



# FluoGuide

---

Maximizing Surgical Outcomes  
Intelligent Targeting

Nordea & HC Andersen Capitals  
Small Cap Seminar

15 December 2020  
Morten Albrechtsen, CEO

# FluoGuide at a glance

## Population

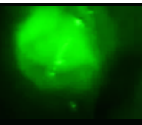
15 million new patients with cancer per year;  
Over 80% will need surgery

## Problem

Cancer recurs locally post surgery in more than 50% of patients

## Solution

uPAR targeted illumination  
of the cancer

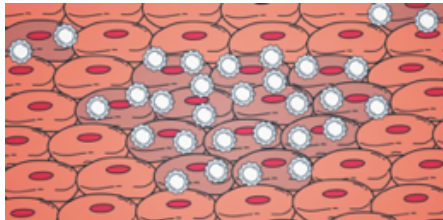
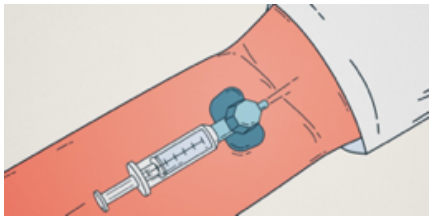


## Key investment highlights

- Clear unmet medical need in **glioblastoma**, with excellent pre-clinical results for FG001 and **first results of phase I/II clinical trial in 2020**
- FG001 has a **short path to market**
- uPAR targeted surgical guidance is relevant for general **oncology surgery**
- Market potential **>3 million procedures per year**
- **Publicly listed** on Spotlight Stock Market, awarded best IPO in 2019

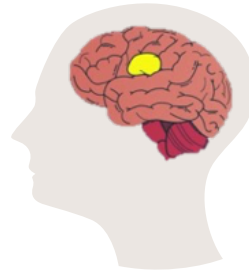
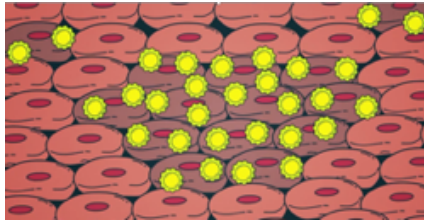
# Simple procedure, profound impact

## 1. Intravenous injection of FG001



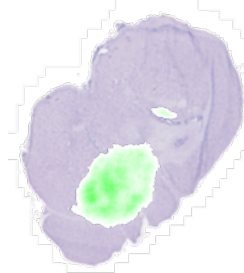
FG001 binds to uPAR on cancer cells within 30 min

## 2. Turn on the light



Cancer "lights up"

## 3. The cancer and local metastases are visible



Fluorescence allows the surgeon to remove the cancer while sparing normal tissue

## Everyone benefits



**Patients:** Reduce stress and side-effects, and increase change of surviving



**Hospitals:** Increase speed and efficiency, decrease costs



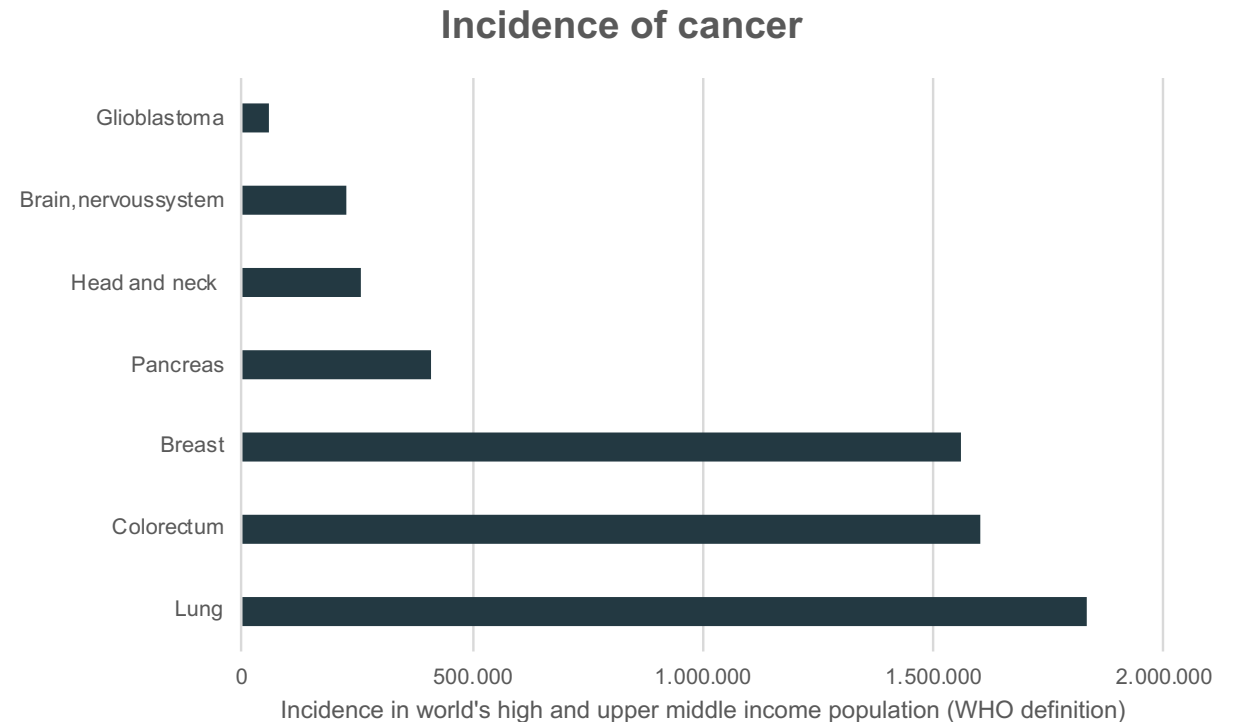
**Surgeons:** Increase speed, improve track record and decrease risk of errors



**Equipment manufactures:** Enhance equipment functionality and clinical value creation

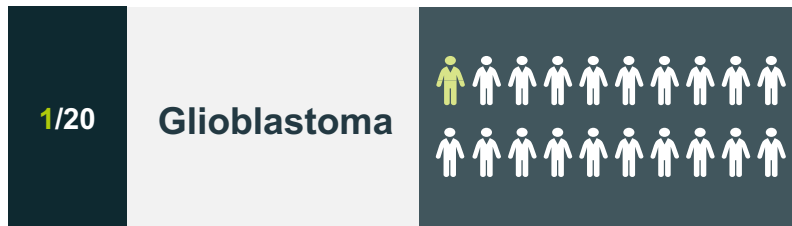
# uPAR products have great potential in most cancers

- **uPAR is extensively expressed** in most solid cancers, including in **three of the four** most prevalent cancers:
  - **Breast** cancer
  - **Colorectal** cancer
  - **Lung** cancer
- uPAR is also expressed in other cancers:
  - **Glioblastoma**
  - **Head and neck** cancer
  - **Pancreatic** cancer



# Glioblastoma – unmet medical need

## Five-year survival rate for GBM



- One of the **lowest five-year survival rates** in oncology
- Almost **no improvement in survival** in the last decade
- Profound **invasive growth**
- **Local recurrence nearly 100%** – precise removal of brain cancer is difficult
- Approximately **8-12% are children**
- Potential for **orphan drug designation**

# FG001 has a direct and short path to market

Classified as an imaging agent  
within medicinal product regulation

Glioblastoma qualifies for orphan drug  
designation

Clinical studies are straightforward  
and require few patients

- **Clear endpoint:** Positive predictive value (relative # cancer biopsies light up validated by pathologist)
- **No/small placebo arm:** Fewer patients needed
- **Short time frame:** Enrollment to surgery
- **Single blind:** Initial results known after the first few patients
- **No competition for patients:** Treatment can be done in addition to other treatments

## Clinical trials

1. Inclusion

2. Surgery done  
under white light

3. Switch to  
fluorescent light

4. Pathologist  
result available

2-4 weeks per patient

**Phase I/II**  
Up to 36  
pts

### Phase I/II:

- Demonstrate safety
- Optimal dose
- Proof-of-concept in humans
- Proof effect (magnitude of benefit)

2020/1

**Phase IIb/III**  
150 pts

### Phase II/III:

- Statistical demonstration of performance (150 pts)
- Sufficient safety to support broad commercial use (150-500 pts)

2022

**Approval**



2024

# Design and key outcomes from ongoing clinical trial

Phase I/II design addressing: Safety, Proof-of-concept, magnitude of benefit and pivotal design

## Part 1 (phase I/II)

**Endpoints:** Safety and dose selection  
**Outcome:** Confirm safety, define optimal dose and proof-of-concept (FG001 illuminates cancer)

Dose  
selection

## Part 2 (phase II)

**Endpoints:** Positive and Negative Predictive Value, sensitivity and specificity  
**Outcome:** Effect (magnitude of benefit) and basis for power calculation for pivotal trial

**Patients:** up to 36 patient in total with glioma grade III or IV (glioma grade IV = 'Glioblastoma' = 'GBM')

3 patients per group and up to 8 groups (up to 24 pts in total)

12 patients

## Key outcomes

Safety (tolerability profile)

PoC for FG001/GBM

uPAR in surgical guidance

Value of FG001 in GBM

Test of pivotal design

Hospitals (International and multicenter)



+

Sweden

# Enabled by EU funding of MEUR 2.5



Phase I/II design addressing: Safety, Proof-of-concept, magnitude of benefit and pivotal design

Dose  
selection

## Part 2 (phase II)

**Endpoints:** Positive and Negative Predictive Value, sensitivity and specificity

**Outcome:** Effect (magnitude of benefit) and basis for power calculation for pivotal trial

Patients: up to 36 patient in total with glioma grade III or IV (glioma grade IV = 'Glioblastoma' = 'GBM')

12 patients

## Key outcomes

Value of FG001 in GBM

Test of pivotal design

Hospitals (International and multicenter)

Sweden



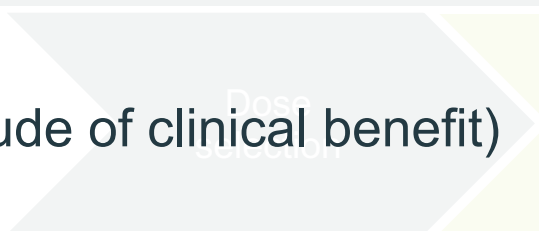
# Profound impact



Phase I/II design addressing: Safety, Proof-of-concept, magnitude of benefit and pivotal design

- Additional benefits:

- Value of FG001 in GBM (magnitude of clinical benefit)
- Phase III design
- Two centers / two countries



## Part 2 (phase II)

Endpoints: Positive and Negative Predictive Value, sensitivity and specificity

Outcome: Effect (magnitude of benefit) and basis for power calculation for pivotal trial

- Impact:

Patients: up to 36 patient in total with glioma grade III or IV (glioma grade IV = 'Glioblastoma' = 'GBM')

- Testing the **design of the phase III**: E.g. end-points, equipment, number of patients

12 patients

Key outcomes



Value of FG001 in GBM

- Obtain better quality feedback from agencies **FDA and EMA**

Reduced risk

and

Higher value

Hospitals (International and multicenter)

- Set **specifications for equipment**

Sweden

# Precision required in all surgical methods – different equipment partner opportunities in different indications



**Open** (e.g. breast cancer): E.g. Medtronic and Stryker



**Endoscopic** (e.g. lung cancer): E.g. Medtronic, J&J and Karl Storz

The shift from analogue to digital cameras opens many new opportunities

uPAR targeted illumination is effective across all surgical methods

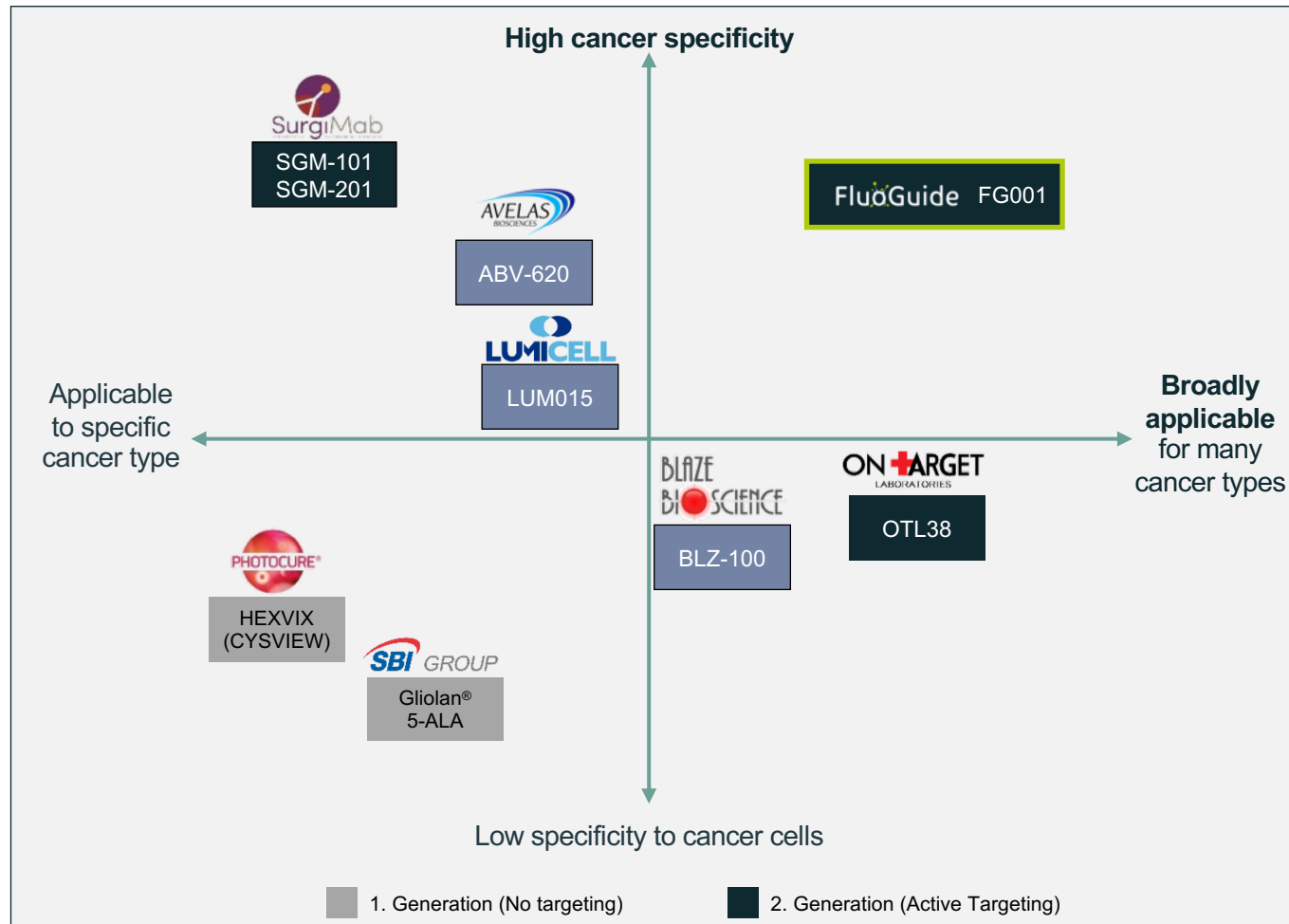


**Microscopic** (e.g. brain cancer): E.g. Leica, Zeiss, Karl Storz and Olympus



**Robot-assisted**: (e.g. prostate, head & neck cancer): E.g. Intuitive

# Market favors active targeting



## FG001 - key differentiators

-  **Only maker that targets uPAR**
  - High cancer specificity
-  **Targets almost all solid tumour types**
  - Obviates the need for patient screening
-  **Standard near infrared fluorophore**
  - Fits with equipment
-  **Fits within existing work flow**
-  **Illuminates the cancer margins – where the surgeon needs it**

# Strong and motivated leadership

## Management:



### Morten Albrechtsen, CEO

- MD, BBA
- Seasoned life sciences entrepreneur
- Led launch and implementation of new treatments and oncology technology internationally
- Boehringer Ingelheim, Nycomed, Nanovi



### Grethe Rasmussen, CDO

- MSc, PhD
- Seasoned leader in life science with strong development record
- Advanced seven projects from research to clinical development (protein, peptide, small molecule)
- Ascendis Pharma, Maxygen, Novo Nordisk



### Henrik Moltke, CFO

- MSc (Int'l economics and strategic management)
- Seasoned Life Science executive with strong background as CFO, investor relation and business development
- Allarity Therapeutics, Scandinavian Micro Biodevices, Astion Pharma, NeuroSearch, Novo, and Ferrosan



### Andreas Kjaer – Founder, CSO

- MD, PhD, DMSc, MBA
- Professor at the University of Copenhagen and chief physician at Rigshospitalet, Denmark. Research focused on molecular imaging with PET, PET/MRI and optical and targeted radionuclide therapies in cancer
- Minerva Imaging and CuraSight



### Dorthe Grønnegaard Mejer, VP Clin. Dev.

- MSc in Pharmacy
- Seasoned leader in life science with strong clinical development record
- Genmab, Larix, Orphazyme, Oncology Venture

## Board of Directors:

### Arne Ferstad (Chairman)

Broad experience from board and executive positions in biotech, pharma and medtech, including business development, international marketing and development



### Peter M Eriksen

CEO of BioPorto A/S and serves on the Medical Device and Diagnostics Advisory Committee of Cincinnati Children's Hospital Medical Center in Ohio, US. 20+ years of experience within MedTech and life science incl. Vice President of Medtronic in USA



### Shomit Ghose

19+ years of executive experience at high-tech companies in Silicon Valley with a degree in Computer Science from the University of California Berkeley



### Micaela Sjökvist

Head of Investor Relations at Securitas AB, previously operative IR and PR roles



### Andreas Kjær

# Awarded best IPO in 2019

- **Publicly listed on Spotlight Stock Market**
  - Danish legal entity, Swedish exchange, DK&SE regulations
- **Affärsvärlden's 2019 IPO Guiden evaluated 42 Swedish IPOs – hereof 13 micro-cap companies**
  - Best in micro-cap category
  - Honorary quality award
- **Steady increase in interest**
  - Volume, turnover, trades and shareholders



# Next 12 months transform FluoGuide from pre-clinical to phase III stage company

## FG001 in glioblastoma (GBM)

- Result of first dose escalation group of patients (safety)
- Result of following dose escalation groups of patients (safety and proof-of-concept)

## Advance develop FG001 toward approval in GBM

- **Regulatory confirmation of discussions on FG001** with European and US regulatory agencies
- Prepare **phase III study**

## Expand market (increase number of patients)

- Initiate clinical studies for **other prevalent indications** for FG001
- Establishment a **prioritized pipeline of uPAR targeted products**

## Increase the clinical benefit (increase the price)

- Document clinical benefit
- Enhance the clinical benefit

FluorGuide