

Bone from the 3D printer

BIOVARIA 2019

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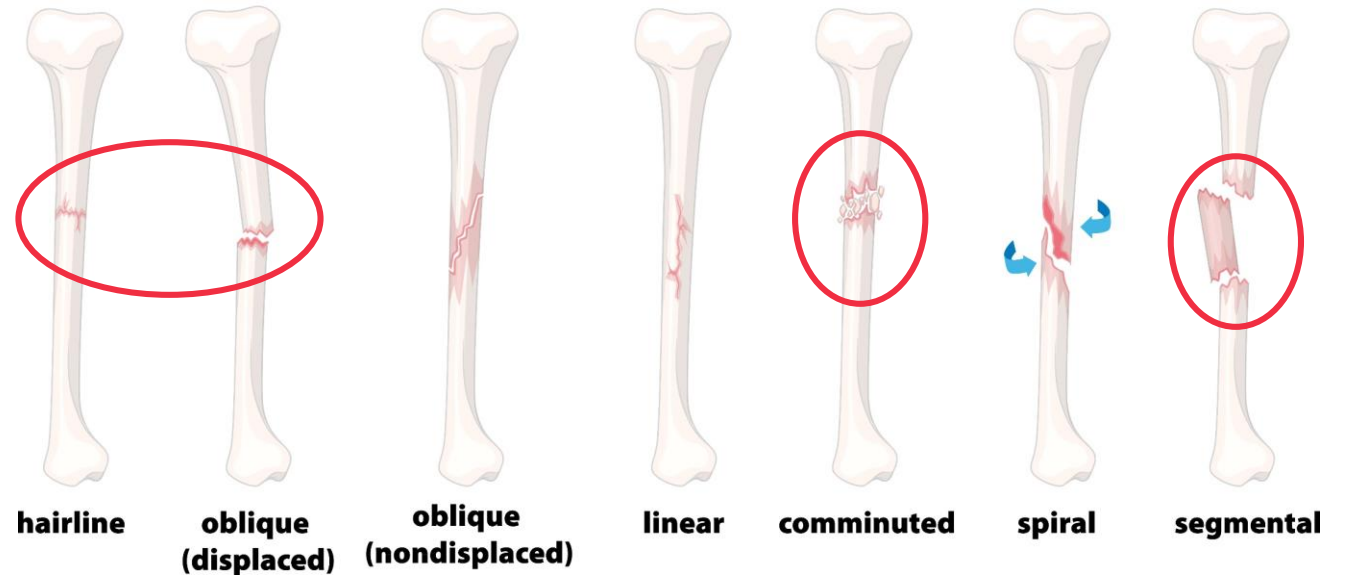
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Problem and unmet need

- Complex non-union fractures
- Segmental bone defects
 - Injuries and trauma
 - Osteoporosis
 - Bone cancer
 - Joint replacement
 - Age

Types of Fractures



Current solutions

Major Competition



Autograft (own bone)

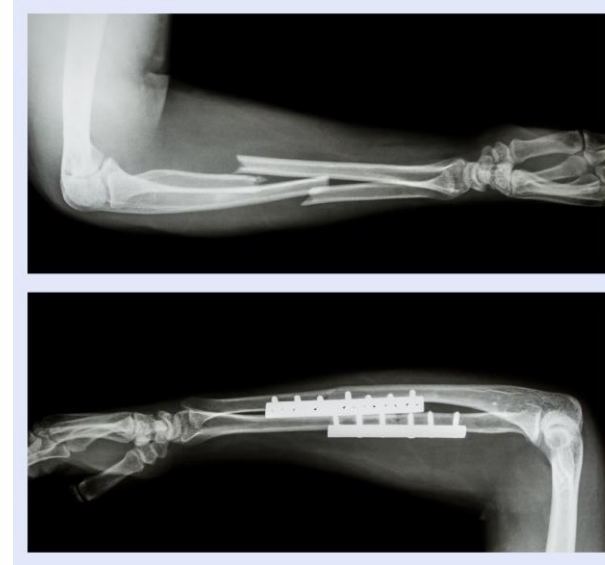
- High risk for post-operational complications
- Need for two operational sites
- Limited amount of bone to take

Allograft (donor bone)

- Insufficient amount
- Graft failure (25-35%)
- Ethical issues

Bone substitute materials

- Synthetic and natural
- Ceramic, polyesters, metallic
- Cellulose, natural HA



- Severe, long-lasting pain
- Limited mobility
- Pain killers dependence
- Related mental health issues
- Productivity loss (annual cost of non-unions in the US is 9.2bn USD)

Our Solution - 3D-printed scaffold

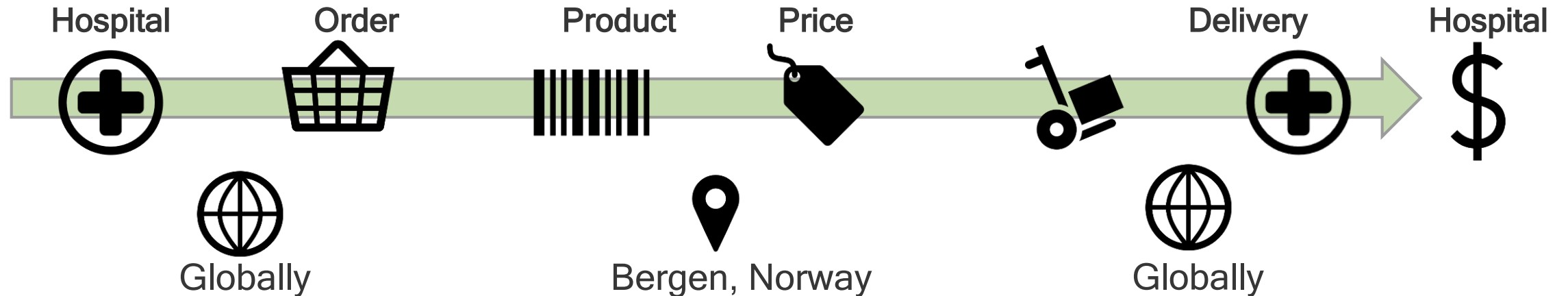
- Integrated into new growing bone
- Blood vessels supply
- Permanent solution
- Force-resistant
- Personalized

Process and business model

Technology/Process



Business model



Commercial potential

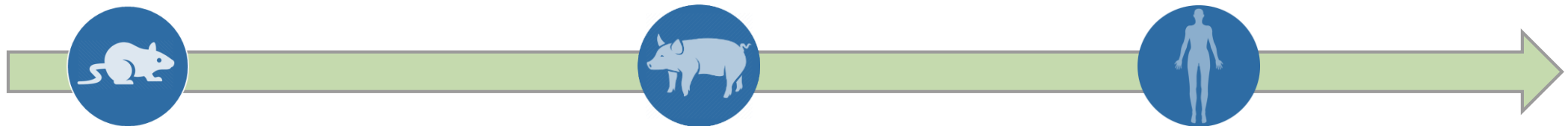
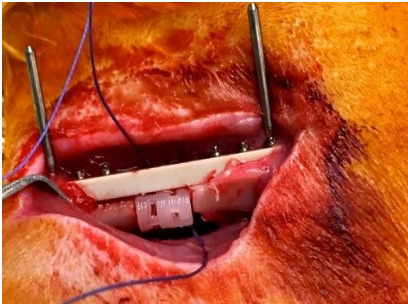
- Total market value (750 m€ - 1250 m€)

Market penetration	€ 1	€ 2
	500	500
	37 500	62 500
5%000		000
	75 000	125 000
10%000		000
	112 500	187 500
15%000		000
	150 000	250 000
20%000		000
	187 500	312 500
25%000		000

Development status

Pig model is ready
Starting experiments with
scaffolds in September

3D-printed scaffold in rat



2017 - 2018

2019 - 2020

2021 - 2023



Resources needed



Proof-of-concept (granted)

Project at VIS and UiB

EU programs/ investors/ VC/ industry collaborations

Startup activities

Verification-pre-clinical testing

Estimate: 0.5 m€

Personnel: 1 researcher

2-3 persons - Business development team

(VIS)

Legal (IP handling) and BD consulting

Regulatory consulting

Clinical trials

1. Feasibility study (10-40 patients): safety, benefit vs. risk

2. Pivotal study (up to 1000 patients)

Estimate: 10-20 m€ depending on regulatory pathway

Personnel: 4-5 technicians/researchers/nurses

3-4 persons - Business development team (VIS) + external CEO

Legal (IP handling) and BD consulting

Regulatory consulting

2019

2020

2021

2021

2022

2023

Intellectual Property status

- **PCT/EP2018/056124**
Priority date March 10, 2017
Protection of the scaffold design

Opportunities, risks and bottlenecks

- **Opportunities**

- Significant and recognised disease burden
- Clear unmet need for less burdensome alternatives to autograft
- Sizeable target population

- **Risks**

- Clinical trials inconsistency
- Established current competition - autograft is method of choice
- Competing solutions not in a public domain yet

- **Bottlenecks**

- Regulatory path
- Selected applications
- Patient sample too small or inconsistent

Project team

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