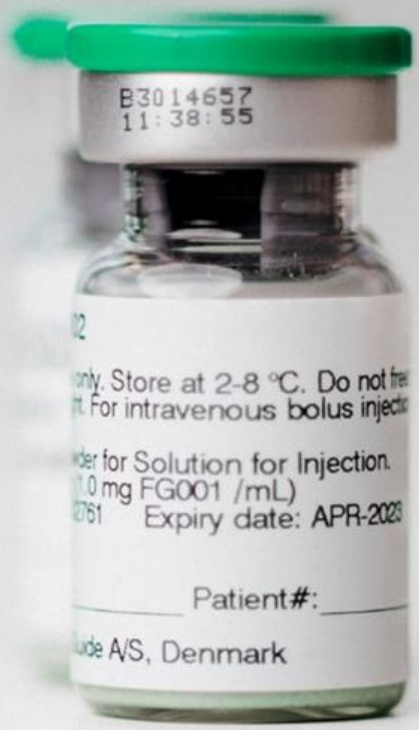
Precision surgery improving outcome for cancer patients

Q3 2023



FluoGuide

"FluoGuide has reached a major landmark in its development. The positive completion of our phase II trial in brain cancer, following the recent U.S. Orphan Drug Designation in the same indication, sets the stage for further clinical development of FG001 and defining our strategy towards commercialization."

Morten Albrechtsen, CEO

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COMPANY INFORMATION & MANAGEMENT REVIEW

In this document, the following definitions shall apply unless otherwise specified: “the Company” or “FluoGuide” refers to FluoGuide A/S, with CVR number 39 29 64 38. Figures in ‘()’ refer to the same period last year.

The Company

FluoGuide A/S
Ole Maaløes Vej 3
DK-2200 Copenhagen N
CVR no.: 39 29 64 38

Board of Directors

Peter Mørch Eriksen (Chairman)
Mats Thorén (Vice Chairman)
Lisa Micaela Sjökvist
Shomit Adhip Ghose
Andreas Kjær
Michael Engsig

Executive Management

Morten Albrechtsen, CEO

Auditors

PricewaterhouseCoopers
Statsautoriseret Revisionspartnerselskab
CVR-no. DK 33 77 12 31

NASDAQ

FluoGuide is listed on Nasdaq First North Growth Market, Sweden (FLUO).

CEO LETTER TO SHAREHOLDERS

Dear shareholder,

We are very proud that FluoGuide has successfully reached a major landmark, which opens further opportunities for the Company's future development. Positive topline results from a phase IIb trial of our lead product FG001 in aggressive brain cancer were reported after the end of the third quarter. The data showed that the primary endpoint was reached and indicated a clear path to approval of FG001 in its first indication.

We also published topline results of a phase IIa trial in head and neck cancer, in which FG001 once again demonstrated its ability to illuminate cancer. The result gained high interest when presented at the International Academy of Oral Oncology (IAOO) conference. We are now consolidating feedback from key opinion leaders (KOL) and other stake holders as we consider the optimal path for future development in this indication.

The very strong data generated so far is only the tip of the iceberg, we have many other highly promising opportunities for FG001, including photothermal therapy, and several other cancer indications such as breast and colorectal, in which we have not yet conducted clinical trials. While all projects offer great benefit to patients with cancer, the commercial profiles of these different projects vary significantly: for example, aggressive brain cancer presents a relatively low risk but also has a smaller market potential compared to photothermal therapy. The latter has a much larger market potential but is associated with high development risk, longer time horizons, and higher development costs.

This puts FluoGuide in a very strong position, with numerous highly promising opportunities that can be combined in several very different ways. Our task for Q4 is to consolidate the data generated on FG001 and feedback from KOLs, regulators, and others. Based on this, we will select and combine the opportunities, with careful consideration given to synergy and fit to the market. FluoGuide is well-positioned with a low fixed rate of cash burn, providing high flexibility under current market conditions.

The outlook for FluoGuide is promising, with a robust platform for transitioning the Company into advanced clinical development, approvals, and commercialization.

It is truly a privilege to serve as the CEO of this dynamic and groundbreaking company, benefiting from strong support from our shareholders, investigators, and a dedicated team. We all share the common objective of improving surgery for patients with cancer, and together we have the potential to make a real difference to these people.

Morten Albrechtsen
CEO, FluoGuide A/S

FINANCIAL HIGHLIGHTS

In Q3 2023, FluoGuide completed patient recruitment for two clinical phase II trials of FG001, in aggressive brain cancer and head and neck cancers. The positive results in these indications, some of which were published after the end of Q3, as well as positive phase II data in lung cancer reported earlier in 2023, put FluoGuide in a uniquely promising position. Financial flexibility enables the Company to fully capitalize on the good clinical results.

FluoGuide had no revenue for the period and posted a net result of TDKK -9,314 (TDKK -7,041) for the period 1 January to 30 September 2023. The financial result for the period is in line with the Company's development plans.

Summary	Q3 23	Q3 22	YTD 2023	YTD 2022	2022
DKK thousands	1-Jul-23	1-Jul-22	1-Jan-23	1-Jan-22	1-Jan-22
	30-Sep-23	30-Sep-22	30-Sep-23	30-Sep-22	31-Dec-22
Net Revenue	-	-	-	-	-
Operating result	-10,862	-8,416	-31,164	-21,358	-32,461
Net result	-9,314	-7,041	-25,990	-16,743	-27,340
Cash and bank	8,945	31,700	8,945	31,700	26,013
Result per share (DKK) *)	*-0.78*	*-0.60*	*-2.19*	*-1.43*	*-2.33*
Solidity (%) **)	*73%*	*91%*	*73%*	*91%*	*90%*

**) Result per share (DKK per share): Operating result divided by the average number of shares during the period.*
***) Solidity: Total equity divided by total capital and liability.*

PROMISING RESULTS OF FG001 ACROSS ALL INDICATIONS

HIGHLIGHTS DURING Q3

- Positive interim data from phase lla trial of FG001 in head and neck cancer presented as a case report at the World Molecular Imaging Congress in Prague
- Further positive interim data from phase lla trial of FG001 in head and neck cancer
- Completes patient enrollment and treatment in FG001 phase llb clinical trial in aggressive brain cancer
- Completes a Directed Share Issue raising SEK 15 million
- Issues warrants to Board members, management, and employees, as well as the investors participating in the Directed Share Issue

HIGHLIGHTS AFTER Q3

- Receives FDA Orphan Drug Designation for FG001 in high-grade glioma
- Confirms positive topline results from phase lla trial of FG001 in head and neck cancer at IAOO
- Announces FG001 meets primary endpoint in phase llb trial in aggressive brain cancer

TOPIC OF THE QUARTER: AGGRESSIVE BRAIN CANCER

***"Topic of the quarter"* is an addition to FluoGuide's quarterly reports, providing information on a selected topic. This first topic will focus on aggressive brain cancer.**

Aggressive brain cancer and how it is treated

Aggressive brain cancer is categorized by the World Health Organization (WHO) as grade 3 or 4, which refers to the tumor's likelihood of growing and spreading. Surgery is the primary and often initial line of treatment for aggressive brain cancer, specifically grade 3 and 4 gliomas. The surgical procedure commonly employed is known as craniotomy, a complex and delicate intervention that involves the opening of the skull to access and remove as much of the tumor as possible. The neurosurgeon's objective during a craniotomy is to navigate through the intricate structures of the brain and meticulously excise the tumor. However, due to the complexity of the brain's anatomy and the limitations in detecting the entirety of the tumor, complete removal remains a challenging task.

Clinical trial design & result

The phase IIb clinical trial for FG001 in aggressive brain cancer was designed as a controlled randomized trial, with 24 patients randomly assigned to two groups: one receiving FG001 and the other receiving 5-ALA. The trial aimed to inform further clinical development and confirmed FG001's safety, efficacy, and performance. All 24 patients, regardless of the agent received, had additional cancer tissue identified and removed when inspected using optical guidance. The primary endpoint focused on evaluating how many patients had additional cancer tissue removed when guided by FG001 fluorescence. The trial results showed that all patients (12/12) receiving FG001 had additional cancer detected by optical guidance, emphasizing its significance in preventing the oversight of malignant tissue during surgery, possibly enabling greater accuracy.

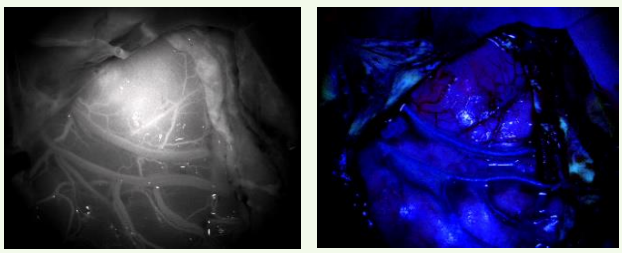
Safety

The safety profile of FG001 was re-confirmed in the phase IIb clinical trial, further reinforcing previous data demonstrating FG001 being safe and well tolerated. Only 2 (mild, grade 1) out of the total 12 drug related adverse events found could be related to FG001 and it was safe and well-tolerated in all patients. The remaining 10 related adverse events (grade 1 and 2) were related to 5-ALA (liver toxicity and gastrointestinal related).

Contrast

The effectiveness of FG001 was evaluated based on the tumor-to-background ratio (TBR), a measurement of contrast. The trial demonstrated an average TBR exceeds 5, indicating a substantial contrast between tumor and normal tissue. This high contrast is crucial for guiding surgeons effectively during surgery. The topline results highlighted that FG001 lit up all 12/12 patients' cancer and a TBR in all patients well above the generally accepted lower limit needed for surgical guidance, reaffirming its efficacy in providing a clear and distinguishable optical signal for precision surgery.

FG001 **5-ALA**



FG001's use of Near Infrared (NIR) light means that it penetrates deeper into the tissue compared to use of visible light. The images are from the same patient (phase I/II trial) where both FG001 and 5-ALA were administered, and the tumor is clearly visible deep into the tissue on the FG001 image and not on the 5-ala image where the tumor cannot be identified.

FLUOGUIDE

FluoGuide powers precision surgery through optical guiding surgery with the fluorescent probe FG001 to improve the outcome for cancer patients

About FluoGuide

FluoGuide enhances precision surgery by using the urokinase-type plasminogen activator receptor (uPAR) targeted luminescent technology to illuminate tumors during surgical procedures, aiming to improve outcomes for cancer patients. FluoGuide is listed on Nasdaq First North Growth Market, Stockholm under the ticker "FLUO".

FG001

The Company's lead product, FG001, is a uPAR targeting fluorescent drug that lights up the cancer and works with many commonly available imaging devices. The goal is to improve surgical precision by illuminating cancer cells intraoperatively in real-time, allowing complete removal of tumor tissue while leaving healthy tissue unharmed.

FG001 is safe, well tolerated and has shown efficacy across brain, head & neck and lung cancers

The improved precision is expected to have a dual benefit of reducing both the frequency of local recurrence post-surgery and surgical sequelae. Ultimately, this could improve patients' chance of being cured and lower system-wide healthcare costs.

FG001 was first shown to be effective and well tolerated by patients undergoing surgery in phase I/IIa clinical trials testing for removal of aggressive brain cancer (high grade glioma). Later, this efficacy and safety was further documented in a phase IIb trial in aggressive brain cancer. The Company has also reported positive topline results in two phase IIa trials, in head & neck and lung cancers.

uPAR – cancer specific, yet expressed in most solid cancer types

uPAR is a protein present on the cells in the surface of the cancer. The expression directly correlates to the aggressiveness of the cancer and its ability to metastasize.

uPAR is broadly expressed in over 80% of all solid cancers

uPAR is part of a cell-bound enzyme system present on the invasive forefront of cancer where it degrades normal tissue to allow the cancer to spread. The luminescence associated with uPAR proves to be an exceptional method for surgeons to distinguish cancerous tissue from normal healthy tissue. The protein is extensively expressed in most solid tumors, including prevalent cancer types like breast, colorectal, lung, and head & neck, as well as in less common yet highly aggressive forms such as high-grade glioma and pancreatic cancer. The pervasive expression of uPAR is a notable characteristic, with estimates indicating its presence in over 80 percent of all cancers subject to surgical removal. This prevalence means FG001 has the potential to improve surgical outcomes for millions of oncology patients worldwide.

FG001 ongoing trials and results

Key results have been reported from four clinical trials with FG001:

- Phase I/IIa trial in aggressive brain cancer (key results reported)
  - Positive topline data communicated
- Phase IIb trial in aggressive brain cancer (key results reported)
  - Positive topline data communicated
- Phase IIa trial in head and neck cancer (key results reported)
  - Positive topline data communicated
- Phase IIa trial in lung cancer (key results reported)
  - Positive topline data communicated

Photothermal therapy with FG001

Research has shown that when exposed to light, FG001 undergoes a process that releases energy in the form of heat. Preclinical *in vivo* data indicates that this generated heat has the potential to selectively eliminate cancer cells bound to FG001, with a notable sparing effect on surrounding normal tissue.

Photothermal therapy with FG001 has already demonstrated a clear effect in preclinical models and was shown to be safe to normal tissue. These data were published in August 2021. Photothermal therapy has the potential to take treatment to the next level of cellular precision. FluoGuide has acquired the exclusive rights to use FG001 for photothermal therapy from Rigshospitalet, Copenhagen.

Innovation Fund Denmark (Innovationsfonden) has awarded its largest and most prestigious grant for research and development of photothermal therapy to a consortium of four highly reputed academic groups and FluoGuide. The grant is valued at DKK 49.1 million and structured through a combination of a cash contribution from Innovation Fund Denmark and a co-financing from the consortium. The grant is a significant milestone for FluoGuide, and it aims to support the research and development of the optimal molecule for photothermal therapy while using FG001 as a model molecule to feed information from the surgical room back into research.

Photothermal therapy could become a new pillar in the treatment of cancer and has the potential to significantly contribute to the long-term growth of FluoGuide.

FG002

FG002 is a uPAR targeted IRDye800 product with particular use in abdominal cancers (e.g. colorectal) and is excreted from the body differently than FG001. FG002 manufacturing is currently being prepared for pre-clinical and clinical development.

Intellectual property protection

FluoGuide has established strong IP protection related to FG001, FG002 and, more broadly, uPAR targeted cancer imaging agents in general. Several patent families contribute to the protection of FG001. The first filed patent family, issued in US and EU, last until 2035. The earliest patent family filed is being processed around the world and is expected to prolong the protection until 2039. The following patent families are in the public domain: WO2016041558, WO2021009219, WO2021009237, WO2021144450 and WO2021130237. FluoGuide owns or is granted an exclusive license to the patent families.

Outlook for FluoGuide

FluoGuide's main goal is to advance its lead product FG001 to improve outcomes for approximately 60,000 patients worldwide who are diagnosed annually with aggressive brain cancer. The second objective is to evaluate the commercial potential in carefully selected indications including head & neck and lung cancers. More broadly, our mission is to realize the vast potential of uPAR for guiding surgery and treating cancer, for the benefit of the growing number of patients diagnosed with cancer.

The key milestones in 2023 are:

Consolidated plans clinical development of FG001 in aggressive brain cancer and other indications

FG001

FG001 is an uPAR target imaging agent designed to work with any standard imaging device

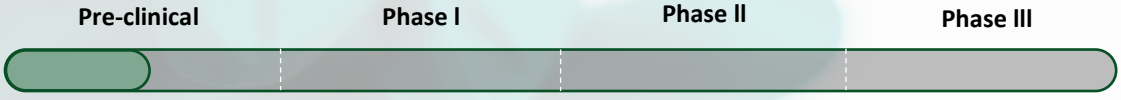
Brain cancer (CT-001)
High-grade glioma

Lung cancer (CT-002):
Non-small cell

Head and neck cancer (CT-003)
Squamous cell carcinoma

Photothermal therapy
Undisclosed indication
Supported by grant

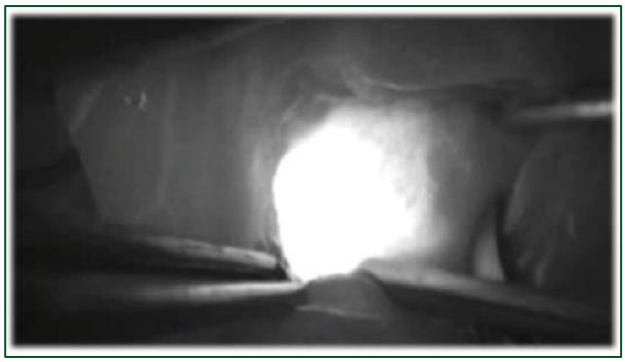
FG002
Undisclosed indication
GMP material produced



Clinical Status of FG001

Clinical data in aggressive brain cancer

The phase I/II results in 40 patients were reported in April 2022. FG001 was well tolerated.



The picture shows the illumination of the brain tumor compared to surrounding healthy tissue after administration of FG001 36 mg the evening before surgery. The picture is a part of a video shown at the SNS Congress (Source: Data from phase I/IIa trial testing FG001 in patients with aggressive brain cancer).

The controlled, randomized, multi-center phase IIb trial (FG001-CT-001) investigated the effect of FG001 in guiding surgery of patients with aggressive brain cancer and compared FG001's effect to 5-ALA. The patients were randomized 1:1 to FG001 or 5-ALA. Fluorescence-guided surgery using FG001 or 5-ALA were compared to white light surgery with each patient serving as its own control. The trial was not designed to show statistical difference (superiority, non-inferiority). The results are used to plan further clinical development.

The topline results are:

- All patients receiving FG001 (12/12) or 5-ALA (12/12) had additional cancer detected by optical guidance, showing FG001 was superior to white light
- FG001 was safe and well tolerated with 2 mild (grade 1) related adverse events
- FG001 lit up 12/12 patients' cancer with a tumor to background ratio (TBR) larger than 2
- No statistically significant differences were observed between FG001 and 5-ALA in histopathology (sensitivity, specificity, negative predictive value and positive predictive value) or gross total resection (GTR) measured on MRI
- Pharmacokinetics of FG001: T1/2 was 13 hours and Cmax was 9.35 mg/L.

White light means that no product is used to guide the surgeon in removing the aggressive brain cancer. 5-ALA is the only approved imaging agent in the world, including Europe and US, for guiding surgery of aggressive brain cancer (grade III and IV glioma). Hospitals around the world use either white light – ie nothing – 5-ALA, or an off-label product, which has not been approved for guiding brain surgery without clinical documentation for effect and safety accepted by regulatory agencies.

FG001 has several technological advantages over 5-ALA, such as being more specific to cancer and based on near infrared light which gives deeper visibility (1-2 cm versus 1-2 mm) and hence an anticipated higher chance of detecting cancer located deeper in tissue. FG001 also reported less drug related adverse events.

Phase IIa trial in head and neck cancer – topline reported topline reported and primary endpoint met

The phase IIa trial was designed to obtain proof-of concept. The primary endpoint was sensitivity defined

as the relative number of patients where FG001 lights up the cancer confirmed by histopathology.

The positive top-line result demonstrated that FG001 lighted up the cancer in all 16 patients enrolled. The effect of FG001 has been very robust across a broad dose range. The trial is conducted at the department of Otolaryngology, Head & Neck Surgery and Audiology, Rigshospitalet, University of Copenhagen, Copenhagen, Denmark.

Phase IIa trial in lung cancer – key result reported topline reported and primary endpoint met

The efficacy of FG001 (as a tumor imaging agent) was examined by sensitivity verified by the contrast expressed as tumor-to-background ratio (TBR) showing that 11/15 (73%) patients had a clinically relevant TBR value. The TBR values were measured under conditions with varying amounts of lung tissue covering the tumors, thus attenuating the signal from FG001. If the tumors had been uncovered, the proportion lightening up would likely have been even higher.

The first lung cancer cohort (7 patients) received 36 mg administered in the evening before surgery. The second cohort (8 patients) received 36 mg administered 2 days prior to surgery. The ability of FG001 to illuminate the tumors was similar in the two cohorts, indicating a broad time window for administration of FG001.

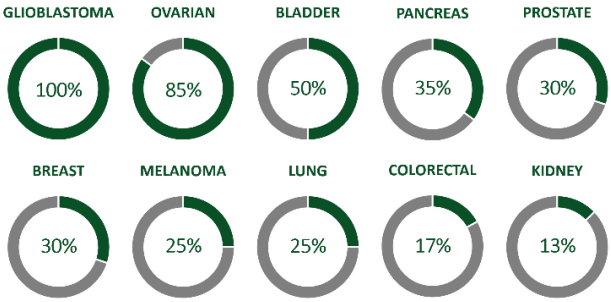
FG001 was shown to be safe and well tolerated in all patients. The pharmacokinetic (PK) profile for FG001 was determined in lung cancer patients and the half-life (t1/2) was found to be comparable with that of aggressive brain cancer (high grade glioma).

Market potential for our portfolio

Surgery is the cornerstone of cancer therapy – of the 15 million new cancer patients each year, 80 percent will need surgery. For localized cancers, surgery is performed with a curative intent, with the surgeon using vision and palpation to find and delineate cancer from normal tissue.

Due to the limitations of the current approach, the average recurrence rate post-surgery is approximately 50 percent, with wide variation, depending on the type of cancer.

Percent local recurrence after surgery



Significant potential for FG001

FluoGuide has chosen high-grade glioma as the primary indication for development of FG001, due to the significant unmet need of these patients. Nearly all high-grade gliomas express uPAR, and high-grade glioma is an aggressive form of brain cancer that has a nearly 100 percent local recurrence rate post-surgery, translating into a very poor prognosis for most patients. Half of all high-grade glioma patients die within 14 months, with only 5 percent surviving after five years. The improved precision that FG001 can offer in this setting has the potential to dramatically improve patient outcomes.

FG001 has demonstrated efficacy in head and neck cancer. Head and neck cancer includes cancers in the lining of the lips, tongue, mouth, or upper throat. Head and neck cancers often occur in close anatomical proximity to small vital structures such as blood vessels supplying the brain and many important nerves. Further, cosmetic considerations are important for most locations of head and neck cancers. Surgical precision is therefore essential for surgical removal of head and neck cancers. Most head and neck cancers arise from squamous cells and termed oral oropharyngeal squamous cell carcinomas cancer (OPSCC). Worldwide, head and neck cancer accounts for approximately 900,000 cases and over 400,000 deaths annually. There are approximately 66,000 cases of head and neck cancer in the USA annually and 15,000 deaths, and 250,000 cases and 63,500 deaths in the EU.

FG001 has also demonstrated efficacy in lung cancer. Globally, there are 2.2 million individuals diagnosed with lung cancer annually, and 1.8 million patients die each year. Lung cancer is the second most diagnosed cancer and was the leading cause of cancer deaths in 2020.

Meningioma accounts for approx. 35 percent of primary brain tumors worldwide. Approx. 7 per 100,000 are diagnosed with meningioma annually. Approx. 20-30 percent of patients will have cancer recur locally within 10 years after their first surgery. FluoGuide estimates that around 60,000 meningioma patients annually will undergo surgery. This is more patients than undergo surgery for high grade gliomas. Surgery is particularly relevant when a cancer is localized. The shift toward identifying cancer earlier will increase the number of patients qualifying for surgery and will drive increased demand for a product that can guide the surgeon.

Sources and references

Skjøth-Rasmussen, J., Azam, A., Larsen, C. C., Scheie, D., Juhl, K., & Kjaer, A. (2021). A new uPAR-targeting fluorescent probe for optical guided intracranial surgery in resection of a meningioma—a case report. Acta Neurochirurgica. https://doi.org/10.1007/s00701-021-05051-3. • Christensen, A., Juhl, K., Persson, M., Charabi, B. W., Mortensen, J., Kiss, K., … Kjær, A. (2017). uPAR-targeted optical near-infrared (NIR) fluorescence imaging and PET for image-guided surgery in head and neck cancer: proof-of-concept in orthotopic xenograft model. Oncotarget, 8(9), 15407–15419. https://doi.org/10.18632/oncotarget.14282. • Juhl, K., Christensen, A., Persson, M., Ploug, M., & Kjaer, A. (2016). Peptide-Based Optical uPAR Imaging for Surgery: In Vivo Testing of ICG-Glu-Glu- AE105. PLoS ONE, 11(2), 1–15. https://doi.org/10.1371/journal.pone.0147428. • Juhl, K., Christensen, A., Rubek, N., Schmidt, K. K., Buchwald, C. Von, & Kjaer, A. (2019). Improved surgical resection of metastatic pancreatic cancer using uPAR targeted in vivo fluorescent guidance : comparison with traditional white light surgery. Oncotarget, 10(59), 6308–6316. • Simón, M., Jørgensen, J. T., Juhl, K., & Kjaer, A. (2021). The use of a uPAR-targeted probe for photothermal cancer therapy prolongs survival in a xenograft mouse model of glioblastoma. Oncotarget, 12(14), 1366–1376. https://doi.org/10.18632/oncotarget.28013. • Kurbegovic, S., Juhl, K., Sørensen, K. K., Leth, J., Willemoe, G. L., Christensen, A., … Kjaer, A. (2021). IRDye800CW labeled uPAR-targeting peptide for fluorescence-guided glioblastoma surgery: Preclinical studies in orthotopic xenografts. Theranostics, 11(15), 7159–7174. https://doi.org/10.7150/thno.49787. • Metrangolo, V., Ploug, M., & Engelholm, L. H. (2021). The Urokinase Receptor (uPAR) as a “Trojan Horse” in Targeted Cancer Therapy: Challenges and Opportunities. Cancers, 13(21), 5376. https://doi.org/10.3390/cancers13215376. • Sung, H., Ferlay, J., Siegel, R. L., Laversanne, M., Soerjomataram, I., Jemal, A., & Bray, F. (2021). Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. CA: A Cancer Journal for Clinicians, 71(3), 209–249. https://doi.org/10.3322/caac.21660. • Yousaf-Khan, U., Van Der Aalst, C., De Jong, P. A., Heuvelmans, M., Scholten, E., Lammers, J. W., … De Koning, H. (2017). Final screening round of the NELSON lung cancer screening trial: The effect of a 2.5-year screening interval. Thorax, 72(1), 48–56. https://doi.org/10.1136/thoraxjnl-2016-208655. • The National Lung Screening Trial Research Team. (2011). Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening. N Engl J Med, 365(5), 395–409. Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening. N Engl J Med, 365(5), 395–40. • Abstract, 68th Scandinavian Neurosurgical Society (SNS) Congress held 14-16 May 2022 in Bergen, Norway. Presentation by Chief Surgeon Jane Skjøth Rasmussen, The Norwegian Neurosurgical Society

BOARD OF DIRECTORS

Peter Mørch Eriksen – Chairman of the Board since 2021

Peter has 20+ years of experience within medtech/life science both in Denmark and abroad. Peter has been CEO of BioPorto A/S until 2021 and is now member of the BoD at BioPorto A/S. Peter has been the CEO of Sense A/S and before this, he held positions as Vice President/GM of Medtronic in both USA and Denmark. From these positions Peter brings extensive experience in creating growth, restructuring, and funding in technology intensive and complex companies. Peter has a background in accounting supplemented by management courses. In addition to being a member of the BoD at BioPorto A/S, Peter also chairs the boards of Monsenso A/S (Nasdaq, first North). He also serves on the Medical Device and Diagnostics Advisory Committee of Cincinnati Children's Hospital Medical Center in Ohio, US.

Mats Thorén – Vice-Chairman of the Board since 2022

Mats has 25 years of experience in the financial markets, where he has worked in the healthcare industry both as an equity analyst and in corporate finance. For the past 19 years, Mats has been a Healthcare investment professional. He has worked with Nalka Life Science AB and MedCap AB and now manages his own investment focused company, Vixco Capital. He currently serves on the board in multiple publicly listed companies, including Xbrane BioPharma AB, Arcoma AB, and Herantis Pharma Oy. He has previous board experience from C-Rad AB, as well as Cellartis AB, Duocort AB, MIP Technologies AB and several other private companies. Mats has a background in Economics, with a specialization in Accounting and Financial Economics as well as studies in medicine at the Karolinska Institute in Stockholm.

Micaela Sjökvist – Board member since 2019

Micaela is Head of Investor Relations at Securitas AB, a publicly listed company active in the security sector. Sjökvist has 20+ years of experience within corporate communications, financial communications, and investor relations in listed international companies. Previous experience includes operative roles at both the international PR consultancy company Grayling and Telia Sonera AB. Micaela Sjökivst holds a B.Sc in Economics and Business Administration from Uppsala University.

Andreas Kjær – Board member since 2018

Andreas is an MD, PhD, DMS, and professor at the University of Copenhagen as well as chief physician at Rigshospitalet, the National University Hospital of Denmark. His research is focused on molecular imaging with PET and PET/MRI in cancer and cardiovascular disease and his achievements include the development of several new tracers that have reached first-in-humans clinical use. He is the holder of an ERC Advanced Grant, has published 400+ peer-review articles, and has received multiple prestigious scientific awards throughout the years. Andreas also holds an MBA from Copenhagen Business School.

Michael Engsig – Board member since 2023

Michael has extensive experience within the pharmaceutical industry with 20+ years of experience in both foreign capital markets and publicly listed companies. This includes a successful track record in general management, R&D, and commercial functions. Since 2019 Michael has been CEO at Nykode Therapeutics, Norway. Michael holds a M.Sc. in chemistry with a specialization in biotechnology from the Technical University of Denmark and a graduate diploma in Business Administration (HD) from Copenhagen Business School.

Shomit Ghose – Board member since 2019

Shomit is an adjunct professor in entrepreneurship at the University of San Francisco and lecturer in engineering at UC Berkeley. He was most recently Managing Director and General Partner at Silicon Valley venture fund ONSET Ventures, which he joined in 2001. He here led the funds to invest in data-driven start-ups for more than 20 years. He is a seasoned technology executive and a venture capitalist with technology operating experience. In addition to his time as an investor, he has 19 years of executive experience at high-tech companies in Silicon Valley. Shomit specializes in the IT sector with a focus on software, networking, and infrastructure. He has been instrumental in several IPOs and holds a degree in Computer Science from UC Berkeley.

MANAGEMENT

Morten Albrechtsen – CEO since 2018

Morten Albrechtsen is an MD and BBA ('HD' in marketing, CBS). Morten is a seasoned entrepreneur with a strong medical, commercial, and financial background. The expertise is gained within a broad range of therapeutic areas and with both drugs and devices. Morten has developed and launched new health care products and concepts internationally, e.g., in Nycomed Pharma, now Takeda Pharmaceuticals Ltd. (pain control), Nanovi (brought a new cancer product to the market in Europe and prepared it for US) and Boehringer Ingelheim GmbH (hospital sales, cardiovascular, stroke female health and pain control).

Ole Larsen – CFO since 2023

Ole Larsen is an experienced CFO with a strong history of working in various industries in both listed and unlisted companies, including Bavarian Nordic, BioPorto, Nordisk Film and Berlingske Tidende. He is skilled in growth/start-ups, M&A and Corporate Finance, and has a finance professional background with a MSc focused on Economics from Copenhagen Business School. Besides takings on the position as CFO, Ole currently serves as member of the board at Linkfire, as well as working as an independent advisor at the medical device company CathVision.

Andreas Kjær – CSO and CMO since 2018

Andreas Kjær is an MD, PhD, DMSc and professor at the University of Copenhagen and chief physician at Rigshospitalet, the National University Hospital of Denmark. His research is focused on molecular imaging with PET, PET/MRI and OPTICAL IMAGING in cancer and cardiovascular disease and his achievements include development of several new tracers that have reached first-in-humans clinical use. He is the holder of an ERC Advanced Grant, has published more than 400 peer-review articles and has received numerous prestigious scientific awards over the years. Andreas Kjaer also has an MBA from Copenhagen Business School.

Grethe Nørskov Rasmussen – CDO since 2019

Grethe Nørskov Rasmussen holds an M.Sc and PhD. Grethe Rasmussen is an experienced product developer with a profound understanding of CMC and former Senior Vice President Product Development at Ascendis Pharma A/S, where Rasmussen worked for over 10 years. Previously, Grethe Rasmussen served as Vice President for Protein Science at Maxygen, Inc. and later as Managing Director for the Danish subsidiary of Maxygen. Prior to joining Maxygen, Dr. Rasmussen held various positions at Novo Nordisk A/S, a global healthcare company, where she contributed to research and development. Dr. Rasmussen holds a PhD in Biochemistry from the Danish Technical University.

Dorthe Grønnegaard Mejer - VP Clinical Development since 2020

Dorthe Grønnegaard Mejer has a M.Sc. in Pharmaceutical Sciences from Copenhagen University. She has previously held several positions across different clinical development disciplines as well as positions within clinical oncology development in other biotech companies such as Genmab, Larix, Orphazyme, and Oncology Venture.

FINANCIAL DEVELOPMENT

Operating income and operating results
The net revenue amounted to DKK 0 (0) and the operating result for the period 1 January to 30 September 2023 showed a loss of TDKK 31,164 (loss of TDKK 21,358). The operating result is in alignment with expectations as the Company is currently in the development stage with three phase IIa/b studies ongoing and no product on the market. The operating result for the three months period ending 30 September 2023 showed a loss of TDKK 10,862 (loss of TDKK 8,416).

Balance sheet and solidity
Total assets as of 30 September 2023 was TDKK 22,357 (TDKK 46,173) and the total equity as of 30 September 2023 was TDKK 16,383 (TDKK 41,913). On July 5, 2023, the Company completed a directed share issue raising TSEK 15,290 (equivalent to TDKK 9,909). On July 24, 2023, FluoGuide signed a credit facility of TDKK 20,000. As of reporting date the credit facility has not been drawn upon. The solidity as of 30 September 2023 was 73% (91%).

Cash flow and investments
The total cash position on 30 September was TDKK 8,945 (TDKK 31,700). Total cash preparedness on 30 September was TDKK 28,945 (TDKK 31,700). No investments were made during the period.

Accounting policy
The financial statements for the first nine months of 2023 are prepared in accordance with International Financial Reporting Standards as adopted by the EU and further provisions of the Danish Financial Statements Act for annual reports of class B companies. For further information on accounting policies, please see the Annual Report of 2022.

Subsequent events
In October the Company drew TDKK 10,000 on the credit facility and thereby also increased the cash position accordingly.

Operational risks and uncertainties
The risks to and uncertainties of FluoGuide's operations are related to several factors such as development, clinical trials, regulatory, patents and other intellectual property rights, key individuals and employees, registration and licensing with agencies/governmental authorities, competitors, customers, suppliers/manufacturers, international operations and exchange rate changes, interest rates, tax, financing needs and capital. During the current period, no significant changes in risk factors or uncertainties have occurred. For a more detailed description of risks and uncertainties, please refer to the company description published in February 2021. The company description is available on FluoGuide's website: www.fluoguide.com/investor/filings-archive/.

Auditor's review
This report has not been audited by FluoGuide's auditor.

Financial calendar
Year-end report 2023 28 February 2024

Miscellaneous

The share

The shares in FluoGuide were listed in 2019 on Spotlight Stock Market and moved from Spotlight to Nasdaq First North Growth Market, Sweden in February 2021. The ticker is FLUO, and the ISIN code is DK0061123312.

The total number of outstanding shares as of 30 September 2023 amounted to 12,025,889 shares, each with a nominal value of DKK 0.10. Each individual share entitles one vote in the company and has an equal right to the company's assets and profits.

Shareholders	Number of Shares	Votes & Capital
Flagged		
Life Science IvS[1)]	2,126,107	17.68%
Wexotec ApS[2)]	1,488,610	12.38%
Aktieselskabet Arbejdernes Landsbank[7)]	861,556	7.16%
Linc AB	850,046	7.07%
Management & Board of Directors		
Management and BoD together owns 34.85% of the total amount of outstanding shares		
Grethe Nørskov Rasmussen[3)]	373,185	3.10%
Pme Holding ApS[4)]	115,669	0.96%
Micaela Sjökvist[5)]	62,163	0.52%
Shomit Ghose[5)]	21,143	0.18%
nuso ApS[6)]	1,431	0.01%
Mats Thorén[5)]	741	0.01%
Dorthe Grønnegaard Mejer[3)]	724	0.01%
Other shareholders		
Other	6,124,514	50.93%
Total	**12,025,889**	**100%**

1) Life Science IvS is a wholly owned company by Board Member, CSO and CMO Andreas Kjaer
2) Wexotec ApS is a wholly owned company by CEO Morten Albrechtsen
3) Grethe Nørskov Rasmussen and Dorthe Grønnegaard Mejer is part of Management
4) Pme Holding ApS is a wholly owned company by Chairman of the Board Peter Mørch Eriksen
5) Micaela Sjökvist, Shomit Ghose and Mats Thorén are members of the Board of Directors
6) nuso ApS is a wholly owned company by CFO Ole Larsen
7) Including withholds repositories from holding for clients

INCOME STATEMENT

Income Statement	Q3 23	Q3 22	YTD 2023	YTD 2022	2022
DKK thousands	1-Jul-23	1-Jul-22	1-Jan-23	1-Jan-22	1-Jan-22
	30-Sep-23	30-Sep-22	30-Sep-23	30-Sep-22	31-Dec-22
Revenue	-	-	-	-	-
Other operating income	66	66	291	6,445	6,511
Other operating expenses	-7,271	-5,333	-20,659	-17,276	-24,099
Staff expenses	-3,595	-3,082	-10,592	-10,364	-14,623
Depreciation and amortization	-63	-66	-203	-163	-251
Operating loss before net financials	-10,862	-8,416	-31,164	-21,358	-32,461
Net financials	-149	-54	-326	-178	-379
Loss before tax	-11,011	-8,470	-31,490	-21,536	-32,840
Tax on loss for the period	1,697	1,429	5,500	4,793	5,500
Net result for the period	-9,314	-7,041	-25,990	-16,743	-27,340
Other comprehensive income for the period, net of tax	-	-	-	-	-
Total comprehensive income	**-9,314**	**-7,041**	**-25,990**	**-16,743**	**-27,340**

BALANCE SHEET

Balance Sheet	2023	2022	2022
DKK thousands	30-Sep-23	30-Sep-22	31-Dec-22
Assets			
Acquired patents	378	378	378
Right of use assets	860	265	199
Tangible fixed assets	27	-	43
Deposits	144	91	107
Total non-current assets	1,409	733	726
Tax receivables	11,000	10,293	5,500
Other receivables	850	3,447	3,364
Prepayments	153	-	16
Cash at bank	8,945	31,700	26,013
Total current assets	20,948	45,440	34,894
Total assets	**22,357**	**46,173**	**35,620**
Equity and liabilities			
Equity			
Share capital	1,203	1,181	1,181
Retained earnings	15,181	40,731	30,787
Total equity	16,383	41,913	31,968
Liabilities			
Total non-current liabilities	-	-	-
Lease liabilities	199	200	205
Trade payables	5,118	3,747	3,269
Deferred income	-20	244	178
Total current liabilities	5,297	4,191	3,652
Total liabilities	5,973	4,261	3,652
Total equity and liabilities	**22,357**	**46,173**	**35,620**

STATEMENT OF CHANGES IN EQUITY

Change in Equity: Q3 23	Share-capital	Share Premium	Retained earnings	Shareholder equity
DKK thousands				
01-jul-23	1,181		15,090	16,271
Paid in capital	21	9,888		9,909
Capital contribution		-9,826	9,826	-
Costs relating to contribution		-62	-	-62
Fair value of warrants issued subsequently to directed issue			-1,712	-1,712
Employee share schemes - value of employee services			1,292	1,292
Net result Q3 23			-9,314	-9,314
Rounding difference	-	-	-	-
30-sep-23	**1,202**	**-**	**15,182**	**16,384**

Change in Equity: Q3 22	Share-capital	Share Premium	Retained earnings	Shareholder equity
DKK thousands				
01-jul-22	1,181		46,977	48,158
Paid in capital				-
Capital contribution			-	-
Costs relating to contribution			-	-
Employee share schemes - value of employee services			796	796
Net result Q3 22			-7,041	-7,041
Rounding difference	-	-	-	-
30-sep-22	**1,181**	**-**	**40,732**	**41,913**

Change in Equity: YTD 2023	Share-capital	Share Premium	Retained earnings	Shareholder equity
DKK thousands				
01-jan-23	1,181		30,787	31,968
Paid in capital	21	9,888		9,909
Capital contribution		-9,826	-	-
Costs relating to contribution		-62	-	-62
Fair value of warrants issued subsequently to directed issue			-1,712	-1,712
Employee share schemes - value of employee services			2,269	2,269
Net result YTD 2023			-25,990	-25,990
Rounding difference	-	-	2	-
30-sep-23	**1,202**	**-**	**15,182**	**16,384**

Change in Equity: YTD 2022	Share-capital	Share Premium	Retained earnings	Shareholder equity
DKK thousands				
01-jan-22	1,132	-	37,569	38,701
Paid in capital	49	17,821		17,870
Capital contribution		-17,195	17,195	-
Costs relating to contribution		-626		-626
Employee share schemes - value of employee services			2,710	2,710
Net result YTD 2022			-16,743	-16,743
Rounding difference	-	-	-	-
30-sep-22	1,181	-	40,731	41,912

Change in Equity: 2022	Share-capital	Share Premium	Retained earnings	Shareholder equity
DKK thousands				
01-jan-22	1,132	-	37,569	38,701
Paid in capital	49	17,821		17,870
Capital contribution		-17,195	17,195	-
Costs relating to contribution		-626		-626
Employee share schemes - value of employee services			3,363	3,363
Net result 2022			-27,342	-27,342
Rounding difference	-	-	-	-
31-dec-22	1,181	-	30,787	31,968

CASH FLOW STATEMENTS

Cash flow	Q3 23	Q3 22	YTD 2023	YTD 2022	2022
DKK thousands	1-Jul-23	1-Jul-22	1-Jan-23	1-Jan-22	1-Jan-22
	30-Sep-23	30-Sep-22	30-Sep-23	30-Sep-22	31-Dec-22
Result before tax	-11,011	-8,470	-31,490	-21,536	-32,840
Net financials, reversed	149	54	326	178	379
Change in working capital	2,448	236	4,029	-13,441	-13,919
Depreciation and amortization	63	66	203	163	251
Adjustment for non-cash fair value of warrants	-1,712	-	-1,712	-	-
Adjustment for non-cash employee benefits expense - share-based payments	1,292	795	2,269	2,710	3,363
Cash flow from operating activities before Net financials	-8,771	-7,318	-26,375	-31,926	-42,766
Net financials	-	-54	-	-178	-379
Tax credit paid out	-	-	-	-	5,500
Cash flow from operating activities	-8,920	-7,372	-26,701	-32,104	-37,645
Cash flow from investing activities	-	-	-37	-37	-117
Cash capital increase	-	-	-	17,870	17,870
Contribution					
Principal elements of lease payments	-46	-64	-178	-162	-227
Transaction costs, capital increase	-	-	-	-626	-626
Cash flow from financing activities	9,802	-64	9,670	17,082	17,018
Total cash flow for the period	881	-7,436	-17,068	-15,058	-20,744
Cash, beginning of the period	8,064	39,136	26,013	46,758	46,758
Cash, end of the period	**8,945**	**31,700**	**8,945**	**31,699**	**26,013**

FluoGuide

FluoGuide enhances precision surgery by using the urokinase-type plasminogen activator receptor (uPAR) targeted luminescent technology to illuminate tumors during surgical procedures, aiming to improve outcomes for cancer patients. FluoGuide is listed on Nasdaq First North Growth Market, Stockholm under the ticker "FLUO"