## YEAR END REPORT 2022

PRECISION SURGERY IMPROVING OUTCOME FOR CANCER PATIENTS

# FluoGuide A/S | Ole Maaløes Vej 3 | DK-2200 Copenhagen N | fluoguide.com | CVR no 39296438

*"FluoGuide is on a fast pace to help millions of patients with cancer to a more precise surgery"* 

Morten Albrechtsen, CEO

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## FluoGuide

## **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 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 Lisa Micaela Sjökvist Shomit Adhip Ghose Andreas Kjær

#### **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 fellow shareholders,

I have the honor of updating you on the strong progress of FluoGuide in 2022 towards our mission to help millions of cancer patients benefit from more precise surgeries.

As you are aware, FluoGuide has developed a cutting-edge image-guided surgery technology that helps surgeons accurately locate and remove cancerous tissue. Over the past few years, FluoGuide has made tremendous strides in bringing this technology to market, taking it into multiple clinical trials, which have shown remarkable results so far.

We initiated our first clinical trial with FG001 in 2020 and reported positive interim result. In 2022, we made significant advances with excellent results from our clinical phase I/IIa trial for FG001 in guiding brain cancer surgery as well as initiating trials in lung and head & neck cancer and reporting positive interim results for both these indications.

The 2022 clinical results are potentially transformative for FluoGuide. FG001 was demonstrated to be very well tolerated, which is of general importance for its broad potential use. FG001 was demonstrated to have a high accuracy in aggressive brain cancer and based on these data, we initiated a clinical phase IIb trial to advance FG001 toward late-stage clinical development in this indication. The end point was upgraded from lighting up cancer (positive predictive value) in the Ila trial, to patient benefit (relevant change in surgical strategy) in the phase IIb trial, which includes 24 patients from a Danish (Copenhagen) and a Swedish (Linköping) site. The patients are equally randomized between Gliolan<sup>®</sup> (5-ALA), the only approved product in this indication, and FG001.

The result will be used to determine the size of a phase III trial aiming to show non-inferiority of FG001 against and Gliolan<sup>®</sup>. The IIb trial is not designed to show significant superiority of FG001 over Gliolan<sup>®</sup>.

In 2023, we anticipate three important clinical milestones with FG001. The results of these trials will be critical in guiding the future development of FluoGuide.

We are confident in the broad potential of our technology, as the positive results in three different types of cancer (brain, lung, and head & neck) demonstrate its high likelihood of success in guiding surgeries for a wide range of indications. Our technology is supported by a substantial body of scientific literature that shows its specificity for most solid cancers.

In parallel, we are stepping up preparations for commercialization and look forward to transforming FluoGuide into a leading player in guiding oncology surgery. This is based on a solid position, with funding secured to reach the next key milestones in all of our phase II trials.

Given the current financial market situation, we have postponed investment in expanding our organization to maintain higher financial flexibility. This means that everyone at FluoGuide is working harder than ever and I would like to take this opportunity to thank our tireless employees.

I would also like to express my gratitude to our dedicated clinical collaborators and our supportive shareholders for their contributions to our success in 2022. I look forward to what 2023 will bring and the opportunities and challenges that lie ahead.

Morten Albrechtsen CEO, FluoGuide A/S

## FLUOGUIDE

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

#### About FluoGuide A/S

FluoGuide takes precision surgery to the next level, improving the outcome for cancer patients by illuminating tumors during surgery using urokinasetype 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 was well tolerated and has shown efficacy in aggressive brain cancer in Phase I/IIa

#### clinical testing

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).

## 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, highly selective to delineate 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 and lung cancer, as well as in less prevalent but highly aggressive cancers such as highgrade glioma, pancreatic cancer and head and neck 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 late-stage clinical testing in aggressive brain cancer and is being investigated in clinical trials in more prevalent indications.

#### FG001 ongoing trials and results

One clinical trial with FG001 completed, three are ongoing and one commencing:

- Phase I/IIa trial in aggressive brain cancer (completed)
  - Positive data communicated;
- Phase IIb trial in aggressive brain cancer (ongoing);
  - o No data available

- Phase IIa trial in lung cancer (ongoing)
  - Positive interim data communicated;
- Phase IIa trial in head & neck cancer (ongoing)
  - Positive interim result communicated;
- Phase IIa trial in meningioma and low grade glioma (commencing)
  - $\circ \quad \text{No data available} \\$

#### 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 Rigshospitalt, Copenhagen.

#### 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 is currently being prepared for 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: W02016041558, W02021009219, W02021009237, W02021144450 and W02021130237. 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 high-grade glioma. 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.

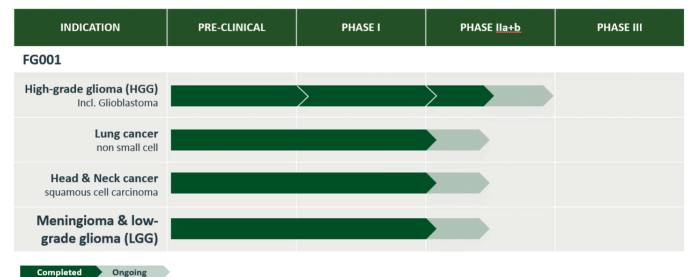
#### The key milestones in 2023 are:

- Topline results of Phase IIb trial with FG001 in aggressive brain cancer
- Topline results of Phase IIa trial with FG001 in lung cancer
- Topline results of Phase IIa trial with FG001 in head and neck cancer
- Approval to initiate Phase IIa trial with FG001 in meningioma and low-grade glioma

## FG001

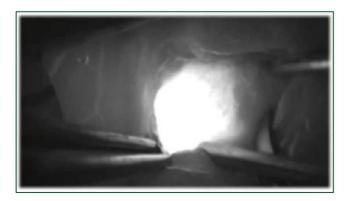
FG001 is an uPAR target imaging agent designed to work with any standard imaging device

#### **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 – no result (ongoing)

A clinical Phase IIb trial was launched based on the excellent Phase I/IIa result and is ongoing.

The end point was upgraded from the IIa trial lighting up cancer (positive predictive value) to the IIb trial - patient benefit (relevant change in surgical strategy). This IIb trial including 24 patients from two sites: Department of Neurosurgery, Neuroscience Center, Rigshospitalet, Copenhagen University Hospital, Copenhagen, Denmark and Department of Neurosurgery and Department of Biomedical and Clinical Sciences, Linköping University, Linköping, Sweden. The trial is not designed to show significances (superiority nor inferiority) but will only be used to size the phase III trial aiming at non-inferiority between Gliolan and FG001. The Phase III trial, which will be launched following the results of the ongoing study and regulatory feedback.

The last patient is expected to be enrolled during the summer 2023 with topline results to be available 8 weeks after.

#### Ongoing: Phase IIa trial in lung cancer - positive interim result (ongoing)

In 2021, the Company selected lung cancer as the second indication for FG001. The Phase IIa trial is designed to enroll up to 24 patients with non-small cell lung cancer (NSCLC). The primary endpoint is sensitivity defined as the relative number of patients, where FG001 lights up the cancer.

The positive interim result following the first eight patients was reported in November 2022. FG001 lighted up the cancer in 5 of the 7 patients with NSCLC and one patient was diagnosed with lung metastases from bladder cancer, rather than NSCLC.

The trial is conducted at the Department of Cardiothoracic Surgery at the University Hospital, Rigshospitalet, in Denmark.

The top line results are expected in the next 6 months.

#### Ongoing: Phase IIa trial in head and neck cancer - positive interim result (ongoing)

The Phase IIa trial is designed to obtain proof-of concept. The plan is to enroll up to 16 patients. 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 following the first four patients was reported in January 2023. FG001 lighted up the cancer in all four patients.

The trial is conducted at the department of Otolaryngology, Head & Neck Surgery and

Audiology, Rigshospitalet, University of Copenhagen, Copenhagen, Denmark.

The topline result is expected in the next 6 months.

## Phase IIa trial in meningioma and low grade glioma

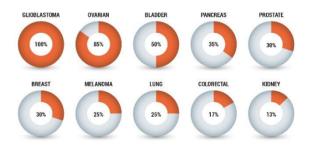
A protocol is pending for a proof-of- concept Phase Ila trial in meningioma and low-grade glioma. The primary endpoint is sensitivity defined as the relative number of patients, where FG001 lights up the cancer confirmed by histopathology. The trial is expected to commence in 2023.

#### 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 and the relative speed of development in this indication. 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.

The second indication for FG001 is 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.

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 are called squamous cell carcinomas. 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.

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.

## **HIGHLIGHTS FROM 2022**

## Q1

- FluoGuide completed a directed share issue approximately SEK 25 million.
- FluoGuide received a grant of approx. DKK 1.0 million together with Rigshospitalet, Denmark to conduct an explorative phase II trial with FG001 in patients with less aggressive brain cancer.
- FluoGuide received regulatory approval from the Danish Medicines Agency to initiate an explorative phase II trial with FG001 in patients with lung cancer.

#### **Q2**

- FluoGuide announced positive top line result from the first part of the ongoing clinical phase I/II trial testing the safety and performance of FG001 in lightening up aggressive brain cancer.
- FluoGuide presented the clinical data on FG001 at the 68<sup>th</sup> Scandinavian Neurosurgical Society Congress in Bergen, Norway.
- FluoGuide hosted a presentation of FG001 results from the first clinical trial with FG001 (phase I/II) in patients with aggressive brain cancer.

## Q3

- Publication of clinical data that showed uPAR is highly expressed in oropharyngeal squamous cell carcinoma (head and neck cancer) in Oncology Report.
- FluoGuide submitted CTA to initiate an explorative clinical phase II trial with FG001 in patients with head and neck cancer.
- FluoGuide received regulatory permissions to start clinical phase IIb trial in patients with aggressive brain cancer in Denmark and Sweden.
- FluoGuide received regulatory approval and initiated clinical phase II trial with FG001 in patients with head and neck cancer.

### **Q4**

- The excellent phase I/IIa clinical data of FG001 in aggressive brain cancer was presented at the World Molecular Imaging Congress and the European Congress of Neurosurgery 2022.
- FluoGuide enrolled first patient in the clinical phase IIb trial with FG001 in patients with aggressive brain cancer.
- FluoGuide announced positive interims result from FG001 phase IIa trial in lung cancer.
- FluoGuide enrolled first patient in the explorative clinical phase IIa trial with FG001 in patients with head and neck cancer.

## **HIGHLIGHTS AFTER 2022**

- FluoGuide announced positive interim result of FG001 in the clinical explorative phase II trial in patients with head and neck cancer.
- FluoGuide appointed Ole Larsen as CFO.
- FluoGuide updated the clinical timelines for the ongoing clinical phase IIb trial of FG001 in patients with aggressive brain cancer (high grade glioma) undergoing surgery.

#### 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 imageguided 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 Board since 2021

Peter Mørch Eriksen has more than 20 years of experience within medtech/life science both in Denmark and abroad. Peter Mørch Eriksen has been CEO of BioPorto A/S until 2021, and is now board member of BioPorto A/S, Peter Mørch Eriksen has been the CEO of Sense A/S and before this, he held positions as Vice President of Medtronic in both the USA and Denmark. From these positions Peter Mørch Eriksen brings extensive experience in creating growth, restructuring and funding in technology intensive and complex companies. Peter Mørch Eriksen has an accounting background supplemented with courses in management. In addition to being Board member of BioPorto A/S, Peter Mørch Eriksen chairs the board of MTIC, is a board member at Nervex A/S, member of Lund University Advisory Board, and Director of PMEconsult ApS. He also serves on the Medical Device and Diagnostics Advisory Committee of Cincinnati Children's Hospital Medical Center in Ohio, US.

#### Mats Thorén – Board member since 2021

Mats Thorén has 25 years of experience from the financial markets, where he has worked in the Healthcare both as an equity analyst and in corporate finance. For the past seventeen years, Mats Thorén has been a Healthcare investment professional. He has worked with Nalka Life Science AB and MedCap AB and now manages his own company, Vixco Capital, with a focus on investments. He currently serves on the boards of Xbrane BioPharma AB (Stockholm Smallcap), Arcoma AB (Stockholm First North) and Herantis Pharma Oy (Stockholm and Helsinki First North). He has previous board experience from C-Rad AB (Stockholm First North), as well as Cellartis AB, Duocort AB, MIP Technologies AB and several other private companies. Mats Thorén has studied at the Stockholm School of Economics focusing on Accounting and Financial Economics as well as studies in medicine at the Karolinska Institute in Stockholm.

#### Shomit Ghose – Board member since 2019

Shomit Ghose 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, and where he led the fund's investing 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 the Silicon Valley. Shomit Ghose specializes in the information technology sector with a focus on software, networking and infrastructure. He has been instrumental in several IPOs. Shomit Ghose holds a degree in Computer Science from the University of California Berkeley.



#### Micaela Sjökvist – Board member since 2019

Micaela Sjökvist is Head of Investor Relations at Securitas AB, a public listed company active in the security sector. Sjökvist has over 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 Kjaer, 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 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 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.





## 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, currently listed on Nasdaq First North Growth Market, 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.

## **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 December 2022 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.

In March 2022, FluoGuide completed a directed share issue and raised of SEK 25 million by issuing 495,000 new shares.

SHAREHOLDERS	NUMBER OF SHARES	<b>VOTES &amp; CAPITAL</b>
Flagged		
Life Science IvS <sup>1)</sup>	2,126,107	18.0%
Wexotec ApS <sup>2)</sup>	1,488,610	12.6%
LINC AB	819,630	6.9%
Arbejdernes Landsbank A/S	800,005	6.8%
Management & Board of Directors		
Grethe Nørskov Rasmussen 3)	373,185	3.2%
PME Holding ApS <sup>5)</sup>	117,297	1.0%
Micaela Sjökvist <sup>4)</sup>	62,163	0.5%
Shomit Ghose 4)	21,143	0.2%
Mats Thorén	1,216	0.0%
Dorthe Grønnegaard Mejer 3)	724	0.0%
Other Shareholders		
Others	6,003,204	50.8%
Total	11,814,500	100.00%

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) Management

4) Member of the Board of Directors

5) PME Holding ApS is a wholly owned company by Board member Peter Mørch Eriksen

Data comes from Euroclear December 2022.

Every share equals the same rights to the Company's assets and results.

#### Warrants

FluoGuide has established incentive programs for its employees, management, and Board. On 29 March 2022, the Board of Directors of FluoGuide has exercised its authorization to issue new warrants by issuing 40,000 warrants to employees and management. On 28 May 2021, the Company decided to issue 272,700 warrants to employees and management and 50,000 warrants to the Board of Directors.

The two warrant programs are issued to ensure alignment of interests between the Company's employees, management, Board of Directors, and shareholders. The Company believes that the issue of warrants will provide motivation for the achievement of FluoGuide's short-term and long-term goals to support the Company's business strategy, sustainability, and value creation for the benefit of shareholders. Warrants represent a total dilution of 3.1 percent of the current share capital, if vested and exercised. Please see note 5.

#### Proposed appropriation of retained earnings

The Board of Directors have proposed that no dividend is paid out for the fiscal year, 1 January 2022 – 31 December 2022.

#### **Financial calendar for 2023**

Annual General Meeting:	21 March 2023
Interim report Q1 2023:	31 May 2023
Half-year report:	30 August 2023
Interim report Q3 2023:	29 November 2023
Year-end report 2023:	28 February 2024

#### **More information**

A comprehensive description of the company's strategy, development plans and programs can be found on our website: www.fluoguide.com

## FINANCIAL HIGHLIGHTS AND RATIOS

KEY FIGURES		2022	2021	2020	2019	2018
	Amounts in DKK '000					
Income Statement						
Operating Loss		-32,463	-28,809	-22,161	-10,644	-52
Net financial items		-379	-461	-25	-1,062	1
Loss for the period		-27,342	-23,770	-17,460	-9,653	-53
Balance sheet						
Total assets		35,620	53,309	16,742	5,238	75
Equity		31,968	38,701	4,411	4,542	7
Cash flows						
Cash flows from:						
Operating activities		-37,647	-15,062	-8,847	-10,553	-1
Investing activities		-117	0	-42	-390	0
Financing activities		17,019	51,183	17,182	13,228	60
The period's cash flow		-20,745	36,121	8,293	2,285	59
Dividend		0	0	0	0	0
Ratios						
Solvency ratio		90%	73%	26%	87%	9%
Earnings per share (DKK)		-2.33	-2.15	-1.78	-1.49	-0.08
Earnings per share (DKK)		-2.33	-2.15	-1.78	-1.49	

For definitions of ratios, see under accounting policies.

The total number of shares as of 31 December 2022 amounted to 11,814,500 shares. The total number of shares as of 31 December 2021 amounted to 11,319,500 shares.

## **FINANCIAL REVIEW**

#### **Financial Development**

#### Operating income and operating results

Net revenue amounted to DKK 0 (0) and the loss for the period was amounted to DKK -27,342 thousand (DKK - 23,770 thousand) in 2022. The increased net loss is related to the three ongoing clinical development trials with FG001 in 2022. The loss for the period 2022 were as expected.

#### Balance sheet and solidity

The total equity on 31 December 2022 was amounted to DKK 31,968 thousand (DKK 38,701 thousand). The solidity as per 31 December 2022 was 90 (73) percent.

#### **Cash flow and investments**

The total cash position on 31 December 2022 amounted to DKK 26,013 thousand (DKK 46,758 thousand). During the year, FluoGuide has invested in minor equipment for the ongoing clinical trials and amounted to DKK 64 thousand (DKK 0).

#### **Capital resources**

As a development stage start-up life-science company, and like other similar development stage companies, the Company expects negative cash flow in 2023 from operating activities. The company completed a directed share issue in March 2022 and raised SEK 25 million to fund the ongoing and planned activities. The company is dependent on being recapitalized or selling rights to its products against cash until reaching the point where the size of the revenue in-creases the costs resulting in a positive cash flow. The activities of the company in the future will depend on proceeds obtained from capital increases or sales of rights. Please refer to note 2 to the Financial Statements.

#### Subsequent events

The Company have not experienced any subsequent events during 2023, except for FluoGuide announced positive interim result of FG001 in head and neck cancer, appointed Ole Larsen as CFO and updated the clinical timelines for the ongoing clinical phase IIb trial of FG001 in patients with aggressive brain cancer (high grade glioma) undergoing surgery.

## Management Statement on the Annual Report

The Board of Directors and the Executive Management have today considered and adopted the Annual Report of FluoGuide A/S for the financial year 1 January – 31 December 2022.

The Financial Statements have been prepared in accordance with International Financial Reporting Standards as adopted by the EU and further requirements in the Danish Financial Statements Act for annual reports of class B companies. Management's Review has been prepared in accordance with the Danish Financial Statements Act.

In our opinion, the Financial Statements give a true and fair view of the financial position on 31 December 2022 of the Company and of the results of the Company operations and cash flows for the financial year 1 January - 31 December 2022.

In our opinion, Management's Review includes a true and fair account of the development in the operations and financial circumstances of the Company, of the results for the year and of the financial position of the Company as well as a description of the most significant risks and elements of uncertainty facing the Company.

We recommend that the Annual Report be adopted at the Annual General Meeting.

Copenhagen, 28 February 2023

**Executive Management** 

Morten Albrechtsen
CEO

**Board of Directors** 

Peter Mørch Eriksen Chairman Mats Thorén Vice chairman Shomit Ghose

Lisa Micaela Sjökvist

Andreas Kjær

## **Independent Auditor's Report**

#### To the shareholders of FluoGuide A/S

#### Opinion

In our opinion, the Financial Statements give a true and fair view of the financial position of the Company on 31 December 2022 and of the results of the Company's operations and cash flows for the financial year 1 January to 31 December 2022 in accordance with International Financial Reporting Standards as adopted by the EU and further requirements in the Danish Financial Statements Act for annual reports of class B companies.

We have audited the Financial Statements of FluoGuide A/S for the financial year 1 January - 31 December 2022, which comprise income statement, statement of comprehensive income, balance sheet, statement of changes in equity, statement of cash flows and notes, including a summary of significant accounting policies ("financial statements").

#### **Basis for Opinion**

We conducted our audit in accordance with International Standards on Auditing (ISAs) and the additional requirements applicable in Denmark. Our responsibilities under those standards and requirements are further described in the *Auditor's Responsibilities for the Audit of the Financial Statements* section of our report. We are independent of the Company in accordance with the International Ethics Standards Board for Accountants' International Code of Ethics for Professional Accountants (IESBA Code) and the additional ethical requirements applicable in Denmark, and we have fulfilled our other ethical responsibilities in accordance with these requirements and the IESBA Code. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

#### Statement on Management's Review

Management is responsible for Management's Review.

Our opinion on the financial statements does not cover Management's Review, and we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read Management's Review and, in doing so, consider whether Management's Review is materially inconsistent with the financial statements, or our knowledge obtained during the audit, or otherwise appears to be materially misstated.

Moreover, it is our responsibility to consider whether Management's Review provides the information required under the Danish Financials Statements Act.

Based on the work we have performed, in our view, Management's Review is in accordance with the Financial Statements and has been prepared in accordance with the requirements of the Danish Financial Statement Act. We did not identify any material misstatement in Management's Review.

#### Management's Responsibilities for the Financial Statements

Management is responsible for the preparation of Financial Statements that give a true and fair view in accordance with International Financial Reporting Standards as adopted by the EU and further requirements in the Danish Financial Statements Act, and for such internal control as Management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, Management is responsible for assessing the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting in preparing the financial statements unless Management either intends to liquidate the Company or to cease operations, or has no realistic alternative but to do so.

#### Auditor's Responsibilities for the Audit of the Financial Statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with ISAs and the additional requirements applicable in Denmark will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit conducted in accordance with ISAs and the additional requirements applicable in Denmark, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud
  or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that
  is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material
  misstatement resulting from fraud is higher than for one resulting from error as fraud may involve
  collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by Management.
- Conclude on the appropriateness of Management's use of the going concern basis of accounting in
  preparing the financial statements and, based on the audit evidence obtained, whether a material
  uncertainty exists related to events or conditions that may cast significant doubt on the Company's ability
  to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw
  attention in our auditor's report to the related disclosures in the financial statements or, if such
  disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence
  obtained up to the date of our auditor's report. However, future events or conditions may cause the
  Company to cease to continue as a going concern.
- Evaluate the overall presentation, structure and contents of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that gives a true and fair view.

We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

Hellerup, 28 February 2023 PricewaterhouseCoopers Statsautoriseret Revisionspartnerselskab CVR No 33 77 12 31

Torben Jensen State Authorised Public Accountant Mne18651 Claus Carlsson State Authorised Public Accountant Mne29461

## Income statement and statement of comprehensive income

2022	2021
( <i>'000</i> 01-Jan	01-Jan
31-Dec	31-Dec
6,511	9,613
-24,100	-20,593
-14,623	-17,671
-251	-158
-32,463	-28,809
-379	-461
-32,842	-29,270
5,500	5,500
-27,342	-23,770
0	0
-27,342	-23,770
-2.33	-2.15
	(*000 01-Jan 31-Dec 6,511 -24,100 -14,623 -251 -32,463 -379 -32,842 5,500 -27,342 0 0 -27,342

## **Balance Sheet**

	2022	202
Amounts in DKK '000	31-Dec	31-De
Note		
8 Acquired patents	378	378
9 Right of use assets	199	5
10 Tangible Fixed assets	43	(
Deposit	107	54
Total non-current assets	727	48
Other receivables	3,364	56
7 Receivable corporate tax	5,500	5,50
Prepayments	16	
Cash	26,013	46,75
Total current assets	34,893	52,82
Total assets	35,620	53,30
	2022	
Amounts in DKK '000	<b>2022</b> 31-Dec	
Amounts in DKK '000 Note	31-Dec	31-De
Amounts in DKK '000 Note Share capital	31-Dec 1,181	31-De
Amounts in DKK '000 Note Share capital Share premium	31-Dec 1,181 0	31-De
Amounts in DKK '000 Note Share capital Share premium Retained earnings	31-Dec 1,181 0 30,787	31-De 1,13 37,56
Amounts in DKK '000 Note Share capital Share premium Retained earnings 11 Total equity	31-Dec 1,181 0	31-De 1,13 37,56 38,70
Amounts in DKK '000 Note Share capital Share premium Retained earnings	31-Dec 1,181 0 30,787 31,968	31-De 1,13 37,56 38,70
Note         Share capital         Share premium         Retained earnings         11         Total equity         12       Lease liabilities	31-Dec 1,181 0 30,787 31,968 0	31-De 1,13 37,56 38,70
Amounts in DKK '000 Note Share capital Share premium Retained earnings 11 Total equity 12 Lease liabilities Non-current liabilities 12 Lease liabilities	31-Dec 1,181 0 30,787 31,968 0 0 205	31-De 1,13 37,56 38,70 5
Amounts in DKK '000 Note Share capital Share premium Retained earnings 11 Total equity 12 Lease liabilities Non-current liabilities 12 Lease liabilities Trade payables	31-Dec 1,181 0 30,787 31,968 0 0	31-De 1,13 37,56 38,70 5 6,83
Amounts in DKK '000 Note Share capital Share premium Retained earnings 11 Total equity 12 Lease liabilities Non-current liabilities 12 Lease liabilities	31-Dec 1,181 0 30,787 31,968 0 0 205 1,604	31-De 1,13 37,56 38,70 5 6,83 3,82
Amounts in DKK '000 Note Share capital Share premium Retained earnings 11 Total equity 12 Lease liabilities Non-current liabilities 12 Lease liabilities 12 Trade payables Other payables	31-Dec 1,181 0 30,787 31,968 0 0 0 205 1,604 1,665	31-De 1,13 37,56 38,70 5 6,83 3,82 3,89
Amounts in DKK '000         Note         Share capital         Share premium         Retained earnings         11         Total equity         12         Lease liabilities         Non-current liabilities         12         Lease liabilities         Other payables         Other red income	31-Dec 1,181 0 30,787 31,968 0 0 205 1,604 1,665 178	202 31-De 1,132 37,569 38,70 5 6,833 3,820 3,820 14,600 14,600
Amounts in DKK '000 Note Share capital Share premium Retained earnings 11 Total equity 12 Lease liabilities Non-current liabilities 12 Lease liabilities 12 Lease liabilities 12 Deferred income Current liabilities	31-Dec 1,181 0 30,787 31,968 0 0 0 205 1,604 1,665 178 3,652	31-De 1,13 37,56 38,70 5 6,83 3,82 3,89 14,60

## Statement of changes in equity

EQUITY Amounts in DKK '000	Share capital	Share premium	Retained earnings	Total equity
Equity as at 31 December 2020	1,053	0	3,358	4,411
Total comprehensive income 2021			-23,770	-23,770
Contribution - cash	79	55,069		55,148
Expenses in connection with capital increase			-3,804	-3,804
Employee share schemes – value of employee services			6,716	6,716
Transfer/rounding		-55,069	55,069	0
Equity as at 31 December 2021	1,132	0	37,569	38,701
Total comprehensive income 2022			-27,342	-27,342
Contribution - cash	49	17,821		17,870
Expenses in connection with capital increase			-624	-624
Employee share schemes – value of employee services			3,363	3,363
Transfer/rounding		-17,821	17,821	0
Equity as at 31 December 2022	1,181	0	30,787	31,968

## **Cash flow statement**

ASH FLOW	2022	2021
Amounts in DKK '000	01-Jan	01-Jar
pte	31-Dec	31-De
Loss before tax	-32,842	-29,270
Financial expenses, net, reversed	379	46
1 Change in working capital	-13,919	2,608
Depreciation and amortisation	251	158
Adjustment for non-cash employee benefits expense – share-based payments	3,363	6,716
Cash flows from operating activities before net financials	-42,768	-19,327
Financial expenses net paid	-379	-461
Tax credit paid out	5,500	4,726
Cash flows from operating activities	-37,647	-15,062
Purchase of tangible assets	-64	(
Paid deposit	-53	(
Cash flows from investing activities	-117	(
Cash capital increase	17,870	55,148
Principal elements of lease payments	-227	-16
Bridge financing and contribution	0	(
Transaction cost, cash capital increase	-624	-3,804
Cash flows from financing activities	17,019	51,183
Total cash flows for the year	-20,745	36,121
Cash, beginning of year	46,758	10,637
Cash, end of year	26,013	46,758
ovement in liabilities from financing activities		
1 January	57	218
New leases	375	(
Interest	12	7
Repayment	-239	-168
31 December	205	57

## NOTES

- 1. Accounting policies
- 2. Capital resources and liquidity
- 3. Other income
- 4. Staff expenses
- 5. Warrants
- 6. Financial Income and Expenses
- 7. Tax
- 8. Intangible assets
- 9. Right of use of assets
- 10. Tangible fixed assets
- 11. Equity
- 12. Lease Liabilities
- 13. Distribution of profit/loss for the year
- 14. Change in working capital
- 15. Financial risks and financial instruments
- 16. Related parties
- 17. Operating lease commitments and other commitments
- 18. Events occurring after the balance sheet date

#### 1. Accounting policies

FluoGuide A/S is a limited liability company domiciled in Denmark. The Financial Statements have been prepared in accordance with International Financial Reporting Standards as adopted by the EU and further requirements in the Danish Financial Statements Act.

Danish kroner (DKK) is the Company's presentation currency and functional currency. The financial statements are presented in Danish kroner (DKK '000).

#### Financial statements

The financial statements of FluoGuide A/S for 2022 are the Company's fourth financial year and are prepared in accordance with International Financial Reporting Standards as adopted by the EU and further requirements in the Danish Financial Statements Act for annual reports of class B companies.

#### New standards not yet effective

There are no IFRSs or IFRIC interpretations that are not yet effective that is expected to have a material impact on the Company.

#### Foreign currency translation

On initial recognition, transactions in currencies other than the functional currency of the Company are recognized at the exchange rate applicable at the transaction date. Receivables, payables and other monetary items denominated in foreign currency not settled at the balance sheet date are translated using the exchange rate applicable at the balance sheet date. Exchange rate differences between the exchange rate applicable at the transaction date and the exchange rate at the date of payment and the balance sheet date, respectively, are recognized in the income statement as net financials.

#### Leases

Leases in terms of which the Company assumes substantially all the risks and rewards of ownership (finance leases) are recognized in the balance sheet at the lower of the fair value of the leased asset and the net present value of the lease payments computed by applying the interest rate implicit in the lease or an approximated value as the discount rate, if leases exceed DKK 33,000 in value and are longer than twelve months.

Assets acquired under finance leases are depreciated and written down for impairment under the same policy as determined for the other fixed assets of the Group.

The remaining lease obligation is capitalized and recognized in the balance sheet under debt, and the interest element on the lease payments is charged over the lease term to the income statement.

All other leases are considered operating leases. Payments made under operating leases are recognized in the income statement on a straight-line basis over the lease term.

#### Tax

Tax for the year, consisting of current tax and changes in deferred tax, is recognized in the income statement with the portion attributable to tax on the profit or loss for the year, and directly in equity or in other comprehensive income with the portion attributable to amounts recognized directly in equity or in other comprehensive income, respectively.

Current tax payables and receivables are recognized in the balance sheet as tax computed on the basis of the taxable income for the year results in taxes to be paid or refunded.

Current tax for the year is computed based on the tax rules and tax rates applicable at the balance sheet date.

Deferred tax is recognized using the balance sheet liability method on the basis of all temporary differences between the carrying amounts and tax bases of assets and liabilities, except for deferred tax on temporary differences due to either initial recognition of goodwill or initial recognition of a transaction that is not a business combination, and where the temporary difference ascertained at the time of initial recognition does not affect either the tax results or the taxable income. The deferred tax is calculated based on the planned use of the individual asset or settlement of the individual liability.

Deferred tax is measured applying the tax rules and tax rates expected to be applicable when the deferred tax is expected to crystallize as current tax. Any change in deferred tax as a result of changes in tax rules or rates is recognized in the income statement, unless the deferred tax is attributable to transactions that have previously been recognized directly in equity or in other comprehensive income. In the latter case, the change is recognized directly in equity or in other comprehensive income.

Deferred tax assets, including the tax value of tax losses allowed for carryforward, are recognized in the balance sheet at the expected realizable value, either through offsetting against deferred tax liabilities or as a net tax asset for offsetting against future positive taxable incomes. An assessment is made on each balance sheet date of whether it is probable that sufficient taxable income will be generated in future to enable utilization of the deferred tax asset.

#### Statement of comprehensive income

#### Other operating income

Other income comprises income of a secondary nature in relation to the group's activities, including grants and license income. Income from licenses that do not transfer the right of ownership to an intangible asset are recognized over time in accordance with the substance of the agreements. Government grants relating to costs are deferred and recognised in profit or loss over the period necessary to match them with the costs that they are intended to cover.

#### Other external expenses

Other external expenses comprise expenses relating to administrative expenses, costs of premises, etc.

#### Staff expenses

Staff expenses comprise wages and salaries as well as social security expenses, pensions for group staff, other staff-related expenses and share-based payment compensation.

#### Employee benefits

Share-based (warrants) compensation benefits are provided to employees via the FluoGuide A/S's Employee Option Plan which was adopted in 2021, an employee and executive short-term incentive share scheme. *Employee options Plan* 

The fair value of warrants granted under the FluoGuide A/S's Employee Option Plan is recognized as an employee benefits expense, with a corresponding increase in equity. The total amount to be expensed is determined by reference to the fair value of the options granted: - including any market performance conditions (e.g. the entity's share price) - excluding the impact of any service and non-market performance vesting conditions (eg profitability, sales growth targets and remaining an employee of the entity over a specified time period), and - including the impact of any non-vesting conditions (eg the requirement for employees to save or hold shares for a specific period of time).

The total expense is recognized over the vesting period, which is the period over which all of the specified vesting conditions are to be satisfied. At the end of each period, the entity revises its estimates of the number of options that are expected to vest based on the non-market vesting and service conditions. It recognizes the impact of the revision to original estimates, if any, in profit or loss, with a corresponding adjustment to equity.

#### Net financials

Net financials comprise interest income and expenses, realized and unrealized gains and losses on transactions in foreign currency and realized and unrealized gains and losses on other financial assets.

Amortization of capital losses and borrowing costs relating to financial liabilities is recognized on an ongoing basis as part of the interest expenses.

#### Earnings per share

Basic net result per share is calculated as the net result for the year divided by the weighted average number of outstanding ordinary shares, excluding treasury shares.

Diluted net result per share is calculated as the net result for the year divided by the weighted average number of outstanding ordinary shares, excluding treasury shares adjusted for the dilutive effect of share equivalents. As the income statement shows a net loss, no adjustments have been made for the dilutive effect.

#### **Balance sheet**

#### Acquired patents

Acquired patents are measured in the balance sheet at the lower of cost less accumulated amortization and recoverable amount.

Cost comprises the acquisition price, costs directly related to the acquisition and costs for preparation of the asset until such time as the asset is ready for use. The amortization is performed on a straight-line basis with no residual value over the period of validity starts when patent is taken into commercial use. Amortization methods, useful lives and residual values are reviewed every year.

#### Receivables

Receivables comprise trade receivables and other receivables. Receivables are included in the category loans and receivables, which are financial assets with fixed or determinable payments that are not listed in an active market and are not derivative financial instruments.

On initial recognition, receivables are measured at the amount of consideration that is unconditional unless they contain significant financing components, when they are recognized at fair value and subsequently at amortized cost, which usually corresponds to the nominal value, less write-downs for bad debts.

The Company applies the IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for all receivables

#### Cash

Cash includes deposits in bank accounts as well as operating cash.

#### Equity

Direct and incremental costs associated with capital increases are accounted for as a reduction in the proceeds from the capital increase and recognized in shareholders' equity.

#### Liabilities

Other financial liabilities comprise trade payables, other payables to public authorities and other liabilities. On initial recognition, other financial liabilities are measured at fair value less any transaction costs. Subsequently, the liabilities are measured at amortized cost according to the effective interest method, so that the difference between the proceeds and the nominal value is recognized in the income statement as a financial expense over the period of the loan.

#### Cash flow statement

The cash flow statement shows cash flows from operating, investing and financing activities as well as cash at the beginning and end of the year. Cash flows from operating activities are presented in accordance with the indirect method and are determined as the operating profit or loss adjusted for non-cash operating items, changes in working capital and paid financial income, financial expenses and income tax.

Cash flows from investing activities comprise payments in connection with the acquisition and sale of companies and financial assets as well as the purchase, development, improvement and sale of property, plant and equipment and intangible assets.

Cash flows from financing activities comprise changes in the Company's share capital and associated costs as well as the raising and repayment of loans, the repayment of interest-bearing debt, the purchase and sale of treasury shares and the payment of dividends.

Cash flows in currencies other than the functional currency are recognized in the cash flow statement using average exchange rates, unless they deviate significantly from the actual exchange rates at the transaction dates.

Cash and cash equivalents comprise cash less overdraft facilities that are an integrated part of the cash management.

#### Financial highlights Explanation of financial ratios:

Solvency ratio:	Equity at year end x 100
Solvency ratio.	Total assets at year end
Earnings per share:	Net loss for the year
Lamings per share.	Average numbers of outstanding shares

#### Significant accounting estimates and assessments

In connection with the preparation of the financial statements, the management performs accounting estimates and assessments that affect the recognized values of assets, liabilities, income, expenses and cash flows as well as their presentation.

Accounting estimates reflect the management's best estimates in terms of amounts where the measurement is subject to uncertainty, typically because the estimate is based on assumptions concerning future events. The accounting estimates are based on historical experience and other assumptions deemed relevant, but the actual results may, naturally, deviate from the estimates made. The estimates are regularly reassessed, and the effect of changes is recognized in the consolidated financial statements.

Accounting judgements reflect decisions made by the management as to how the accounting policies are applied in specific situations where the accounting treatment depends on qualitative assessments. Examples could be when the risk passes or how a certain transaction or item is best presented to provide reliable and relevant information.

Costs incurred in relation to individual development projects are capitalized only when the future economic benefit of the project is probable and the following main conditions are met: (i) the development costs can be measured reliably, (ii) the technical feasibility of the product has been ascertained and (iii) Management has the intention and ability to complete the intangible asset and use or sell it.

Currently no other significant accounting estimates and judgements have been applied in the preparation of the financial statements for 2021.

#### 2. Capital resources and liquidity

As a development stage start-up life-science company, and like other similar development stage companies, the Company has had a negative cash flow in 2022 why the company is dependent on being recapitalized or selling rights to its products against cash until reaching the point where the size of the revenue exceeds the costs resulting in a positive cash flow. The activities of the company in the future will depend on proceeds obtained from capital increases or sales of rights. The company, if necessary, will in the future carry out external capital increases to finance the future activities.

The Board of Directors and Executive Management are constantly monitoring the Company's financial position to be prepared to take adequate measures to secure the company.

The Company became listed on Spotlight Stock Market Copenhagen in May 2019. The Company moved its listing to Nasdaq First North Growth Market, Sweden in February 2021. A directed share issue was completed on 12 May 2021. 789,474 shares were issued with a total proceed SEK 75 million before cost. An additional directed share issue was completed in March 2022 of SEK 25 million before cost.

An EU grant was awarded in June 2020 with a total payout on EUR 2.5 million and with two instalments played out in 2020 and 2021 of EUR 2.1 million. The last instalment is expected paid in 2023.

The Board of Directors and Executive Management has reviewed the company's capital resources, including the SEK 25 million capital raise in March 2022, together with the planned activities and the budget for 2023 and concluded that the Company has the necessary capital resources to finance the planned activities for 2023.

The Board of Directors and Executive Management have based on the above concluded that the company is a going concern for 2023.

#### 3. Other income

Other income		2022	2021
		01-Jan	01-Jan
	Amounts in DKK '000	31-Dec	31-Dec
EU-grant		6,247	9,305
Other, including subsidy/grant for business PhD		264	308
Total		6,511	9,613

The EU grant was awarded in June 2020 with a total payout on EUR 2.5 million. The two instalments paid out in 2020 and 2021 of EUR 2.1 million. The last instalment is expected paid in 2023. The income is recognized over the duration of the project. The Project was finished 31 December 2022 and the final reporting to EU has been submitted and is now awaiting approval from the EU.

#### 4. Staff Expenses

STAFF EXPENSES		2022	2021
		01-Jan	01-Jan
	Amounts in DKK '000	31-Dec	31-Dec
Wages and salaries		11,117	10,858
Employee share schemes - value of employee services		3,363	6,716
Other social security costs etc.		143	97
Total		14,623	17,671
Compensation for key management personal			
Short term employee benefits		2,675	4,394
Share based payments		2,432	5,008
		3 -	- 3

Compensation for key management personal includes Morten Albrechtsen, Andreas Kjær and the Board of Directors.

The average number of full-time employees during 2022 was 7.9 (5.6).

#### 5. Warrants

FluoGuide has an established incentive programs for its employees, management, and Board. In May 2021, the Company issued 272,700 warrants to employees and management and 50,000 warrants to the Board of Directors. In March 2022 FluoGuide issued 40,000 warrants to management and employees (vesting from 1 April 2022). Each warrant grants the holder the right to subscribe for one (1) new share in FluoGuide. The warrants are issued to ensure alignment of interests between the Company's employees, management, Board of Directors, and shareholders. The Company believes that the issue of warrants will provide motivation for the achievement of FluoGuide's short-term and long-term goals to support the Company's business strategy, sustainability, and value creation for the benefit of shareholders. Warrants represent a total dilution of 3.1 percent of the current share capital, if vested and exercised.

The number of warrants that will vest depends mainly on receiver does not leave the Company in the vesting period and vest with 1/36 per months. For 200,000 warrants granted to management in 2021 vesting furthermore depends on achievement of certain activities-based milestones KPI's and vest with 1/60 per months. Warrants are granted under the plan for no consideration and carry no dividend or voting rights. The vested warrants remain exercisable for a period 10 years after the grant date. The exercise price of warrants is based on the Company's prevailing share price at the day of grant.

Set out below are summaries of warrants granted under the plan:

	2022 Average exercise price per warrant (SEK)	Number of warrants	2021 Average exercise price per warrant (SEK)	Number of warrants
As at 1 January		322,700		
Granted during the year	65	40,000	95	322,700
Exercised during the year				
Forfeited during the year				
As at 31 December	92	362,700	95	322,700
Vested and exercisable at 31 December	-	-	-	-

#### Warrants outstanding at the end of the year have the following expiry dates and exercise prices:

Grant date - warrants	Expiry date	Exercise price	2022	2021
			31-Dec	31-Dec
28 May 2021	31 August 2031	SEK 95.00	322,700	322,700
29 March 2022	30 June 2032	SEK 65.00	40,000	
Total			362,700	322,700
Weighted average remaining contractual life of warrants outstanding at e Expenses arising from share-based payment transactions	·		5.41	6.37
			2022	2021
Amounts in DKK '000	0			
Warrants issued under employee share scheme			3,363	6,716
Total for the year			3,363	6,716

Fair value of options granted:

The assessed fair value at grant date of warrants granted during the year ended 31 December 2022 was SEK 30.74 / DKK 21.83 per warrants (2021 – respectively SEK 47.29 and SEK 50.32 / DKK 34.73 and DKK 36.96). The fair value at grant date is independently determined using the Black-Scholes model which includes, the share price at grant date and expected price volatility of the underlying share, the expected dividend yield, the risk-free interest rate for the term of the warrants, and the correlations and volatilities of the peer group companies.

The model inputs for granted warrants during the year ended 31 December 2022 included:

	2022	2021
Exercise price (SEK)	65	95
Grant date	29/3 2022	28/5 2021
Expiry date	30/6 2032	31/8 2031
Expected price volatility of the company's shares	48.30%	53.50%
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	0.63%	-0.07%

Warrants are granted for no consideration and vest based on receiver does not leave the Company and certain activity-based milestones. Vested options are exercisable for a period of 10 years after grant date. Vesting period are from 36 months to 60 months (the later only apply to warrants granted to management in 2021).

The expected price volatility is based on the historic volatility (based on the remaining life of the options), adjusted for any expected changes to future volatility due to publicly available information.

#### 6. Financial Income and Expenses

FINANCIAL INCOME AND EXPENSES	2022	2021
	01-Jan	01-Jan
Amounts in D	<i>KK '000</i> 31-Dec	31-Dec
Interest expense on liabilities measured at amortized costs	163	209
Interest related to right-of-use assets	12	7
Net exchange rate losses	203	242
Other	1	3
Finance expenses	379	461
Total	-379	-461

#### 7. Tax

ТАХ	2022	2021
	01-Jan	01-Jan
Amounts in DKK '000	31-Dec	31-Dec
Tax on profit/loss for the year:		
Current tax (tax under the tax credit scheme)	5,500	5,500
Total	5,500	5,500
Reconciliation of effective tax:		
Tax computed on loss	-7,225	6,440
Non-deductible expenses	741	-1,595
Other permanent differences	-2,056	1,662
Non-recognized deferred tax asset	3,040	-1,007
Effective tax (17% / 19%)	-5,500	5,500
Deferred tax:		
Tax loss carried forward	5,956	2,932
Right of use assets	6	1
Intangible and tangible fixed asset	10	
Total	5,972	2,933
Write down to accessed value	-5,972	-2,933
Total	0	0

Under the Danish tax credit scheme, the 22 percent tax value of negative taxable income related to costs from development activities up to DKK 25 million can be received in cash. Tax value of costs to the related to development activities amounts to DKK 5,500 thousand (DKK 5,500 thousand), is anticipated to be paid out from tax authority in Q4 2023 to the Company. The tax credit is not considered as a subsidy as the paid-out tax credit reduces the Company's tax loss carry forward.

The unrecognized deferred tax assets amounted to DKK -5,972 thousand (DKK -2,933 thousand) can be carried forward indefinitely.

Tax has been computed at 22 percent corresponding to the current tax rate.

#### 8. Intangible Assets

INTANGIBLE ASSETS	Acquired patents	Intangible assets
Amounts in DKK '000		
Costs at 1 January 2022	378	378
Addition for the year	0	0
Costs 31 December 2022	378	378
Amortization and impairment losses 1 January 2022	0	0
Amortization and impairment losses for the year	0	0
Amortization and impairment losses 31 December 2022	0	0
Net book value 31 December 2022	378	378

#### 9. Right of use of assets

RIGHT OF USE ASSETS		Buildings	Right of use assets
	Amounts in DKK '000		
Costs at 1 January 2022		330	330
Addition for the year		375	375
Costs 31 December 2022		705	705
Depreciation 1 January 2022		277	277
Depreciation for the year		229	229
Depreciation 31 December 2022		506	506
Net book value 31 December 2022		199	199

#### 10. Tangible fixed assets

TANGIBLE FIXED ASSETS	Equipment	Tangible assets
Amounts in DKK '000		
Costs at 1 January 2022	0	0
Addition for the year	64	64
Costs 31 December 2022	64	64
Amortization and impairment losses 1 January 2022	0	0
Amortization and impairment losses for the year	21	21
Amortization and impairment losses 31 December 2022	21	21
Net book value 31 December 2022	43	43

#### 11. Equity

#### Share capital

The share capital consists of 11,814,500 shares with a nominal value of DKK 0.1 each. The shares are not divided into classes, and no shares have special rights.

SHARE CAPITAL	2022	2021	2020	2019	2018
Shares issued, 1 January	11,319,500	10,530,026	7,224,274	5,000,000	
Shares issued, 30 January at formation paid in by cash		-	-	-	105,500
Capital increase by conversion of debt to shareholders and conversion from IVS to ApS		-		-	4,894,500
Cash contribution 8 March 2019 and conversion from ApS to A/S				35,000,000	-
Reverse share split (10:1) 8 March 2019		-		-36,000,000	
Total shares after reverse split and before the IPO				4,000,000	5,000,000
Increase in shares in relation to the IPO (incl. conversion of bridge loan)		-		3,224,274	
Increase in shares in directed issue and exercise of warrants	495	789,474	3,305,752	-	
Shares issued, 31 December	11,814,500	11,319,500	10,530,026	7,224,274	5,000,000
Weighted average number of shares used as the denominator, when calculating earnings per share	11,720,925	11,036,051	9,797,895	6,477,565	688,179

#### Capital management

The Company aims to ensure structural and financial flexibility as well as competitive strength. For that purpose, the Company regularly assesses what the appropriate capital structure for the Company. FluoGuide completed SEK 25 million capital increase by issuing 495,000 shares to several exciting and new investors on 10 March 2022.

#### 12. Lease Liabilities

LEASE LIABILITIES		2022	2021
	Amounts in DKK '000	31-Dec	31-Dec
Non-current		0	0
Current		205	57
Total		205	57

#### 13. Distribution of Profit / loss for the year

DISTRIBUTION OF PROFIT/LOSS FOR THE YEAR		2022	2021
	Amounts in DKK '000	31-Dec	31-Dec
Proposed dividend for the year		0	0
Retained earnings		-27,342	-23,770
Total		-27,342	-23,770

## 14. Change in working capital

CHANGE IN WORKING CAPITAL		2022	2021
	Amounts in DKK '000	31-Dec	31-Dec
Other receivables and prepaym	ents	-2,815	170
Change in trade payables		-5,231	4,146
Change in other payables		-2,155	2,326
Change in deferred income		-3,718	-4,034
Total		-13,919	2,608

#### 15. Financial risks and financial instruments

#### Risk management policy

The Company's financial risks are managed by the Executive Management. The Company has an insurance plan. Otherwise, the company has not prepared policies for the identification and handling of risks. The management of the Company's risks is included in the Executive Management's day-to-day monitoring of the Company.

#### Interest rate risk

The Company is not subject to material interest rate risks.

#### Currency risk

The Company is not subject to material currency risks.

#### Credit risk

The Company is not subject to material credit risks.

#### Liquidity risk

The Company's liquidity risk covers the risk that the Company is not able to meet its liabilities as they fall due.

As a development stage start-up life-science company, and like other similar development stage companies, the Company has had a negative cash flow in 2022, why the company is dependent on being recapitalized or selling rights to its products against cash until reaching the point where the size of the revenue increases the costs resulting in a positive cash flow.

The Board of Directors and Executive Management are constantly monitoring the Company's financial position to be prepared to take adequate measures to secure the company. Several options are possible such as partnering deals, service agreements, reduce investments in fixed assets and increase the capital in the company.

The Board of Directors and Management have confidence in the company as a going concern.

The maturities of financial liabilities appear from the tables below. All amounts are contractual cash flows, i.e. inclusive of interest.

2022 - MATURITIES OF FINANCIAL LIABILITIES	< 1 year	1-2 year(s)	2-5 years	> 5 years	Total
Amounts in DKK '000					
As at 31 December 2022					
Lease Liabilities	205	0	0	0	205
Trade payables	1,604	0	0	0	1,604
Other payables	1,665	0	0	0	1,665
Total	3,474	0	0	0	3,474
2021 - MATURITIES OF FINANCIAL LIABILITIES	< 1	1-2	2-5	> 5	Total
	year	year(s)	years	years	
Amounts in DKK '000					
As at 31 December 2021					
Lease Liabilities	57	0	0	0	57
Trade payables	6,835	0	0	0	6,835
Other payables	3,820	0	0	0	3,820
Total	10,712	0	0	0	10,712

There were no assets nor liabilities measured at fair value as of 31 December 2022 and 2021.

#### 16. Related parties

#### Transactions with related parties

There have been no transactions with related parties.

#### Transactions with key management personnel

For remuneration to key management please refer to note 4.

#### 17. Operating lease commitments and other commitments

The company has entered into purchase obligations with suppliers in the amount of DKK 15 million.

#### 18. Events occurring after the balance sheet date

FluoGuide announced positive interim result of FG001 in head and neck cancer, appointed Ole Larsen as CFO and updated the clinical timelines for the ongoing clinical phase IIb trial of FG001 in patients with aggressive brain cancer (high grade glioma) undergoing surgery.