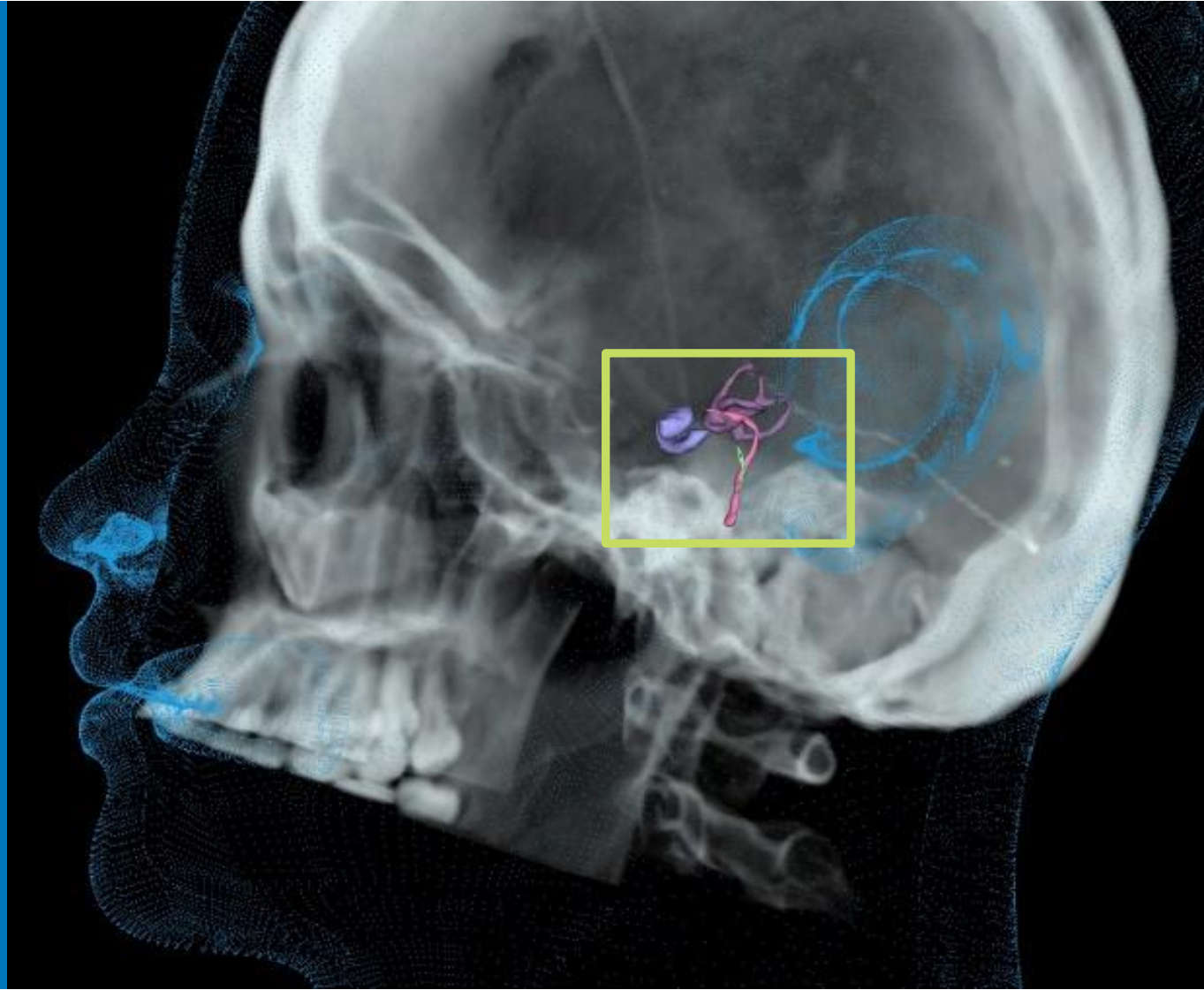




Bacta Implants
Your personalized therapy

Revolution of Hearing Loss Therapy



Team: Clinic of Otorhinolaryngology, Hannover Medical School



Verena Scheper

Professor Dr. med. vet.

Business Development
and Clinical Translation



Martina Knabel

*M. Sc. Biomedical
Engineering*

Technical Development
and Production



Annika Buchholz

M. Sc. Economics

Finance and
Controlling



Marleen Grzybowski

*M. Sc. Hearing Technology &
Audiology*

Quality Control and
Clinical Trial Conduction

Innovation: Individualized Drug Eluting Elastic Implants

Design

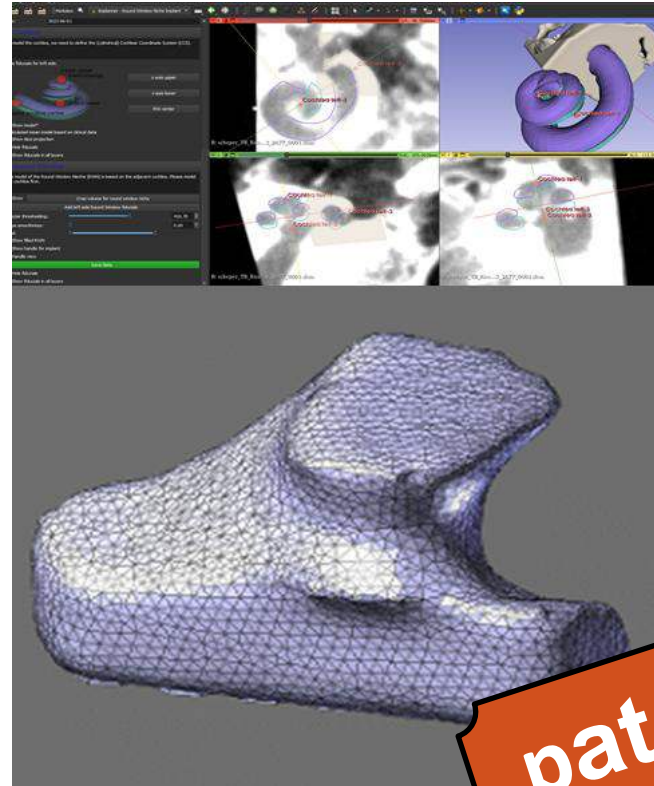
&

Manufacturing

Individualized

Elastic

Drug eluting



patented



Product:
Round Window Niche Implant (RNI)



Challenge

Key factor for a successful pharmacotherapy is the sufficient drug concentration at the target region.

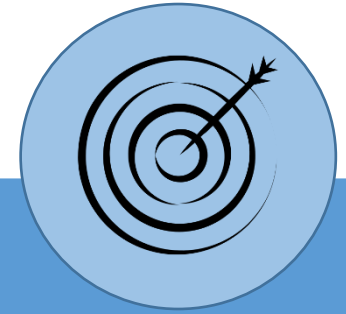
Drugs are most commonly administered orally or intravenously, exposing the entire body to achieve a therapeutic concentration at the target site. In poorly perfused organs such as the inner ear, however, sufficient drug levels may not be reached at all, resulting in a lack of therapeutic effect.



Problem

High drug doses can cause severe adverse effects.

To ensure a therapeutic drug concentration at the target organ, high systemic doses are often required. This can lead to adverse side effects in parts of the body where the drug is not needed.



Solution

Placing a drug eluting implant at the target requires lower doses and is more effective.

The drug can directly reach the target organ and achieve its desired effect. No systemic effects are expected.

To be able to place an implant in a small bony cavity, it needs to be individualized and elastic to ensure an optimal fit.

Challenge: Effective Treatment of Sudden Hearing Loss



160T/year &



>6M/year in need of treatment

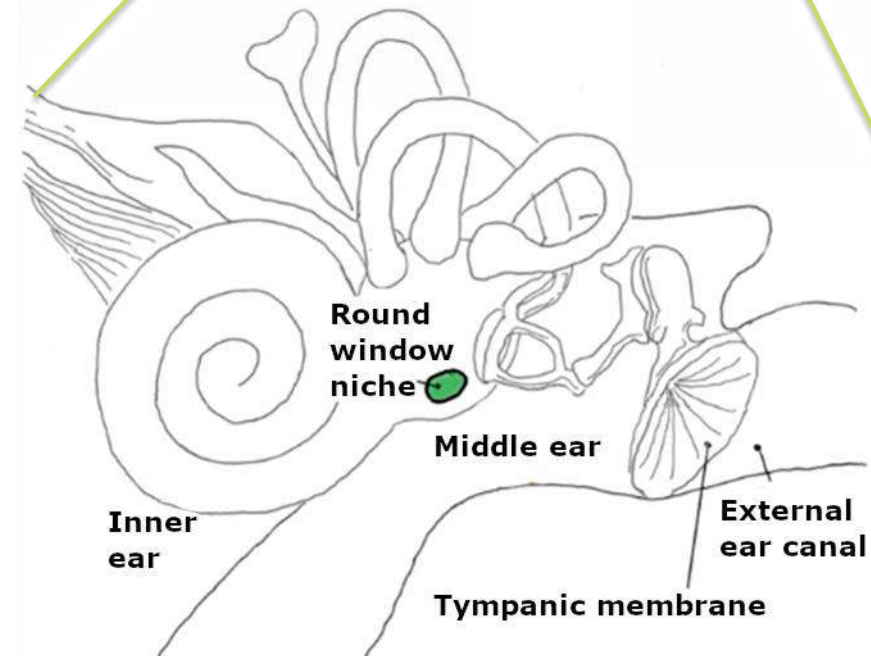
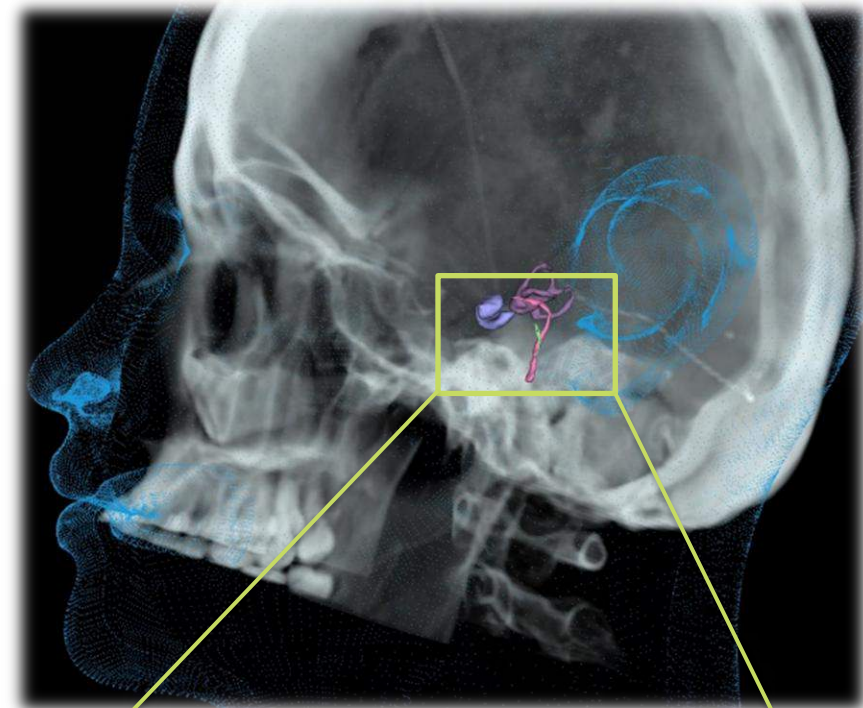
There are drugs known to be effective against SHL, however common treatment attempts are all off-label. Drugs approved for other applications are used

- either in high concentrations intravenously or orally
- or with soaked hand-cut sponges
- or by uncontrolled middle ear injections

All treatment options have the **problem that the target region is not reached** and therefore no proven benefit has been achieved yet.



There are effective drugs, but none have been approved against SHL.



Solution: Controlled Local Drug Release

A **local controlled release of drugs** in the middle ear via an implant will make sudden hearing loss treatable.

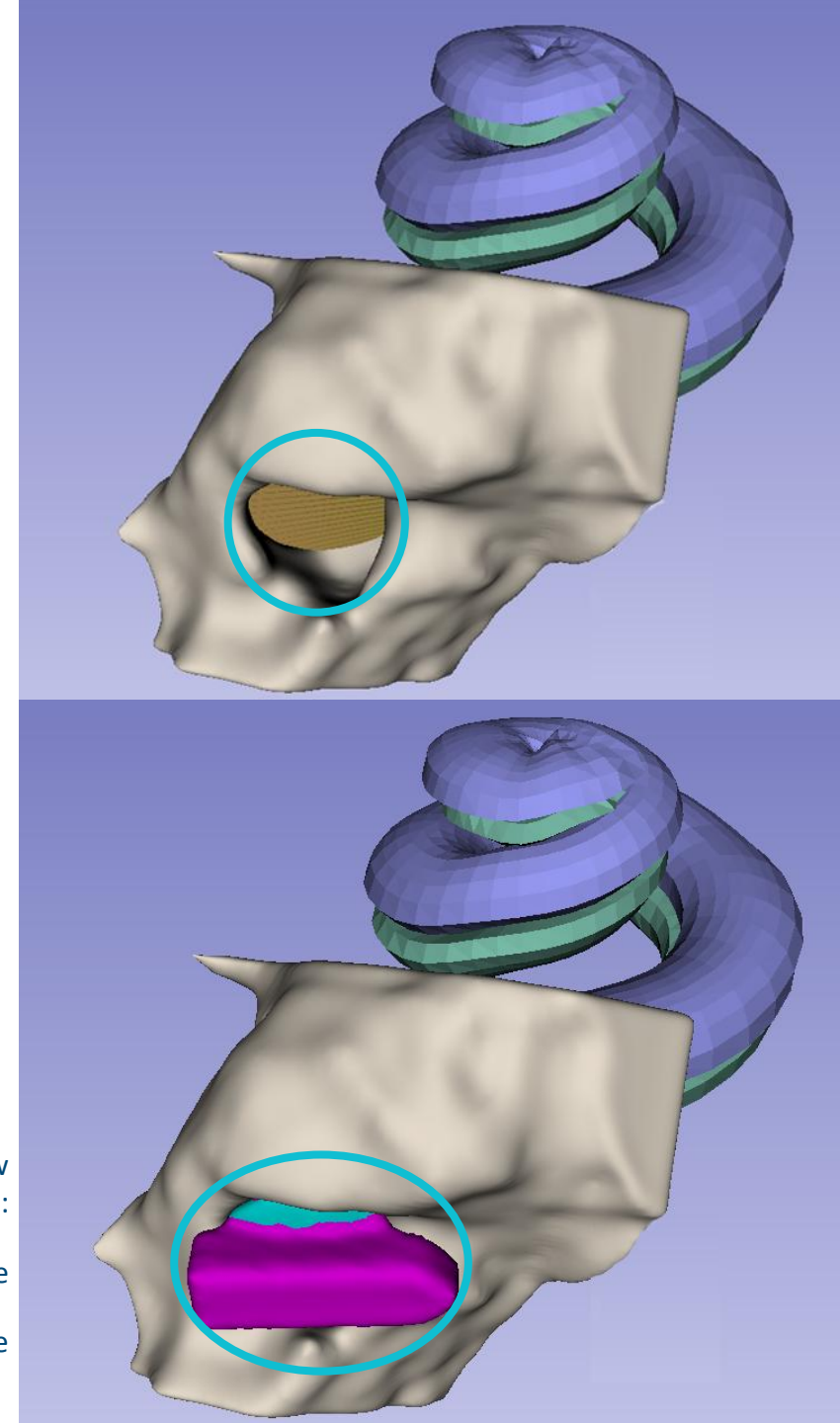
The best access to the inner ear is via the **round window niche** at the transition between middle and inner ear. The round window niche is a small bony cavity. The border to the inner ear is a membrane, passable for drugs.

The **Round Window Niche Implant (RNI)** contains drugs, that diffuse out of the implant through the membrane into the inner ear.

The Pictures show the inner ear (blue), bone (grey) and round window niche with membrane (brown):

Upper picture: empty round window niche

Lower picture: RNI (turquoise) with handle (purple) filling the niche



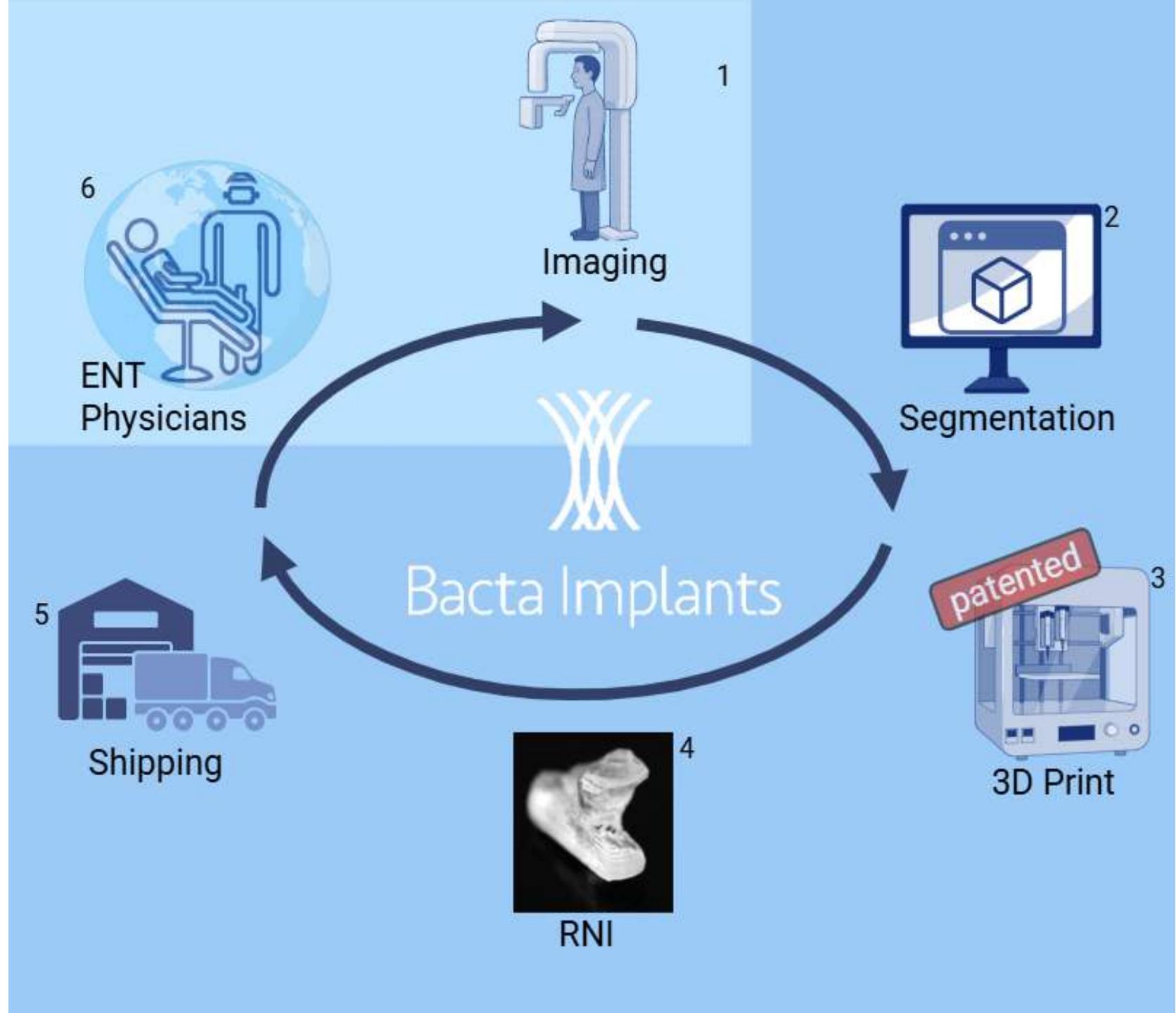
Workflow: RNI (*medicinal product*)

To assure a perfect fit, the implant has to be

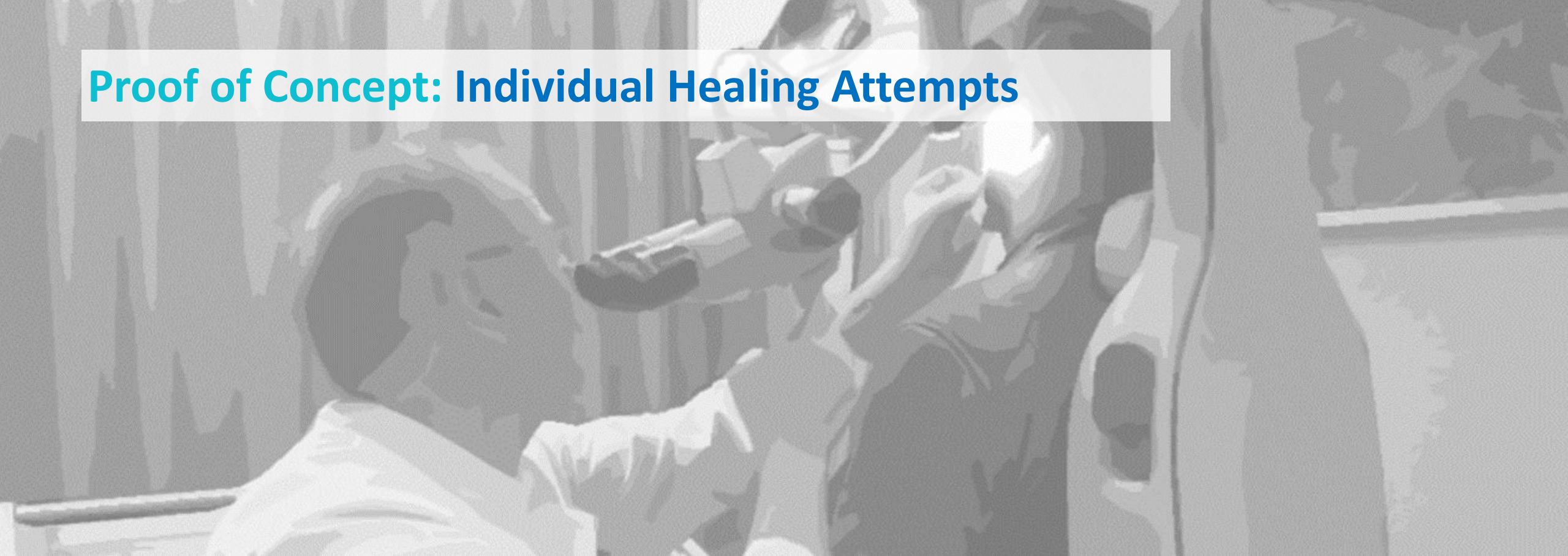
- individualized
- elastic

Workflow:

- (1) The physicians order the RNI and send us 3D images of the patient.
- (2) Bacta Implants segments those images and designs the individualized RNI.
- (3) The RNI is being 3D printed using silicone containing dexamethasone.
- (4) The elastic, drug eluting sterile RNI passes the quality control.
- (5) The RNI is shipped within 24h to the physician
- (6) In a short outpatient treatment in local anesthesia the RNI is implanted.



Proof of Concept: Individual Healing Attempts



Seven patients have already received our RNI

- Weeks after SHL – after unsuccessful currently used off-label therapies - they received our RNI.
- No adverse effects were observed.
- All RNIs fit well.
- In the majority the hearing improved after implantation in at least three different frequencies.

Business Model



ENT physicians

Physicians order and buy the implant from us (800€).



Patients

Patient will, at first, have to reimburse the doctors for the implant.

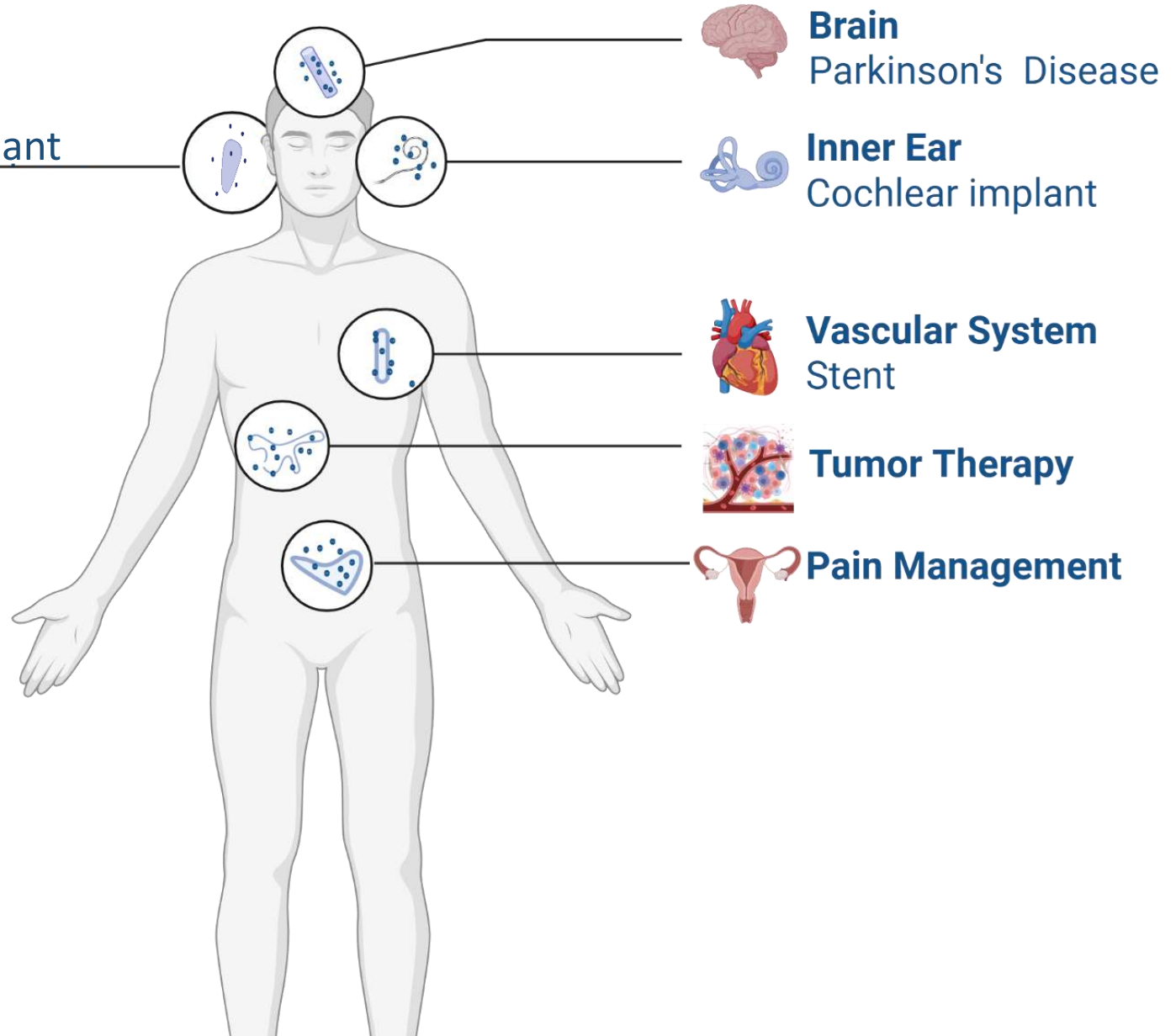
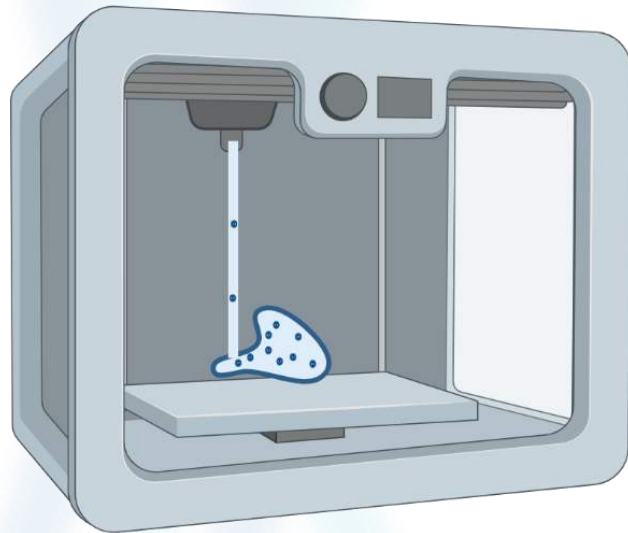


Health insurance

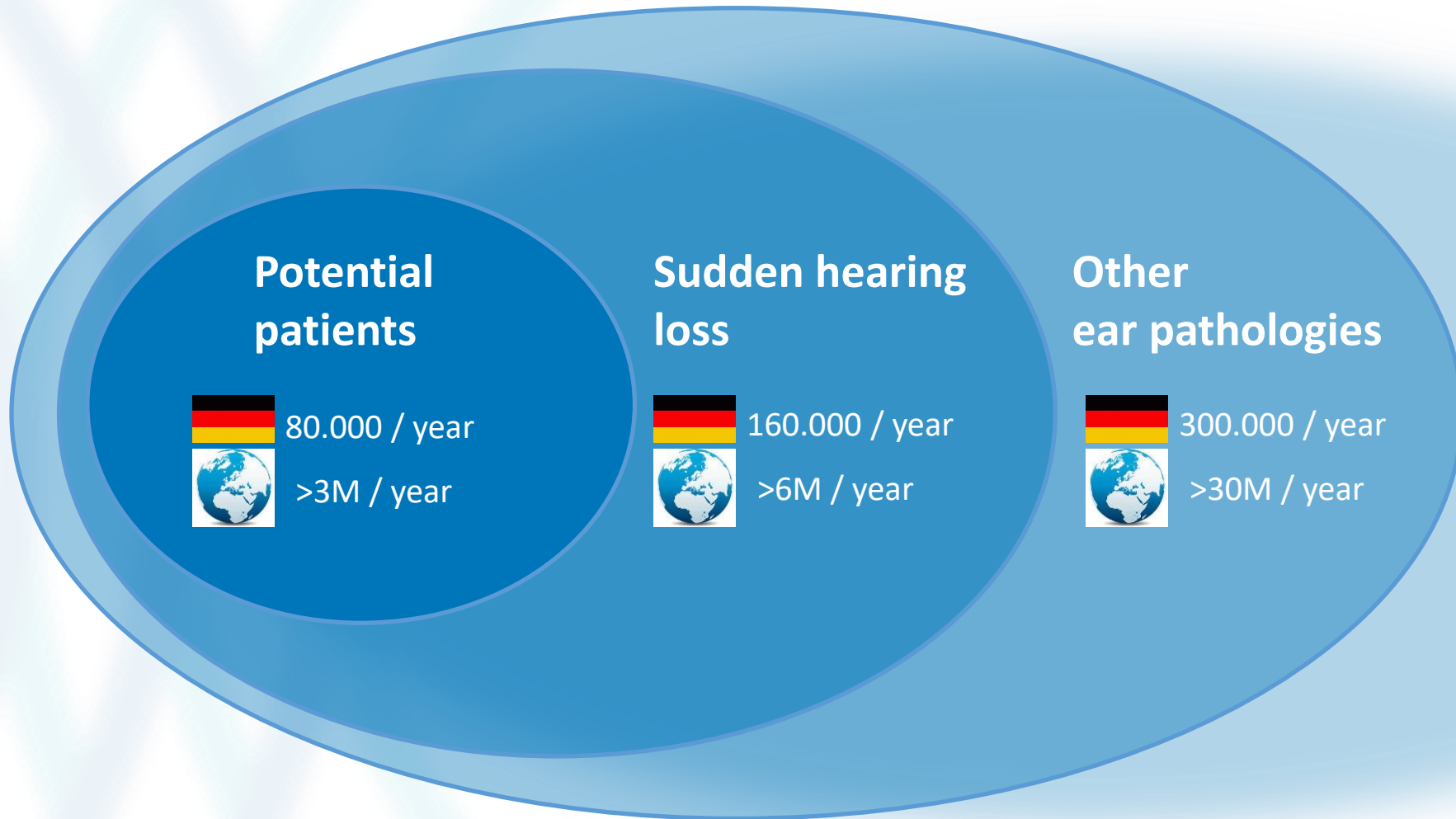
After proof of efficacy, health insurances will cover the costs and our product will be the **primary therapy against SHL**.

Technology: other possible applications

Middle Ear
External Ear Canal Implant



Market



Market potential
€ 64 M / y
€ 2.4 B / y









Other applications and countries



Factor 100
scaling potential

Competitors

Distinction to competitors: We develop local drug delivery rather than new compounds against inner ear pathologies

COMPANY	INNER EAR PATHOLOGY	SUDDEN HEARING LOSS	REPURPOSING OF APPROVED DRUG	LOCAL APPLICATION
 Bacta Implants	✓	✓	✓	✓
 AudioCure	✓	✓	X	✓
 Sensorion	✓	✓	X	X
 SOUND PHARMACEUTICALS	✓	X	X	X
 spiral therapeutics	✓	X	X	✓
 acousia therapeutics	✓	X	X	X
 FENNEC PHARMA	✓	X	X	X
 OTOMAGNETICS	✓	X	X	✓

* Gene and cell therapy approaches are not included

Unique Selling Point

Controlled local long term pharmacotherapy with  Bacta Implants



Effective therapy

No other method manages to effectively treat SHL, yet. Our RNI delivers established effective license-free drugs directly to the target region. Making it the first and only successful treatment.



Adverse effects reduction

Our implants reduce the overall amount of drugs and deposit them only where they are needed, thus reducing adverse effects. The treatment is more effective and more gentle to the patient.



Approved therapy

Safety for the patient and the clinicians as our product will be the first and only approved method to treat sudden hearing loss.

Market Penetration

For the purpose of market penetration Bacta Implants will engage in a multi channel marketing strategy:

- Conferences
- Fairs
- Homepage www.bacta-implants.com
- Seminars for physicians
- Targeted patient- and interest-group marketing



← ↻ 🏠 🔒 <https://bacta-implants.com/en/> 🔍 ⌵ ⌵ ⌵ ⌵ ⌵

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Interested ▾ About us ▾

Bacta Implants

Active ingredient at its site of action

Personalized implants that release drugs exactly where they are supposed to act

[More Information](#)


Bacta Implants
Your personalized therapy

Roadmap

Int. patent application
7 first-in-patient cases
Proof of concept



M4H Pre-seed

 Bacta Implants **Seed**

 Bacta Implants **Series A**



Pre-seed: Phase I/II Clinical trial secured

- GMP manufacturing permission
- Proof of safety and efficacy

Seed: Phase II clinical trial

- GMP Production
- Proof of efficacy

4.8
Mio. €

Series A: Multicenter study

- Proof of efficacy
- Market entry

7.2
Mio. €

Network

Clinic



Prof. Dr. med. Anke Leichtle

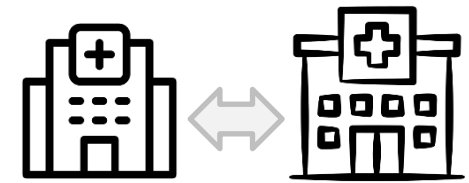
Director Clinic of Otorhinolaryngology,
Hannover Medical School (MHH), Germany

Pharma



Sara Maier

Pharmacist, Qualified person,
GMP-Consultant mai-q



Hospital network



Clinic



Prof. Prof. Dr. med. Thomas Lenarz

Research Professor and Emeritus Director Clinic
of Otorhinolaryngology, Hannover Medical School
(MHH), Germany

(Past) Chairman of e.g. DGHNO, DGBMT, NHNO,
DGSB, DGA, CURAC

Start-up



Samuel John

CEO and Co-founder OtoJig
Clinical imaging data processing and
Software Engineering



Health insurance

Capital Need

We need:

- Capital
- Expertise in regulatory processes and market penetration

Manufacturing permit & Clinical trial in CI 2025/26

Funded

Clinical trial Phase II 2026 - 2029

4,8 Mio. €

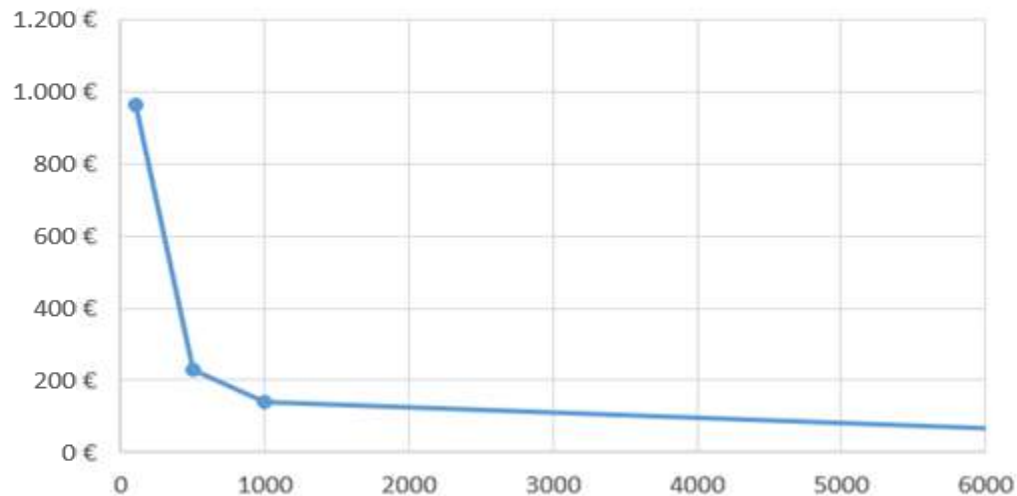
CBR: 30 months

Clinical trial Phase III 2029

7,2 Mio. €

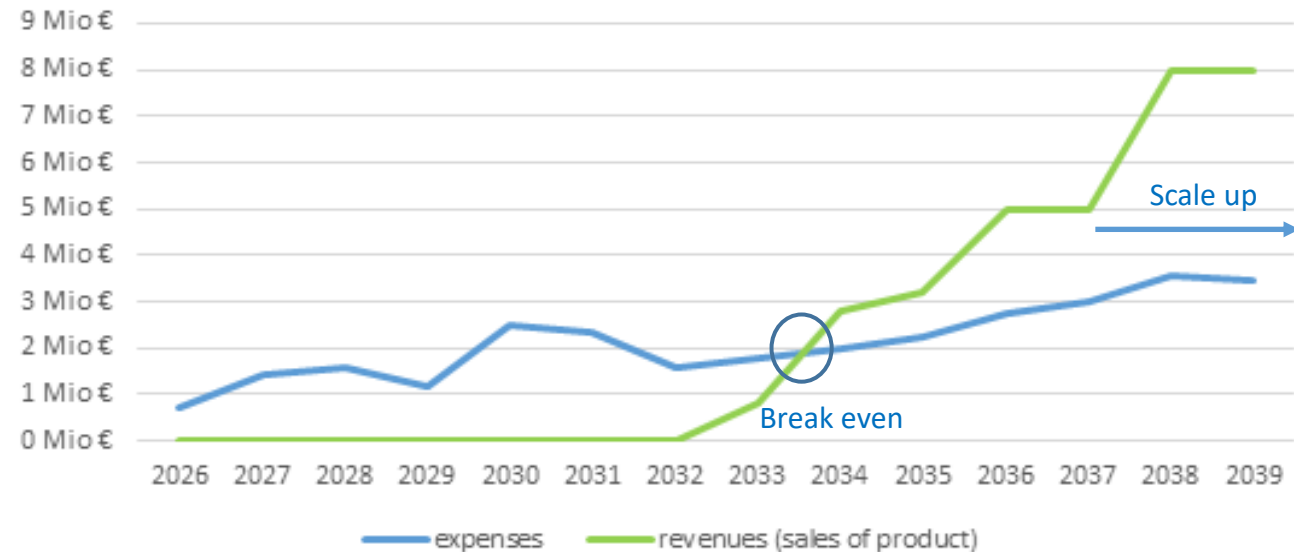
CBR: 42 months
Break Even Point: 2033

Production costs per unit



Price per RNI: 800€

Development of expenses and revenues



Why Us?



Concrete clinically driven demand on 3 levels

1. Each individual patient suffers massively.
2. There are millions of patients worldwide without help.
3. Clinicians wish to have an effective therapy for their patients.



Patient acceptance



Innovative platform technology for a scale up



bacta-implants.com

Together, we will revolutionize the world of drug therapy.