

# Q2 REPORT

2023

A photograph of a surgical team in an operating room, wearing blue scrubs and masks, illuminated by large overhead surgical lights. The image is overlaid with a diagonal split: the top-left and bottom-right areas are light blue, while the bottom-left and top-right areas are a darker teal.

**FluoGuide**

FluoGuide A/S | Ole Maaløes Vej 3 | DK-2200 Copenhagen N | [fluoguide.com](http://fluoguide.com) | CVR no 39296438

***“We have a uniquely promising position with financial flexibility to fully capitalize on positive clinical data across all indications, and topline results of the phase IIb trial in aggressive brain cancer due in the coming months.”***

*Morten Albrechtsen, CEO*

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# COMPANY INFORMATION & MANAGEMENT REVIEW

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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 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

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Dear shareholder,

In the second quarter, the entire FluoGuide team has been focused on advancing our three ongoing clinical phase II trials. These are investigating FG001 in guiding surgery for patients with aggressive brain cancer, head & neck cancer, and lung cancer.

I am very pleased to report strong progress in all three trials. We have had positive results and interim results across all indications and are now working towards the topline result of the phase IIb trial in aggressive brain cancer, which is expected in the coming months.

FG001 is the lead product in our pioneering image-guided technology with the aim of enhancing precision in cancer surgery. This can improve outcomes for patients by ensuring the cancer is removed, while leaving healthy tissue.

The lung and head & neck phase II trials are both explorative. We have reported positive topline results in the lung cancer trial and repeated positive interim results in the head & neck cancer trial. The topline for the head & neck trial is expected to be in line with the interim result.

The topline data in head & neck cancer will be reported during H2 2023, after our priority - the topline result of the completed aggressive brain cancer phase IIb clinical trial. This trial is blinded, and data analysis is needed before it can be unblinded and reported in approximately 2-3 months from now.

The clinical data that has already been reported, and results still to come this year, are important in shaping FluoGuide. The phase IIb trial in aggressive brain cancer will inform the design of a phase III trial, along with valuable feedback from our ongoing discussions with regulatory authorities, surgeons, and potential partners.

The outstanding progress achieved so far in 2023 puts FluoGuide in a uniquely promising position, having already generated positive results or promising interim results across all indications. This serves as a major de-risking factor and justifies initiation of planning for late-stage clinical development and commercialization.

We have secured the financial flexibility to fully capitalize on these strong clinical results. A directed share issue in July raised 15 MSEK and was combined with a 1:1 warrant that can be exercised in late November 2023. The warrants can provide further proceeds of up to approximately 25 MSEK. In addition, we have secured a plain credit facility of up to 20 MDKK, which is not drawn upon.

With these solid foundations in place, we are looking forward to some exciting quarters ahead. The FluoGuide team are ready to build on the robust clinical results and we are grateful for the support of our investors as we seek to improve cancer surgery for patients in need.

Morten Albrechtsen  
CEO, FluoGuide A/S

# PROMISING RESULTS OR INTERIM RESULTS OF FG001 ACROSS ALL INDICATIONS

In Q2 2023, FluoGuide prepared completion of all three clinical phase II trials of FG001 in different types of cancers. Positive results or interim results in all indications and the forthcoming topline result of the phase IIb trial in aggressive brain cancer 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 DKK -7,139 (DKK -5,749) for the period 1 January to 30 June 2023. The financial result for the period is in line with the Company's development plans.

Summary	Q2 23	Q2 22	YTD 2023	YTD 2022	2022
<b>DKK thousands</b>	1-Apr-23 30-Jun-23	1-Apr-22 30-Jun-22	1-Jan-23 30-Jun-23	1-Jan-22 30-Jun-22	1-Jan-22 31-Dec-22
<b>Net Revenue</b>	-	-	-	-	-
<b>Operating result</b>	-8,656	-7,514	-20,302	-12,942	-32,461
<b>Net result</b>	-7,139	-5,749	-16,674	-9,701	-27,340
<b>Cash and bank</b>	8,064	39,136	8,064	39,136	26,013
<b>Result per share (DKK) *</b>	-0.60	-0.49	-1.41	-0.82	-2.33
<b>Solidity (%) **)</b>	83%	92%	83%	92%	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.

## HIGHLIGHTS DURING Q2

- FluoGuide provides update on strong clinical trial progress
- FluoGuide announces positive topline results from phase IIa trial of FG001 in lung cancer
- FluoGuide announces positive interim results from phase IIa trial of FG001 in head & neck cancer

## HIGHLIGHTS AFTER Q2

- FluoGuide completes a Directed Share Issue raising SEK 15 million. Investors received one warrant per share to exercise in the period 27 November to 1 December
- FluoGuide completes patient enrollment and treatment in FG001 phase IIb clinical trial in aggressive brain cancer
- FluoGuide reports further positive interim data from phase IIa trial of FG001 in head & neck cancer

# FLUOGUIDE

## FluoGuide takes precision surgery to the next level to improve the outcome for cancer patients

### About FluoGuide

FluoGuide takes precision surgery to the next level, improving the outcome for cancer patients by illuminating tumors during surgery using urokinase-type plasminogen activator receptor (uPAR) targeted luminescent technology. 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 selectively lights up cancer cells and works with common 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 avoiding healthy tissue.

*FG001 is well tolerated and has shown efficacy in all indications tested*

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’ chances of being cured and lower system-wide healthcare costs.

FG001 was effective and well tolerated by patients undergoing surgery in phase I/IIa clinical testing for removal of aggressive brain cancer (high grade gliomas). Further positive topline result of phase II trials has been reported in lung cancer and repeated positive interim results have been reported in in head & neck cancer.

### UPAR IS SPECIFIC TO CANCER CELLS ACROSS MOST CANCERS

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

*uPAR – broadly expressed and selective to cancer*

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. uPAR luminescence is therefore an outstanding way to delineate cancer from normal tissue for surgeons. The protein is extensively expressed in most solid tumors, including prevalent forms of cancer such as breast, colorectal, lung cancer and head & neck cancer, as well as in less prevalent but highly aggressive cancers such as high-grade glioma and pancreatic cancer. Estimates indicate that uPAR is expressed in over 70-80 percent of all cancers that undergo surgical removal, making FG001 an attractive target to improve surgical outcomes for millions of oncology patients worldwide.

### Clinical Data

After good safety data and proof-of-concept in the first indication (aggressive brain cancer), FG001 is being advanced into a late-stage phase IIb clinical trial testing in aggressive brain cancer where recruitment and treatment of patients are completed, data analysis ongoing and topline result reporting forthcoming. It is also being investigated in clinical phase IIa trials in more prevalent indications with positive topline results and interim results in lung and head & neck cancer, respectively.

### ***FG001 ongoing trials and results***

Two clinical trials with FG001 have reported key results two are ongoing and one commencing:

- Phase I/IIa trial in aggressive brain cancer (key results reported)
  - Positive topline result communicated
- Phase IIb trial in aggressive brain cancer (ongoing)
  - Patient recruitment and treatment are completed
  - Data analysis is ongoing
  - Topline result reporting is forthcoming
- Phase IIa trial in lung cancer (key results reported)
  - Positive topline data communicated
- Phase IIa trial in head & neck cancer (ongoing)
  - Patient recruitment and treatment are completed
  - Repeated positive interim results communicated
  - Topline result reporting is forthcoming
- Phase IIa trial in meningioma and glioma (commencing)
  - Permission granted to start the trial

## Photothermal therapy with FG001

It has been demonstrated that light excitation of FG001 will cause it to release energy in the form of heat. Preclinical *in vivo* data suggests that the generated heat will kill the cancer cells to which FG001 is bound, while sparing 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 a new 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 valued at DKK 49.1 million 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) being 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 the 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 such as lung cancer and head & neck cancer. 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:

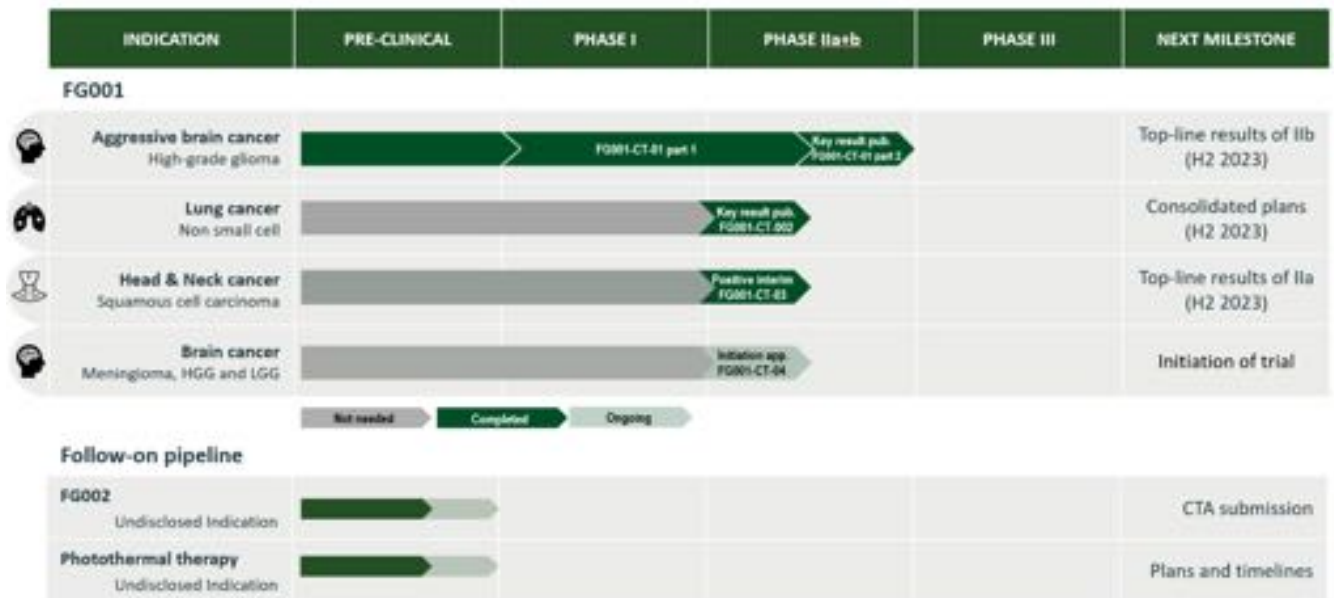
- Topline results of phase IIb trial with FG001 in aggressive brain cancer
- Topline results of phase IIa trial with FG001 in head & neck cancer
- Phase III plans for FG001 in aggressive brain cancer
- Timelines for the phase IIa trial with FG001 in meningioma and glioma



# FG001

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

## Clinical Status of FG001



### Phase IIa clinical data in aggressive brain cancer - positive topline result

The results in 40 patients were reported in April 2022. FG001 was well tolerated. The specificity was 100% and the sensitivity was 79%, validated by two independent blinded histopathologists. They evaluated 31 biopsies from the dose cohort 7a (36 mg, evening before surgery) and dose cohort 8a (48 mg, evening before surgery).



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).

### ***Phase IIb clinical trial in aggressive brain cancer – patient recruitment and treatment are completed (topline result is forthcoming)***

A clinical phase IIb trial was launched based on the excellent phase I/IIa result. The controlled, randomized, multi-center phase IIb trial (FG001-CT-001) investigates the effect of FG001 in guiding surgery of patients with aggressive brain cancer and compares FG001's effect compared to 5-ALA and white light. The patients are randomized in 1:1 between FG001 and 5-ALA. FG001 and 5-ALA are compared to white light in their respective arm with the patients as their own control. The trial was based on the highly promising results from a phase I/IIa trial in the same indication, where 100% of the biopsies from patients treated with FG001 illuminated cancer.

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 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 which is located deeper in tissue.

### ***Ongoing: phase IIa trial in lung cancer – key result reported***

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 (t<sub>1/2</sub>) was found to be comparable with that of aggressive brain cancer (high grade glioma).

### ***Ongoing: phase IIa trial in head & neck cancer - patient recruitment and treatment are completed (positive interim result)***

The phase IIa trial is designed to obtain proof-of-concept. The initial plan was to enroll up to 12 patients but encouraging data merited expansion of the cohort and adding further cohorts. The primary endpoint is sensitivity defined as the relative number of patients where FG001 lights up the cancer confirmed by histopathology.

The positive interim 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.

The topline result for the trial is expected to be released in H2 2023.

### ***Phase IIa trial in meningioma and glioma***

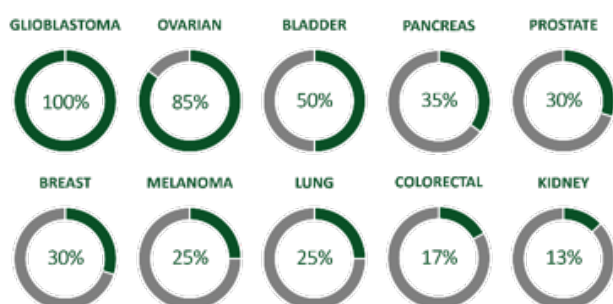
FluoGuide has received permission from the Danish Medicines Agency and ethical committee to start a proof-of-concept phase IIa trial in meningioma and glioma. The primary endpoint is sensitivity defined as the relative number of patients, where FG001 lights up the cancer confirmed by histopathology. The trial will include patients with both high- and low-grade glioma. Further details on timelines, design and possible outcomes are expected to be communicated in H2 2023.

## 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 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.

FG001 has also demonstrated efficacy in head & neck cancer. Head & neck cancer includes cancers in the lining of the lips, tongue, mouth, or upper throat. Head & 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 & neck cancers. Surgical precision is therefore essential for surgical removal of head & neck cancers. Most head & neck cancers arise from squamous cells and termed oral oropharyngeal squamous cell carcinomas cancer (OPSCC). Worldwide, head & neck cancer accounts for approximately 900,000 cases and over 400,000 deaths annually. There are approximately 66,000 cases of head & neck cancer in the USA annually and 15,000 deaths, and 250,000 cases and 63,500 deaths in the EU.

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 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., Willemoie, 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 with management courses. In addition to being member of the BoD at BioPorto A/S, Peter also chairs the boards of My Blue Label A/S and 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 from 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.



## **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.



## **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 Sjökvist 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 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.

# 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 holds an MSc. 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. Ole 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. 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 Kjær 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 June 2023 showed a loss of TDKK 20,302 (loss of TDKK 12,942). 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 June 2023 showed a loss of TDKK 8,656 (loss of TDKK 7,514).

## Balance sheet and solidity

Total assets as of 30 June 2023 was TDKK 19,588 (TDKK 52,353) and the total equity as of 30 June 2023 was TDKK 16,272 (TDKK 48,159). The solidity as of 30 June 2023 was 83% (92%).

## Cash flow and investments

The total cash position on 30 June was TDKK 8,064 (TDKK 39,136). No investments were made during the period.

## Accounting policy

The financial statements for the first six 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

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.

## 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/](http://www.fluoguide.com/investor/filings-archive/).

## Auditor's review

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

## Financial calendar

Interim report Q3, 2023	29 November 2023
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 31 March 2023 amounted to 11,814,500 (11,319,500) shares, each with a nominal value of DKK 0.10. Each individual share entitles to one vote in the company and has an equal right to the company's assets and profits.

Shareholders	Number of Shares	Votes & Capital
<b>Flagged</b>		
Life Science Ivs	2,126,107	18.01%
Wexotec Aps	1,488,610	12.61%
Aktiesel. Arbejdernes Landsbank	860,161	7.16%
Linc AB	850,046	7.08%
<b>Management &amp; Board of Directors</b>		
<i>Management and BoD together owns 35.4% of the total amount of outstanding shares</i>		
Grethe Nørskov Rasmussen	373,185	3.11%
Pme Holding Aps	115,669	0.96%
Micaela Sjøkvist	62,163	0.52%
Shomit Ghose	21,143	0.18%
nuso ApS	1,431	0.01%
Mats Thorén	741	0.01%
Dorthe Grønnegaard Mejer	724	0.01%
<b>Other shareholders</b>		
Other	6,114,542	50.35%
<b>Total</b>	<b>12,014,522</b>	<b>100%</b>

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 Director of the Board Peter Mørch Eriksen

5) Member of the Board of Directors

6) nuso ApS is a wholly owned company by CFO Ole Larsen

# INCOME STATEMENT

Income Statement	Q2 23	Q2 22	YTD 2023	YTD 2022	2022
DKK thousands	1-Apr-23 30-Jun-23	1-Apr-22 30-Jun-22	1-Jan-23 30-Jun-23	1-Jan-22 30-Jun-22	1-Jan-22 31-Dec-22
Revenue	-	-	-	-	-
Other operating income	159	3,027	225	6,379	6,511
Other operating expenses	-5,376	-6,717	-13,388	-11,942	-24,099
Staff expenses	-3,370	-3,767	-6,998	-7,282	-14,623
Depreciation and amortization	-69	-57	-140	-97	-251
Operating loss before net financials	-8,656	-7,514	-20,302	-12,942	-32,461
Net financials	-118	-72	-175	-124	-379
Loss before tax	-8,775	-7,586	-20,477	-13,065	-32,840
Tax on loss for the period	1,636	1,837	3,803	3,364	5,500
Net result for the period	-7,139	-5,749	-16,674	-9,701	-27,340
Other comprehensive income for the period, net of tax	-	-	-	-	-
<b>Total comprehensive income</b>	<b>-7,139</b>	<b>-5,749</b>	<b>-16,674</b>	<b>-9,701</b>	<b>-27,340</b>

# BALANCE SHEET

Balance Sheet	2023	2022	2022
DKK thousands	30-Jun-23	30-Jun-22	31-Dec-22
<b>Assets</b>			
Aquired patents	378	378	378
Right of use assets	917	331	199
Tangible fixed assets	32	0	43
Deposits	144	91	107
<b>Total non-current assets</b>	<b>1,471</b>	<b>800</b>	<b>726</b>
Tax receivables	9,303	8,864	5,500
Other receivables	625	3,554	3,364
Prepayments	124	0	16
Cash at bank	8,064	39,136	26,013
<b>Total current assets</b>	<b>18,116</b>	<b>51,554</b>	<b>34,894</b>
<b>Total assets</b>	<b>19,588</b>	<b>52,353</b>	<b>35,620</b>
<b>Equity and liabilities</b>			
<b>Equity</b>			
Share capital	1,181	1,181	1,181
Retained earnings	15,090	46,977	30,787
<b>Total equity</b>	<b>16,272</b>	<b>48,159</b>	<b>31,969</b>
<b>Liabilities</b>			
<b>Total non-current liabilities</b>	<b>-</b>	<b>-</b>	<b>-</b>
Lease liabilities	193	264	205
Trade payables	2,349	3,551	3,269
Deferred income	46	310	178
<b>Total current liabilities</b>	<b>2,588</b>	<b>4,125</b>	<b>3,652</b>
<b>Total liabilities</b>	<b>3,316</b>	<b>4,194</b>	<b>3,652</b>
<b>Total equity and liabilities</b>	<b>19,588</b>	<b>52,353</b>	<b>35,620</b>

# STATEMENT OF CHANGES IN EQUITY

Change in Equity: Q2 23	Share-capital	Share Premium	Retained earnings	Shareholder equity
DKK thousands				
01-apr-23	1,181		21,790	22,971
Paid in capital	-	-		-
Capital contribution		-	-	-
Costs relating to contribution		-	-	-
Employee share schemes - value of employee services			439	439
Net result Q2 23			-7,139	-7,139
30-jun-23	1,181	-	15,090	16,271

Change in Equity: Q2 22	Share-capital	Share Premium	Retained earnings	Shareholder equity
DKK thousands				
01-apr-22	1,181		51,864	53,045
Paid in capital				0
Capital contribution			0	-
Costs relating to contribution			-144	-144
Employee share schemes - value of employee services			1,006	1,006
Net result Q2 22			-5,749	-5,749
30-jun-22	1,181	-	46,977	48,158

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	-	-		-
Capital contribution		-	-	-
Costs relating to contribution		-	-	-
Employee share schemes - value of employee services			977	977
Net result YTD 2023			-16,674	-16,674
30-jun-23	1,181	-	15,091	16,272

<b>Change in Equity: YTD 2022</b>	<b>Share-capital</b>	<b>Share Premium</b>	<b>Retained earnings</b>	<b>Shareholder equity</b>
<b>DKK thousands</b>				
<b>01-jan-22</b>	1,132	-	37,569	38,701
<b>Paid in capital</b>	49	17,821		17,870
<b>Capital contribution</b>		-17,195	17,195	-
<b>Costs relating to contribution</b>		-626		-626
<b>Employee share schemes - value of employee services</b>			1,915	1,915
<b>Net result YTD 2022</b>			-9,701	-9,701
<b>30-jun-22</b>	<b>1,181</b>	<b>-</b>	<b>46,978</b>	<b>48,159</b>

<b>Change in Equity: 2022</b>	<b>Share-capital</b>	<b>Share Premium</b>	<b>Retained earnings</b>	<b>Shareholder equity</b>
<b>DKK thousands</b>				
<b>01-jan-22</b>	1,132	-	37,569	38,701
<b>Paid in capital</b>	49	17,821		17,870
<b>Capital contribution</b>		-17,821	17,821	-
<b>Costs relating to contribution</b>			-624	-624
<b>Employee share schemes - value of employee services</b>			3,363	3,363
<b>Net result 2022</b>			-27,342	-27,342
<b>31-dec-22</b>	<b>1,181</b>	<b>0</b>	<b>30,787</b>	<b>31,968</b>

# CASH FLOW STATEMENTS

Cash flow	Q2 23	Q2 22	YTD 2023	YTD 2022	2022
DKK thousands	1-Apr-23	1-Apr-22	1-Jan-23	1-Jan-22	1-Jan-22
	30-Jun-23	30-Jun-22	30-Jun-23	30-Jun-22	31-Dec-22
<b>Result before tax</b>	-8,775	-7,586	-20,477	-13,065	-32,840
<b>Net financials, reversed</b>	118	72	175	124	379
<b>Change in working capital</b>	159	-4,127	1,580	-13,678	-13,919
<b>Depreciation and amortisation</b>	69	57	140	97	251
<b>Adjustment for non-cash employee benefits expense - share-based payments</b>	439	1,006	977	1,915	3,363
<b>Cash flow from operating activities before Net financials</b>	-7,990	-10,578	-17,605	-24,608	-42,766
<b>Net financials</b>	-118	-72	-175	-124	-379
<b>Tax credit paid out</b>	-	-	-	-	5,500
<b>Cash flow from operating activities</b>	-8,108	-10,650	-17,780	-24,731	-37,645
<b>Cash flow from investing activities</b>	-32	-36	-37	-37	-117
<b>Cash capital increase</b>	-	0	-	17,870	17,870
<b>Contribution</b>					
<b>Principal elements of lease payments</b>	-65	-56	-132	-99	-227
<b>Transaction costs, capital increase</b>	-	-144	-	-626	-626
<b>Cash flow from financing activities</b>	-65	-200	-132	17,146	17,018
<b>Total cash flow for the period</b>	-8,205	-10,886	-17,949	-7,622	-20,744
<b>Cash, beginning of the period</b>	16,269	50,021	26,013	46,758	46,758
<b>Cash, end of the period</b>	<b>8,064</b>	<b>39,135</b>	<b>8,064</b>	<b>39,135</b>	<b>26,013</b>



# FluorGuide