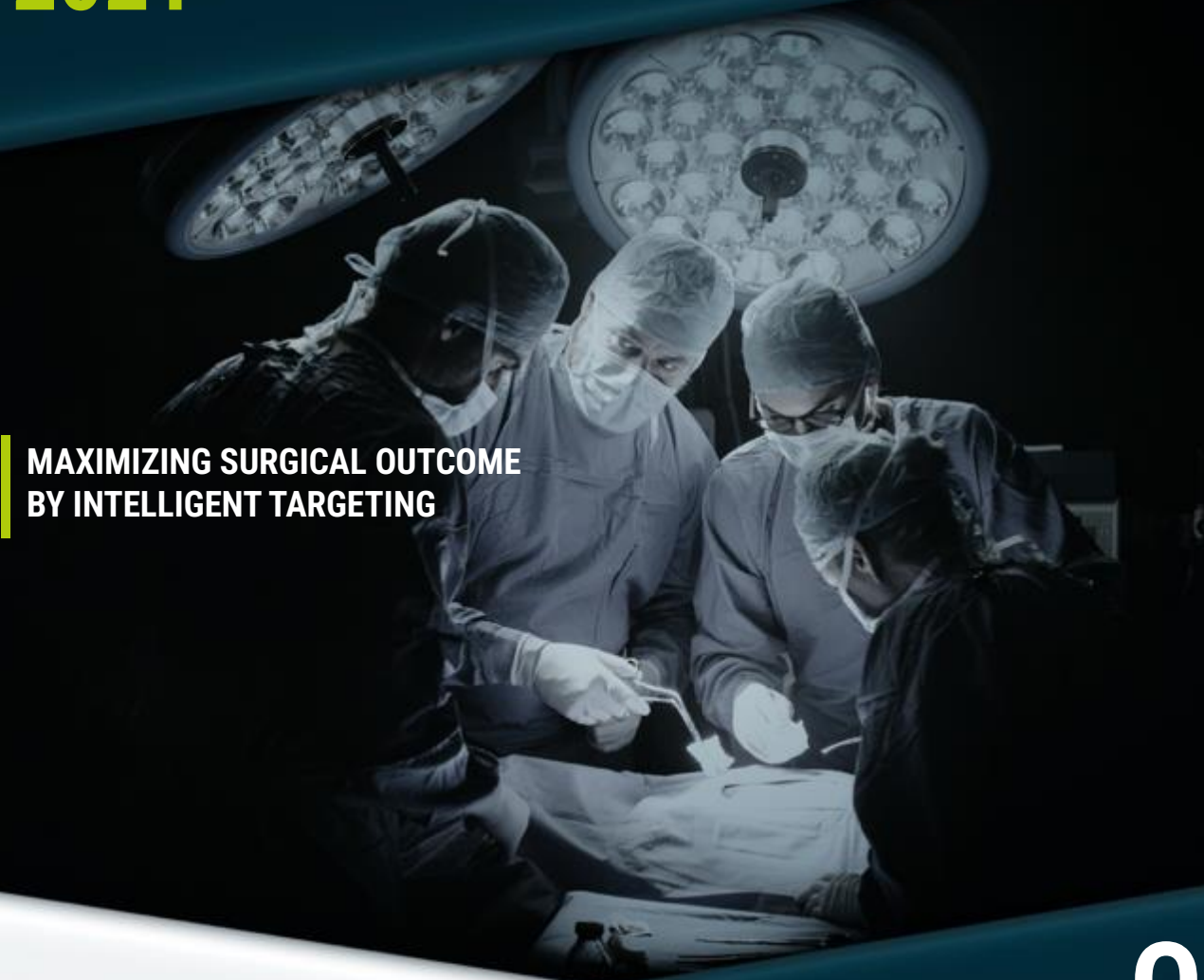


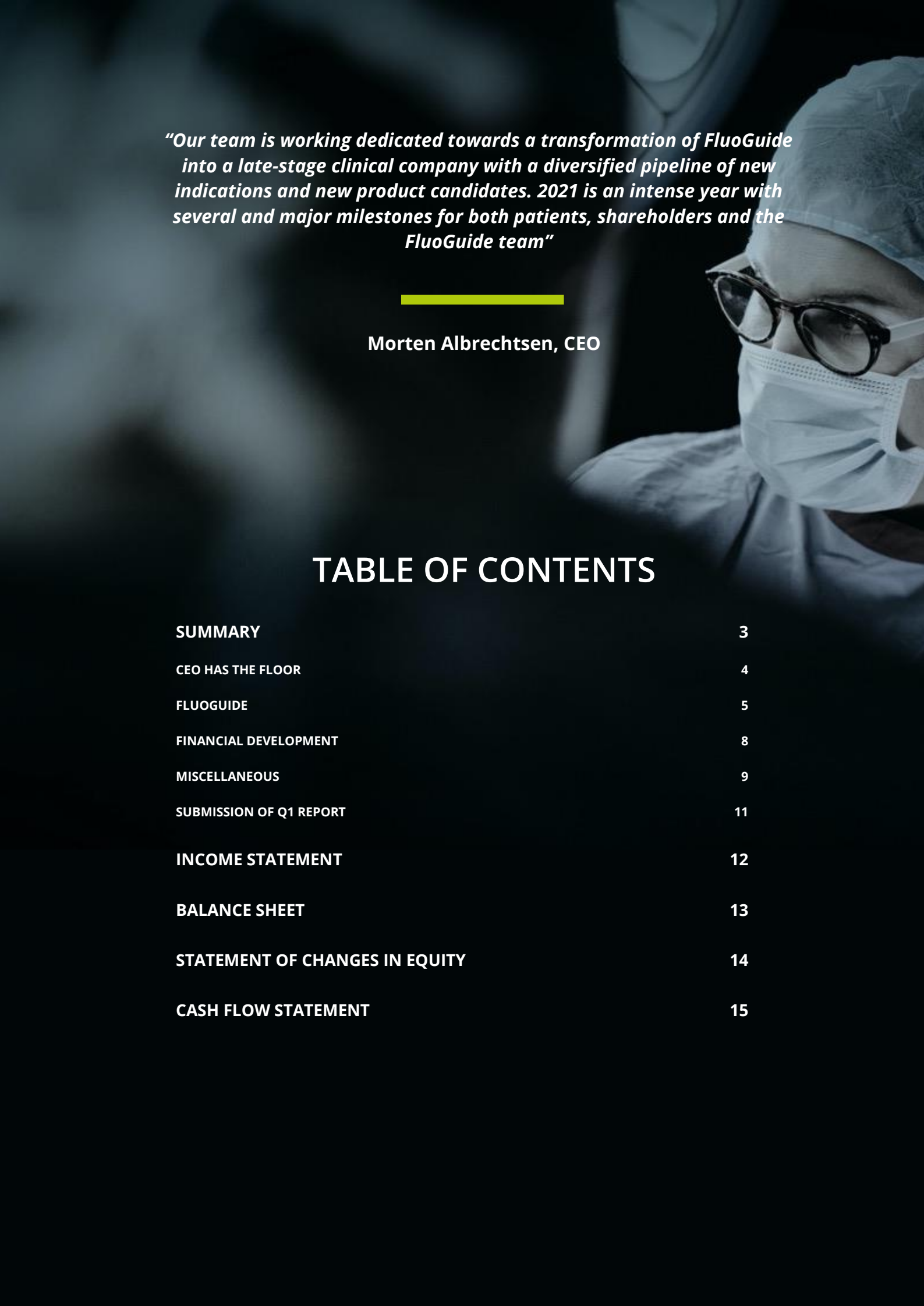
# INTERIM REPORT JANUARY – MARCH 2021



MAXIMIZING SURGICAL OUTCOME  
BY INTELLIGENT TARGETING

Q1

FluoGuide



*"Our team is working dedicated towards a transformation of FluoGuide into a late-stage clinical company with a diversified pipeline of new indications and new product candidates. 2021 is an intense year with several and major milestones for both patients, shareholders and the FluoGuide team"*

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Morten Albrechtsen, CEO

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# SUMMARY

## The Board of Directors and CEO of FluoGuide hereby publish the Q1 financial report 2021

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 a net loss of KDKK 3,343 for Q1 2021 (-3,088). 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, will have a comparatively short time from the initiation of product development to revenue generation.

Summary	Q1-2021	Q1-2020	2020
	01/Jan/21	01/Jan/20	01/Jan/20
( '000 DKK)	31/Mar/21	31/Mar/20	31/Dec/20
Net Revenue	0	0	0
Operating result	-4,201	-3,923	-22,161
Net result	-3,343	-3,088	-17,460
Cash and bank	3,514	11,031	10,637
Result per share (DKK) <sup>*)</sup>	-0.32	-0.38	-1.78
Solidity (%) <sup>**)</sup>	10%	88%	26%

<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 March 2021 totaled 10,530,026 shares (9,455,268). The average number of shares for the first quarter of 2021 was 10,530,026 shares (8,057,832). The average number of shares for the period 1 January – 31 December 2020 was 9,797,895 shares (6,477,565). After the end of the period, FluoGuide conducted a directed share issue which have increased the number of shares to 11,319,500.

<sup>\*\*) Solidity: Total equity divided by total capital and liability.</sup>

## HIGHLIGHTS DURING Q1

- 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 publishes annual report for the fiscal year 2020
- FluoGuide announces the publication of two patent applications covering the Company's uPAR technology platform for improving surgery
- FluoGuide announces approval for listing on Nasdaq First North Growth Market Sweden on the 24 February 2021
- FluoGuide gets green light to proceed to fourth dose level with FG001 in the ongoing clinical phase I/II trial in patients with high grade glioma
- FluoGuide acquires rights to photothermal therapy using FG001

## HIGHLIGHTS AFTER Q1

- FluoGuide receives green light to proceed to fifth dose level with FG001 in the ongoing clinical phase I/II trial in patients with high grade glioma
- FluoGuide completes a directed share issue raising SEK 75 million on the 12 of May 2021.
- FluoGuide receives approval from ethical committee and the Danish Medicines Agency to commence with FG001 in evening dosing in the ongoing clinical phase I/II trial in patients with high grade glioma undergoing surgery
- FluoGuide announces the initiation of evening dosing after a satisfactory conclusion of the fifth dose level with FG001.

# CEO HAS THE FLOOR

FluoGuide has had a fantastic start in 2021 with significant progress in our development pipeline.

We are very pleased to report a satisfactory enrollment rate of patients with high grade glioma and that the first five dose levels demonstrated FG001 to be well tolerated. In all five dose levels we have also seen that FG001 lights up the tumor.

Based on the promising data with FG001, the next key task ahead is optimizing the go-2-market activities, so we prove the most benefit for patients and are being paid fairly to the benefit of our shareholders. This is an iterative process with market research, Key Opinion Leader interaction and regulatory consultations in parallel with being guided by the clinical results from the ongoing trial with FG001 in high grade glioma.

Importantly, FluoGuide is less than ever a binominal investment case but a case with a robust foundation and a potential huge upside.

During the first quarter we have strengthened our patent portfolio extending the protection of FG001 to potentially 2039. Furthermore, we have acquired rights to photothermal therapy taking surgery to a cellular precision (see more info later). FluoGuide can now not only guide surgery through FG001, but potentially also help the surgeon to destroy hidden cancer cells.

We moved FluoGuide from Spotlight Stock Market to Nasdaq First North Growth Market, Stockholm. The Company has developed very fast since its IPO in May '19. We have demonstrated that FG001 is well tolerated and illuminates aggressive brain cancer. The next phase of our ambitious plan is to prepare FG001 for broad clinical use to benefit patients around the world. The move to Nasdaq First North is a natural step in supporting our plan of a global focus. In short, we aim at helping patients undergoing cancer surgery anywhere in the world by building a strong international company

with deep roots in and for the benefit of the Scandinavian community.

The change to Nasdaq First North was also part of an important plan to increase the number of institutional investors to gain credibility, flexibility and robustness.

We could announce a successfully capital raise of SEK 75 million in May to facilitate our development plans for FG001 and FG002. On top of the SEK 75 million we have also gotten new international institutional investors as shareholders, which we of course are very proud of.

I would like to welcome our new shareholders and thanking our institutional investors for supporting this. It has been satisfying to deliver a structure being beneficial for both existing and new shareholders, and support FluoGuide long term.

Together with an extraordinary team, I am looking forward to an intense and exciting year ahead.



**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 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 well tolerated and has shown positive preliminary results in an ongoing phase I/II study**

## Pipeline

FluoGuide's lead product, FG001, is in phase I/II targeting patients undergoing surgical removal of high-grade glioma, an indication that was chosen for several reasons including the significant unmet medical need. FluoGuide is also preparing FG001 for clinical testing in other oncology indications, including prevalent cancers such as lung and breast cancer. To expand the pipeline, the Company has secured rights to FG002, which is excreted differently than FG001 from the body and 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 risk of local recur of the cancer 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 and dose expansion 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. FluoGuide has amended the trial to include dosing in the evening for doses that have already been demonstrated safe when administered in the morning. The number of cohorts will probably remain the same but some of the planned high dose cohorts will be replaced with evening dosing cohorts. However, FluoGuide continues to increase the dose if the images improve.
- (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 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 inform pricing for FG001.

As of May 2021, FluoGuide has completed the first five dose levels in the first phase of the trial. The safety and tolerability profiles are as expected in line with the pre-clinical safety studies, namely that FG001 is very well tolerated.

Furthermore, luminescence from FG001 was detected already from the first dose level. The light intensity increases with dose and in the last doses tested, light from background reduced full benefit from the higher dose. Therefore, to get the full benefit from the higher doses and make an informed decision of the which optimal combination of FG001 dose and time of



administration to carry forward in the clinical development, the company has therefore amended the protocol to explore evening administration as well as morning dosing. Evening administration is expected to reduce light from background.

These findings are as good as can be hoped at this stage – FG001 is well tolerated and lights up cancer tissue. However, the first phase of the trial must be completed, and the data analyzed before any firm conclusions can be made. The pathological examination of the tissue that lights up is important to establish that cancer lights up and normal tissue does not. The pathologist will read the slides of the tissue blinded after the first part and after the second part. This is very important data to have for estimate the magnitude of benefit of FG001 for the patients and hence giving a first guidance of the expected price of the product.

The recruitment of patients over the next several months may be slowed down 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.

### Photothermal therapy

FluoGuide has acquired the exclusive rights to use FG001 for Photothermal therapy. Light excitation of FG001 will cause it to release energy in the form of heat. Under optimal conditions, the generated heat will kill the cells to which FG001 is bound, namely cancer cells, while sparing normal tissue.

Photothermal therapy with FG001 has already demonstrated a clear effect in preclinical models and shown to be safe to normal tissue in these models. With the obtained exclusive rights, FluoGuide can now not only guide surgery through FG001, but potentially also help the surgeon to destroy hidden cancer cells, or cancer that cannot be removed, e.g., because it has invaded a vital structure in, for instance, the brain. Photothermal therapy has the potential to take surgery to a cellular precision.

### FG002

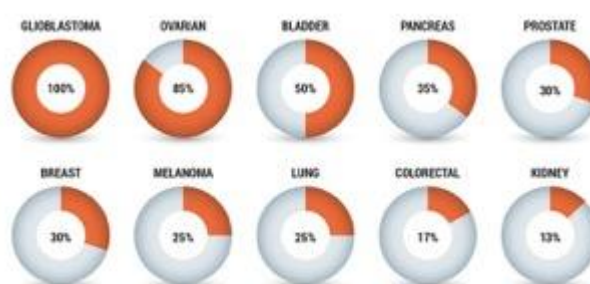
FluoGuide's second product, FG002, is designed similarly to FG001 in that it will allow surgeons to clearly differentiate cancer from normal tissue during surgery through a novel uPAR-targeted luminescent technology. FG002 is particularly relevant for colorectal cancer. FluoGuide is currently conducting preclinical studies with FG002.

### 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.

Due to the limitations in 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

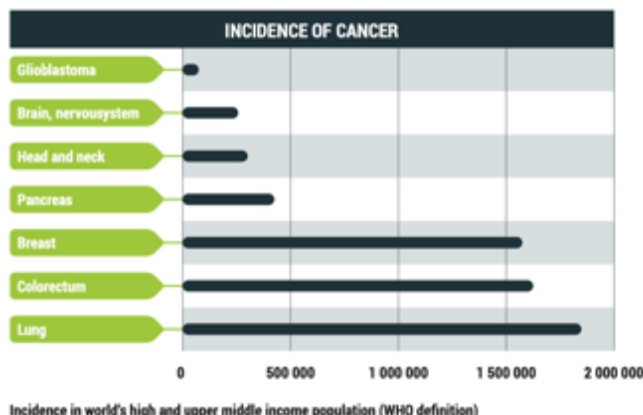


### Significant potential for FG001

FluoGuide has chosen high-grade glioma for the initial indication of FG001 due to a number of reasons including 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



### 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 and 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.

### 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 patent/patent applications do not expire 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

FluoGuide could in May announce a successfully SEK 75 million financing round with international institutional investors. With this financing in place the company can continue its development of FG001 and FG002.

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

Approx. half of the grant has been paid out in 2020 and the remaining half is paid out in 2021 and 2022.

### Outlook for FluoGuide

FluoGuide's first goal is to advance its lead product – FG001 – to improve outcomes for the approx. 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.

The key milestones for 2021 are:

- (i) Q3 2021: Results from the first phase clinical study (safety and selection of optimal dose)
- (ii) Q4 2021: Efficacy results from the second phase.
- (iii) Initiation of a new prevalent indication for FG001

# FINANCIAL DEVELOPMENT

## Operating income and operating results

The net revenue amounted to DKK 0 (0) and the net result for Q1 2021 was KDKK -3,343 (-3,088). The net result is in line with expectations as the Company is currently in the development stage, hence conducting development activities with no product on the market.

## Balance sheet and solidity


The total assets as of 31 March 2021 was KDKK 10,371 (14,629) and the total equity as of 31 March 2021 was KDKK 1,069 (12,863). The solidity as of 31 March 2021 was 10% (88%).

## Cash flow and investments

The total cash position on 31 March 2021 was KDKK 3,514 (11,031). There were no investments during the period.

## Financial calendar

Q2 and half-year report:	25 August 2021
Q3 report:	24 November 2021



Currently, the Company is conducting a proof-of-concept clinical trial (phase I/II) to demonstrate the effect of FG001



# MISCELLANEOUS

## The share

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

The total number of shares as of 31 March 2021 totaled 10,530,026 (9,455,268). Every share equals the same rights to the Company's assets and results. The company had 9,507 shareholders as of 31 March 2021. After the end of the period, FluoGuide conducted a directed share issue which have increased the number of shares to 11,319,500.

Shareholders	Number of shares	Votes and capital
Flagged		
Life Science IVS <sup>1)</sup>	2,124,891	20.2%
Wexotec ApS <sup>2)</sup>	1,487,394	14.1%
SEB nom, Sweden <sup>6)</sup>	807,347	7.7%
Management and board of directors		
Grethe Nørskov Rasmussen <sup>3)</sup>	373,185	3.5%
PME HOLDING APS <sup>5)</sup>	117,297	1.1%
Micaela Sjøkvist <sup>4)</sup>	61,422	0.6%
Shomit Ghose <sup>4)</sup>	39,810	0.4%
Dorthe Grønnegaard Mejer <sup>3)</sup>	3,241	0.0%
Other shareholders		
Others	5,515,439	52.4%
<b>TOTAL</b>	<b>10,530,026</b>	<b>100.0%</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.

6) Linc AB has 718,500 shares as of 31 March 2021

## Warrants

There are no outstanding warrants in FluoGuide.

## Accounting policy

The financial statements for the first quarter 2021 of FluoGuide 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 2020.

### **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 the Company remain optimistic in maintaining the timelines and stay on track towards the goal of improving outcome in surgical oncology.

Subsequent to the balance sheet date, the company has conducted a directed share issue of SEK 75 million which has a significantly positive effect on the Company's cash position and balance sheet.

### **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, 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.

# SUBMISSION OF Q1 REPORT

The Board of Directors hereby certifies that this interims report for the period 1 January to 31 March 2021 provides a true and fair view of the Company's business.

**Copenhagen**  
**26 May 2021**  
**The Board of Directors**

# INCOME STATEMENT

Income statement (‘000 DKK)	Q1-2021 01/Jan/21 31/Mar/21	Q1-2020 01/Jan/20 31/Mar/20	2020 01/Jan/20 31/Dec/20
Revenue	0	0	0
Other operating income	1,747	150	3,218
Other operating expenses	-4,001	-3,543	-20,644
Staff expenses	-1,907	-530	-4,616
Depreciation and amortisation	-40	0	-119
Operating loss before net financials	-4,201	-3,923	-22,161
Financial costs	-11	45	-25
Loss before tax	-4,212	-3,878	-22,186
Tax on loss for the period	869	790	4,726
Net loss for the period	-3,343	-3,088	-17,460
Other comprehensive income for the period, net of tax	0	0	0
<b>Total comprehensive income</b>	<b>-3,343</b>	<b>-3,088</b>	<b>-17,460</b>



# BALANCE SHEET

Balance Sheet (‘000 DKK)	Q1-2021 31/Mar/21	Q1-2020 31/Mar/20	2020 31/Dec/20
<b>Assets</b>			
Aquired patents	378	378	378
Right of use assets	171	0	211
Deposit	54	12	54
Total non-current assets	603	390	643
Tax receivables	5,595	2,843	4,726
Other receivables	544	237	554
Prepayments	115	128	182
Cash at bank	3,514	11,031	10,637
Total current assets	9,768	14,239	16,099
<b>Total assets</b>	<b>10,371</b>	<b>14,629</b>	<b>16,742</b>
<b>Equity and liabilities</b>			
<b>Equity</b>			
Share capital	1,053	946	1,053
Share premium	0	0	0
Retained earnings	16	11,917	3,358
Total equity	1,069	12,863	4,411
<b>Liabilities</b>			
Lease liabilities	14	0	57
Total non-current liabilities	14	0	57
Convertible loan	0	0	0
Lease liabilities	164	0	161
Trade payables	2,941	1,766	4,183
Deferred income	6,183	0	7,930
Total current liabilities	9,288	1,766	12,274
Total liabilities	9,302	1,766	12,331
<b>Total equity and liabilities</b>	<b>10,371</b>	<b>14,629</b>	<b>16,742</b>

# STATEMENT OF CHANGES IN EQUITY

<b>Change in Equity: Q1-21</b> ( ' 000 DKK)	Share-capital	Share Premium	Retained earnings	Shareholders equity
01/Jan/21	1,053		3,358	4,411
Paid in capital				
Capital contribution				
Costs relating to contribution				
Employee share schemes - value of employee services				
Net result Q1-21			-3,343	-3,343
Rounding difference			1	1
31/Mar/21	1,053		16	1,069
<b>Change in Equity: Q1-20</b> ( ' 000 DKK)	Share-capital	Share Premium	Retained earnings	Shareholders equity
01/Jan/20	722		3,820	4,542
Paid in capital	223	11,378		11,601
Capital contribution				
Costs relating to contribution		-192		-192
Net result Q1-20			-3,088	-3,088
Transfer				
Rounding difference				
31/Mar/20	945	11,186	732	12,863
<b>Change in Equity: 2020</b> ( ' 000 DKK)	Share-capital	Share Premium	Retained earnings	Shareholders equity
01/Jan/20	722		3,820	4,542
Paid in capital	331	17,665		17,996
Capital contribution				
Costs relating to contribution		-702		-702
Employee share schemes - value of employee services			35	35
Net result 2020			-17,460	-17,460
31/Dec/20	1,053	16,963	-13,605	4,411

# CASH FLOW STATEMENT

Cash flow (‘000 DKK)	Q1-2021 01/Jan/21 31/Mar/21	Q1-2020 01/Jan/20 31/Mar/20	2020 01/Jan/20 31/Dec/20
<b>Loss before tax</b>	-4,212	-3,878	-22,186
Financial expenses, reversed	11	-45	25
Change in working capital	-2,912	1,158	11,133
Depreciation and amortisation	40		119
Adjustment for non-cash employee benefits expense - share-based payments			35
Cash flow from operating activities before net financials	-7,073	-2,765	-10,874
Financial expenses net, paid	-11	45	-25
Tax credit paid out			2,053
Cash flow from operating activities	-7,084	-2,720	-8,846
<b>Cash flow from investing activities</b>			-42
Cash capital increase		11,601	17,996
Contribution			
Principalelements of lease payments	-39		-112
Convertible loan			
Transaction cost, cash capital increase		-194	-703
<b>Cash flow from financing activities</b>	-39	11,407	17,181
<b>Total cash flow from the period</b>	-7,123	8,687	8,293
Cash, beginning of the period	10,637	2,344	2,344
<b>Cash, end of the period</b>	<b>3,514</b>	<b>11,031</b>	<b>10,637</b>

LAST PAGE