

# INTERIM REPORT

## JANUARY–JUNE 2022

MAXIMIZING SURGICAL OUTCOMES  
THROUGH INTELLIGENT TARGETING

Q2

FluoGuide



***“The convincing clinical data has  
significantly de-risked FG001”***

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*Morten Albrechtsen, CEO*

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# CLINICAL DATA SIGNIFICANTLY DE-RISKED FG001

In H1 2022, FluoGuide reached a major milestone in the clinical development showing that FG001 is very well tolerated and FG001 illuminates aggressive brain cancer. This has significantly de-risked FG001.

FluoGuide had no revenue for the period and posted a net loss of DKK -9,702 for the period 1 January to 30 June 2022 (-7,778). The financial result for the period is in line with the Company's development plans. It is the Board's opinion that FluoGuide, unlike many other life science companies, may have a comparatively short time from the initiation of product development to revenue generation.

Summary	Q2 22	Q2 21	H1 22	H1 21	2021
(DKKK)	01/Apr/22 30/Jun/22	01/Apr/21 30/Jun/21	01/Jan/22 30/Jun/22	01/Jan/21 30/Jun/21	01/Jan/21 31/Dec/21
Net Revenue	0	0	0	0	0
Operating result	-7,514	-6,034	-12,942	-10,233	-28,809
Net result	-5,749	-4,437	-9,702	-7,778	-23,770
Cash and bank	39,136	49,712	39,136	49,712	46,758
<i>Result per share (DKK) *)</i>	-0.50	-0.40	-0.83	-0.72	-2.15
<i>Solidity (%) **)</i>	92%	82%	92%	82%	73%
<i>Average shares for the period</i>	11,435,000	10,963,803	11,625,798	10,748,113	11,036,155

\*) Result per share (DKK per share): Operating result divided by the average number of shares during the period.

\*\*) Solidity: Total equity divided by total capital and liability.

## HIGHLIGHTS DURING Q2

- FluoGuide announces 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
- Presentation of clinical data on FG001 at the 68th Scandinavian Neurosurgical Society Congress held 14-16 May 2022 in Bergen, Norway
- FluoGuide published interim report for the period January – March 2022 on 31 May 2022

## HIGHLIGHTS AFTER Q2

- Overview on Investor presentations for H2 2022
- A publication of clinical data that shows uPAR is highly expressed in oropharyngeal squamous cell carcinoma (Head and Neck cancer). The article is published in ONCOLOGY REPORTS 48: 147, 2022
- Has submitted a CTA to initiate a phase II trial in head and neck cancer
- FluoGuide's update on clinical development

# CEO HAS THE FLOOR

## **Convincing clinical data has significantly de-risked FG001**

FluoGuide reached a major milestone in its development in H1 2022, with the exciting data from our phase I/IIa trial of FG001 in aggressive brain cancer, or high-grade glioma.

We are especially pleased with this very positive result as 100% of patients (n=8) on the optimal dose and 100% of biopsies (n=33) from these patients had their cancer illuminated, and FG001 to be very well tolerated with only few patients (3:40) reporting mild adverse events.

The data is a major milestone for FluoGuide as it makes it significantly more likely that FG001 will become a commercial product. Based on this strong result, we have reviewed our development plans and strengthened the design of the phase IIb trial in aggressive brain cancer. We will now test FG001 in a larger trial (24 patients versus 12) compared against Gliolan (5-ALA) with a randomized, two-arm design. The primary endpoint has also been updated from imaging to patient benefit. The patients will remain in the trial for less than 48 hours.

Data from the phase IIb trial is expected in H1 2023. The design of this phase IIb trial in aggressive brain cancer aims at non-inferiority to 5-ALA on the primary endpoint. The trial is not powered to show significance, and the result will be used to calculate the number of patients needed for the phase III trial. The rationale is to reduce any clinical and regulatory process risks as much as possible. This supports our broader strategy of bringing the first product to the market as soon and as predictable as possible while expand its commercial potential in parallel.

Based upon the positive phase I/IIa results, we have also started clinical phase IIa trials to explore the commercial potential for FG001 in other cancer indications.

We received approval for the lung cancer phase IIa trial in H1. Due to slower-than-anticipated patient enrollment, FluoGuide has amended the protocol with broader inclusion criteria, which has now been approved by both the Ethical Committee and the DMA in Denmark and we anticipate the patient recruitment to speed up. Interim data is expected in Q4 2022 and final data in H1 2023.

We have submitted a Clinical Trial Application (CTA) for a phase IIa trial in head and neck cancer, which we expect to initiate in Q4 2022. The trial is designed to enroll up to 16 patients with the aim of obtaining proof-of-concept in head and neck cancer for our uPAR platform technology, used to guide surgical removal of cancer. The primary endpoint is sensitivity, defined as the relative number of patients whose cancer is lit up by FG001, confirmed by histopathology. The result is anticipated in H1 2023.

Together with Rigshospitalet, a leading oncology center in Denmark, we are continuing to prepare a CTA for a phase IIa trial to obtain proof-of-concept in meningioma and low-grade glioma cancer. We plan to have top line data in H2 2023. FluoGuide and Rigshospitalet have received a grant of approx. 1 million DKK from Life Science Innovation North Denmark to fund this trial.

In March, FluoGuide successfully completed a directed share issue, raising approximately SEK 25 million in gross proceeds. The issue was subscribed by several institutional investors, including A/S Arbejdernes Landsbank, Linc AB, OP Fund Management-Nordic Microcap Fund, Eastbridge, AP2 and others.

With the proceeds from this issue, FluoGuide has secured funding to reach the next key milestones in our phase II trials.

The FluoGuide team has made significant progress in the planning of the trials, with inspiring alignment across the organization, and we have learned a lot from our strong clinical result in aggressive brain cancer in the clinical operation, regulatory and device interaction, which makes an even stronger FluoGuide.



Morten Albrechtsen, CEO

# FLUOGUIDE

**The primary focus of FluoGuide is to maximize surgical outcomes in oncology. FluoGuide's lead product, FG001, is designed to improve the precision of surgery by illuminating cancer cells.**

## **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 phase IIb clinical trial with its lead product, FG001, in patients with aggressive brain cancer (high-grade glioma, including glioblastoma) and phase IIa trial (ongoing) in lung and head & neck cancer (commencing).

**FG001 is well tolerated and has shown excellent safety data and early efficacy in the ongoing phase I/IIa trial**

## **Pipeline**

FluoGuide's lead product, FG001, is in phase 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 H1 2022, FluoGuide has started a phase IIa 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 tumors. This binding identifies the cancer through fluorescence during surgery.

## **Clinical trial of FG001 in aggressive brain cancer**

The ongoing phase I/II clinical trial in patients with high-grade glioma has completed the first part (I/IIa) to establish safety and tolerability, select the optimal dose and obtain proof-of-concept. The second part (IIb) is ongoing efficacy assessment.

In total, 40 patients have been included in the first phase of the trial, of whom 36 had aggressive brain cancer (high-grade glioma) and four patients had cancer of a type other than high-grade glioma

Estimation of the magnitude of benefit of FG001 (efficacy) will be done in the second phase of the trial and will include 24 patients to be recruited in both Denmark and Sweden. The design of this phase IIb trial in aggressive brain cancer aims at non-inferiority to 5-ALA on the primary endpoint. The trial is not powered to show significance, and the result will be used to calculate the number of patients needed for the phase III trial. The rationale is to reduce any clinical and regulatory process risks as much as possible. This supports our broader strategy of bringing the first product to the market as soon and as predictable as possible while expand its commercial potential in parallel.

The evidence of FG001's effect has been proven in steps: (1) An image where the cancer is seen distinct from the normal tissue; (2) The neurosurgeon's positive feedback, (3) Histology of selected tumors (removed), (4) The randomized reading of the samples of all patients, and (5) Ultimately, the clinical results. Steps 1-4 are now realized successfully.

The investigation of the clinical benefit will be the primary endpoint of the phase IIb - 24 patients planned included in both Denmark and Sweden are anticipated top line result in H1 2023.

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

The results including 40 patients were finalized and reported in April 2022. FG001 was proven to have a very satisfactory safety and tolerability profile in all 40 treated patients. 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, as is 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. The contrast also increased with increasing doses and starting at an 8 mg dose it appeared relevant for guiding surgery.

Safety and efficacy result - FG001 in HGG <sup>1</sup>					
Dose (mg/pt)	Dosing (time)	Patients (#)	Surgery HGG (#)	Light in HGG (#)	Light in HGG (%)
1	Morning	3	3	2	67%
2	Morning	3	3	3	100%
4	Morning	3	3	2	67%
8	Morning	4	3	3	100%
16	Morning	3	3	3	100%
16	Evening	5	4	4	100%
24	Morning	3	3	3	100%
36	Morning	3	3	3	100%
36	Evening	5	4	4	100%
48	Morning	4	2	2	100%
48	Evening	4	4	4	100%
Total		40	<sup>1</sup> High Grade Glioma		

Four patients had other diagnoses than aggressive brain cancer (high grade glioma): One patient had a lung cancer metastasis (adenocarcinoma metastasis) in the brain, one patient had meningioma, and two patients had malignant melanoma metastases in the brain. Intriguingly, the patients with lung cancer metastasis and meningioma demonstrated good illumination of the cancers. One patient with high grade glioma received FG001 but did not undergo surgery, and only safety was monitored.

The pharmacokinetic (PK) profile for FG001 was assessed for all the dose levels. FG001 showed dose-dependent increases in exposure across dose levels in a linear manner.

Tumor-to-background ratio (TBR) is a measure of the contrast. At the optimal dose and time, 36 mg administered the evening before, all patients revealed a clinically relevant TBR value.

The histology samples from dose cohort 7a (36 mg, evening) and dose cohort 8a (48 mg, evening) have been unblinded and analyzed. The histology results confirm that FG001 lights up aggressive brain cancer.

The clinical data of FG001 were presented at the 68th Scandinavian Neurosurgical Society (SNS) Congress held 14-16 May 2022 in Bergen, Norway. The abstract and presentation by Chief Surgeon Jane Skjøth-Rasmussen in Bergen was rewarded as the "Best abstract and Presentation 2022" by The Norwegian Neurosurgical Society.



The picture shows the lighting up of the brain tumor compared to healthy tissue at 36 mg in the evening. The picture is a part of a video shown at the SNS Congress.

## Clinical development of FG001 in other cancer indications

### Lung Cancer

In 2021, the Company selected lung cancer as the second indication for FG001. Permission to start the phase II trial was received from the Danish health authorities in March 2022. Due to slower-than-anticipated patient enrollment, FluoGuide has amended the protocol with broader inclusion criteria, which has now been approved by both the Ethical Committee and the DMA in Denmark and we anticipate the patient recruitment to speed up. Interim data is expected in Q4 2022 and final data in H1 2023.

### Head and Neck

FluoGuide has filed a CTA in Denmark for starting a phase II trial in head and neck cancer. The trial designed as a phase IIa trial to obtain proof-of. 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 result is anticipated in H1-23.

### Meningioma and low grade glioma

The Company is finalizing a protocol to initiate a proof-of-concept phase II trial in meningioma and low grade glioma. The primary endpoint is expected to be sensitivity defined as the relative number of patients, where FG001 lights up the cancer confirmed by histopathology. The results is expected in H2-2023.

### 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. The Company has initiated preclinical development of FG002 and anticipates starting clinical development in 2024.

### 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 suggest the generated heat will kill the cancer cells to which FG001 is bound, while sparing normal tissue.

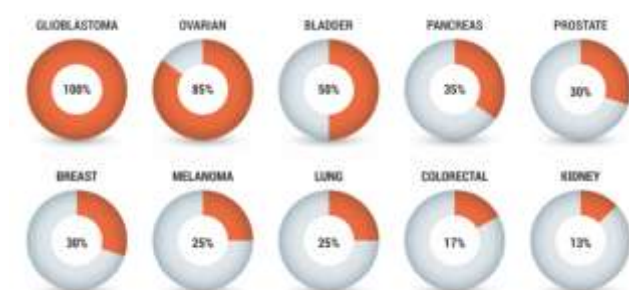
Photothermal therapy with FG001 has already demonstrated a clear effect in preclinical models and was shown to be safe to normal tissue. These data were published in August 2021. Photothermal therapy has the potential to take treatment to a new level of cellular precision.

### 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 chosen high-grade glioma, due to the significant unmet need of these patients. Nearly all high-grade gliomas express uPAR, and high-grade glioma is an aggressive form of brain cancer that has a nearly 100% 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.

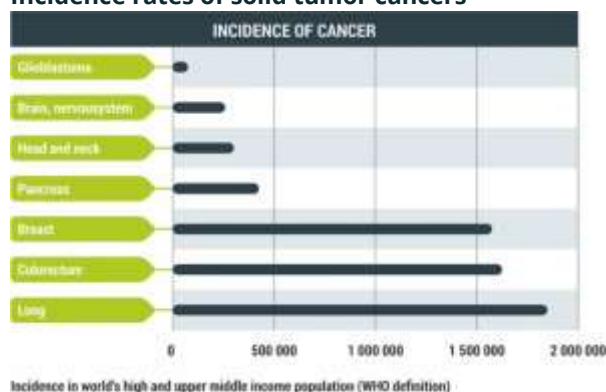
Second indication for FG001 is lung cancer. Globally, there are 2.2 million individuals diagnosed with lung cancer annually, and 1.8 million patients die each year. Lung cancer is the second most commonly diagnosed cancer and was the leading cause of cancer deaths in 2020.

Head and neck cancer includes cancers in the lining of the lips, tongue, mouth, or upper throat. Head and neck cancers are often occurring 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. In USA and EU head and neck cancer accounts for approximately 66,000 cases annually and 15,000 deaths, and 250,000 cases and 63,500 deaths, respectively.

Meningioma accounts for approx. 35% of primary brain tumors worldwide. Approx. 7 per 100,000 are diagnosed with meningioma annually. Approx. 20-30% patients will have cancer recur locally within 10 years after their first surgery. FluoGuide estimates that around 60,000 meningioma patients will annually undergo surgery. This is more patients that undergo surgery for high grade gliomas.

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 and benefited from work continuing under this grant until it was finalized in 2021. 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, FluoGuide could announce a successful SEK 25 million financing round with international institutional investors. With this financing in place the company will be able to continue its clinical development plans.

The funding of EUR 2.5 from the prestigious EIC grant (European Union), 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.

### **Outlook for FluoGuide**

FluoGuide's first 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.

More broadly, our mission is to realize the vast potential of uPAR for guiding cancer surgery by conducting clinical trials.

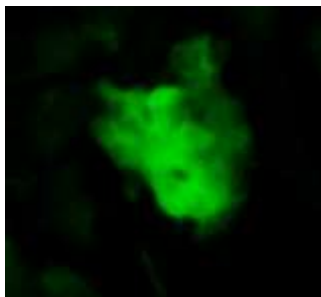
### **The key milestones for the next 12 months are:**

- Initiate phase IIa with FG001 in head & neck cancer
- Initiate phase IIa trial with FG001 in meningioma and low-grade glioma
- Phase IIa result (FG001 / lung)
- Phase IIb data with FG001 in aggressive brain cancer
- Phase IIa results in head and neck cancer

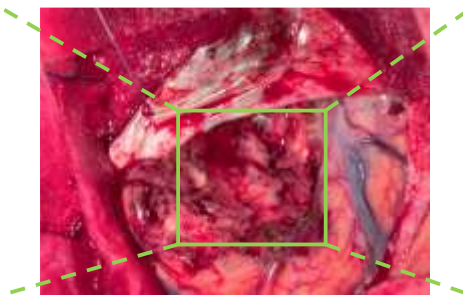


# FIRST HUMAN DATA –FG001 CAN BE USED TO GUIDE THE SURGEON

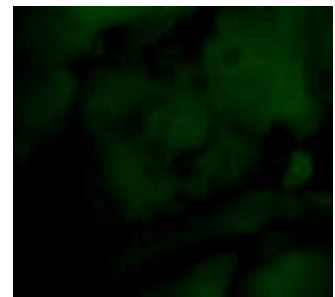
Illustration of what FG001 can accomplish



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 one patient enrolled in the ongoing dose escalation clinical phase I/II trial for patients with high-grade glioma undergoing surgery. The patient was 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 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>)

The safety and efficacy of FG001 is the basis for advancing FG001 toward the market and into other cancer indications.

# FINANCIAL DEVELOPMENT

## **Operating income and operating results**

The net revenue amounted to DKK 0 (0) and the net result for the period 1 January to 30 June 2022 was KDKK -9,702 (-7,778). The net result is in line with expectations as the Company is currently in the development stage and is conducting development activities with no product on the market.

## **Balance sheet and solidity**

The total assets as of 30 June 2022 were KDKK 52,354 (58,360) and the total equity as of 30 June 2022 was KDKK 48,158 (47,977). The solidity as of 30 June 2022 was 92% (82%).

## **Cash flow and investments**

The total cash position on 30 June 2022 was KDKK 39,136 (49,712). There were no investments during the period.

## **Accounting policy**

The financial statements for the first six months of 2022 are prepared in accordance with International Financial Reporting Standards as adopted by the EU and further provisions of the Danish Financial Statements Act for annual reports of class B companies. For further information on accounting policies, please see the Annual Report of 2021.

## **Subsequent events**

No events have had a significant influence on FluoGuide's operations.

## **Operational risks and uncertainties**

The risks to and uncertainties of FluoGuide's operations are related to several factors such as development, competition, permissions, capital requirements, customers, suppliers/manufacturers, currencies, and interest rates. During the current period, no significant changes in risk factors or uncertainties have occurred. For a more detailed description of risks and uncertainties, please refer to the company description published in February 2021. The company description is available on FluoGuide's website: [www.fluoguide.com](http://www.fluoguide.com).

## **Auditor's review**

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

## **Financial calendar 2022**

Q3 2022 report: 24 November 2022

# LISTING INFORMATION

## The shares

Shares in FluoGuide are listed on Nasdaq First North Growth Market Stockholm. The ticker is FLUO and the ISIN code is DK0061123312.

The total number of shares as of 30 June 2022 was 11,814,500 (10,963,803). Every share equals the same rights to the Company's assets and results. The company had 8,649 shareholders as of 7 July 2022.

Shareholders	Number of shares	Votes and capital
Flagged		
Life Science IVS <sup>1)</sup>	2,126,107	18.00%
Wexotec ApS <sup>2)</sup>	1,488,610	12.60%
LINC AB	819,630	6.94%
Arbejdernes Landsbank A/S	798,158	6.76%
Management and board of directors		
Grethe Nørskov Rasmussen <sup>3)</sup>	373,185	3.16%
PME HOLDING APS <sup>5)</sup>	117,297	0.99%
Micaela Sjøkvist <sup>4)</sup>	62,163	0.53%
Shomit Ghose <sup>4)</sup>	21,143	0.18%
Henrik Kristian Moltke <sup>3)</sup>	1,216	0.01%
Mats Thorén <sup>4)</sup>	1,216	0.01%
Dorthe Grønnegaard Mejer <sup>3)</sup>	724	0.01%
Other shareholders		
Others	6,005,051	50.83%
<b>TOTAL</b>	<b>11,814,500</b>	<b>100.00%</b>

1) Life Science IVS (CVR DK-38453726) is a wholly owned company by Board Member and CSO/CMO Andreas Kjaer.

2) Wexotec ApS (CVR DK-26301149) 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 Chairman of the Board Peter Mørch Eriksen.

## Warrants

FluoGuide has established an incentive program for its employees, management, and Board.

In June 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).

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% of the current share capital, if vested and exercised. There are no other warrant programs. More information can be found on [www.fluoguide.com](http://www.fluoguide.com).

**Analyst Coverage:**

Following Analysts is covering the FluoGuide stock:

- ABG Sundal Collier
- Redeye
- SEB
- Økonomisk Ugebrev

**Planned Investor Relation Presentations in 2H 2022:**

- 7-8 September, Pareto Securities 13th Annual Health Care Conference, Stockholm
- 15 September, Redeye Investor AW, Malmö
- 26 October, Redeye theme event, Stockholm
- 21-23 November, SEB Healthcare seminar, Stockholm
- 24 November, Redeye Life Science Day, Stockholm



# SUBMISSION OF Q2 2022 REPORT

The Board of Directors hereby certifies that this interim report for the period 1 January to 30 June 2022 provides a true and fair view of the Company's business.

Copenhagen  
25 August 2022  
The Board of Directors

# INCOME STATEMENT

Income statment (‘000 DKK)	Q2 22 01/Apr/22 30/Jun/22	Q2 21 01/Apr/21 30/Jun/21	H1 22 01/Jan/22 30/Jun/22	H1 21 01/Jan/21 30/Jun/21	2021 01/Jan/21 31/Dec/21
Revenue	0	0	0	0	0
Other operating income	3,027	4,544	6,379	6,291	9,613
Other operating expenses	-6,717	-7,241	-11,942	-11,241	-20,593
Staff expenses	-3,767	-3,297	-7,282	-5,204	-17,671
Depreciation and amortisation	-57	-40	-97	-79	-158
Operating loss before net financials	-7,514	-6,034	-12,942	-10,233	-28,809
Financial costs	-72	-262	-124	-273	-461
Loss before tax	-7,586	-6,296	-13,066	-10,506	-29,270
Tax on loss for the period	1,837	1,859	3,364	2,728	5,500
Net loss for the period	-5,749	-4,437	-9,702	-7,778	-23,770
Other comprehensive income for the period, net of tax	0	0	0	0	0
<b>Total comprehensive income</b>	<b>-5,749</b>	<b>-4,437</b>	<b>-9,702</b>	<b>-7,778</b>	<b>-23,770</b>

# BALANCE SHEET

Balance sheet ('000 DKK)	2022 30/Jun/22	2021 30/Jun/21	2021 31/Dec/21
<b>Assets</b>			
Acquired patents	378	378	378
Right of use assets	331	132	53
Deposit	91	54	54
Total non-current assets	800	564	485
Tax receivables	8,864	7,454	5,500
Other receivables	3,554	590	566
Prepayments		40	
Cash at bank	39,136	49,712	46,758
Total current assets	51,554	57,796	52,824
<b>Total assets</b>	<b>52,354</b>	<b>58,360</b>	<b>53,309</b>
<b>Equity and liabilities</b>			
<b>Equity</b>			
Share capital	1,181	1,132	1,132
Share premium		51,265	51,265
Retained earnings	46,977	-4,420	-13,696
Total equity	48,158	47,977	38,701
<b>Liabilities</b>			
Lease liabilities	69		
Total non-current liabilities	69		
Convertible loan			
Lease liabilities	264	138	57
Trade payables	3,553	8,606	10,655
Deferred income	310	1,639	3,896
Total current liabilities	4,127	10,383	14,608
Total liabilities	4,196	10,383	14,608
<b>Total equity and liabilities</b>	<b>52,354</b>	<b>58,360</b>	<b>53,309</b>

# STATEMENT OF CHANGES IN EQUITY

<b>Change in Equity: Q2 22</b> (KDKK)	Share-capital	Share Premium	Retained earnings	Shareholders equity
01/Apr/22	1,181		51,864	53,045
Paid in capital				
Costs relating to contribution Q1 22			-144	-144
Employee share schemes - valute of employee services			1,006	1,006
Net result Q2 22			-5,749	-5,749
Rounding difference				
30/Jun/22	1,181		46,977	48,158

<b>Change in Equity: Q2 21</b> (KDKK)	Share-capital	Share Premium	Retained earnings	Shareholders equity
01/Apr/21	1,053		16	1,069
Paid in capital	79	55,069		55,148
Capital contribution		-51,266	51,266	
Costs relating to contribution		-3,803		-3,803
Employee share schemes - valute of employee services				
Net result Q2 21			-4,437	-4,437
Rounding difference				
30/Jun/21	1,132		46,845	47,977

<b>Change in Equity: H1 22</b> (KDKK)	Share-capital	Share Premium	Retained earnings	Shareholders equity
01/Jan/22	1,132		37,569	38,701
Paid in capital	49	17,821		17,870
Capital contribution		-17,195	17,195	
Costs relating to contribution		-626		-626
Employee share schemes - valute of employee services			1,915	1,915
Net result H1 22			-9,702	-9,702
Rounding difference				
30/Jun/22	1,181		46,977	48,158

<b>Change in Equity: H1 21</b> (KDKK)	Share-capital	Share Premium	Retained earnings	Shareholders equity
01/Jan/21	1,053		3,358	4,411
Paid in capital	79	55,069		55,148
Capital contribution		-51,266	51,266	
Costs relating to contribution		-3,803		-3,803
Employee share schemes - valute of employee services				
Net result H1 21			-7,778	-7,778
Rounding difference			-1	-1
30/Jun/21	1,132		46,845	47,977

<b>Change in Equity: 2021</b> (KDKK)	Share-capital	Share Premium	Retained earnings	Shareholders equity
01/Jan/21	1,053		3,358	4,411
Paid in capital	79	55,069		55,148
Capital contribution		-51,266	51,266	
Costs relating to contribution		-3,803		-3,803
Employee share schemes - value of employee services			6,717	6,717
Net result 2021			-23,770	-23,770
Transfer			-2	-2
31/Dec/21	1,132		37,569	38,701



# CASH FLOW STATEMENT

Cash flow (’000 DKK)	Q2 22 01/Apr/22 30/Jun/22	Q2 21 01/Apr/21 30/Jun/21	H1 22 01/Jan/22 30/Jun/22	H1 21 01/Jan/21 30/Jun/21	2021 01/Jan/21 31/Dec/21
<b>Loss before tax</b>	-7,586	-6,296	-13,066	-10,506	-29,270
Financial expenses, reversed	72	262	124	273	461
Change in working capital	-4,126	1,149	-13,676	-1,764	2,607
Depreciation and amortisation	57	40	97	79	158
Adjustment for non-cash employee benefits expense - share-based payments	1,006		1,915		6,716
Cash flow from operating activities before net financials	-10,577	-4,845	-24,606	-11,918	-19,328
Financial expenses net, paid	-72	-262	-124	-273	-461
Tax credit paid out					4,726
Cash flow from operating activities	-10,649	-5,107	-24,730	-12,191	-15,063
<b>Cash flow from investing activities</b>	-36		-37		
Cash capital increase		55,148	17,870	55,148	55,148
Contribution					
Principi elements of lease payments	-56	-40	-99	-79	-161
Convertible loan					
Transaction cost, cash capital increase	-144	-3,803	-626	-3,803	-3,803
<b>Cash flow from financing activities</b>	-200	51,305	17,145	51,266	51,184
<b>Total cash flow from the period</b>	-10,885	46,198	-7,622	39,075	36,121
Cash, beginning of the period	50,021	3,514	46,758	10,637	10,637
<b>Cash, end of the period</b>	<b>39,136</b>	<b>49,712</b>	<b>39,136</b>	<b>49,712</b>	<b>46,758</b>

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