

**INTERIM REPORT**  
**JANUARY - MARCH, 2019**

**Q1**

**INCREASE SURGICAL PRECISION STARTING  
BY LIGHTING UP THE CANCER**

**2019**

**FluoGuide's innovative solution reduces suffering for the cancer patients and increases the likelihood of cure as well as reduces costs for the health care system**

**FluoGuide**

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**"I am very pleased that we are now more than 1,000 shareholders working together to transform cancer surgery by lighting up the cancer for the benefit of patients and society in general. We have initiated the critical development activities needed for announcing the first clinical result for FG001 in second half of 2020 as planned."**

**Morten Albrechtsen**  
CEO FluoGuide A/S

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# SUMMARY

## The Board of Directors and CEO of FluoGuide hereby publish the Q1 report of 2019

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.

FluoGuide was formed on 30 January 2018 but had very limited business activities during its first fiscal year 2018. Amount within brackets corresponds to comparable period in the previous year.

(DKK)	Q1	Q1
	01/Jan/2019 31/Mar/2019	30/Jan/2018 31/Mar/2018
Net Revenue	0	0
Operating result	-442	0
Net result	-953	0
Cash and bank	4,717	1
<i>Result per share* (DKK)</i>	-0.20	0.00
<i>Solidity** (%)</i>	-10%	100%

## DEFINITIONS

**\*Result per share (DKK per share):** Operating result divided by the average number of shares during the period. Total number of shares as of 31 March 2019, amounted to 4,000,000 (105,500). Average number of shares during Q1 2019 amounted to 4,733,333 (105,500). Please observe that the Company has conducted a capital raise in April 2019 and that an additional 3,224,274 shares have been issued after the period.

**\*\*Solidity:** Equity divided by total capital.

## HIGHLIGHTS DURING Q1

- FluoGuide announces its ambition to be listed at Spotlight Stock Market and that the Company is preparing an IPO during Q2 2019.
- FluoGuide receives a preliminary approval to be listed at Spotlight Stock Market under the condition that the Company reaches the minimum limit in the upcoming IPO and that the Company receives a sufficient number of shareholders.

## HIGHLIGHTS AFTER Q1

- FluoGuide conducts a successful IPO that initially provides the Company approx. DKK 15.9 million and more than 1,000 new shareholders.
- The trading in FluoGuide's shares and warrants commences at Spotlight Stock Market.

# CEO HAS THE FLOOR

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Not even a month has passed since FluoGuide's very successful IPO and listing at Spotlight Stock Market. The journey of FluoGuide has only started and I want to start by once again thanking all shareholders that have chosen to be part of our journey and believe in our exciting technology that can transform cancer surgery. Below follows some of my thoughts on the FluoGuide case and our upcoming activities.

As you all know, cancer is a disease that affects everyone, and surgery is a cornerstone in cancer treatment. The challenge is to distinguish the normal tissue from the cancer tissue. FluoGuide increases the surgical precision, which reduces the suffering for patients and increases the likelihood of cure. Initially, we increase the surgical precision by lighting up the cancer with our first product FG001, but FluoGuide's products have a potential beyond cancer surgery. Today, robotic assisted surgery is rapidly expanding, and it will likely move towards more automation, which will be accelerated by guidance. In many ways, we believe that our technology will also enable further automation of robotic surgery in the future.

Following the successful IPO, we have now secured the proceeds needed to deliver our milestones until the end of first half of 2020, when we can be provided additional capital through the exercise of the publicly traded warrants of series TO 1 that was issued in connection with the IPO. We have since the IPO focused on starting the development activities for FG001. Our view is not only to reach a fast result of the first clinical trial but also to reach broad clinical use as fast as possible to the benefit of patients and society. We will maintain a low burn-rate to provide maximum flexibility on the development of FG001, which is our current main focus.



Morten Albrechtsen - CEO, FluoGuide A/S

During the quarter, we have looked at several high-quality manufactures for FG001, and we remain confident that we will deliver our promised milestones regarding the FG001 development. Partner search and discussions have also been initiated as it is important for us to understand how to best possible structure an agreement ahead of committing to any commercial partners. This is a focus area for us during the next quarters, and we believe that it will prepare FluoGuide for a favorable position when having obtained the first result from the proof-of-concept clinical study with FG001 in second half of 2020.

We are happy to tell that we will deploy a Q&A section on our website that will be available to the market. The objective is to be transparent towards investors and through the Q&A section, we will keep shareholders' questions and our answers publicly available. Please feel free to ask us questions concerning our business, products and objectives and we will collect them and publish the answers in the Q&A.

As a summary, FluoGuide has a very exciting news pipeline with many value driving activities during the upcoming quarters. The route to approval of our first product FG001 is well defined and associated with low risk compared to regular drug development. The first results from our planned proof-of-concept study are planned to be available during the first half of 2020 and the top-line results from the study is expected in the second half of 2020. The market launch is planned in a first country in 2022/2023.

We look forward to our upcoming journey, where we improve the precision in cancer surgery!



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Morten Albrechtsen - CEO, FluoGuide A/S



# FLUOGUIDE

**FluoGuide increases surgical precision starting out by lighting up the cancer. The FluoGuide technology is explained in a video that can be watched [here](#).**

## **FLUOGUIDE DEVELOPS INNOVATIVE MEDICAL PRODUCTS FOR INCREASING THE SURGICAL PRECISION - INTELLIGENT SURGICAL TARGETING**

FluoGuide's first product FG001 lights up the cancer and its invasive growth into the surrounding tissue. FG001 is expected to reduce suffering for the patients and increase the likelihood of their cure. It can also reduce costs for the health care system to the benefit of society. FluoGuide focuses on demonstrating the effect of FG001 in patients by conducting a human proof-of-concept clinical trial and announce the first result of this study during the first half of 2020. However, the potential of FluoGuide goes far beyond FG001 and cancer surgery, and FluoGuide will explore this further during 2019.

## **PIPELINE**

FluoGuide intends to expand its portfolio of products and the Company expects to initiate formal development of a second product after FG001 no later than at completion of the proof-of-concept study with FG001. The Danish Innovationsfonden has awarded a Grand Solution grant with the title: "FluoGuide: Optical probe to guide cancer surgeons". FluoGuide's Head of Scientific Advisory Board, Andreas Kjaer, is the project leader of the grant. It will run until the end of 2021 with a total of EUR 1.39 million being allocated to its work. FluoGuide has a first right to new inventions from this grant within its field.

## **PARTNERSHIPS**

In parallel with the FG001 development, FluoGuide will explore commercial partnerships. FluoGuide will finance the development of FG001 until the Company has completed the proof-of-concept clinical trial. The Company thereafter will consider entering into a commercial partnership to accelerate the full potential of FG001. Partnerships might also be formed with companies developing surgical equipment who could benefit from the launch of FluoGuide's products.

## **MARKET FOR SURGERY**

The market for surgery is huge and approximately 5% of the GDP (gross domestic product) is spent on surgery in the USA and Europe. The target groups are hospitals and surgeons. FluoGuide's products will be used in hospitals and paid for by the hospital's insurance and/or governments as well as patients. FluoGuide's customers are therefore highly concentrated why the cost of sales is attractive for serving some of the customers directly by FluoGuide.

## **PATENTS**

FluoGuide owns the IPR (WO/2016/041558A1, "uPAR targeting peptide for use in peroperative optical imaging of invasive cancer"). The patent relates to a novel conjugate that binds to the cell surface receptor urokinase-type plasminogen activator receptor (uPAR). More specifically the conjugate is based on a fluorescence labeled targeting molecule useful as a diagnostic probe binding to the surfaces of cells expressing uPAR. The invention is capable of carrying a suitable detectable and imageable label that will allow for clear tumor delineation both in vitro and in vivo. This renders the surgical resection of tumors to a higher quality.

- PATENT NAME: uPAR targeting peptide for use in peroperative optical imaging of invasive cancer
- PATENT NUMBER: WO/2016/041558A1
- TYPE: Pending being Issued (issued in USA)
- FILED: 17/Sep/2014
- EXPIRES: 16/Sep/2034
- OWNER: FluoGuide A/S



# FG001

**FG001 is an innovative and patentable product that lights up the cancer and its invasive growth into the surrounding tissue.**

## **UPAR IS A PERFECT TARGET TO DELINEATE CANCER FROM NORMAL TISSUE**

FluoGuide utilizes the fact that cancer cells overexpress uPAR and has developed a fluorescing molecule that binds to uPAR – FG001. It binds to cells expressing uPAR, which is a protein present on the surface of the tumor. Cancer cells extensively express uPAR and is directly correlated to the aggressiveness of the cancer. Even more importantly it is in particular expressed in the aggressive invasive front of the cancer, which means that it is perfect to delineate the cancer.

## **SWITCH TO FLUORESCENT LIGHT – AND SEE THE ENTIRE TUMOR**

FG001 is the first product from FluoGuide, which lights up the cancer and its invasive growth into the surrounding tissue. It helps the surgeon to remove the entire tumor during surgery and increases the chance for complete cure of the patient. The task for the surgeon is simply to "turn the lights on and see the entire tumor". The solution results in the surgeon not having to cut more tissue than necessary and it also reduces the risk of leaving behind cancer tissue and local metastasis in the body. This reduces suffering for the patient and increases the likelihood of cure as well as reducing costs for the health care system.

## **A GOOD FIT TO THE CURRENT WORK FLOW**

FG001 is injected into a vein of the patient during anaesthesia and therefore fits into the workflow at the hospital when conducting a surgery. Further, the present equipment in the surgical operating room is available and prepared to utilize FG001. FG001 is therefore equipment independent, which means that surgeons are not restricted by which equipment is available at the hospital.

## **FG001 HAS SUCCESSFULLY BEEN TESTED IN PRECLINICAL STUDIES**

One preclinical study was designed similar to the planned clinical Phase IIb/III study needed for approval. In this recently performed non-human preclinical study on eight subjects, additional metastasis was found in four of the eight subjects using FG001 and fluorescent light. This means that in half (50 %) of the subjects, traditional white light surgery overlooked cancer tissue that was

identified by FG001. These results demonstrate the potential of FG001 to vastly improve the likelihood of performing radical surgery (removal of all cancer) and thereby improving outcome and survival.

Preclinical studies have confirmed the effect of FG001 in glioblastoma, pancreatic and head and neck cancers. As uPAR is extensively expressed in most aggressive cancer types including glioblastoma (aggressive brain cancer), breast cancer, as well as colorectal and pancreatic cancer, FG001 is expected to demonstrate a clinical benefit in all of these indications.

## **LIKELY TO BE WELL TOLERATED IN HUMANS**

FG001 is made of a targeting molecule linked to a fluorophore. Both the targeting molecule and the fluorophore have demonstrated to be well tolerated in humans in doses exceeding the anticipated doses of FG001. The targeting molecules used by FluoGuide are very well suited since they bind rapidly to cancer cells but quickly disappear from the systemic circulation.

Initially, FluoGuide's focus for FG001 is glioblastoma and breast cancer, but as FG001 has potential in several other cancer indications it is likely that FG001 will be evaluated in more indications. Glioblastoma is a high priority indication due to a high unmet medical need. Essentially all patients with glioblastoma have a cancer expressing uPAR. The marketing approval for FG001 will likely be limited to one indication why the Company is planning to focus on one indication for initial market launch of FG001.

## **EARLY COMMERCIALIZATION IS IMPORTANT FOR PATIENTS**

FluoGuide's ambition for FG001 is to initiate compassionate use sales (a treatment option that allows the use of an unapproved medicine because it is considered unethically not to) by the end of 2020 provided a positive result from the proof-of-concept study with FG001. FluoGuide considers a strong focus on early commercialization important.

# MARKET AND OBJECTIVES

## MARKET FOR FG001

FluoGuide is initially focusing on glioblastoma (brain tumor). A total of 60,000 patients are diagnosed with glioblastoma annually in the EU and USA and approximately 8-12 % of the patients are children. The prognosis for individuals with glioblastoma is very poor. Approximately 50 % of the patients die within 14 months and only 5 % are alive after five years from diagnosis.

Precise removal of glioblastoma tumors is very difficult and local recurrence is frequent. Since uPAR is also extensively expressed in other solid cancers, the Company has the ambition to expand its business to other solid tumors. The second priority indication is breast cancer but, in the future, also head and neck cancer, colorectal cancer, pancreas cancer and lung cancer. The ultimate prioritization between the different indications will be guided by clinical data to be generated with FG001.

## DEVELOPMENT OF FLUORESCENT TARGETING PRODUCTS

Active fluorescent targeting products requires the national health authority to approve the documentation of safety and efficacy before FluoGuide is allowed to commercialize its products broadly. FDA and EMA are responsible for granting such approval for USA and Europe, respectively. Active fluorescent targeting products are regulated by guidelines of pharmaceutical drugs (Medical Products), more specifically image agents.

## OPERATIVE OBJECTIVES

2019

H1

- Prepare toxicity testing on FG001
- Initiate partnering discussions
- CMC production partner decided
- Production process for FG001 established
- Formulation of FG001 developed
- Define FG002

H2

- Safety of FG001 confirmed in toxicity studies
- Prepare clinical trial application for proof-of-concept Phase I/IIa study on FG001
- Initiate regulatory discussions with national, European and/or US regulatory health care authority (e.g. EMA, FDA or DMA) on FG001

2020

H1

- Initiate clinical proof-of-concept Phase I/IIa study on FG001
- Initiate clinical study on second indication for FG001
- First result for proof-of-concept Phase I/IIa study on FG001 in first indication

H2

- Initiate phase III production in commercial scale of FG001
- Initiate planning of the Phase IIb/III study
- Establish compassionate use sales and/or partnering agreement of FG001
- Establish first commercial partnerships
- Initiate pre-clinical development of FG002
- Obtain result of second indication for FG001
- Define FG003

# FINANCIAL DEVELOPMENT

## OPERATING INCOME AND OPERATING RESULTS

Net revenue amounted to DKK 0 and the operating result was KDKK -953 (0) in Q1 2019. The operating result was as expected as the Company is currently conducting development activities.

## BALANCE SHEET AND SOLIDITY

The total equity at 31 March 2019 was KDKK -547 (1) as the operating result exceeded share capital, due to a not yet converted bridge loan. The conversion of the loan to share capital took place after the end of the first quarter 2019. The solidity as per 31 March 2019 was therefore also negative, -10% (100).

## CASH FLOW AND INVESTMENTS

The cashflow and investments were as expected. The total cash flow was KDKK 4,658 (1). There were no investments during the period.

## 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 per 1 January 2019 was 5,000,000 (105,500) and the total number of shares as per 31 March 2019, amounted to 4,000,000 (105,500). During Q1 2019, FluoGuide has conducted a split and made the Company public. The average number of shares during Q1 2019 amounted to 4,733,333 (105,500). Every share equals the same rights to the Company's assets and results. Please observe that the Company has conducted a capital raise after first quarter (April 2019) where additional 3,224,274 shares have been issued.

## WARRANTS

The warrants of series TO 1 in FluoGuide were listed at Spotlight Stock Market on 7 May 2019. The ticker is FLUO T01 and the ISIN code is DK0061138773. In total, there is a total of 1,074,758 outstanding warrants. Each warrant entitles the holder the right to subscribe for one (1) new share in FluoGuide at a subscription price of DKK 5.95 per share during the exercise period 16 April – 7 May 2020. The warrants can provide the Company a total of DKK 6,394,810.10 if all warrants are exercised.



# MISCELLANEOUS

## SHAREHOLDERS AFTER THE IPO

SHAREHOLDER	NUMBER OF SHARES	VOTES AND CAPITAL (%)
Life Science IVS*	2,124,891	29.4
Wexotec ApS**	1,487,394	20.6
Grethe Nørskov Rasmussen***	254,218	3.5
Arne Ferstad****	254,218	3.5
PME Holding ApS*****	112,577	1.6
Micaela Sjøkvist****	57,678	0.8
Shomit Ghose****	39,810	0.6
Others (> 1,000 shareholders)	2,893,488	40.0
<b>Total</b>	<b>7,224,274</b>	<b>100.00</b>

\* Life Science IVS is a wholly owned company by Board Member and Head of the Scientific Advisory Board Andreas Kjaer.

\*\* Wexotec ApS is a wholly owned company by CEO Morten Albrechtsen.

\*\*\* Management

\*\*\*\* Member of the Board of Directors

## FINANCIAL CALENDER

January - June 2019 (Q2):	30 August 2019
January - September 2019 (Q3):	30 November 2019
Year-end report 2019:	28 February 2020

## ACCOUNTING POLICY

The financial statements 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 2018.

## 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 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](http://www.fluoguide.com)

## AUDITOR'S REVIEW

The Q1 report has not been reviewed or audited by FluoGuide's auditor.

# SUBMISSION OF Q1 REPORT

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The Board of Directors hereby certify that the Q1 report provides a true and fair view of the Company's business.

**Copenhagen**  
**31 May 2019**  
**The Board of Directors**

# INCOME STATEMENT

('000 DKK)	01/Jan/2019 31/Mar/2019	30/Jan/2018 31/Mar/2018	30/Jan/2018 31/Dec/2018
<b>Revenue</b>	<b>0</b>	<b>0</b>	<b>0</b>
Other operating income	0	0	0
Other operating expenses	-442	0	-52
<b>Operating loss before net financials</b>	<b>-442</b>	<b>0</b>	<b>-52</b>
Financial costs	-551	0	-1
<b>Loss before tax</b>	<b>-953</b>	<b>0</b>	<b>-53</b>
Tax on loss for the period	0	0	0
<b>Net loss for the period</b>	<b>-953</b>	<b>0</b>	<b>-53</b>
Other comprehensive income for the period, net of tax	0	0	0
<b>Total comprehensive income</b>	<b>-953</b>	<b>0</b>	<b>-53</b>

# BALANCE SHEET

(’000 DKK)	31/Mar/2019	31/Mar/2018	31/Dec/2018
<b>ASSETS</b>			
Total non-current assets	0	0	0
Prepayments	512	0	16
Cash at bank	4,717	1	59
Total current assets	5,229	1	75
<b>TOTAL ASSETS</b>	<b>5,229</b>	<b>1</b>	<b>75</b>
<b>LIABILITIES AND EQUITY</b>			
Equity	400	1	50
Share capital	50	0	10
Retained earnings	-997	0	-53
<b>Total equity</b>	<b>-547</b>	<b>1</b>	<b>7</b>
<b>Short-term liabilities</b>			
Equity	4,801	0	0
Share capital	0	0	0
Retained earnings	975	0	68
<b>Total equity</b>	<b>5,776</b>	<b>0</b>	<b>75</b>
<b>Equity</b>	<b>5,776</b>	<b>1</b>	<b>75</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>5,229</b>	<b>1</b>	<b>75</b>

# CHANGE IN EQUITY

(’000 DKK)	Share capital	Share premium reserve	Transferred results	Total equity
<b>Equity per 01/Jan/2019</b>	<b>50</b>	<b>0</b>	<b>-43</b>	<b>7</b>
Paid in capital	350	50		400
Capital contribution				0
Costs relating to contribution				0
Net result			-953	-953
<b>Equity per 31/Mar/2019</b>	<b>400</b>	<b>50</b>	<b>-996</b>	<b>-547</b>
<b>Equity per 30/Jan/2018</b>	<b>1</b>			<b>1</b>
Capital contribution			64	64
Capital increase - conversion	49		-49	0
Costs relating to contribution			-5	-5
Net result			-53	-53
<b>Equity per 31/Dec/2018</b>	<b>50</b>	<b>0</b>	<b>-43</b>	<b>7</b>

# CASH FLOW ANALYSIS

('000 DKK)	01/Jan/2019 31/Mar/2019	30/Jan/2018 31/Mar/2018	30/Jan/2018 31/Dec/2018
<b>Loss before tax</b>	<b>-953</b>	<b>0</b>	<b>-53</b>
Financial expenses, reversed	551	0	1
Change in working capital	-141	0	52
<b>Cash flow from operating activities before net financials</b>	<b>-543</b>	<b>0</b>	<b>0</b>
Financial expenses paid	0	0	-1
<b>Cash flow from operating activities</b>	<b>-543</b>	<b>0</b>	<b>-1</b>
<b>Cash flow from investing activities</b>	<b>0</b>	<b>0</b>	<b>0</b>
Cash capital increase	400	1	1
Contribution	0	0	64
Convertible loan	4,801	0	0
Transaction cost, cash capital increase	0	0	-5
<b>Cash flow from financing activities</b>	<b>5,201</b>	<b>1</b>	<b>60</b>
<b>Total cash flow from the period</b>	<b>4,658</b>	<b>1</b>	<b>59</b>
Cash, beginning of the period	59	0	-
<b>Cash, end of the period</b>	<b>4,717</b>	<b>1</b>	<b>59</b>





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