

INTERIM REPORT

JANUARY 2019 - SEPTEMBER 2019

Q3


MAXIMIZING SURGICAL OUTCOME
BY INTELLIGENT TARGETING

2019

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

FluoGuide

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“I am very pleased that we now have established a supply chain for FG001 and that we have transferred the process to vendors who can manufacture it for human use. We have made the first larger scale batch in an amount that could serve early commercialization through compassionate use sale. This is according to plan which we consider great news and a major de-risking for first proof-of-concept results from a clinical study in 2020”

Grethe Nørskov Rasmussen
Chief Development Officer, FluoGuide A/S

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SUMMARY

The Board of Directors and CEO of FluoGuide hereby publish the Q3 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. Amounts within brackets corresponds to comparable period in the previous year.

FluoGuide had no revenue for the period and a negative result. The financial result for the period follows the plan outlined in the IPO prospectus and as expected for an early life science development company. It is the Board's opinion that FluoGuide - in contrast to many life science companies - has a relative short time to revenue from products.

Summary	Q3 2019	Q3 2018	Q1-Q3 2019	Q1-Q3 2018
	01/Jul/19	01/Jul/18	01/Jan/19	30/Jan/18
(KDKK)	30/Sep/19	30/Sep/18	30/Sep/19	30/Sep/18
Net Revenue	0	0	0	0
Operating result	-5.057	0	-6.842	0
Net result	-4.047	0	-6.540	0
Cash and bank	9.630	1	9.630	1
Result per share (DKK) ^{*)}	-0,56	0,00	-1,05	0,00
Solidity (%) ^{**)}	65%	100%	65%	100%

^{*)} **Result per share (DKK per share):** Operating result divided by the average number of shares during the period. There was no change to the number of shares during third quarter. Total average number of shares was equal to the total number of shares at the beginning of the period (1 July 2019), during the period and at the end of the period (30 September 2019), and amounted to 7,224,274 shares (105,500). The average number of shares for the period from 1 January 2019 to 30 September 2019 was 6,222,256 shares (105,500).

^{**)} **Solidity:** Total equity divided by total capital and liability.

HIGHLIGHTS DURING Q3

- FluoGuide announces registration of ownership to the key patent family. The patent is valid until 2034.
- The Company presented data at WMIC^{*)} confirming FG001's effect in guiding surgical removal of glioblastoma at different doses for use in first clinical study.
- A study demonstrating that FG001 helped to identify and remove local additional metastases in 50% of the subjects that were overlooked during the standard white light procedure was also presented at WMIC^{*)}

HIGHLIGHTS AFTER Q3

- First result of FG001 tested in pre-clinical safety studies
- Additional patent applications submitted, and patents granted
- Publication of the preclinical data of FG001 tested in pancreatic cancer presented at the WMIC in peer-review scientific paper
- FluoGuide holds presentations at Sedermeradagen (Stockholm) and Investordagen (Aalborg)

^{*)} World Molecular Imaging Congress, held in Montreal, 4-7 September 2019

CEO HAS THE FLOOR

We are continuing the work on maximizing surgical outcome through intelligent targeting and our main focus is to help patients with glioblastoma undergoing surgery by making FG001 available to the surgeons and the patients.

We had a busy third quarter of 2019 getting the development activities for FG001 up to speed to fulfill both short and long-term objectives. We also participated in the WMIC where important data were presented on FG001. There, FluoGuide had a chance to interact with other companies working in the field of image guided surgery, an important event for us.

I would like to take this opportunity to comment on the development status of FG001 and the important data presented at WMIC for FG001.

The development of FG001 is advancing according to plan

The supply chain for FG001 has been established to support the first clinical study in humans and the process for FG001 manufacturing was successfully transferred to vendors who can make it to a quality needed for human use (Good Manufacturing Practices, GMP). This is good news and a major de-risking for a positive proof-of-concept clinical result in patients with glioblastoma undergoing surgery. Also, we were successful in making the first larger scale batch in an amount that could serve early commercialization through compassionate use sale, ahead of plan.

We initiated the first study in the pre-clinical safety program which we need to conduct in order to establish the safety profile of FG001. This is required before submission of the application for the first clinical study in humans. It is a successive process with several separate studies proposed in regulatory guidelines.

The species selection studies are ongoing, and we expect the result in December 2019. FG001 is designed to bind to human uPAR and before testing FG001 in humans we need to demonstrate that it is safe in a pre-clinical study in a relevant species. uPAR differs from species to species and it is important that we do our outmost to prove FG001's binding to uPAR in the species to be used in the main pre-clinical safety study. This is important for patient safety and for minimizing the risk of regulatory delays in obtaining approval for starting the first clinical study.

The result of the proof-of-concept study in patients with glioblastoma undergoing surgery is anticipated no later than Q3 2020. The delivery time is longer for some species than others and slots have been preliminary reserved at vendors specialized in doing such pre-clinical

studies for the species with the longest delivery time. The budget and all other milestones remain unchanged regardless a possible longer delivery time for the selected species.

Great data presented at WMIC

During the third quarter of 2019 we have been able to present data from two important studies with FG001 that were presented at the WMIC.

The first study was a repetition of FG001's effect in glioblastoma and its effect was reconfirmed. The study was very important as it in addition tested different doses which will guide the dose to be used in the proof-of-concept study in patients with glioblastoma undergoing surgery. A new equipment (VisionSense, Medtronic) was also tested in this study and again demonstrated the important feature of FG001 to be equipment independent as it works well with equipment used in the clinics today.

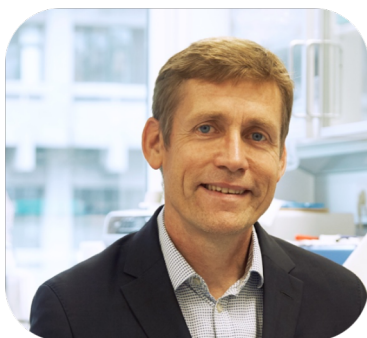
The other study was conducted in pancreatic cancer with yet another equipment (da Vinci robot from Intuitive Surgery). The importance of this study is that the design is similar to upcoming human clinical studies; human cancer removed by a surgeon who operates on humans, using standard equipment. The study demonstrated that FG001 helped identify and remove local additional metastases in 50% of the subjects that were overlooked during the standard white light procedure. Additionally, the study underlined the importance of uPAR targeted products for a broad range of different cancer types.

Other events in third quarter

We are very pleased that we were able to announce the registration of ownership to the key patent family, which was acquired by FluoGuide prior to the IPO in April and May 2019. The patent family is valid until 2034.

We did not have any revenue in the third quarter of 2019, which is completely in line with the plan that was outlined in the IPO prospectus and is conventional from an early stage life science company. Our focus remains on preparing FG001 for the first clinical study and to bring the product to the market. We have a clear plan going forward and follow the path outlined in the IPO prospectus.

I would like to thank the shareholders for their continuing trust and our dedicated team for their hard work. We will continue the work bringing FG001 to the market and look forward to some exiting quarters ahead of us.



"We are very happy to see another series of promising data now obtained with FG001 and demonstrating the relevance of uPAR target product for a number of different cancer types"

Morten Albrechtsen - CEO, FluoGuide A/S

FG001

FluoGuide provides solutions for maximizing surgical outcome through intelligent targeting.

FluoGuide A/S (Spotlight Stock Market: FLUO) provides solutions for maximizing surgical outcome through intelligent targeting. FluoGuide's first product, FG001, improves precision in cancer surgery by lighting up the cancer and its invasive growth into the surrounding tissue. FG001 is made of a cancer targeting molecule linked to a fluorophore. FluoGuide's products are expected to reduce the suffering of patients and increase the likelihood of cure. They can also reduce costs for the health care system and thus benefit society. Currently, FluoGuide focuses on demonstrating the effect of FG001 in patients by conducting a human proof-of-concept clinical study.

FG001

FG001, FluoGuide's first product, lights up the cancer and its invasive growth into the surrounding tissue. It helps the surgeon 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 helps surgeons remove a minimal amount of normal tissue while also reducing the risk of leaving cancer tissue behind. This reduces the suffering of the patient and increases the likelihood of cure, and also reduces costs for the health care system. FG001 is currently prepared for a proof-of-concept clinical study (Phase I/IIa).

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

How it works

FG001 is made of a cancer targeting molecule linked to a fluorophore. The targeting molecules bind to the urokinase-type plasminogen activator receptor ("uPAR"), which is extensively expressed by cancer cells. FluoGuide utilizes this fact in the development of FG001 – a fluorescing molecule that binds to uPAR on the cancer cells.

Fits into current work flow

FG001 is injected into a vein of the patient during anesthesia, and therefore fits into the hospital workflow when surgery is performed. Furthermore, the use of FG001 is equipment independent, which means that surgeons are not restricted by available equipment; the present equipment in the surgical operating room remains available and is compatible with FG001.

A product with significant potential

FluoGuide's focus for the initial clinical development of FG001 is glioblastoma (aggressive form of brain cancer) even though the potential of the product goes beyond a single indication. Glioblastoma has high priority due to its large unmet medical need. Essentially every patient with glioblastoma has a cancer expressing uPAR.

Preclinical studies have confirmed the effect of FG001 in glioblastoma, pancreatic cancer and head and neck cancer. However, as uPAR is extensively expressed in most aggressive cancer types, also including breast cancer and colorectal cancer, FG001 has the potential to demonstrate a clinical benefit in more indications than those mentioned.

FG001's route to the market

Active fluorescent targeting products require that the national health authorities approve the documentation of safety and efficacy. Broad commercialization of FluoGuide's products is contingent on such approval, which in USA and Europe is granted by FDA and EMA, respectively. Active fluorescent targeting products are regulated by guidelines for pharmaceutical drugs (Medicinal Products).

Although both the targeting molecule and the fluorophore have demonstrated to be well tolerated in humans, FluoGuide has initiated the production of high quality FG001 in a step wise process and in parallel initiated the documentation of the safety of before administering it to humans in a clinical study.

Early commercialization is important for patients

FluoGuide's ambition for FG001 is to initiate compassionate use sales (a treatment option where a not yet approved medicine is allowed to be used because withholding it would be considered unethical) by the end of 2020, provided that a positive result is obtained from the proof-of-concept clinical study with FG001. FluoGuide considers early commercialization to be of utmost importance, since FG001 has the potential of improving the surgical outcome for thousands of patients with cancer every year.

Patent protection

The patent family protecting FG001 is owned by FluoGuide and is issued in the USA. The protection will last until 2034.

PATENT NAME: uPAR targeting peptide for use in peroperative optical imaging of invasive cancer
PATENT NUMBER: WO/2016/041558A1
TYPE: Issued in USA and pending in EU.
FILED: 17/Sep/2014
EXPIRES: 16/Sep/2034
OWNER: FluoGuide A/S

The market for FG001

FluoGuide is initially focusing on glioblastoma (an aggressive form of brain cancer). 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 five years after the diagnosis. Precise removal of glioblastoma tumors is very difficult and local recurrence is frequent.

Since uPAR is also extensively expressed in other solid cancers, FluoGuide has the ambition to expand its business to other solid cancers. Several malignant cancers are treated primarily with surgical tumor resections, and in e.g. the UK approximately 45% of all patients undergo surgery as primary treatment. This underlines the significant potential of FG001, as its potential goes far beyond glioblastoma. FG001 could be used for other types of cancer indications as well, enhancing the effectiveness of surgery for cancer indications such as breast or colorectal cancer which to a high degree are treated with surgical tumor resections. FluoGuide sees a huge potential for FG001 in improving the lives of patients with cancer.

FluoGuide

FluoGuide A/S provides solutions for maximizing surgical outcome through intelligent targeting. FG001 is the lead product of FluoGuide but the potential of FluoGuide goes beyond FG001 and cancer surgery.

**uPAR – broadly expressed, highly selective
and perfectly delineating cancer**

Robust scientific foundation on uPAR - a perfect target to guide surgical removal of cancer

uPAR is a perfect target to delineate cancer from normal tissue. It is a protein present on the surface of cancer cells. uPAR is directly correlated to the aggressiveness of the cancer. More importantly, uPAR is particularly expressed in the aggressive invasive front of the cancer – the more uPAR, the more invasive the cancer. This means that lighting up cells expressing uPAR is a perfect help for the surgeon to delineate the cancer from normal tissue.

uPAR is extensively expressed in most solid cancers, including glioblastoma, breast, colorectal and lung cancer. uPAR is a highly relevant target for more than 50% of all cancers undergoing surgical removal, and it is therefore an attractive target for guiding the surgeons in removal of several types of cancer, maximizing the surgical outcome for patients and society.

Pipeline

The Innovation Fund Denmark 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 which will run until the end of 2021, with a total of EUR 1.39 million being allocated to the project. FluoGuide has a first right to new inventions arising from the project within its field.

Partnerships

In parallel with the development of FG001, FluoGuide will explore commercial partnerships to accelerate its value creation. FluoGuide will finance the development of FG001 until completion of the proof-of-concept clinical study. The Company thereafter plans to enter into a commercial partnership securing, at least partly, funding for further development and to unfold the full potential of FG001. Partnerships are also being investigated to explore new uses of FG001, new products, and commercialization in selected geographic regions.

Market for maximizing surgical outcome

The market for surgery is huge and surgical costs account for more than 5% of the GDP (Gross Domestic Product) in the USA and Europe. FluoGuide’s products will be used in hospitals and paid for by patients’ insurance and/or by governments through hospitals, as well as by patients themselves. FluoGuide’s customers are hospitals and surgeons. The customers are highly concentrated and therefore provide an opportunity to be served directly by FluoGuide for selected geographic regions.

The team

FluoGuide has a strong management team representing the entire value chain, from discovery of imaging products and development of health care products to international commercialization of health care solutions.

FluoGuide has an experienced Board of Directors representing diverse skill sets and networks to guide FluoGuide’s ambitious value creation.

Outlook for FluoGuide

FluoGuide’s first product – FG001 – can help 60,000 patients with glioblastoma in USA and Europe alone.

uPAR targeted products for guiding cancer surgery can help many patients with cancer undergoing surgery every year. Realizing this huge potential, FluoGuide works on accelerating the development of FG001 in indications beyond glioblastoma as well as developing even brighter and more selective products targeting uPAR, in order to develop FluoGuide into a leading position in guiding cancer surgery.

**uPAR targeting – a potential help for more
than 3,000,000 patients undergoing surgery for
removal of cancer every year**

FINANCIAL DEVELOPMENT

OPERATING INCOME AND OPERATING RESULTS

The operating income and result for Q3 of 2019 were as expected. Net revenue amounted to DKK 0 (0) and the operating result was KDKK -5,057(0) in Q3 2019. The operating result was as expected as the Company is currently conducting development activities.

BALANCE SHEET AND SOLIDITY

The total equity at 30 September 2019 was KDKK 7,656 (1). The solidity as per 30 September 2019 was 65% (100).

CASH FLOW AND INVESTMENTS

The total cash flow was KDKK -1,581 (1) in Q3 2019. 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 30 September 2019 and during third quarter, amounted to 7,224,274 (105,500). Hence the average number of shares during Q3 2019 amounted to 7,224,274 (105,500). Every share equals the same rights to the Company's assets and results.

WARRANTS

The warrants of series TO 1 in FluoGuide were listed at Spotlight Stock Market on 7 May 2019. The ticker is FLUO TO1 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 (Shares)	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 shareholders	2.893.488	40,1%
TOTAL	7.224.274	100,0%

* 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,

***** PME Holding ApS is a wholly owned company by Board member Peter Mørch Eriksen.

FINANCIAL CALENDER

Year-end report 2019: 28 February 2020

ACCOUNTING POLICY

The financial statements for 2018 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.

This interim report has been prepared using unchanged accounting policies for recognition and measurement as the Annual Report for 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

AUDITOR'S REVIEW

The Q3 report has not been reviewed or audited by FluoGuide's auditor.

SUBMISSION OF Q3 REPORT

The Board of Directors hereby certify that the Q3 report provides a true and fair view of the Company's business.

Copenhagen
29 November 2019
The Board of Directors

INCOME STATEMENT

Income Statement	Q3 2019	Q3 2018	Q1-Q3 2019	Q1-Q3 2018	2018
('000 DKK)	01/Jul/19 30/Sep/19	01/Jul/18 30/Sep/18	01/Jan/19 30/Sep/19	30/Jan/18 30/Sep/18	01/Jan/18 31/Dec/18
Revenue	0	0	0	0	0
Other operating income	0	0	0	0	0
Other operating expenses	-4.657	0	-5.523	0	-52
Staff expenses	-400	0	-1.319	0	0
Operating loss before net financials	-5.057	0	-6.842	0	-52
Financial costs	-48	0	-1.066	0	-1
Loss before tax	-5.105	0	-7.908	0	-53
Tax on loss for the period	1.058	0	1.368	0	0
Net loss for the period	-4.047	0	-6.540	0	-53
Other comprehensive income for the period, net of tax	0	0	0	0	0
Total comprehensive income	-4.047	0	-6.540	0	-53

BALANCE SHEET

Balance Sheet ('000 DKK)	30/Sep/19	30/Sep/18	31/Dec/18
Assets			
Total non-current assets	12	0	0
Tax receivables	1.368	0	0
Other receivables	37	0	0
Prepayments	753	0	17
Cash at bank	9.630	1	59
Total current assets	11.788	1	75
Total assets	11.799	1	75
Equity and liabilities			
Equity			
Share capital	722	0	50
Share premium	13.516	1	0
Retained earnings	-6.583	0	-43
Total equity	7.656	1	7
Liabilities			
Total long term liabilities	0	0	0
Convertible loan	0	0	0
Trade payables	4.026	0	68
Other payables	118	0	0
Total current liabilities (short-term)	4.144	0	68
Total liabilities	4.144	0	68
Total equity and liabilities	11.799	1	75

CHANGE IN EQUITY

Change in Equity: Q3 2019 (KDKK)	Share-capital	Share Premium	Retained earnings	Shareholders equity
01/Jul/19	722	13.516	-2.536	11.703
				0
Paid in capital				0
Capital contribution				0
Costs relating to contribution				0
Net result Q3			-4.047	-4.047
30/Sep/19	722	13.516	-6.583	7.656

Change in Equity: Q3 2018 (KDKK)	Share-capital	Share Premium	Retained earnings	Shareholders equity
01/Jul/18	1	0	0	1
				0
Paid in capital	0	0		0
Capital contribution				0
Costs relating to contribution		0		0
Net result Q3			0	0
30/Sep/18	1	0	0	1

Change in Equity: Q1-Q3 2019 (KDKK)	Share-capital	Share Premium	Retained earnings	Shareholders equity
01/Jan/19	50	0	-43	7
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 Q1-3			-6.540	-6.540
30/sep/19	722	13.516	-6.583	7.656

Change in Equity: Q1-Q3 2018 (KDKK)	Share-capital	Share Premium	Retained earnings	Shareholders equity
30/Jan/18	0	0	0	0
Paid in capital	1			1
Capital contribution				0
Costs relating to contribution				0
Net result Q1-3			0	0
30/sep/18	1	0	0	1

Change in Equity: 2018 (KDKK)	Share-capital	Share Premium	Retained earnings	Shareholders equity
30/Jan/18	0	0	0	0
Paid in capital	50			50
Capital contribution	0		15	15
Costs relating to contribution			-5	-5
Net result 2018			-53	-53
31/Dec/18	50	0	-43	7

CASH FLOW ANALYSIS

Cash flow (‘000 DKK)	Q3 2019 01/Jul/19 30/Sep/19	Q3 2018 01/Jul/18 30/Sep/18	Q1-Q3 2019 01/Jan/19 30/Sep/19	Q1-Q3 2018 30/Jan/18 30/Sep/18	2018 01/Jan/18 31/Dec/18
Loss before tax	-5.105	0	-7.908	0	-53
Financial expenses, reversed	48	0	1.066	0	1
Change in working capital	3.475		3.302		52
Cash flow from operating activities before net financials	-1.581	0	-3.540	0	0
Financial expenses paid	-48		-106		-1
Cash flow from operating activities	-1.630	0	-3.646	0	-1
Cash flow from investing activities	0		-12		
Cash capital increase	0	0	10.599	1	1
Contribution					64
Convertible loan			4.801		
Transaction cost, cash capital increase			-2.172		-5
Cash flow from financing activities	0	0	13.228	1	60
Total cash flow from the period	-1.630	0	9.571	1	59
Cash, beginning of the period	11.259	1	59	0	
Cash, end of the period	9.630	1	9.630	1	59



FluoGuide

www.fluoguide.com