
</tbody>
</table>
Bone anchored hearing systems (BAHS) market

- Growth in BAHS market is highly product-driven

Growth drivers:
- Education, awareness, reimbursement, innovation, cosmetics

Penetration rate and only approx. 20,000 implantations per year

190,000+ users across the world and fastest growing hearing implant segment

Total market size of EUR 150+ million

Note: Company estimates
Where does BAHS market growth come from?

<table>
<thead>
<tr>
<th>Emerging markets</th>
<th>Developed markets</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Moderate growth</strong></td>
<td><strong>Strong growth</strong></td>
</tr>
<tr>
<td>• Increased focus but from a low starting point</td>
<td>• Better technology and cosmetics</td>
</tr>
<tr>
<td>• Limited or no reimbursement in place</td>
<td>• Awareness of consequences of hearing loss</td>
</tr>
<tr>
<td><strong>Limited growth</strong></td>
<td><strong>Strong growth</strong></td>
</tr>
<tr>
<td>• Generally limited focus</td>
<td>• Awareness of consequences of hearing loss</td>
</tr>
<tr>
<td>• No reimbursement in place</td>
<td>• Reimbursement in place</td>
</tr>
</tbody>
</table>
History of Oticon Medical

Bone anchored hearing systems (BAHS)

2007 Oticon Medical established in Gothenburg, Sweden
2009 Launch of the Ponto System – bringing digital sound quality to BAHS
2011 Ponto Pro Power – the first bone anchored digital power processor
2012 Wide Ponto implant – the industry’s largest bone-to-implant contact
2013 Oticon Medical/William Demant acquires Neurelec
2013 Ponto Plus and Ponto Plus Power – the first and most powerful family of processors with wireless connectivity
2015 Minimally Invasive Ponto Surgery (MIPS) – a truly new perspective on tissue preservation
2016 Ponto 3 family – the world’s most powerful family of abutment-level sound processors

Cochlear implants (CI)

1976 First multi-channel cochlear implantation in France by Prof. Chouard
1977 Development and production of cochlear implants established in Nice, France
1992 Digisonic DX10 – the first digital multi-channel cochlear implant
2001 Digisonic BTE – our first BTE sound processor
2012 Digisonic® SP EVO – the atraumatic electrode array to preserve residual hearing
2013 Saphyr Neo collection – better speech understanding in noise with Voice Track & Crystalis XDP
2015 Launch of the Neuro system Neuro Zti implant and Neuro One sound processor
2016 Today Neuro 2 – where sound meets design

Today
Oticon Medical’s position in hearing implants

**Product innovation**
- Size and cosmetics
- Audiology
- Fitting software
- Reliability

**Market access**
- Access to key markets
- Brand recognition
- Global infrastructure

- End-user lead generation

Leading in BAHS  Advancements  Leading in CI
Synergies with the William Demant Group

<table>
<thead>
<tr>
<th>Leading cross-functional R&amp;D</th>
<th>Strong retail network</th>
<th>Power house of hearing</th>
<th>Global operations infrastructure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proven ability to grow businesses</td>
<td>Financial strengths and committed owner</td>
<td>Specialised primary research facility</td>
<td>Founded on care</td>
</tr>
</tbody>
</table>

Founded on care
BrainHearing™

“The ears hear things...

...the brain makes sense of them “
From BrainHearing™ in hearing aids ...

OpenSound Navigator

Keeping speech clear and other sounds available, but not disturbing

Enjoy 30% better speech understanding

Reduce your listening effort by 20%

Remember 20% more of your conversations
... to BrainHearing™ in hearing implants

BAHS

SWIR: Direct Sound Transmission vs. Skin drive

Recall is significantly better for abutment compared to softband fitting

13% improvement of words correctly recalled

Lunner et al. (2016) Using speech recall in hearing aid fitting and outcome evaluation under ecological test conditions. *Ear & Hearing*, vol 37, supplement 1, 145S-154S

CI: Combined SWIR and pupilometry

Speech audiometry scores with Speech Omni Compared to Opti Omni in 6 Neuro CI users
Committed to BrainHearing™

• Our portfolio of studies is large and growing
  • EEG measures
  • Behavioural tests, e.g. SWIR Recall
  • Pupilometry solutions (several set-ups, SMI, Tobii, Pupil labs etc.)
  • Functional near-infrared spectrometry
  • Heart rate changes
  • Infield research platform (self-assessment app, sound, HR data)
  • ....

• Partner in several EU H2020 projects on cognitive hearing
Patient journey – focus on people

• With hearing implants, you are on a life-long journey with the end-user
• Continuous innovation and long-term commitment are crucial factors for success
• Winning the customers takes time – and it should
• You should be easy to do business with and ensure easy access to information
• Recurring business and obligations when winning the customers’ loyalty
Patient journey – funnel

- ENT
- Newborn hearing screening
- Hospital
- Retail
- Communities
- On-line activities

- Availability
- Functionality
- Product sourcing
- Partnerships
- Research

- Fine-tuning
- Innovation (upgrades)
- Accessibility
- Compatibility

Awareness
Counselling
After care
Patient journey – synergies with rest of Group

Customer network
Group retail
Diagnostic division
Power house of hearing
On-line communities

Global presence
Strong infrastructure
Audiological expertise
Professional relations
Strong brand

Support centres
Global presence
On-line activities
In it to win it

Awareness
Counselling
After care
Oticon Medical: Our world
The Neuro system: Scientific-based outcomes
Neuro Zti cochlear implant

New standard in MRI compatibility

No risk of magnet extrusion at 1.5T – rigid body
No pain due to receiver movement – fixation system
Removal made easy and safe for compatibility at 3T

First independent study published
Todt et al., JOHNS 2018

Comparing two technical solutions for MRI compatibility:
Neuro Zti and Competitor A

Neuro Zti is comparable to the best competitor product in the domain and outperforms products from two other manufacturers.

Fig. 1. AP skull film demonstrating 90 degree rotation of the internal magnet. There is associated protrusion of the scalp tissues (arrowheads).
BrainHearing™ and the Neuro 2 sound processor

Speech Omni setting in FreeFocus directional system

Technology inspired by the brain

Providing measurable benefits ...

... that patients want to use

Speech audiometry scores with Speech Omni compared to Optimised Omni in six Neuro CI users

Subjective preference in different listening situations for Speech Omni vs. Optimised Omni in 35 Neuro CI users
Neuro 2 sound processor

New standard in terms of battery life and design
Industry-unique aesthetic characteristics in combination with superior performance and increased outcomes

Objective measure: Speech audiometry scores

<table>
<thead>
<tr>
<th></th>
<th>Quiet</th>
<th>Noise</th>
</tr>
</thead>
<tbody>
<tr>
<td>V1: Neuro 1 - experienced</td>
<td>64.8</td>
<td>43.7</td>
</tr>
<tr>
<td>V2: Neuro 2 - upgrade</td>
<td>68.1</td>
<td>54.9</td>
</tr>
<tr>
<td>V3: Neuro 2 - 3m habituation</td>
<td>76.0</td>
<td>61.1</td>
</tr>
</tbody>
</table>
Opening Up the World of Sound
With Hearing Implants

Thomas Lenarz, MD PhD

Department of Otolaryngology
Hannover Medical School, Germany

WDH Capital Market´s Day, London June 12, 2018
Hearing Disorders

Outer and middle ear

Inner ear

Auditory pathway

Cortex

Midbrain

Brainstem

Cochlea

Conductive loss

Sensory or cochlear loss

Retrocochlear loss
Hearing Loss: A GROWING GLOBAL EPIDEMIC

- 2018: 466 million people
- 2030: 630 million people
- 2050: 900 million people
Hearing Loss in Germany

14 Mio. Hearing Impaired in Germany
Every 2nd above 65 Years
2 in 1000 Children

1,6 % > 250,000
Deafness - CI

7,2 % > 1 Mio
Profoundly D. - CI

32,2 % > 4 Mio Persons
Moderate – Hearing Aid

56,6 % > 8 Mio Persons
Minimally – Hearing Aid

80 % Normal Hearing

CI = Cochlea Implant
Hearing Loss: Auditory Devices

Number of affected persons:

-10 dB  -5 dB  0 dB  5 dB  10 dB  SNR

Severity of hearing loss:

Loss of clarity  ?

Loss of detail  ?

Hearing assistance:

Hearing aids

Cochlear implants
Cochlear Implant

Electrode

Auditory Nerve

low

high
The “success story” of Neuroprotheses

> 500,000 Recipients Worldwide

Candidates in Germany: 1 Million
Implanted in Germany: 50,000

Contact with the world of sound

Speech discrimination in a majority

Speech discrimination in all

Speech in noise & music perception in all

Time

First
Then
Now
Future

Fig. 49: Photograph of the portable prototype speech processor developed by the University of Melbourne.
“...implants that rely for functioning on a source of electrical energy or any source of power other than that directly generated by the human body ...(90/385/EEC MEDDEV)

- Pacemakers
- Cochlear Implants
Conservative Market - Expectations

Conservative means early Saturation!

Innovative Breakthrough like PM are always possible, but:

Medical Devices have long Delays due to Testing & Approval!
The “success story” of Neuroprotheses

> 500,000 Recipients Worldwide

Candidates in Germany: 1 Million
Implanted in Germany: 50,000

Contact with the world of sound

Speech discrimination in a majority

Speech discrimination in all

Speech in noise & music perception in all

Time

First

Then

Now

Future

Fig. 49: Photograph of the portable prototype speech processor developed by the University of Melbourne.
Objective: Develop auditory precision medicine

Every patient with hearing impairment is unique.
Precision Treatment for Hearing Loss

Diagnostics

IT-Based Classification & Recommendation

Treatment Options

Option 1

Differential Indication

Option N

Individualized Treatment

Precision Therapy

Hearing-Impaired Patient

Thread I

Thread II

Thread IV
Hearing Implant of the Future

Individualized Computer-Aided System Fabrication Platform

- Sensors
- Hardware & Software
- Stimulation

Interfaces

Patient Monitoring

Algorithm Configuration/Fitting

Stimulation Options
Spotlight — Advanced Auditory Implants

CHALLENGES

OBJECTIVES

- Degenerated epithelium
- Inflammation and fibrotic tissue
- Degenerated neurons

- Reduction of distance for improved electrode-neuron-interface
- Neuronal protection and directed dendrite outgrowth
- Inhibition of inflammation and fibrosis
drug therapy

gene therapy

mesenchymal stem cell (MSC)
Clinical translation challenges

- Bionic devices: bring biology into technical hearing solutions
- Artificial synapse
- Analogue-digital conversion
- Complete restoration of physiological hearing
Cochlear Implant Program in Hannover

Steps toward excellence:

- 1984 1st CI
- 1992 Children´s implant Center
- 2003 German Hearing Center
- 2003 Collaborative Research Grant Medical implants
- 2013 Center of Excellence Hearing4All
- 2016 VIANNA in NIFE
- 2016 Fraunhofer Center of Biomedical Excellence

Clinic – with 25,000 outpatients and 6,000 inpatients each year
600 Cochlear Implantations per year – 10,000 in total

German Hearing Center – patients go with hearing loss

NIFE – laboratories of experimental otology basic research

VIANNA – transfer basic science into new products Companies

Fraunhofer ITEM – production, testing and certification
Centre of BioMedical Excellence
Translational Medical Engineering

Fraunhofer Excellence Cluster
Supporting Structure

Institute of AudioNeuroTechnology (VIANNA) NIFE

Hearing 4all
German Hearing Center (DHZ)

- Integrated care for hearing impaired people
- One-stop shop
- Complete spectrum of diagnostic procedures
- Candidate selection
- Postoperative care and rehabilitation
- Conservative treatment of hearing loss
- Service centers of manufacturers for direct support of patients
- Remote care center hub and spoke
- Clinical research in fields of speech coding, electrodes, and acoustic implants

Head of clinical service:
Prof. Dr. Anke Lesinski-Schiedat

Head of technical service and research:
Prof. Dr. Andreas Büchner
Remote Care: Patient monitoring and Service

Hub and Spoke: 25 partners across Germany

Full service with spare parts, implant check and upgrade

Can be connected to the CI center any time

Future self-fitting and automated patient monitoring through data transfer
Remote Care with 2 way audio-visual connect

CI Center

Satellite

2 MBit SDSL

2 MBit SDSL
Hannover Medical School Experience with Oticon Neuro Implant
The Neuro Cochlea-Implant system

Neuro One
- Oticon Technology Inside (Inium)
- Coordinated Adaptive Processing

Neuro Zti
- Compact design
- Future-proof technology
- Conventional and atraumatic electrode arrays
The Neuro Cochlea-Implant system

**Neuro 2**
- Oticon Technology Inside (Inium)
- Coordinated Adaptive Processing
- Smallest BTE processor in the market

**Neuro Zti**
- Compact design
- Future-proof technology
- Conventional and atraumatic electrode arrays
Neuro Zti: feature summary

- Antenna protection inside the case
- 2nd generation fixation system
- Removable magnet
- MRI safe up to 3T with magnet removed
  - 1.5T with magnet in place
Electrode options

**EVO**
- Silicon Push-Rings for insertion
- Diameter at base: 0.5 mm
- Diameter at apex: 0.4 mm
- Insertion Length: 25 mm
- Active Length: 24 mm

**CLASSIC**
- Silicon Push-Rings for insertion
- Diameter at base: 1.07 mm
- Diameter at apex: 0.5 mm
- Insertion Length: 26 mm
- Active Length: 25 mm
Technological highlights: Neuro Zti

- 24 independent high-precision current sources
- Configurable ASIC with substantial reserves for future development in the area of signal processing
- 28 hermetic sealed feed through
- Build-in DSP for signal processing
  - ECAP
  - future: E-BERA or other AEPs
Neuro Cochlea Implants at MHH

- Up to now, 67 Oticon Neuro ZTI systems implanted at MHH
  - Average age: 62.3 yr.; avg. hearing impairment: 26.7 yr.; avg. deafness: 13.5 yr.
  - All patients fulfill our expectations related to achieved listening performance with CI
  - Automatic features of the Inium Sense chipset (AGC-free signal processing, beam former, noise reduction, etc.) are easy to program and perfectly accepted by the patients
  - ECAP measurement system provides curves with good signal-to-noise ratio. We are collecting data for further analysis of reliability.
Oticon Neuro Implantation at Hannover Medical School
First data on Neuro 2

- Since February 2018, the Neuro 2 sound processor is available
- Up-to-now, 55 upgrades have been conducted
- Patients report significant improvements in sound quality and clarity
- Therefore, we are conducting comparing measurements at each upgrade visit with both, Neuro One and Neuro 2 sound processors in the sound field.
Preliminary performance data

N = 8
Average Age: 68.5 yr.
Preliminary performance data

Wilcoxon matched pairs signed rank test

HSM Sentence Test

<table>
<thead>
<tr>
<th>Score in percent correct words (%)</th>
<th>Quiet</th>
<th>Noise</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neuro One</td>
<td>20</td>
<td>55</td>
</tr>
<tr>
<td>Neuro 2</td>
<td>30</td>
<td>50</td>
</tr>
<tr>
<td>Neuro 2 fine-tuned</td>
<td>40</td>
<td>35</td>
</tr>
</tbody>
</table>

Wilcoxon matched pairs signed rank test

- p = .03 *
- p = .13 n.s.
Summary

• In total, 67 Oticon Neuro Systems have been implanted at MHH
  – All surgeries have been conducted without complication
  – Pleased with level of OM inter-operative support provided

• All Neuro Zti patients at MHH are within expected listening performance, Neuro 2 obtains significantly better speech understanding results compared to Neuro One

• The signal processing chain in Neuro 2 is controlled by the Inium Sense Chip. Der Inium Sense Chip is widely used in Oticon’s high-end hearing aids and allows for latest signal processing advances to be utilised in cochlear implant systems.

• As for all CI systems, technical support by the producer is essential. We are very satisfied with the support provided by Oticon Medical.
Thank you
The Neuro system: Status
The Neuro system
Neuro 2 launch status

• 500+ patients fitted with Neuro 2 in key markets
  • First users fitted at the end of February

• Focus on upgrading Neuro One exchange program users
  • Excellent feedback from users on: Sound quality, usability, battery life, rechargeable batteries and the comfortable physical fit of BTE on their ear

• Professionals are very excited about the easy fitting process and the general quality of the new Genie Medical CI

• Significant interest in the system; comprehensive training programmes are ongoing at key CI centres

• The vast majority of exchanges have been completed in the addressable markets

• Focus on roll-out to remaining markets
Genie Medical CI – designed for audiologists

Logarithmic frequency axis

Remote fitting

Audiometric frequency table

Live bilateral loudness adjustments

Free frequency selection
Smooth adjustments
Multiple design awards for Neuro 2

- **Red Dot Award 2018 Winner** for Excellent Product Design (Healthcare)
- **Red Dot Award 2017 Winner** for Design Concept (Bionics)
- **IF Design Award 2018 Winner** for Product Design (Medical Device)
- **Danish Design Award Finalist 2018** (Daily Life)
- **European Product Design Award 2018 Gold prize winner** (Life Science Design/Aids/Prosthetics)
- **German Design Award Winner 2018** for Excellent Product Design (Medical, Rehabilitation and Health Care)
- **Good Design 2017 Winner** (Personal)
- **A’Design Award Winner 2018 Gold** (Scientific Instruments, Medical Devices and Research Equipment Design)
- **IDA Design Awards Gold Winner 2017** (Industrial And Life Science Design-Aids/Prosthetics)
The Ponto system:
Innovation fuelling better outcomes
Ponto 3 SuperPower: The strongest abutment-level sound processor

Significantly better speech understanding in complex situations
• Including effect of FreeFocus feature

Significantly better patient ratings
• Including effect of higher maximum output

Ponto on softband: A proven solution for children

*Data from bilateral microtia-atresia infants*

(i) **Children’s auditory development reported for 40 infants**
   - Ponto sound processor on a softband improves auditory development

(ii) **Treatment gives significant improvement over time**
   - On average, close to normal scores being achieved after 24 months’ use of the sound processor

Ponto: Long-term randomised controlled study of 60 implants

**Excellent stability and survival over three years**
- High implant stability and survival rates

**Very few skin complications with Ponto implants**
- Only 2% of visits reported skin complication in need of treatment (Holgers ≥2)

*Kruyt, I. J., et al. (2018). Three-year Outcomes of a Randomized Controlled Trial Comparing a 4.5-mm-Wide to a 3.75-mm-Wide Titanium Implant for Bone Conduction Hearing. Otology & Neurotology.*
First clinical data on the Ponto BHX implant support earlier pre-clinical data

Clinical data from world-leading centres
- High implant stability and survival rates

Supporting unique osseointegration properties
- Stronger than bone
Oticon Medical – well positioned for growth

- Strong product portfolio in BAHS and CI with great outcomes
- Scientific approach to support customer choice
- Well integrated with Group R&D and Operations
- Positioned to exceed long-term market growth
- Global infrastructure and a strong local support organisation
- Substantial synergies for market access
- Long-term commitment and support from owner
Q&A