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Precision surgery improving outcome for cancer patients

Investor Konferences
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FluoGuide at a glance

2018 Year founded	**CPH, DK** Headquarter & location	**FLUO** Listed at First North Stockholm
Oncology surgery Large unmet medical need	**FG001** Improving outcome for cancer patients	**≈20 millions** Patients per year
Intuitive Surgical Non-exclusive partnership	**Phase II** Stage of most advanced clinical asset	**3** Positive phase II results in different cancer types

Sources: Company information; FactSet as of 5 April 2024.
Notes: (1) Rebased to Fluoguides share price as of 2 January 2023. (2) Defined as total # of annual incidence applicable for FG001:

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A huge need for precision surgery

≈20 million
new patients
are diagnosed with cancer every year

Surgery is the primary treatment
when the goal is to cure. Surgery, radiation- and/or chemotherapies are the options

≈12 million cancer patients
each year undergo surgery with the purpose of cure

50% of the patients
experience local recurrence of cancer after the surgery

Sources: World Health Organization, 2022; The University of Texas MD Anderson Cancer Center; Ivy Brain Tumor Center; Zhang et al: Advancements of radiotherapy for recurrent head and neck cancer in modern era, 2023; Company information.

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Increasing demand for precision and image guidance in surgery

Market drivers

Growing aging population

The world's population aged 65 or older is projected to more than double by 2050

Surgeon shortage

The world faces a shortage of surgeons

Need for new surgical technologies

Rising demand, lack of skilled surgeons and increased complexity of surgery, lead to an increased need for new technologies

Sources: Company information; American College of Surgeons; Codman Specialty Surgical; Khanna et. al: "The Path to Surgical Robotics in Neurosurgery"

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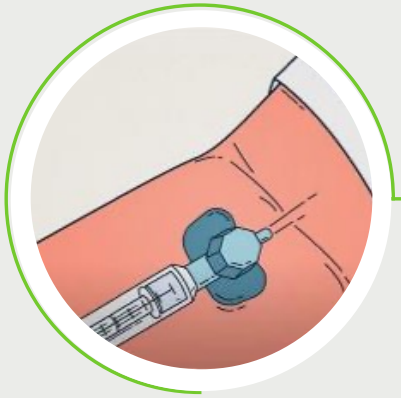
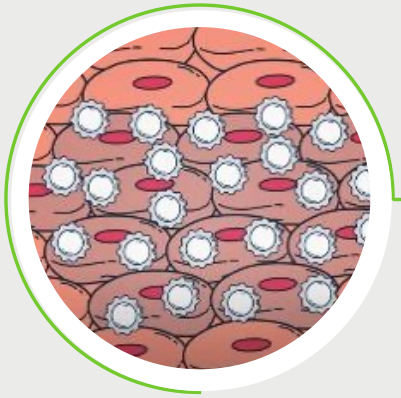
FluoGuide-powered precision surgery: Proprietary uPAR probe

Fluorescent Probe FG001

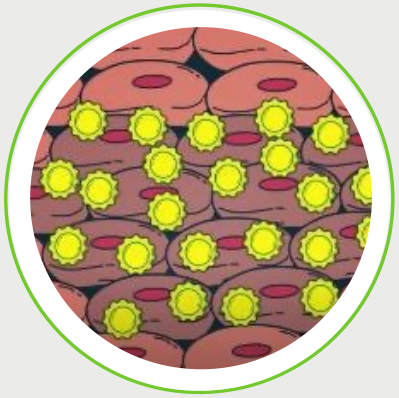
Injected prior to surgery



Binding to cancer



Guiding during surgery



4 hours – 2 days

Sources: Company information; FG001-CT-001, data on file.

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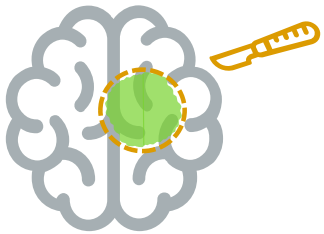
Precision improves outcome of surgical treatment

Precision surgery

Enhance precision surgery through illumination of cancer cells and guiding the surgeon

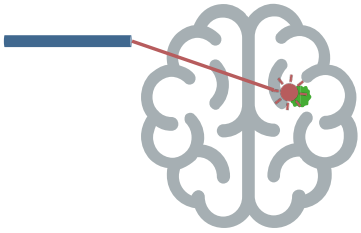


FG001

uPAR-binding fluorescent molecule

Precision treatment

Property as photosensitizer can remove cancer cells while sparing surrounding tissue



Sources: Company information; Cancer worldwide market research report by Marketline, 2020

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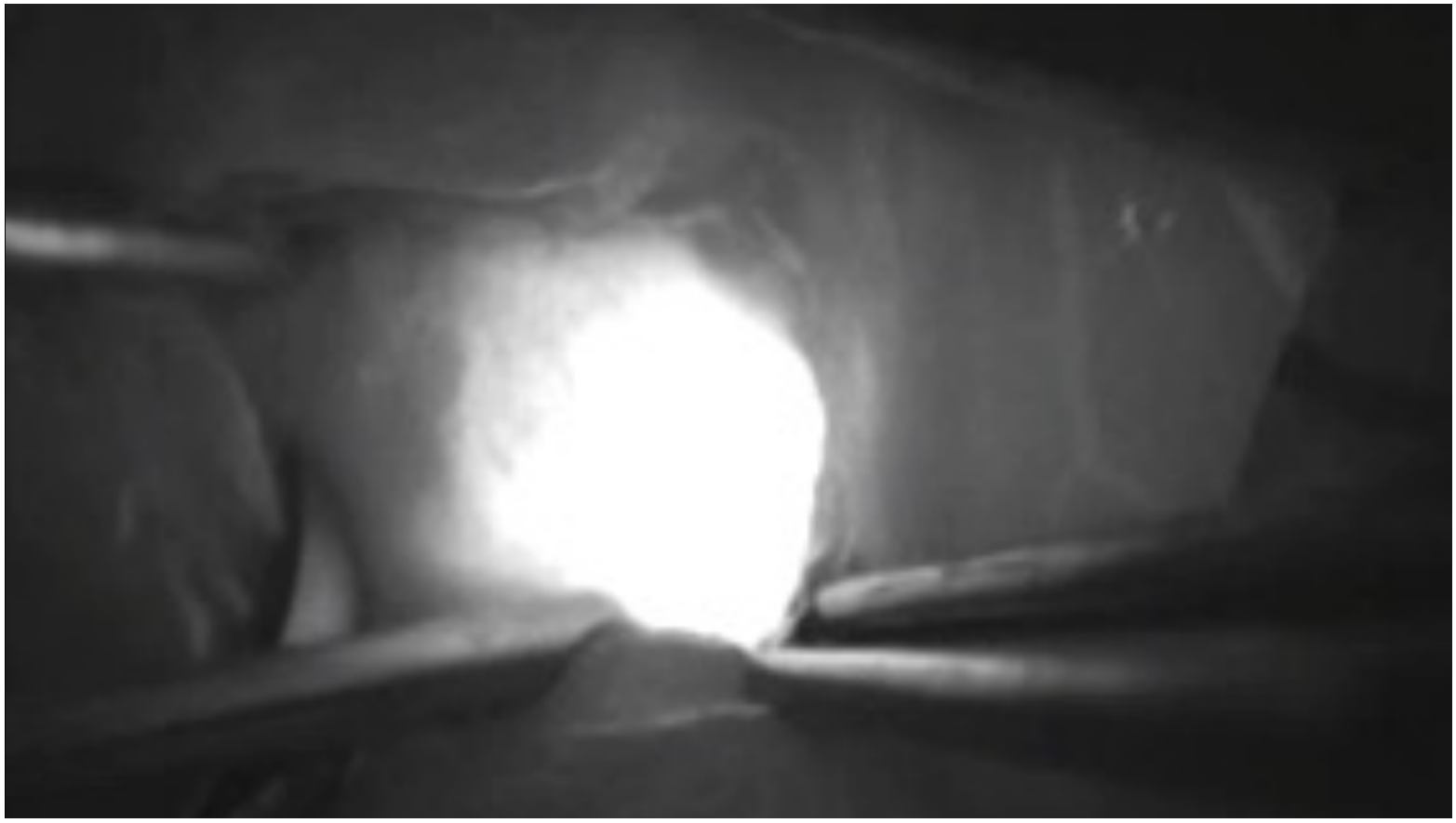
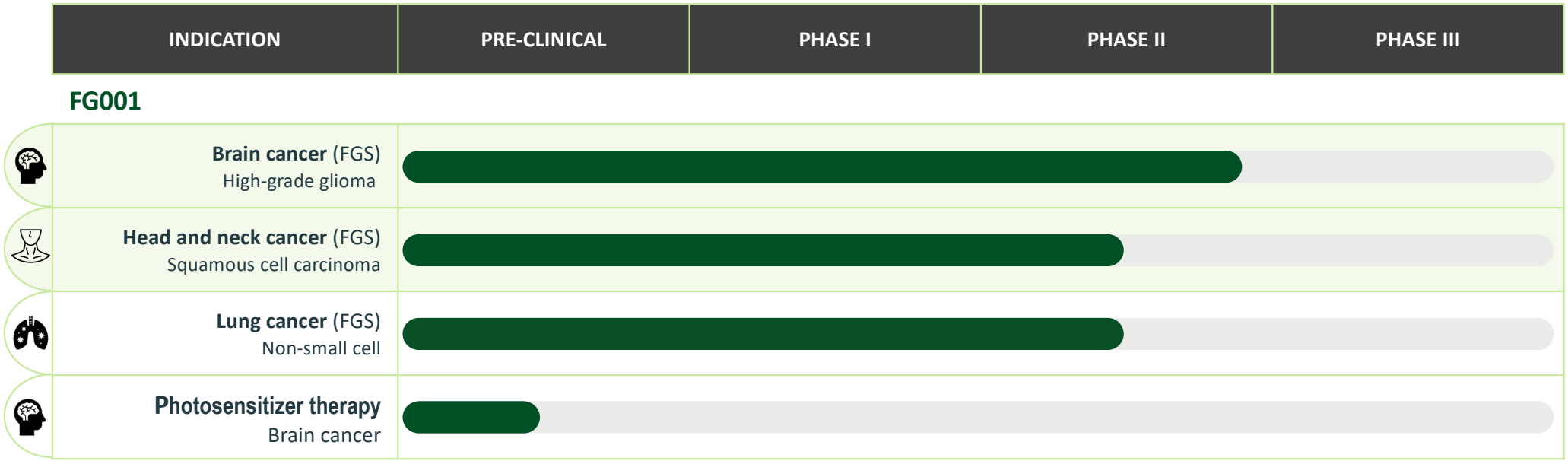
FluoGuide illuminates cancer



Source: FG001-CT-001, data on file

Pipeline with low risk and long-term patent protection



- FG001 patent protected until 2035 (granted in Europe, USA, Canada and Australia)
- Patent for several products targeting uPAR until 2040 (pending applications in Europe and USA)
- Additional patent applications are pending offering additional protection

Source: Company information.
Terminology: FGS (Fluorescent guided surgery)

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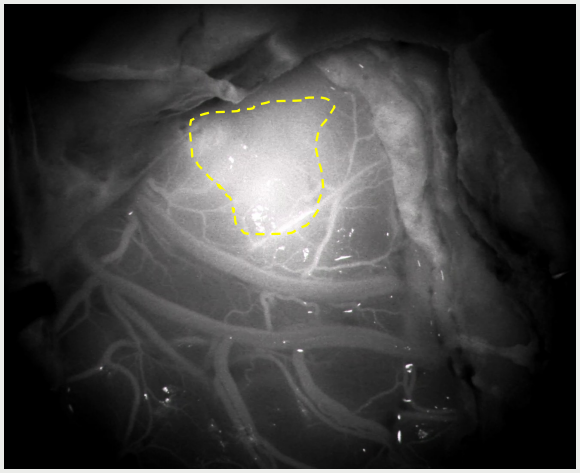
Aggressive brain cancer – positive results

	Phase I/II	Phase II
Status	Top line results presented	
Inclusion	Patients with suspected high-grade glioma undergoing surgery	
#	40	24
Primary endpoint	Safety and tolerability of FG001 and dose finding	Patients with at least one indeterminated tissue or unexpected fluorescent tissue at the end of surgery
Drug	FG001 and 5-ALA were co-administered in all patients	Randomization 1:1 between FG001 or 5-ALA (12 patient on each)
FG001 dose	Dose escalation from 1 mg to 48 mg per patient	36 mg per patient the evening before the surgery

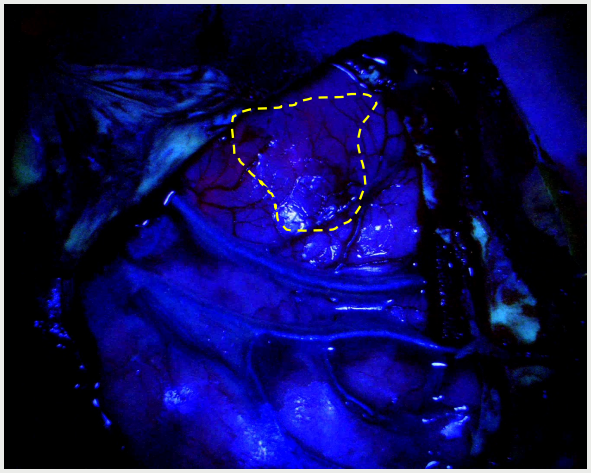
Trial results (FG001-CT-001)

1. **All patients receiving FG001 (12/12) had additional cancer detected showing FG001 was superior to white light**. The result for 5-ALA was 12/12.
2. **FG001 was safe and well tolerated in all patients with 2 related AEs (grade 1)**
   The result for 5-ALA was 10 related AEs (8 grade 1 and 2 grade 2).
3. **FG001 visualize tumor on dura prior to incision in 4/12 patients (deeper visualization)**.
   The result for 5-ALA was 0/12.

FG001



5-ALA



Sources: Company information; FG001-CT-001, data on file.

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The market on brain tumor - more precise surgery is needed

The surgeon's dilemma

The cavity after removal of obvious cancerous tissue

- Removing too much, risking to **destroy critical functions** in the patient
- Leaving too much and **risk of recurrence**

Need

- Most patients experience cancer recurrence
- The brain is a vital organ
- 5-ALA is approved in <10% of brain cancer indications

Market characteristics

- Duopoly within surgical equipment
- The market is well-penetrated with equipment
- Limited innovation within equipment

Customer base

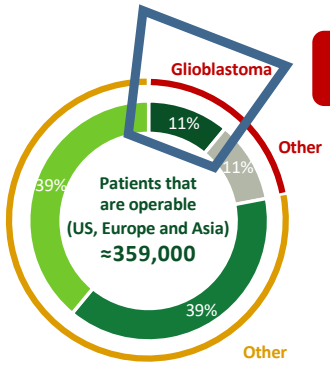
- Focused group of neurosurgeons with knowledge about the fluorescence-guided surgery

The market in numbers

Primary brain-tumors

Non-malignant ≈78%

Malignant ≈22%



Secondary brain-tumors

Malignant ≈100%

Brain-metastases typically originate from lung (60%) or breasts (11%)

Sources: (1) Miller KD et al. Brain and other central nervous system tumor statistics, 2021. CA Cancer J Clin. 2021 Sep;71(5):381-406; (2) World Health Organization (International Agency for Research on Cancer); (3) The brain tumour charity; (4) Habbous et al., "Incidence and real-world burden of brain metastases from solid tumors and hematologic malignancies in Ontario: a population-based study", 2021; (5) Company information (6) Company information; (7) Gittleman, H., Liao, P., Rouse, C., Chen, Y., & Dowling, J. et al. (2014). CBTRUS Statistical Report: Primary Brain and Central Nervous System Tumors Diagnosed in the United States in 2007-2011. Neuro-Oncology, 16(suppl 4), iv1-iv63. doi: 10.1093/neuonc/nou223.

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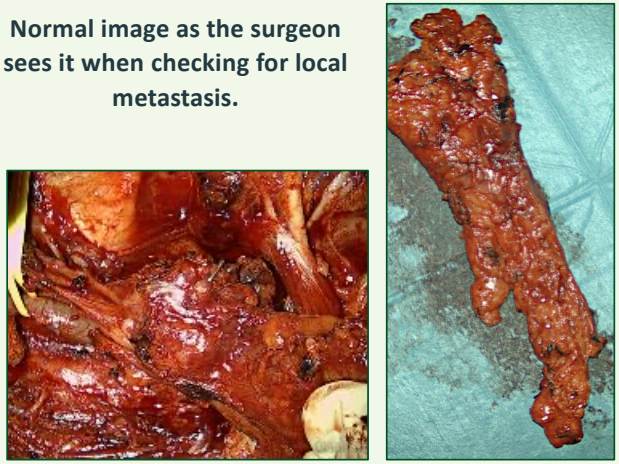
Head and neck cancer (CT-003): Positive results

	Phase II
Status	Top line result presented
Inclusion	Oral and oropharyngeal squamous-cell carcinoma scheduled for surgery
#	16
Primary endpoint	Sensitivity (PoC)
Drug	FG001
FG001 dose	4, 16, 36mg per patient the evening before the surgery

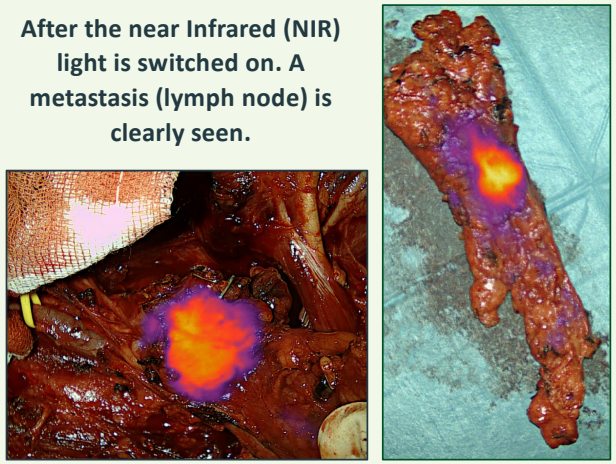
Trial results (FG001-CT-003)

1. **FG001 demonstrated a sensitivity on 100%**
   Relevant contrast - TBR*) - in all 16 patients on >2.00 and (2.99 in average)
2. **FG001 was safe and well tolerated in all patients**
3. **FG001 revealed several demonstrated fulfilment of several unmet medical needs in head & neck cancer surgery, eg.: Lymph node cancer detection and cancer margins assessment**

Normal image as the surgeon sees it when checking for local metastasis.



After the near Infrared (NIR) light is switched on. A metastasis (lymph node) is clearly seen.



Sources: Company information; FG001-CT-001, data on file.
*) TBR (Tumor to background ratio)

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The challenge in head and neck cancer - more precise surgery is needed

High unmet need

- High recurrence and surgical quality control issues
- Applicable for surgeries on deeply located tumors
- No current imaging agents available

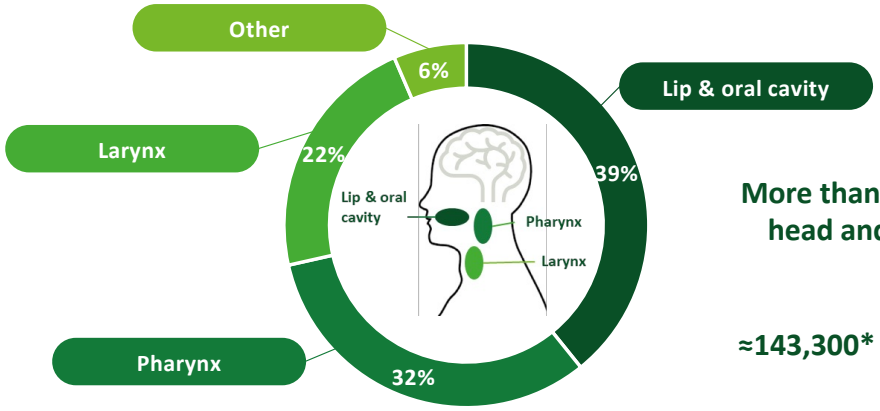
Market characteristics

- Multiple surgical equipment types and companies
- Clear patient benefit
- Clear hospital benefit

Partnering opportunities

- Multiple partnering opportunities with different surgical equipment types
- Huge potential for selling new equipment

Head and neck cancer market



More than 900,000 patients are diagnosed with head and neck cancer annually in the world

≈143,300* patients currently eligible for surgery in US and Europe

The surgeon's dilemma

Image as the surgeon sees it when checking for additional cancer

The solution:
More precise surgery

Sources: Company information; Gal TJ et al. Treatment trends in oropharyngeal carcinoma: Surgical technology meets the epidemic. Oral Oncology, Vol 97, 2019, p 62-68 (2) Cramer JD et al. The changing therapeutic landscape of head and neck cancer. Nat. Rev. Clin. Oncol. 16, 669–683 (2019); *) Eligible defined by WHO reduced from 680,000.

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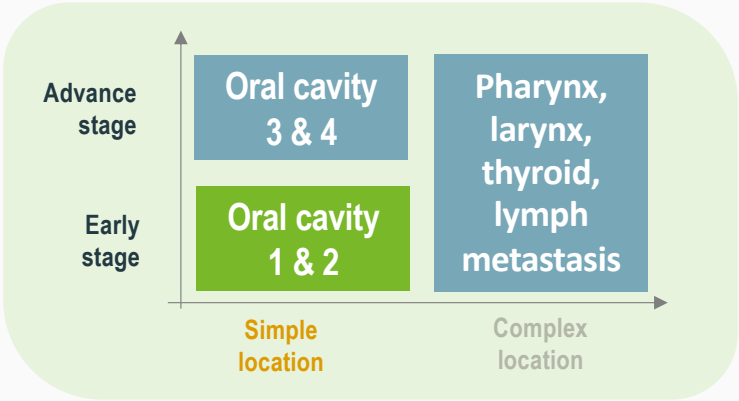
Treatment of head and neck cancer depend on location and stage

"Complex location"

"Simple location"



Offered surgery as first line treatment - if successful, as only treatment *)

Offered radio-chemotherapy alone or surgery combined with radio-chemotherapy *)

*) Simplified after NCCN guidelines

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Side effects from radiotherapy may be avoided with better surgery margin control

Short-term side effect of radiation therapy

- Skin changes, such as sunburn or tanning in the treated area
- Loss of taste
- Redness, soreness, or even pain in the mouth and throat
- Dry mouth
- Difficulty swallowing
- Feeling tired (Fatigue)
- Open sores in the mouth and throat

Long-lasting or permanent side effects of radiation therapy

- Poor nutrition and trouble swallowing
- Dry mouth due to damage to the salivary glands
- Tooth decay (cavities), with tooth extractions often performed as a preventive measure
- Jawbone damage
- Thyroid problems
- Lymphedema
- Damage to the carotid artery

Among long-term survivors treated with head and neck radiation therapy, 77% to 100% experience mild to severe radiation damage to soft tissues and bones

Source: Radiation Therapy for Oral Cavity and Oropharyngeal Cancer | American Cancer Society (accessed 5-JUN-2024) Paulino AC, Simon JH, Zhen W, Wen BC. Long-term effects in children treated with radiotherapy for head and neck rhabdomyosarcoma. Int J Radiat Oncol Biol Phys. 2000;48(5):1489–1495. [PubMed] [Google Scholar]. Raney RB, Anderson JR, Kollath J, Vassilopoulou-Sellin R, Klein MJ, Heyn R, et al. Late effects of therapy in 94 patients with localized rhabdomyosarcoma of the orbit: report from the Intergroup Rhabdomyosarcoma Study (IRS)-III, 1984-1991. Med Pediatr Oncol. 2000;34(6):413–420. [PubMed] [Google Scholar]

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Cancer surgery offers multiple potential partnerships

Surgical equipment		Indications and reason for use	Example of vendors
Microscope		**Brain surgery** Visualization of small structures	ZEISS, Leica, OLYMPUS
Open field camara		**Multiple, eg. head & neck, brain** Visualization of superficial cancers	OLYMPUS, stryker, STORZ KARL STORZ—ENDOSKOPE
Endoscope		**Multiple, eg. head & neck, lung, colorectal** Flexible for visualization and operation inside the body	Boston Scientific, STORZ KARL STORZ—ENDOSKOPE, stryker, Medtronic, Johnson & Johnson, OLYMPUS
Robot		**Multiple, eg. head & neck, lung** Allows multiple arms and remote control	Medtronic, INTUITIVE, ETHICON a Johnson & Johnson company
Back table histology		**Multiple, eg. head & neck** Allows multiple arms and remote control	LI-COR, PerkinElmer

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Effective organization with strong experience in developing and commercializing health care products

Morten Albrechtsen
CEO

Andreas Kjær
CSO

Jens Ellrich
CMO

Grethe Rasmussen
CDO

Ole Larsen
CFO

Board of Directors

Peter Mørch Eriksen
Chairman of the board

Mats Thorèn
Vice chairman of the board

Andreas Kjaer
Member of the board

Donna Haire
Member of the board

Michael Engsig
Member of the board

Combined BoD and mgmt. experience

Takeda · Boehringer Ingelheim · nykode · Bavarian Nordic · bioporto · minerva imaging · MDPI · Medtronic · ascendis pharma · PHILIPS Healthcare · Genmab · larix

Management team

of which all have previously taken a **product from clinical trials to commercialisation**

>90% of FluoGuide's operational costs relates to R&D[1]

Source: Company information, Note: (1) Annual report for the financial year of 2023

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Listed on Nasdaq First North Growth Market Stockholm

Owner distribution (approx. figures)

Analyst coverage

Ticker: FLUO

✓ **ABG Sundal Collier**

✓ **SEB** (commissioned)

✓ **Redeye** (commissioned)

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2025 Outlook

		Ongoing tasks	2025 Milestones	Long term objectives
Brain	FG001 - guiding surgery of **High-Grade Glioma (HGG)**	Continue development and regulatory path towards market approval	**H1: Regulatory evaluation and consultation with FDA to confirm the design of registration trial for FG001 as an imaging agent in guiding aggressive brain cancer** **H2: Submit application for clinical trial**	Approval of FG001 in USA
	FG001 - guiding surgery of **additional brain tumors** (e.g. Meningioma)	Evaluate FG001 for additional brain indications (expand market potential by **up to 20x** compared to HGG)	**H1: Preliminary data from an investigator-initiated trial involving 20 patients with meningioma and low-grade glioma**	Expand FG001 indication to target larger part of the brain tumor market where currently no imaging agents are approved
	FG001 - photosensitizer **therapy** for brain cancer	Evaluate and implement photosensitizer therapy into brain cancer development (expand potential in value by **up to 20x** compared to guiding surgery)	**H1: Complete optimization of the combined use of FG001 and the laser system in pre-clinical models**	Expand FG001 as a photosensitizer to address another large unmet medical need and broaden market potential
Head and neck	FG001 - guiding surgery of **head and neck cancer**	Continue development of head and neck clinical program towards market approval	**Q1: Enrolment of first patient (CT-005)** **H2: Interim data from first 15 patients (CT-005)** **H2: Submit for regulatory feedback for registration trial**	First approval of FG001 in head and neck Expand FG001 indication to large market for head and neck cancer where currently no imaging agents are approved
Partnering	Preparing additional **partnerships** for FG001	Advancing the tasks defined in the partnership with Intuitive Surgical	**H1: 1-2 additional partnerships**	Facilitate commercialization with support from partner(s)

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