# YEAR-END REPORT JANUARY – DECEMBER 2020

MAXIMIZING SURGICAL OUTCOME BY INTELLIGENT TARGETING

**Q4** 





"Forth quarter was a game changer for FluoGuid, with FG001 administered to the first patients undergoing surgery for high-grade glioma, and demonstrated FG001 was well tolerated and light up cancer"

**Morten Albrechtsen, CEO** 

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### **SUMMARY**

#### The Board of Directors and CEO of FluoGuide hereby publish the Q4 and Year-end report of 2020

In this interim report, the following definitions apply, unless stated otherwise: The "Company" or "FluoGuide" refers to FluoGuide A/S with CVR number 39296438. The Company is not part of a group and does not have any subsidiaries. Amounts within brackets correspond to the comparable period in the previous year.

FluoGuide had no revenue for the period and therefore posted an net loss of KDKK 17,460 for full year 2020 (-9,653). The financial result for the period is in line with the Company's development plans and in keeping with expectations for life science companies. It is the Board's opinion that FluoGuide, unlike many life science companies, will have a comparatively short time from the initiation of product development to revenue generation.

Summary	Q4 2020	Q4 2019	Q1-Q4 2020	Q1-Q4 2019
	01/Oct/20	01/Oct/19	01/Jan/20	01/Jan/19
(KDKK)	31/Dec/20	31/Dec/19	31/Dec/20	31/Dec/19
Net Revenue	0	0	0	0
Operating result	-8,532	-3,700	-22,161	-10,645
Net result	-6,497	-3,113	-17,460	-9,653
Cash and bank	10,637	2,344	10,637	2,344
Result per share (DKK) *)	-0.62	-0.43	-1.78	-1.49
Solidity (%) **)	26%	87%	26%	87%

<sup>\*)</sup> Result per share (DKK per share): Operating result divided by the average number of shares during the period. The total number of shares as of 31 December 2020 totaled 10,530,026 shares (7,224,274). The average number of shares for the fourth quarter 2020 was 10,530,026 shares (7,224,274). The average number of shares for the period 1 January – 31 December 2020 was 9,797,895 shares (6,477,565).

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

### HIGHLIGHTS DURING Q4

- FluoGuide was awarded a post doc grant from Innovation Fund Denmark to expand the pipeline
- First patient was enrolled in the phase I/II clinical trial testing FG001 in patients with high- grade glioma
- SEB initiates initiated commissioned research on FluoGuide
- FluoGuide received green light to proceed to second dose level with FG001 in the ongoing clinical phase I/II trial in patients with high-grade glioma

### HIGHLIGHTS AFTER Q4

- FluoGuide gets green light to proceed to third dose level with FG001 in the ongoing clinical phase I/II trial in patients with high-grade glioma
- FluoGuide A/S ("FluoGuide" announces that the chairman of the Board of Directors, Arne Ferstad, will not stand for re-election at the upcoming Annual General Meeting

### **CEO HAS THE FLOOR**

FluoGuide had a strong 2020, with significant progress in our development pipeline and also in establishing a strong financial base.

The most important event in 2020 was the approval by the Danish Medicines Agency and initiation of the phase I/II clinical trial of FG001 in patients with high-grade glioma undergoing surgery. This transformed FluoGuide into a clinical stage company.

FluoGuide is also pleased to report a satisfactory enrollment rate and that the first two dosing levels demonstrated no safety issues and a favorable tolerability profile. This result is in line with our expectations based on our pre-clinical studies. Furthermore, light was detected in five out of six patients. These initial findings are promising, although completion of the full study and the final data analysis are needed before we can draw conclusions on safety or efficacy.

Our financial position was also strengthened in 2020, as a result of a directed share issue in February and a successful warrant exercise in May. In total this provided the company with approximately DKK 11.6 million and DKK 6.4 million (before issuing costs), respectively. FluoGuide was also awarded a EUR 2.5 million grant by The European Innovation Council (EIC), which was partially paid in 2020. The EU funds come from the prestigious SME Instrument grant program, and are being used to accelerate the development of FG001.

We have also continued our business development activities to achieve product portfolio expansion. During the third quarter we entered into an agreement with LI-COR Biosciences to use their proprietary next-generation fluorophore. To fully explore the potential of uPAR-targeted surgical guidance, it is strategically important for FluoGuide to investigate indications beyond glioblastoma and to prepare structured partnerships. FluoGuide anticipates two to three uPAR targeted products will be optimal, with the next product in development being FG002.

In 2020 we also successfully strengthened the skills and expertise of our organization within clinical development and financial management, to further position us to achieve our future goals.

FluoGuide was listed on Spotlight Stock Market in 2019 and in 2020 was awarded "Best IPO" in its category, an accolade of which we are very proud.

The COVID-19 pandemic has impacted health and economics on a global scale, and may continue to have a major impact in the near future. FluoGuide has, thus far, not been directly affected by the pandemic and we remain optimistic about maintaining our timelines and staying on track towards our ultimate goal of improving outcomes in surgical oncology.

I would like to take this opportunity to thank all of our shareholders for their confidence in us, our business, and our product vision. Together with an extraordinary team, I am looking forward to the year ahead and to continuing FluoGuide's ambitious journey to bring new solutions to surgeons and cancer patients worldwide. We are eager to continue the development of our first product and to transforming FluoGuide into a late clinical-phase company with a pipeline of new indications and new development candidates. This year should indeed be a very exciting time for the Company and its shareholders.



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

### **FLUOGUIDE**

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

#### FluoGuide in brief

FluoGuide is a life science company based in Denmark that 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 post-surgery and reducing recurrence 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 and II clinical trial to demonstrate the safety and efficacy of its lead product, FG001, in patients with high-grade glioma (including glioblastoma).

FG001 has shown positive preliminary results in an ongoing phase I/II study

#### **Pipeline**

FluoGuide's lead product, FG001, is in phase I/II targeting high-grade glioma, an indication that was chosen because of the significant unmet medical need. To expand the pipeline, FluoGuide is also preparing FG001 for clinical testing in other oncology indications, including prevalent cancers such as breast and lung cancer. The Company has also secured rights to a follow-on product, FG002, which is based on a novel fluorophore.

#### FG001

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

#### How it works

FG001 is made of a proprietary 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.

#### Ongoing clinical trial with FG001

The ongoing phase I/II clinical trial in patients with high-grade glioma has two phases: (1) a dose escalation phase to establish safety and tolerability, and (2) an efficacy assessment phase.

- (1) The dose escalation phase includes groups of three patients to be dosed with the same amount of FG001, with safety evaluated after dosing. Following a positive evaluation of the patients, the next group of patients is initiated at the next dose level. A total of up to eight groups of three patients each is planned to be tested in this dose escalation phase, totaling up to 24 patients.
- (2) Estimation of the magnitude of benefit of FG001 (efficacy) is done in the second phase of the trial and will include 12 patients. Importantly, this data will 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 inform pricing for FG001.

As of January 2021, FluoGuide has completed the first two dose levels (six patients) in the first phase of the trial. The safety and tolerability profile is thus far in line with the preclinical safety studies, indicating that FG001 should be well tolerated with a good safety profile. Furthermore, luminescence from FG001 was detected in five out of the six patients (two of three in the first dosing group and three of three in the second). These findings are as good as can be hoped for at this early stage, however the first phase of the trial must be completed and the data analyzed before any conclusions on tolerability and safety profile can be drawn. It is likewise too soon make any predictions of the efficacy of FG001 based on the findings from the first two dosing levels. At completion of the phase I/II trial, tissue samples obtained during the trial will be read by blinded pathologists, to confirm that the tissue lighting up is actually cancer, and that tissue that does not light up is free of cancer.

The recruitment of patients over the next several months may be slowed due to the ongoing COVID-19 pandemic. However, at the time of this report, FluoGuide believes that the overall timeline remains as in prior communications, assuming five to eight cohorts are needed to identify the optimal dose. The timeline is: (i) Mid 2021 – Results from the first phase (safety and selection of optimal dose); (ii) Second half of 2021 – Efficacy results from the second phase.

#### FG002

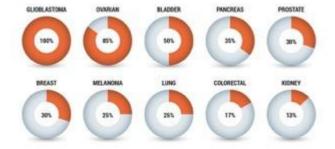
FluoGuide's second product, FG002, is designed similarly to FG001 in that it will allow surgeons to clearly differentiate cancer from normal tissue during surgery through a novel uPAR-targeted luminescent technology. FG002 is particularly relevant for colorectal cancer and is being studied preclinically. FluoGuide will use these results, together with the results from the clinical study of FG001, to select one or two new uPAR-targeted indications to advance into clinical development. This decision is expected in late 2021.

### Market potential in improving the precision of surgery by illuminating cancer cells

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.

Because this is difficult, the average recurrence rate postsurgery is approximately 50%, with wide variation, depending on the type of cancer.

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



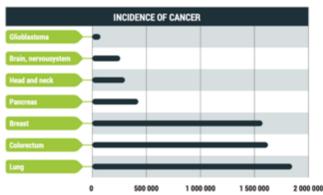
#### Significant potential for FG001

FluoGuide has chosen high-grade glioma for the initial indication of FG001 due to the significant unmet need of these patients and to 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 5 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 tremendous opportunity to address other solid tumors because uPAR is extensively expressed in most aggressive cancers. Preclinical studies have confirmed the effect of FG001 in high-grade glioma, pancreatic cancer, as well as head and neck cancer. FG001 has the potential to demonstrate a clinical benefit in these and other cancers with high incidence rates, including breast cancer and lung cancer.

#### Incidence rates of solid tumor cancers



Incidence in world's high and upper middle income population (WHO definition

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

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

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 breaks down normal tissue to allow the cancer to spread. uPAR is therefore an outstanding target to delineate cancer from normal tissue, 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 50% of all cancers that undergo surgical removal, making FG001 an attractive target to improve surgical outcomes for millions of oncology patients worldwide.

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, but will benefit from work continuing under this grant until the end of 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.

#### EIC grant from the EU was awarded in 2020

FluoGuide was awarded an EIC grant of EUR 2.5 million from the EU which was partly paid in 2020. The grant will help accelerate the development of FG001; the addition of the second phase of the ongoing phase I/II clinical trial is a direct result of this grant. The grant is non-dilutive and is a strong signal from the EU, as it is reserved for top innovators and companies with a demonstrated strategic plan.

#### 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 USA. The patents do not expire until 2034, providing a long period of protection to maximize the commercial opportunity of the product.

PATENT NAME: uPAR targeting peptide for use in peroperative optical imaging of invasive cancer PATENT NUMBER: WO/2016/041558A1

TYPE: Issued in the USA, EU and Australia

FILED: 17/Sep/2014 EXPIRES: 16/Sep/2034 OWNER: FluoGuide A/S

#### 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.

FluoGuide also has an experienced Board of Directors representing diverse skill sets and networks to help guide FluoGuide in its ambitious plans for value creation.

#### **Outlook for FluoGuide**

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

Broadening the mission to realize the vast potential of uPAR for guiding cancer surgery, FluoGuide's second objective is to expand its pipeline by accelerating the development of FG001 for indications beyond high-grade glioma and beginning to develop second generation products. These could include enhanced precision and luminescence to further improve cancer detection through uPAR targeting fluorophores.

The key milestones for 2021 are:

- (i) Mid 2021: Results from the first phase clinical study (safety and selection of optimal dose)
- (ii) Second half of 2021: Efficacy results from the second phase.

uPAR targeting – potential to help more than 3,000,000 cancer patients who undergo surgery every year

#### More information

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

## **FINANCIAL DEVELOPMENT**

#### **Operating income and operating results**

The net revenue amounted to DKK 0 (0) and the net result for Q4 was KDKK –6,497 (-3,113). The net result is in line with expectations as the Company is currently in development stage, hence conducting development activities with no product on the market.

#### **Balance sheet and solidity**

The total assets at 31 December 2020 was KDKK 16,742 (5,238) and the total equity at 31 December 2020 was KDKK 4,411 (4,542). The solidity as per 31 December 2020 was 26% (87%).

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

The total cash position at 31 December 2020 was KDKK 10,637 (2,344). There were no investments during the period.

#### **Financial calendar**

Annual General Meeting 9 February 2021
Q1 report: 26 May 2021
Q2 and half-year report: 25 August 2021
Q3 report: 24 November 2021



### **MISCELLANEOUS**

#### The share

The shares in FluoGuide were listed at Spotlight Stock Market on 7 May 2019. The ticker is FLUO and the ISIN code is DK0061123312.

The total number of shares as of 31 December 2020 totaled 10,530,026 (7,224,274). Every share equals the same rights to the Company's assets and results.

Shareholders	<b>holders</b> Number of		
	shares	capital	
Flagged			
Life Science IVS *	2,124,891	20.2%	
Wexotec ApS **	1,487,394	14.1%	
SEB nom, Sweden	807,347	7.7%	
Management and board of directors			
Grethe Nørskov Rasmussen ***	373,185	3.5%	
Arne Ferstad ****	299,147	2.8%	
PME HOLDING APS *****	117,297	1.1%	
Micaela Sjökvist ****	61,422	0.6%	
Shomit Ghose****	39,810	0.4%	
Other shareholders			
Others	5,219,533	49.6%	
TOTAL	10,530,026	100.0%	

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

#### **Warrants**

There are no outstanding warrants in FluoGuide.

#### **Accounting policy**

The financial statements for the fouth quarter 2020 of FluoGuide 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. For further information on accounting policies, please see the Annual Report of 2020.

<sup>\*\*</sup> Wexotec ApS (CVR DK-26301149) is a wholly owned company by CEO Morten Albrechtsen.

<sup>\*\*\*</sup> Management

<sup>\*\*\*\*</sup> Member of the Board of Directors,

<sup>\*\*\*\*\*</sup> PME Holding ApS is a wholly owned company by Board member Peter Mørch Eriksen.

#### **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 significant affected by the COVID-19 pandemic and we remain optimistic in maintaining our timelines and stay on track towards our goal of improving outcome in surgical oncology.

Subsequent to the balance sheet date, no events have had significantly affect on the financial statements for 2020.

#### **Operational risks and uncertainties**

The risks and uncertainties that FluoGuide's operations are exposed to are summary related to 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, refer to the prospectus published in April 2019. The prospectus is available on FluoGuide's website: www.fluoguide.com

#### **Auditor's review**

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

## **SUBMISSION OF Q4 REPORT**

The Board of Directors hereby certifies that this Q4 and Year-end report provides a true and fair view of the Company's business.

Copenhagen 26 January 2021 The Board of Directors

## **INCOME STATEMENT**

Income Statement	Q4 2020	Q4 2019	Q1-Q4 2020	Q1-Q4 2019	2019
('000 DKK)	01/Oct/20	01/Oct/19	01/Jan/20	01/Jan/19	01/Jan/19
	31/Dec/20	31/Dec/19	31/Dec/20	31/Dec/19	31/Dec/19
Revenue	0	0	0	0	0
Other operating income	2,049	100	3,218	100	100
Other operating expenses	-8,328	-3,255	-20,644	-8,880	-8,880
Staff expenses	-2,134	-545	-4,616	-1,864	-1,864
Depreciation and amortisation	-119	0	-119	0	0
Operating loss before net financials	-8,532	-3,700	-22,161	<b>-</b> 10,645	-10,644
Net financial costs	-37	-99	-25	-1,062	-1,062
Loss before tax	-8,569	-3,799	-22,186	-11,706	-11,706
Tax on loss for the period	2,072	685	4,726	2,053	2,053
Net loss for the period	-6,497	-3,113	-17,460	-9,653	-9,653
Other comprehensive income for the period, net of tax	0	0	0	0	0
Total comprehensive income	-6,497	-3,113	-17,460	-9,653	-9,653

## **BALANCE SHEET**

Balance Sheet	2020	2019
('000 DKK)	31/Dec/20	31/Dec/19
Assets		
Aquired patents	378	377
Right of use assets	211	0
Deposit	54	12
Total non-current assets	643	389
Tax receivables	4,726	2,053
Other receivables	554	325
Prepayments	182	127
Cash at bank	10,637	2,344
Total current assets	16,099	4,849
Total assets	16,742	5,238
Equity and liabilities		
Equity		
Share capital	1,053	722
Share premium	0	0
Retained earnings	3,358	3,820
Total equity	4,411	4,542
Liabilities		
Lease liabilities	57	0
Total non-current liabilities	57	0
Convertible loan	0	0
Lease liabilities	161	0
Trade payables	4,183	696
Deferred income	7,930	0
Total current liabilities	12,274	696
Total liabilities	12,331	696
Total equity and liabilities	16,742	5,238

## STATEMENT OF CHANGES IN EQUITY

Change in Equity: Q4 2020 (KDKK)	Share-capital	Share Premium	Retained earnings	Shareholders equity
01/Oct/20	1,053	0	9,820	10,873
Paid in capital				
Capital contribution				
Costs relating to contribution				
Employee share schemes - valute of employee services			35	35
Net result Q4-20			-6,497	-6,497
Transfer				
31/Dec/20	1,053	0	3,358	4,411
Change in Equity: Q4 2019	Share-capital	Share	Retained	Shareholders
(KDKK)		Premium	earnings	equity
01/Oct/19	722	0	6,933	7,655
Paid in capital				
Capital contribution				
Costs relating to contribution				
Net result Q4-19			-3,113	-3,113
Rounding difference			2,::2	
31/Dec/19	722	0	3,820	4,542
Change in Equity: Q1-Q4 2020	Share-capital	Share	Retained	Shareholders
(KDKK)		Premium	earnings	equity
01/Jan/20	722	0	3,820	4,542
Paid in capital	331	17,665		17,996
Capital contribution	331	17,003		17,550
Costs relating to contribution		-702		<del>-</del> 702
Employee share schemes - valute of employee services		702	35	35
Net result Q1-Q4			-17,460	-17,460
Transfer		-16,962	16,962	17,400
31/Dec/20	1,053	10,502	3,357	4,411
	,,			,,
Change in Equity: Q1-Q4 2019	Share-capital	Share	Retained	Shareholders
(KDKK)	Share capital	Premium	earnings	equity
1/Jan/19	50	0	-43	7
		10.010		40.500
Paid in capital	556	10,043		10,599
Capital contribution	116	5,645		5,761
Costs relating to contribution		-2,172	0.650	-2,172
Net result Q1-Q4		12.516	-9,653	-9,653
Transfer		-13,516	13,516	
Rounding difference	722	0	2.020	4.540
31/Dec/19	722	0	3,820	4,542
Change in Facility 2000	Chana	5	D-t-	Ch and a late
Change in Equity: 2019 (KDKK)	Share-capital	Share Premium	Retained earnings	Shareholders equity
1/Jan/19	50	0	-43	7
B.11:		40 = :=		
Paid in capital	556	10,043		10,599
Capital contribution	116	5,645		5,761
Costs relating to contribution		-2,172		-2,172
Net result 2019			-9,653	-9,653
31/Dec/19	722	13,516	-9,696	4,542
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# CASH FLOW STATEMENT

Cash flow	Q4 2020	Q4 2019	Q1-Q4 2020	Q1-Q4 2019
('000 DKK)	01/Oct/20	01/Oct/19	01/Jan/20	01/Jan/19
	31/Dec/20	31/Dec/19	31/Dec/20	31/Dec/19
Loss before tax	-8,569	-3,799	-22,186	-11,706
Financial expenses, reversed	37	99	25	1,062
Change in working capital	950	-3,109	11,133	193
Depreciation and amortisation	119	0	119	0
Adjustment for non-cash employee benefits expense - share-				
based payments	35	0	35	0
Cash flow from operating activities before net financials	-7,428	-6,809	-10,874	-10,452
Financial expenses net, paid	-37	-99	-25	-102
Tax credit paid out	0	0	2,053	0
Cash flow from operating activities	-7,465	-6,908	-8,846	-10,554
Cash flow from investing activities	0	-378	-42	-389
Cash capital increase	0	0	17,996	10,599
Contribution	0	0	0	0
Princiapl elements of lease payments	-112	0	-112	0
Convertible loan	0	0	0	4,801
Transaction cost, cash capital increase	0	0	-703	-2,172
Cash flow from financing activities	-112	0	17,181	13,228
Total cash flow from the period	-7,577	-7,285	8,293	2,285
Cash, beginning of the period	18,214	9,630	2,344	59
Cash, end of the period	10,637	2,344	10,637	2,344



Intelligent surgical targeting



www.fluoguide.com