

# Annual Report

## 2021



MAXIMIZING SURGICAL OUTCOME  
MAKING CANCER FLUORESCENT

FluoGuide

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# COMPANY INFORMATION & MANAGEMENT REVIEW

In this document, the following definitions shall apply unless otherwise specified: “the Company” or “FluoGuide” refers to FluoGuide A/S, with CVR number 39 29 64 38. Figures in ‘()’ refer to 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)  
Lisa Micaela Sjökvist  
Shomit Adhip Ghose  
Mats Thorén  
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 Sweden (FLUO).

# CEO HAS THE FLOOR

## The year 2021

FluoGuide made important progress during 2021 towards our long-term vision building a company with multiple revenue streams, based on a product portfolio that creates new treatment options for several cancer types, benefitting both patients and healthcare providers.

Most importantly, we demonstrated that our first product (FG001) was safe and successfully lights up aggressive brain cancer. This marks clinical evidence in a first indication, and as such is an important milestone in the transformation of FluoGuide into a company with a broad pipeline of products in late-stage clinical development.

FluoGuide has therefore made a significant step forward in executing on our strategy, focused on obtaining proof of our first product in the first indication, and thereafter investing in broadening the application of our pipeline assets. We will assess each step on its own merits, with a rigorous assessment of commercial potential and progress through clinical milestones.

The impressive safety and preliminary efficacy data suggest that FG001 is significantly more likely to become a commercial product and based on this, we have now initiated the preparation of the manufacturing of FG001 for phase III trial and are working on the design of the phase III trial for FG001 in brain cancer. We expect feedback from US Food and Drug Administration (FDA) during 2022, as well as from clinical experts in the US and EU, which will help us to set up an effective and efficient trial design.

In parallel, our work to optimize the value of FG001 in brain cancer surgery is also progressing well. It consists of a combination of market research, discussion with equipment manufacturers, and clinical key opinion leaders.

As another way to enhance the clinical value of FG001, we have initiated a phase II clinical trial in lung cancer, where we just received permission to start the trial. Interim data are expected during the year and an efficacy data readout at the end of 2022. Our analysis of results obtained so far in aggressive brain cancer, as well as the scientific background literature, form the basis for our optimism that we will observe similar results in lung cancer as in brain cancer. Patients with lung cancer is important to help accounting for 1.8 million new individuals globally every year. Lung cancer is the second most diagnosed cancer and the leading cause of cancer deaths in 2020.

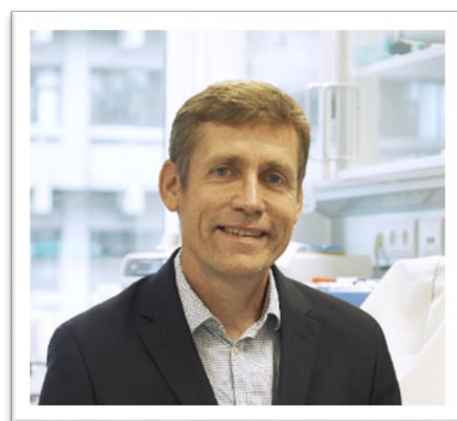
In addition, preclinical data on FG001 as a photothermal therapy have been published, taking surgery to a new level of cellular precision. This suggests that FluoGuide can potentially also help the surgeon to destroy cancer cells that might not otherwise have been removed, as well as guiding surgery through FG001. We have also started preclinical development for FG002 and plan to move this product into the clinic in 2023.

In February 2021, our shares moved from Spotlight Stock Market to the more internationally recognize Nasdaq First North Sweden. Here, we successfully conducted directed issues of shares in May 2021 and in March 2022 to secure the funding of the two phase II results with FG001 (brain and lung) and greater flexibility in an uncertain market. Further, it allows expansion of our investor base strongly supporting FluoGuide going forward.

In 2021 we presented the first, positive, clinical data from FG001. This is a monumental event in any drug development project and only possible with the skill and dedication of our employees and partners, who deserve enormous credit for this achievement

This exciting clinical and financial progress is only possible due to the outstanding support of our shareholders. I would like to thank our investors, both retail and institutional, for their continued cooperation and support of our work.

I, and the team at FluoGuide, are looking forward to continuing to deliver on our goals to benefit patients and shareholders in 2022.



**Morten Albrechtsen**  
CEO, FluoGuide A/S

# FLUOGUIDE 2021 - STRONG PROGRESS IN OUR PIPELINE

The primary focus of FluoGuide is to maximize surgical outcomes in oncology. FluoGuide's lead product, FG001, is well tolerated and shows promising early evidence of efficacy in aggressive brain cancer. Based on this strong data, FG001 is now also being developed in a phase II trial in lung cancer.

## FluoGuide in brief

FluoGuide develops products designed to maximize surgical outcomes through intelligent targeting. The improved surgical precision enabled by FluoGuide's products is expected to have the dual benefit of reducing the frequency of local recurrence post-surgery and reducing surgical complications. Ultimately, these improvements will increase a patient's chance of achieving a complete cure and lower system-wide healthcare costs. The Company is currently undertaking a combined phase I/II clinical trial to demonstrate the safety and efficacy of its lead product, FG001, in patients with high-grade glioma (including glioblastoma).

**FG001 is safe and well tolerated and has demonstrated early efficacy in the ongoing phase I/II study**

## Pipeline

FluoGuide's lead product, FG001, is in phase I/II clinical development targeting patients undergoing surgical removal of aggressive brain cancer (high-grade glioma), an indication that was chosen for several reasons including the significant unmet medical need. In 2022, FluoGuide has started a phase II clinical trial of FG001 in lung cancer being the most prevalent cancer worldwide. To further expand the pipeline, the Company has secured rights to FG002, which is excreted from the body differently than FG001, and is based on a novel fluorophore. FG002 is currently in preclinical development.

## FG001

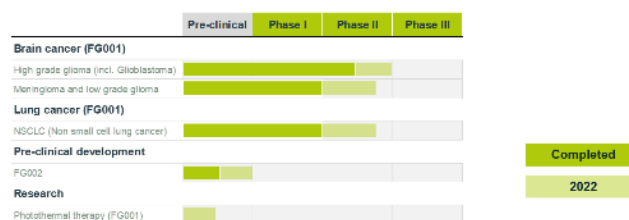
FG001 is designed to allow surgeons to clearly delineate cancer from normal tissue during surgery through FluoGuide's urokinase-type plasminogen activator receptor (uPAR) targeted luminescent technology. The increased surgical precision enabled by FG001 decreases the risk of leaving malignant cells behind, reducing the risk of local recurrence of the cancer and maximizing outcomes compared to standard-of-care treatments.

## How it works

FG001 is a proprietary compound made of a cancer-targeting molecule linked to a fluorophore. The targeting molecule binds to the urokinase-type plasminogen activator receptor (uPAR), which is extensively expressed

on the surface of most types of solid cancers. This binding identifies the cancer through fluorescence during surgery.

## Ongoing clinical trials of FG001



Brain cancer (aggressive and less aggressive) is selected to get to the market quickly. Lung cancer is important being the second most diagnosed cancer and the leading cause of cancer deaths in 2020, globally.

## Ongoing clinical trial of FG001 in aggressive brain cancer

The ongoing phase I/II clinical trial in patients with high-grade glioma has two parts: (1) a phase to establish safety and tolerability, and select the optimal dose and time of administration; and (2) an efficacy assessment phase.

More than 27 patients were included in the first phase of the trial and FG001 was shown to be well tolerated and gave early evidence of efficacy (see section below for data from the first part of this trial).

Estimation of the magnitude of benefit of FG001 (efficacy) will be conducted in the second phase of the trial and will include patients to be recruited in both Denmark and Sweden. Importantly, this data will be used to calculate the number of patients needed (power calculation) for the pivotal phase III trial required for registration. Efficacy data will also be used to help estimating the optimal price for FG001.

The evidence of FG001's effect is coming in steps with increasing validity:

- (1) An image where the cancer can be seen distinct from the normal tissue
- (2) The neurosurgeon's positive feedback
- (3) Histology of selected tumors (removed)
- (4) The randomized reading of the biopsies
- (5) Ultimately, the clinical results



Steps 1 and 2 are now realized and the remaining will come subsequently until final completion of part 2 of the trial. Top-line efficacy data will be published no later than by beginning of Q2-2022 and the efficacy results from the second phase in both Denmark and Sweden are anticipated during 2022.

#### **Ongoing clinical trial of FG001 in lung cancer**

In 2021, the Company selected lung cancer as the second indication for FG001 and received permission to start the phase II trial by the Danish health authorities in March 2022 and plan to treat the first patient in Q2. Globally, there are 2.2 million individuals being diagnosed with lung cancer annually, and 1.8 million patients die each year from lung cancer. Lung cancer is the second most commonly diagnosed cancer and was the leading cause of cancer deaths in 2020. Today, lung cancer is typically diagnosed after it has spread, which is the motivation for implementing screening programs for patients at high risk. The US is the first country to implement lung cancer screening programs, which has increased the number of patients found early in the disease course to about 80%, compared to about 40% in the non-screened population. Early diagnosis has been shown to improve survival for patients diagnosed with lung cancer.

#### **Photothermal therapy: -a new potential treatment**

FluoGuide has acquired the exclusive rights to use FG001 for photothermal therapy. 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 in these models. These data were published in August 2021. With exclusive rights to this application, FluoGuide can now potentially help the surgeon to destroy hidden cancer cells, or cancer that cannot be removed surgically, perhaps due to invasion into a vital organ structure such as the brain. Photothermal therapy has the potential to take treatment to a new level of cellular precision.

#### **FG002**

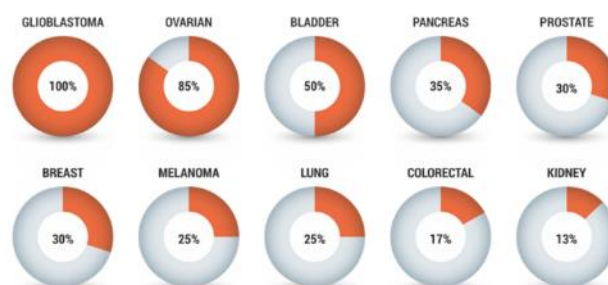
FluoGuide's second product, FG002, has a similar design to FG001 and will also allow surgeons to clearly differentiate cancer from normal tissue during surgery through a novel uPAR-targeted luminescent technology. The first promising research data has been published, and the Company has initiated preclinical development of FG002 and anticipate starting clinical development of FG002 in 2023.

#### **Market potential for our portfolio**

Surgery is the cornerstone of cancer therapy – of the 15 million new cancer patients each year, 80% 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%, with wide variation, depending on the type of cancer.

#### **Percent local recurrence after surgery**



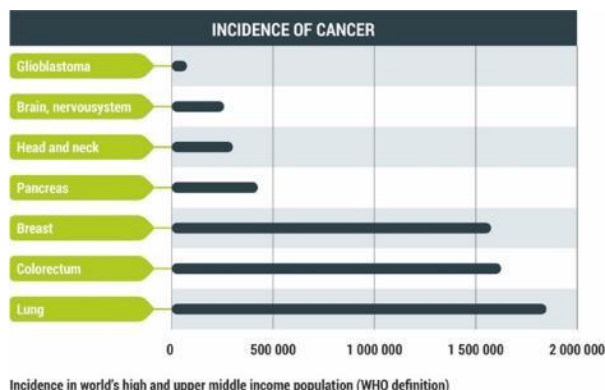
#### **Significant potential for FG001**

FluoGuide has chosen high-grade glioma for the initial indication of FG001 due to several reasons, including the significant unmet need of these patients and the clear commercialization path. Nearly all high-grade gliomas express uPAR, and high-grade glioma is an aggressive form of brain cancer that has a nearly 100% 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% surviving after five years. The improved precision that FG001 can offer in this setting has the potential to dramatically improve patient outcomes.

While high-grade glioma is the initial indication for FG001, there is also a tremendous opportunity to address other solid tumors since uPAR is extensively expressed in most aggressive cancers.

Surgery is particularly relevant when a cancer is localized. The shift toward identifying cancer early will increase the number of patients qualifying for surgery and will drive increased demand for a product that can guide the surgeon.

## Incidence rates of solid tumor cancers



## FluoGuide's uPAR technology platform is supported by a robust scientific foundation

uPAR is a protein present on the surface of cancer cells that directly correlates to the aggressiveness of the 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 is therefore an outstanding target to delineate cancer from normal tissue, and to guide the surgeon in removing the cancer precisely. 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 deadly cancers such as high-grade glioma, pancreatic cancer and head and neck cancer. Estimates indicate that uPAR is expressed in over 70-80% of all cancers that undergo surgical removal, making FG001 an attractive target to improve surgical outcomes for millions of oncology patients worldwide.

### uPAR – broadly expressed, highly selective to delineate cancer

The concept of using uPAR binding fluorophores to guide surgery was developed in 2014 by a research group led by Professor Andreas Kjær at Rigshospitalet and the University of Copenhagen. Proof-of-concept was first demonstrated in a preclinical model using implanted human glioblastoma and was published two years later. In 2017, EUR 1.3 million was awarded to a public-private consortium, led by Professor Andreas Kjær, to develop uPAR targeted products for guided surgery. FluoGuide has received a financial contribution from this grant. FluoGuide was incorporated in 2018 and acquired the intellectual property rights related to the initial uPAR targeted product, FG001, with the strategic intent of becoming a leader in cancer surgery through products designed to maximize surgical outcomes with intelligent targeting.

## Intellectual property protection

FluoGuide has established strong IP protection. The patent family protecting FG001 is owned by FluoGuide and has been issued in Europe and the US. The patent protection from the current filed patent/patent applications will last until 2039, providing a long period of protection to maximize the commercial opportunity of the product.

## The team

FluoGuide has a strong management team with expertise across the entire value chain, from the discovery of imaging techniques and the development of new healthcare products to international commercialization of medical solutions.

## Financing

In March 2022 the Company raised SEK 25 million in a directed issue. In May 2021, FluoGuide could announce a successful SEK 75 million financing round with international institutional investors. With the cash position thereafter FluoGuide can finance the two phase II results (brain and lung) with FG001 and provide flexibility in timing of next funding.

The funding of EUR 2.5 million from the prestigious EIC grant, from the European Union and termed the INSTAGLOW project, accelerates the late-stage development of FG001 to guide surgery in high-grade glioma. The plan is from the European Union's Horizon 2020 research and innovation program under grant agreement No 954904.

Approximately EUR 2.1 million of the grant has been paid out in 2020 and 2021, with the remainder to be paid in 2023.

In March 2022 FluoGuide receive together with Rigshospitalet (DK) a grant of approx. DKK 1 million to co-finance the phase II trial in meningioma and low-grade glioma.

## Outlook for FluoGuide

FluoGuide's first goal is to advance its lead product – FG001 – to improve outcomes for the approximately 60,000 patients worldwide that are diagnosed annually with high-grade glioma.

Broadening our mission to realize the vast potential of uPAR for guiding cancer surgery, FluoGuide's second objective is to expand our pipeline by accelerating the development of FG001 for indications beyond high-grade glioma, beginning with lung cancer and meningioma and low-grade glioma.

**The key milestones for 2022 are:**

- First histology data for selected dose (FG001 / brain)
- Efficacy data (estimate magnitude of benefit of FG001 in brain cancer)
- Regulatory feedback (FG001 / brain)
- Determine the phase III trial design (FG001 / brain)
- Initiate Phase II trial (FG001 / meningioma and low-grade glioma)
- Phase II result (FG001 / lung)

**The impact of COVID-19 and the war in Ukraine**

FluoGuide and its operations have not been directly affected by COVID-19 nor the war in Ukraine. Nevertheless, the Company has experienced that regulatory authorities have heavy demands on their resources and thus the timeframes for both trial approvals and advice have been extended. FluoGuide does not currently expect delays to its timelines due to COVID-19 or the war in Ukraine. Nevertheless, given the volatile situation, FluoGuide cannot exclude the risk for delays due to COVID-19 or from indirect effects of the war in Ukraine.



# FIRST HUMAN DATA

## Results from the phase I/II clinical trial of FG001

In October 2021, FluoGuide reported results from 27 patients with high-grade glioma. FG001 was proven to have a very satisfactory safety and tolerability profile in all 27 treated patients. Early evidence of efficacy was also observed. The safety and efficacy of FG001 is the starting point for advancing its development towards both registration for guiding surgery of aggressive brain cancer as well as expanding its use into other cancer indications.

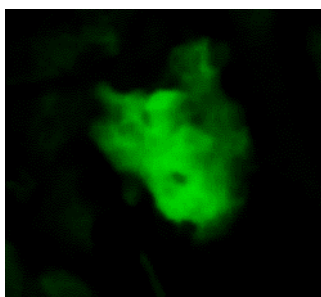
The first patient was dosed with 1 mg, a very low starting point being the standard for a first-in-human clinical trial with a new drug. Light was detected starting even from this first low dose and increased in intensity at subsequent higher doses. Furthermore, the contrast also increased with increasing doses, and when reaching an 8 mg dose it appeared sufficient for guiding surgery.

### Results from phase I:

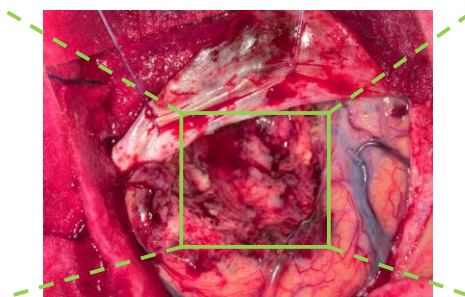
Safety and tolerability overview						
Cohort	Dosing	Dose (mg/pt)	Patients (#)	Light seen (#)	Ligh Seen (%)	Safety
1	morning	1	3	2	67%	Yes
2	morning	2	3	3	100%	Yes
3	morning	4	3	2	67%	Yes
4	morning	8	4	4	100%	Yes
5	morning	16	3	3	100%	Yes
5a	evening	16	5	5	100%	Yes
6	morning	24	3	3	100%	Yes
7	morning	36	3	3	100%	Yes
<b>Total</b>			<b>27</b>	<b>25</b>	<b>93%</b>	<b>Yes</b>

One of the two patients enrolled in the phase I trial turned out not having high-grade glioma but was later diagnosed with meningioma. The other patient had a metastasized lung cancer. The data from the first patient (meningioma) has been published - although treated with the low 8 mg dose level, the case shows intriguing results (see illustration below).

## Illustration of what FG001 can accomplish



FG001 illumination of remaining cancer in cavity



The surgical cavity in white light following removal of a tumor.



Cavity after identified cancer was removed (no FG001 illumination)

The corresponding images with NIR with green color enhancement demonstrate a small dural attachment (left image) and no tumor attachment (right image). Histopathological examination demonstrated meningioma cells in both the small attachment (left) and the main part of the solid tumor. The image is from the patient later diagnosed with meningioma and not high-grade glioma. The dose of FG001 was 8 mg, being one of the first cohorts of treatment. The current dose is 4 times higher. The data is published (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>)

# HIGHLIGHTS FROM 2021

## Q1


- FluoGuide receives green light to proceed to third dose level with FG001 in the ongoing clinical phase I/II trial in patients with high grade glioma
- Announces publication of two patent applications covering the company's uPAR technology platform for improving surgery
- Announces approval for listing on Nasdaq First North Growth Market Sweden on the 24 February 2021
- Receives green light to proceed to fourth dose level with FG001 in the ongoing clinical phase I/II trial in patients with high grade glioma
- Acquires rights to photothermal therapy using FG001

## Q2

- Receives green light to proceed to fifth dose level with FG001
- Completes a directed share issue raising SEK 75 million
- Receives approval from ethical committee and the Danish Medicines Agency to commence with FG001 in evening dosing
- Announces the initiation of evening dosing after a satisfactory conclusion of the fifth dose level with FG001
- Issues new warrants by issuing 272,700 warrants to employees and management, and 50,000 warrants to the Board of Directors
- Arbejdernes Landsbank informs the Company that they have 581,604 shares which corresponds to 5.14 percent of all shares in the Company
- Mats Thorén is elected a new member of the Company's Board of Directors
- New article reveals promising preclinical results of using FluoGuide's FG002 technology in guiding surgical removal of cancer

## Q3

- Enters an agreement with Swedish University Hospital for the second phase of the ongoing FG001 clinical trial
- Proceeds to sixth dose level of FG001 in the ongoing clinical phase I/II trial
- Receives tranche of EUR 750,000 under its ongoing grant from EIC Accelerator
- First publication of preclinical data where FG001 is used as a photothermal therapy agent for treatment of cancer




***"It is no longer a question of make or break it, following a very successful 2021, it is now a question of how big we can make it"***

- Announces regulatory approval from Swedish Authorities (MPA and Ethics committee) to commence Phase II clinical trial of FG001
- Proceeds to seventh dose level (36 mg) with FG001 in the ongoing clinical phase I/II trial
- Executive management members and members of the Board of Directors buy shares and board member Shomit Ghose sells shares

#### Q4

- FG001 is proven safe in patients undergoing surgery for cancer – a significant milestone for FluoGuide to further advance clinical development in aggressive brain cancer, which is a prevalent indication
- Redeye initiates commissioned research on FluoGuide
- FluoGuide initiates preclinical development with FG002
- Publication of a case report showing the first promising clinical data on FG001s use in treatment of a meningioma brain tumor
- Lung cancer selected as the second phase II indication for FG001
- Submits a Clinical Trial Application (CTA) to the Danish Medicines Agency to initiate phase II trial with FG001 in lung cancer



***“It is no longer a question of make or break it, following a very successful 2021, it is now a question of how big we can make it”***



# HIGHLIGHTS AFTER THE PERIOD

- On 10 March 2022 FluoGuide raised SEK 25 million in a directed share issue
- Received a grant of approx. DKK 1.0 million together with Rigshospitalet to partly finance the phase II trial in meningioma and low-grade glioma
- Permission from the Danish health authorities to start phase II in lung cancer
- 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.

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# BOARD OF DIRECTORS



## **Peter Mørch Eriksen – Chairman of Board since 2021**

Peter Mørch Eriksen has more than 20 years of experience in medtech/life science both in Denmark and abroad. Eriksen was CEO for BioPorto A/S until 2021 and previously CEO of Sense A/S. Before this role, he held positions as Vice President of Medtronic in both the USA and Denmark. Eriksen brings extensive experience in creating growth, restructuring and funding for technology intensive and complex companies. Current directorships in other companies includes Member of the Board of BioPorto Diagnostics A/S, BioPorto Inc., BioPorto Diagnostics Inc. and Veterinary Diagnostics A/S and Director in PME Holding. He is also Member of the Advisory Board at Lund University Diabetes Centre and serves on the Medical Device and Diagnostics Advisory Committee of Cincinnati Children's Hospital Center in Cincinnati, Ohio (US). Eriksen holds a degree in Economics/Accounting from the Copenhagen Business School and is an independent Board Member.



## **Shomit Ghose – Board member since 2019**

Shomit A. Ghose is an adjunct professor in entrepreneurship and innovation at the University of San Francisco, and an advisor in the office of Research and Economic Development at the University of California - Riverside. Through 2021, he was a Managing Director and General Partner at ONSET Ventures, a Silicon Valley venture fund, where he led the fund's investments in data-driven companies beginning in 2001. Ghose served on multiple boards within ONSET's portfolio, and previously served as CEO of Truviso, where he also was a board member. Ghose has extensive experience as a technology executive and venture capitalist with widespread start-up operating experience. In addition to his time as an investor, he brings 19 years of executive experience at high-tech companies in the Silicon Valley, and has also for many years been an appointed lecturer at UC Berkeley's College of Engineering. Ghose specializes in the information technology sector with a focus on software, networking and infrastructure. He has been instrumental in several IPOs. Ghose holds a degree in Computer Science from the University of California Berkeley and is an independent Board Member.



## **Micaela Sjökvist – Board member since 2019**

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



## **Andreas Kjær – Board member since 2018**

Andreas Kjær is 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. His achievements include development of several new tracers that have reached first-in-human clinical use. He is an ERC Advanced Grantee, has published more than 500 peer-reviewed articles and has received numerous prestigious scientific awards. Kjær holds an MBA from Copenhagen Business School and is an MD, PhD, DMSc from University of Copenhagen. He is a member of the Danish Academy of Technical Sciences. He is not an independent board member.



**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, 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. 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.

# MANAGEMENT



## **Morten Albrechtsen – CEO since 2018**

Morten Albrechtsen is a physician and seasoned entrepreneur with a strong medical, commercial and financial background that includes expertise gained in a broad range of therapeutic areas in both drugs and devices. His commercial expertise is international and includes sales through partners, affiliates as well as direct-to-patient, -hospital and -end user. Albrechtsen previously founded and acted as CEO for Nanovi A/S, a company guiding radiotherapy treatment of cancer. He has also worked at Nycomed Pharma, now Takeda Pharmaceuticals Ltd, and Boehringer Ingelheim GmbH. He holds a BBA in Marketing from the Copenhagen Business School and an MD from Copenhagen University.



## **Henrik Moltke, CFO since 2020**

Henrik Moltke brings more than 35 years of experience from the life science and healthcare sectors, where he has held roles such as CFO and Senior Vice President. Moltke was a co-founder of NeuroSearch. The primary focus in his previous career has been in venture financing, including IPOs as well as follow on capital increases in the public markets, investor relations, business development, finance planning and strategic development.



## **Andreas Kjær – CSO**

See above under Board of Directors.



## **Grethe Nørskov Rasmussen – Chief Development Officer since 2019**

Grethe Nørskov Rasmussen is an experienced product developer with a deep understanding of CMC gained while serving as Senior Vice President, Product Development at Ascendis Pharma A/S, where she worked for over 10 years. Previously, 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, Rasmussen held various positions at Novo Nordisk A/S, a global healthcare company, where she contributed to research and development. She holds a MSc and a PhD in Biochemistry from the Danish Technical University.



## **Dorte Grønnegaard Mejer - VP Clinical Development since 2020**

Dorte Grønnegaard Mejer has a M.Sc. in Pharmaceutical Sciences from Copenhagen University. Mejer was previously VP Clinical Development at Larix and VP Clinical Operations at Orphazyme.

# MISCELLANEOUS

## The share

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

The total number of shares as of 31 December 2021 amounted to 11,319,500 shares (10,530,026). As of 9 March 2022, the company had, according to VP Securities and Euroclear, 8,775 (7,664) shareholders.

Shareholders	Number of shares	Votes and capital
Flagged		
Life Science ApS <sup>1)</sup>	2,126,107	18.8%
Wexotec ApS <sup>2)</sup>	1,488,610	13.2%
LINC AB	771,130	6.8%
Arbejdernes Landsbank A/S	656,747	5.8%
Management and board of directors		
Grethe Nørskov Rasmussen <sup>3)</sup>	373,185	3.3%
PME Holding ApS <sup>5)</sup>	117,297	1.0%
Micaela Sjøkvist <sup>4)</sup>	62,163	0.6%
Shomit Ghose <sup>4)</sup>	21,143	0.2%
Dorthe Grønnegaard Mejer <sup>3)</sup>	3,241	0.0%
Henrik Kristian Moltke <sup>3)</sup>	1,216	0.0%
Other shareholders		
Others	5,698,661	50.3%
<b>TOTAL</b>	<b>11,319,500</b>	<b>100.00%</b>

1) Life Science IVS is a wholly owned company by Board Member and Head of the Scientific Advisory Board 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

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

In March 2022 the Company did a capital raise of SEK 25 million by issuing 495,000 new shares.

## Warrants

FluoGuide has established an incentive program 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 3,2 % of the current share capital, if vested and exercised. There are no other warrant programs.

## Proposed appropriation of retained earnings

The Board and the CEO have proposed that no dividend is paid out for the fiscal year, 1 January 2021 – 31 December 2021.

## Financial calendar for 2022

Annual General Meeting	18 May 2022
Q1 report:	31 May 2022
Q2 and half-year report:	25 August 2022
Q3 report:	24 November 2022

## More information

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

# FINANCIAL HIGHLIGHTS AND RATIOS

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

*For definitions of ratios, see under accounting policies.*

*The total number of shares as of 31 December 2021 totaled 11,319,500 shares. The total number of shares as of 31 December 2020 totaled 10,530,026 shares. The average number of shares for 2021 was 11,036,051 shares. The average number of shares for 2020 was 9,797,895 shares.*



# FINANCIAL REVIEW

## Financial Development

### Operating income and operating results

The loss for the period 2021 were as expected. Net revenue amounted to DKK 0 (0) and the loss for the period was KDKK 23,770 (17,460) in 2021. The increase in the net loss reflect that the company has recorded the majority of the costs related to the ongoing phase I/II study with FG001 in 2021.

### Balance sheet and solidity

The total equity on 31 December 2021 was KDKK 38,701 (4,411). The solidity as per 31 December 2021 was 73% (26%).

### Cash flow and investments

The total cash position on 31 December 2021 was KDKK 46,758 (10,637). No material investments were done in 2021 (KDKK 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 2022 from operating activities. The company completed a capital increase in March 2022 of SEK 25 million to cover its 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 current COVID-19 pandemic has impacted peoples' health and economies on a global scale and may continue to have a major impact in the near future. FluoGuide has until now not directly been significantly affected by the pandemic. The Company experience that the regulatory authorities is busy and the approvals for trials and advices takes longer time than before the pandemic. It is not possible for FluoGuide today to predict if there will be delays due to the COVID-19 pandemic in the near-term future.

Subsequent to the balance sheet date, the Company raised SEK 25 million in a directed issue of 495,000 shares in March 2022.

# 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 2021.

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 2021 of the Company and of the results of the Company operations and cash flows for the financial year 1 January - 31 December 2021.

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, 30 March 2022

## Executive Management

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Morten Albrechtsen  
CEO

## Board of Directors

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Peter Mørch Eriksen  
Chairman

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Andreas Kjær

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Shomit Ghose

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Lisa Micaela Sjökvist

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Mats Thorén

# 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 2021 and of the results of the Company's operations and cash flows for the financial year 1 January to 31 December 2021 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 2021, 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 Financial 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, 30 March 2022

**PricewaterhouseCoopers**

Statsautoriseret Revisionspartnerselskab

CVR No 33 77 12 31

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Torben Jensen

State Authorised Public Accountant

Mne18651

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Claus Carlsson

State Authorised Public Accountant

Mne29461



# INCOME STATEMENT AND STATEMENT OF COMPREHENSIVE INCOME

INCOME STATEMENT AND STATEMENT OF COMPREHENSIVE INCOME		2021	2020
Amounts in DKK '000		01/Jan 31/Dec	01/Jan 31/Dec
Note			
	Other operating income	9,613	3,218
	Other external expenses	-20,593	-20,644
3	Staff expenses	-17,671	-4,616
	Depreciation and amortisation	-158	-119
	Operating loss before net financials	-28,809	-22,161
4	Financial income	0	26
4	Financial expenses	-461	-51
	Loss before tax	-29,270	-22,186
5	Tax on loss for the year	5,500	4,726
	Net loss for the year	-23,770	-17,460
	Other comprehensive income for the year, net of tax	0	0
	<b>Total comprehensive income</b>	<b>-23,770</b>	<b>-17,460</b>

# BALANCE SHEET

ASSETS		2021	2020
Amounts in DKK '000		31/Dec	31/Dec
Note			
6	Acquired patents	378	378
7	Right of use assets	53	211
	Deposit	54	54
	<b>Total non-current assets</b>	<b>485</b>	<b>643</b>
	Other receivables	566	554
5	Receivable corporate tax	5,500	4,726
	Prepayments	0	182
	Cash	46,758	10,637
	<b>Total current assets</b>	<b>52,824</b>	<b>16,099</b>
	<b>Total assets</b>	<b>53,309</b>	<b>16,742</b>

EQUITY AND LIABILITIES		2021	2020
Amounts in DKK '000		31/Dec	31/Dec
Note			
	Share capital	1,132	1,053
	Share premium	0	0
	Retained earnings	37,569	3,358
8	<b>Total equity</b>	<b>38,701</b>	<b>4,411</b>
9	Lease liabilities	0	57
	Non-current liabilities	0	57
9	Lease liabilities	57	161
	Trade payables	6,835	2,689
	Other payables	3,820	1,494
	Deferred income	3,896	7,930
	Current liabilities	14,608	12,274
	<b>Total liabilities</b>	<b>14,608</b>	<b>12,331</b>
	<b>Total equity and liabilities</b>	<b>53,309</b>	<b>16,742</b>

# STATEMENT OF CHANGES IN EQUITY

EQUITY	Share capital	Share premium	Retained earnings	Total equity
Amounts in DKK '000				
<b>Equity as at 31 December 2019</b>	<b>722</b>	<b>0</b>	<b>3,820</b>	<b>4,542</b>
Total comprehensive income 2020			-17,460	-17,460
Contribution - cash	331	17,665		17,996
Expenses in connection with capital increase			-702	-702
Employee share schemes – value of employee services			35	35
Transfer		-17,665	17,665	0
<b>Equity as at 31 December 2020</b>	<b>1,053</b>	<b>0</b>	<b>3,358</b>	<b>4,411</b>
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
<b>Equity as at 31 December 2021</b>	<b>1,132</b>	<b>0</b>	<b>37,569</b>	<b>38,701</b>

# CASH FLOW STATEMENT

CASH FLOW		2021	2020
		01/Jan	01/Jan
Note	Amounts in DKK '000	31/Dec	31/Dec
	Loss before tax	-29,270	-22,186
	Financial expenses, net, reversed	461	25
11	Change in working capital	2,608	11,132
	Depreciation and amortisation	158	119
	Adjustment for non-cash employee benefits expense – share-based payments	6,716	35
	Cash flows from operating activities before net financials	-19,327	-10,875
	Financial expenses net paid	-461	-25
	Tax credit paid out	4,726	2,053
	Cash flows from operating activities	-15,062	-8,847
	Purchase of intangible assets	0	0
	Paid deposit	0	42
	Cash flows from investing activities	0	42
	Cash capital increase	55,148	17,996
	Principal elements of lease payments	-161	-112
	Bridge financing and contribution	0	0
	Transaction cost, cash capital increase	-3,804	-702
	Cash flows from financing activities	51,183	17,182
	<b>Total cash flows for the year</b>	<b>36,121</b>	<b>8,293</b>
	Cash, beginning of year	10,637	2,344
	<b>Cash, end of year</b>	<b>46,758</b>	<b>10,637</b>

Movement in liabilities from financing activities		
1 January	218	0
New leases	0	330
Interest	7	9
Repayment	-168	-121
<b>31 December</b>	<b>57</b>	<b>218</b>

# NOTES

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1. Accounting policies
2. Capital resources and liquidity
3. Staff expenses
4. Financial Income and Expenses
5. Tax
6. Intangible assets
7. Right of use of assets
8. Equity
9. Lease Liabilities
10. Distribution of profit/loss for the year
11. Change in working capital
12. Financial risks and financial instruments
13. Related parties
14. Operating lease commitments and other commitments
15. 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 2021 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, respectively.

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.

### **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:	$\frac{\text{Equity at year end} \times 100}{\text{Total assets at year end}}$
Earnings per share:	$\frac{\text{Net loss for the year}}{\text{Average numbers of outstanding shares}}$

## 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 2021, 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 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 Sweden in February 2021. A direct share issue was completed on 12 May 2021. 789,474 shares were issued with a total proceed SEK 75 million before cost. A additional directed 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 MEUR 2.5 and with two instalments played out in 2020 and 2021 of MEUR 2.1. 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 in 2022 and the budget for 2022 and concluded that the Company has the necessary capital resources to finance the planned activities for 2022.

The Board of Directors and Executive Management have based on the above concluded that the company is a going concern for 2022.



### 3. Staff Expenses

STAFF EXPENSES	2021	2020
	01/Jan 31/Dec	01/Jan 31/Dec
	Amounts in DKK '000	
Wages and salaries	10,858	4,542
Employee share schemes – value of employee services	6,716	35
Other social security costs etc.	97	39
<b>Total</b>	<b>17,671</b>	<b>4,616</b>
Compensation for key management personal		
Short term employee benefits	4,394	2,071
Share based payments	5,008	0
<b>Total</b>	<b>9,402</b>	<b>2,071</b>

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

The average number of full-time employees during 2021 was 5.6 (2020: 3.0).

## 4. Financial Income and Expenses

FINANCIAL INCOME AND EXPENSES	2021	2020
	01/Jan 31/Dec	01/Jan 31/Dec
	Amounts in DKK '000	
Net exchange rate gains	0	26
Finance income	0	26
Interest expense on liabilities measured at amortized costs	209	42
Interest related to right-of-use assets	7	9
Net exchange rate losses	242	0
Other	3	0
Finance expenses	461	51
<b>Total</b>	<b>-461</b>	<b>-25</b>

## 5. Tax

TAX	2021	2020
	01/Jan 31/Dec	01/Jan 31/Dec
	Amounts in DKK '000	
<b>Tax on profit/loss for the year:</b>		
Current tax (tax under the tax credit scheme)	5,500	4,726
<b>Total</b>	<b>5,500</b>	<b>4,726</b>
<b>Reconciliation of effective tax:</b>		
Tax computed on loss	6,440	4,881
Non-deductible expenses	-1,594	0
Other permanent differences	1,662	1,418
Non-recognized deferred tax asset	-1,007	-1,573
<b>Effective tax (19% / 21%)</b>	<b>5,500</b>	<b>4,726</b>
<b>Deferred tax:</b>		
Tax loss carried forward	2,932	1,924
Right of use assets	1	1
<b>Total</b>	<b>2,933</b>	<b>1,925</b>
Write down to accessed value	-2,933	-1,925
<b>Total</b>	<b>0</b>	<b>0</b>

Under the Danish tax credit scheme, the 22% 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 related to development activities amounts to KDKK 5,500 (2020: KDKK 4,726), is anticipated to be paid out from SKAT in Q4 2022 to the Company.

The unrecognized deferred tax assets from tax losses carried forward of KDKK 2,932 (2020: KDKK 1,924) can be carried forward indefinitely.

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

## 6. Intangible Assets

INTANGIBLE ASSETS	Acquired patents	Intangible assets
Amounts in DKK '000		
Costs at 1 January 2021	378	378
Addition for the year	0	0
<b>Costs 31 December 2021</b>	<b>378</b>	<b>378</b>
<i>Reconciliation of effective tax:</i>		
Amortization and impairment losses 1 January 2021	0	0
Amortization and impairment losses for the year	0	0
Amortization and impairment losses 31 December 2021	0	0
<b>Net book value 31 December 2021</b>	<b>378</b>	<b>378</b>

## 7. Right of use of assets

RIGHT OF USE ASSETS	Buildings	Right of use assets
Amounts in DKK '000		
Costs at 1 January 2021	330	330
Addition for the year	0	0
<b>Costs 31 December 2021</b>	<b>330</b>	<b>330</b>
Depreciation 1 January 2021	119	119
Depreciation for the year	158	158
Depreciation 31 December 2021	277	277
<b>Net book value 31 December 2021</b>	<b>53</b>	<b>53</b>

## 8. Equity

### Share capital

The share capital consists of 11,319,500 shares with a nominal value of DKK 0.1 each. The shares are fully paid in. The shares are not divided into classes, and no shares have special rights.

SHARE CAPITAL	2021	2020	2019	2018
Shares issued and fully paid				
Shares issued, 1 January	10,530,026	7,224,274	5,000,000	0
Shares issued, 30 January at formation paid in by cash		0	0	105,500
Capital increase by conversion of debt to shareholders and conversion from IVS to ApS		0	0	4,894,500
Cash contribution 8 March 2019 and conversion from ApS to A/S		0	35,000,000	0
Reverse share split (10:1) 8 March 2019		0	-36,000,000	0
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)		0	3,224,274	0
Increase in shares in directed issue and exercise of warrants	789,474	3,305,752	0	0
<b>Shares issued, 31 December</b>	<b>11,319,500</b>	<b>10,530,026</b>	<b>7,224,274</b>	<b>5,000,000</b>

## 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 did a SEK 25 million capital increase by issuing 495.000 shares to a number of existing and new investors on 10 March 2022.

## Warrants

On 28 May 2021 the Board of Directors of FluoGuide has exercised its authorization to issue new warrants by issuing 272,700 warrants to employees and management, and 50,000 warrants to the Board of Directors. All warrants are issued free of charge. Each warrant grants the holder the right to subscribe for (1) one new share in FluoGuide. The exercise price is fixed at SEK 95.00 per share. 122,700 of the warrants issued vest with 1/36 per month, and 200,000 warrants issued to certain members of the management shall vest with 1/60 per month subject to certain KPI's.

The warrants program is 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 strengthen 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.

The total fair value of options granted will have a value of DKK 11,652,914. The assessed fair value at expected grant date of options granted is 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 exercise price, the term of the option, the impact of dilution (where material), 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 option, and the correlations and volatilities of the peer group companies.

The model inputs for granted warrants during the year ended 31 December 2021 included:

- Exercise price: SEK 95.00
- Grant date: 28 May 2021
- Expiry date: 31 August 2031
- Expected price volatility of the company's shares: 53.50%
- Expected dividend yield: 0.00%
- Risk-free interest rate: -0.07%

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.

The number of outstanding warrants on 31 December 2021 amounts to 322,700. Weighted average remaining contractual life of the warrants outstanding on 31 December 2021 are 114 months.

## 9. Lease Liabilities

LEASE LIABILITIES	2021	2020
Amounts in DKK '000	31/Dec	31/Dec
Non-current	0	57
Current	57	161
<b>Total</b>	<b>57</b>	<b>218</b>

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

DISTRIBUTION OF PROFIT/LOSS FOR THE YEAR	2021	2020
Amounts in DKK '000	31/Dec	31/Dec
Proposed dividend for the year	0	0
Retained earnings	-23,770	-17,460
<b>Total</b>	<b>-23,770</b>	<b>-17,460</b>

## 11. Change in working capital

CHANGE IN WORKING CAPITAL	2021	2020
Amounts in DKK '000	31/Dec	31/Dec
Other receivables and prepayments	170	-285
Change in trade payables	4,146	2,200
Change in other payables	2,326	1,287
Change in deferred income	-4,034	7,930
<b>Total</b>	<b>2,608</b>	<b>11,132</b>

## 12. 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 2021, 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.

2021 - MATURITIES OF FINANCIAL LIABILITIES	< 1 year	1-2 year(s)	2-5 years	> 5 years	Total
Amounts in DKK '000					
<b>As at 31 December 2021</b>					
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
<b>Total</b>	<b>10,712</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>10,712</b>

2020 - MATURITIES OF FINANCIAL LIABILITIES	< 1 year	1-2 year(s)	2-5 years	> 5 years	Total
Amounts in DKK '000					
<b>As at 31 December 2020</b>					
Lease Liabilities	161	57	0	0	218
Trade payables	2,689	0	0	0	2,689
Other payables	1,494	0	0	0	1,494
<b>Total</b>	<b>4,344</b>	<b>57</b>	<b>0</b>	<b>0</b>	<b>4,401</b>

There were no assets nor liabilities measured at fair value as of 31 December 2021 and 2020.



### **13. 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 3.

### **14. Operating lease commitments and other commitments**

The company has entered into purchase obligations with suppliers in the amount of DKK 9.0 million

### **15. Events occurring after the balance sheet date**

Subsequent to the balance sheet date, The Company has conducted a capital increase of SEK 25 million in March 2022.

# FluoGuide

Intelligent surgical targeting



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