

FluorGuide

Light up cancer
maximize surgical outcome



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BioStock
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FluoGuide is improving cancer surgery – maximizing patient outcomes

Cancer is frequent and recure locally after surgery - huge and growing need for precision surgery

Unique uPAR-targeted image agent with strong clinical data in multiple indications

Orphan Drug Designation in high grade glioma and FDA endorsement

Strategic partnerships with leading MedTechs expanding reach and adoption

Upcoming catalysts in 2025: Phase II data, IND submission, new collaborations

A huge and growing need for precision surgery – 45M procedures by 2030

≈20 million
new patients
are diagnosed with
cancer every year



**Surgery is the primary
treatment**

Radiation- and chemotherapies
are the two other main options



≈12 million
cancer patients
each year undergo cancer surgery



50% of the patients

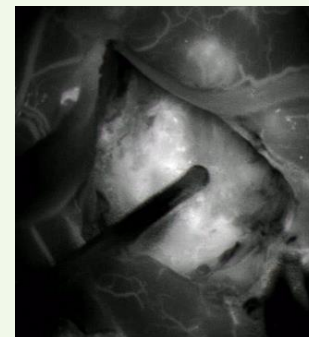
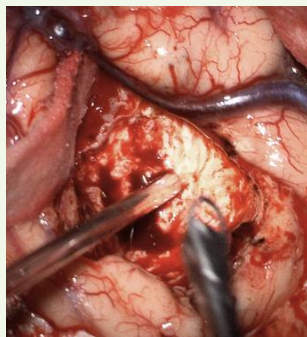
experience local recurrence of
cancer after the surgery

45 million surgical procedures needed annually worldwide in 2030

Unique uPAR-targeted image agent with strong clinical data in multiple indications

Glioblastoma (Trial # CT-001)

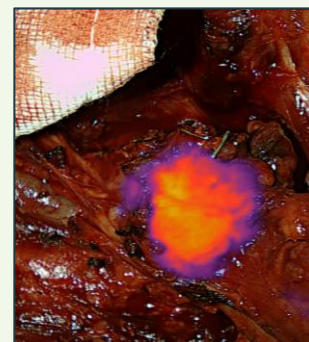
Normal image as the surgeon sees it when checking for cancer tissue.



Near-infrared (NIR) imaging revealed additional cancer left in cavity.

Oral head and neck cancer (Trial # CT-003)

Normal image as the surgeon sees it when checking for cancer tissue.



Near-infrared (NIR) imaging revealed metastasis in a lymph node.

De-risked and proven – Positive clinical data across 3 cancer types

Technical risk: Significantly de-risked

- ✓ **FG001:** An uPAR binding peptide covalently bound to an indocyanine green (ICG) like molecule
 - ✓ Risk mitigation by design
 - ✓ Pre-clinical studies: Robust preclinical data demonstrated safety and feasibility
- ✓ **Pre-clinical treatment potential as photosensitizer:** Demonstrated therapeutic effect when combined with laser in pre-clinical models
- ✓ **Positive clinical results in three cancer indications:** Aggressive brain tumor (glioblastoma), head and neck cancer (OPSCC) and lung cancer (NSCLC)
- ✓ **Well tolerated by patients :** More than 100 patients have received FG001
- ✓ **Regulatory:** Clear path to approval for glioblastoma in USA

Commercial risk: Significantly de-risked

- ✓ **Compatibility with existing equipment:** Tested with multiple different types of equipment
- ✓ **Partnerships:** Established with leading MedTech companies

Orphan Drug Designation in high grade glioma and positive FDA feedback

- FluoGuide received **positive FDA feedback** on FG001 in high-grade glioma
- **Supports** both the **upcoming IND submission** and future **NDA filing**
- **De-risks** the overall regulatory strategy toward NDA submission
- **Orphan drug designation** has been granted for high-grade glioma in US
- **On track to submit IND in Q4 2025** for the US phase 2 clinical trial in HGG
 - 40 pts with HGG
 - MRI assessed Gross Total Resection at 48h post surgery as primary end-point
 - 4-6 US centers
 - Multiple secondary endpoints
 - Planned trial initiation: Q2-26

Strategic partnerships with leading MedTechs – Expanding reach and adoption

FG001 works with all surgical equipment		Non-exclusive partnerships	All benefits from partnerships
Microscope		Intuitive Surgical (robot-assisted surgery)	Patients and society: • Provided better surgery to more people
Open field camera		Olympus (minimally invasive diagnostics and treatment)	Partners: • Help more patients • Sell more equipment
Endoscope		SurgVision (Bracco Group, advance intraoperative imaging)	FluoGuide's objectives: • Build strong collaborative relationships that prepare for deeper market penetration • Support the market entry of FG001 • Ensure smooth integration in surgical workflows • De-risk regulatory approval • Expand the indications for FG001
Robot		Additional 1-2 partnerships during 2025–2026	
Back table histology			

Large commercial potential for scaling sales of FG001

Pricing and reimbursement

Fluorescent guided surgery: 4-5.000 USD per dose
Photosensitizer therapy: 25.000 USD per dose

Business Model

FG001: Recurrent revenue from sales of drug
Surgical system: Revenue from deeper and faster market penetration
Synergies: From FG001 and surgical system to be explored

Go-to-Market Strategy

Combination of selling FG001 directly and through selected surgical systems partners

\$ 2.9 billion potential

EU & US incidence of brain and head & neck cancers per year:
0.64 million currently eligible for surgery (assuming an average price of 4,500 USD per treatment)

Total procedures: 45 million per year

x70

Incidence in highly relevant cancer types: 9 million per year

Incidence of brain and head & neck cancers: 3.7 million per year

Upcoming catalysts 2025: PII-data, IND submission and new collaborations

2025				
Q1		Q2		Q3
Q4				
 Brain	✓	• Preliminary data from an investigator-initiated trial involving 20 patients with meningioma and low-grade glioma • Continue optimization of the combined use of FG001 and the laser system in pre-clinical models as a photosensitizer therapy in brain cancer		• Presentation of data from an investigator-initiated trial involving 20 patients with meningioma and low-grade glioma • Continue optimization of the combined use of FG001 and the laser system in pre-clinical models as a photosensitizer therapy in brain cancer
	✓	• Regulatory evaluation and consultation with FDA to confirm the design of registration trial for FG001 as an imaging agent in guiding aggressive brain cancer		• Submit application for clinical registration trial in High Grade Glioma (HGG)
 Head and neck	✓	• Enrolment of first patient in phase II clinical trial in head and neck cancer (CT-005)		• Interim data from first 15 patients in phase II clinical trial in head and neck cancer (CT-005) • Planning of a registrational trial in head and neck cancer
€ Commercial	✓	• 1-2 additional partnerships		

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Q&A

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