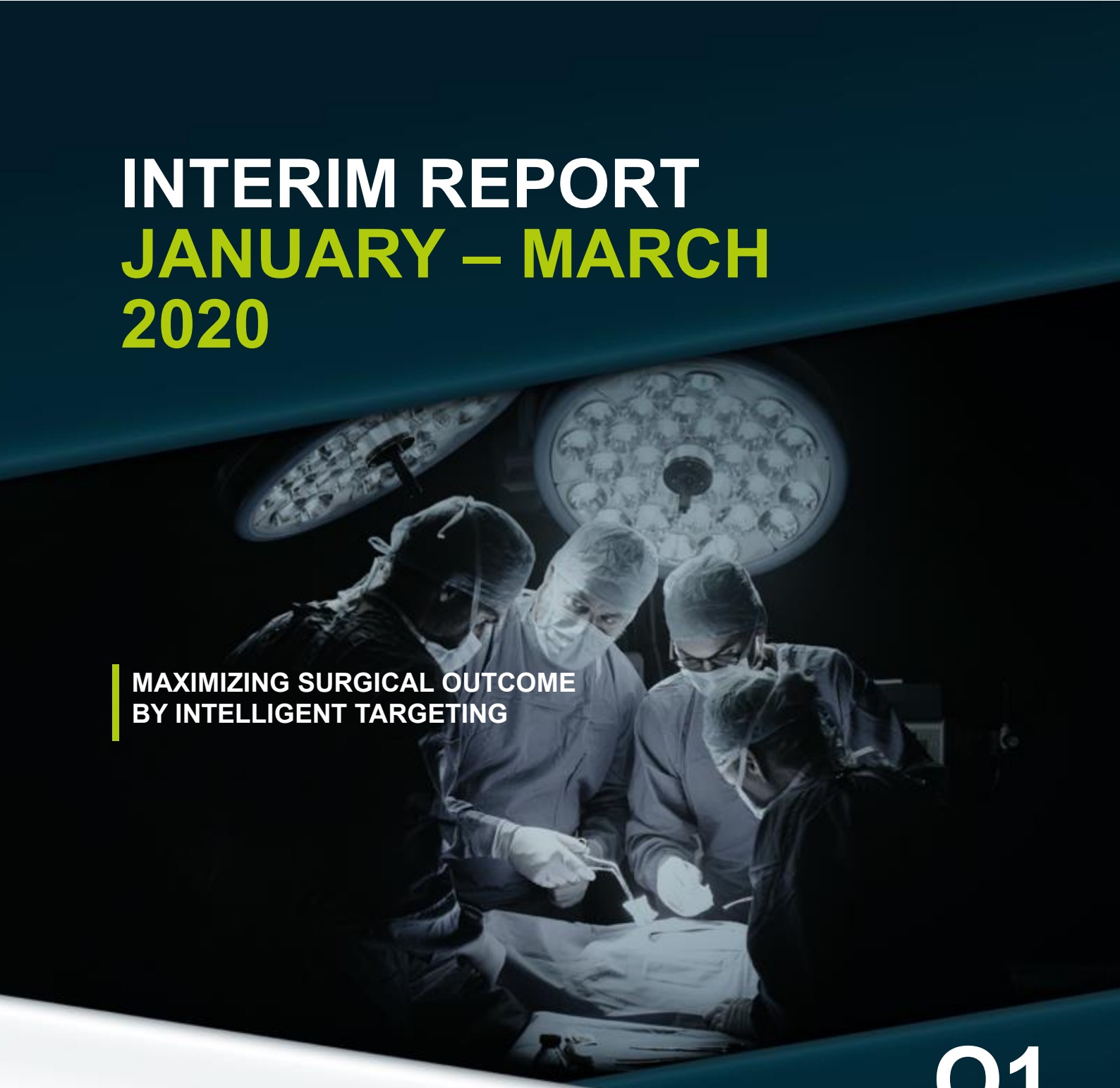
INTERIM REPORT
JANUARY – MARCH 2020

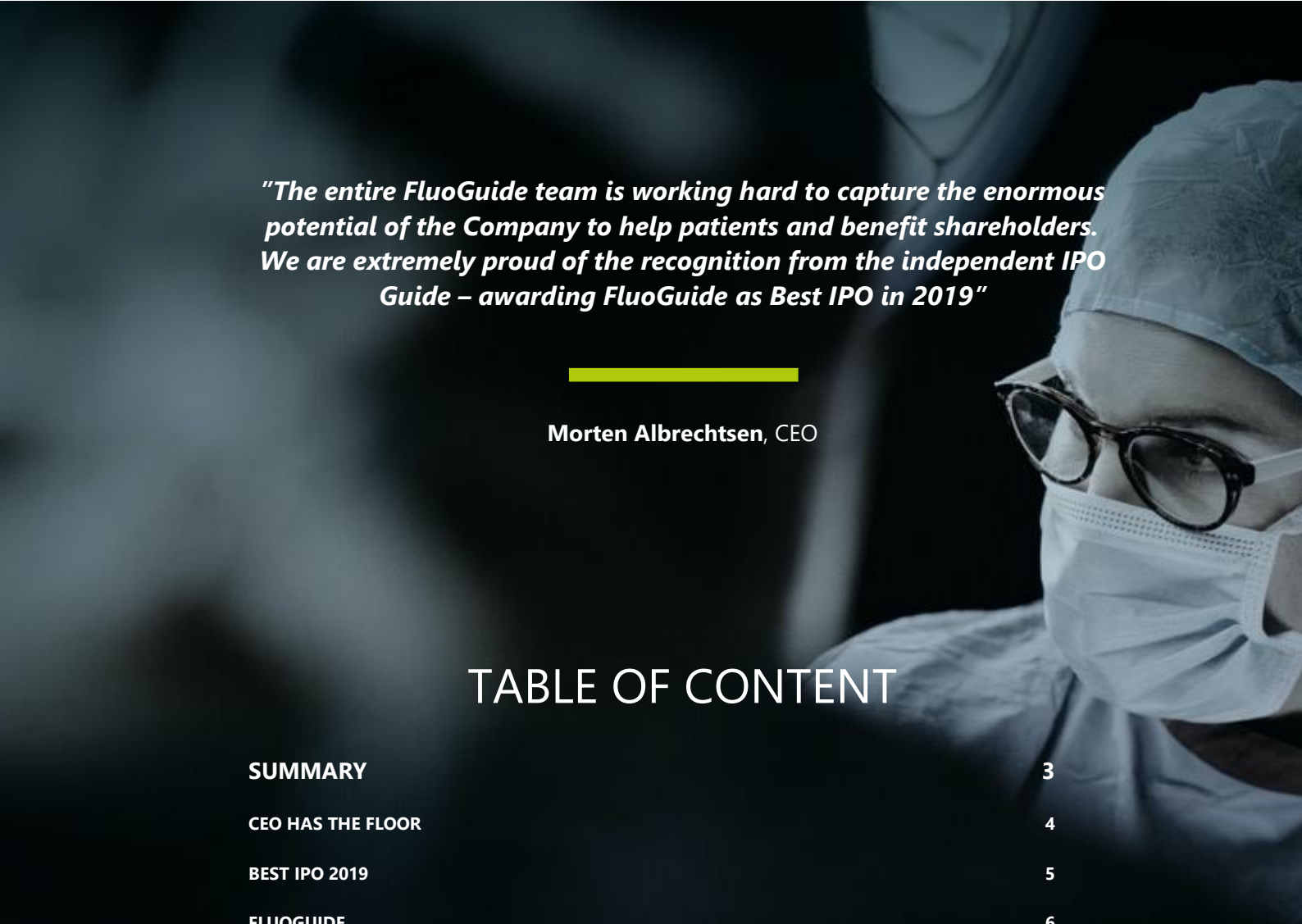


MAXIMIZING SURGICAL OUTCOME BY INTELLIGENT TARGETING

Q1

FluoGuide

årets IPO affärsvärlden ·2019·



"The entire FluoGuide team is working hard to capture the enormous potential of the Company to help patients and benefit shareholders. We are extremely proud of the recognition from the independent IPO Guide – awarding FluoGuide as Best IPO in 2019"

Morten Albrechtsen, CEO

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SUMMARY

The Board of Directors and CEO of FluoGuide publish the 2020 first quarter report
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 operating loss. 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 (KDKK)	Q1 2020 01/Jan/20 31/Mar/20	Q1 2019 01/Jan/19 31/Mar/19	2019 01/Jan/19 31/Dec/19
Net Revenue	0	0	0
Operating result	-3,923	-442	-10,644
Net result	-3,088	-953	-9,653
Cash and bank	11,031	4,717	2,344
Result per share (DKK) *)	*-0.38*	*-0.20*	*-1.49*
Solidity (%) **)	*88%*	*-10%*	*87%*

**) 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 2020 totaled 9,455,268 shares (4,000,000). The average number of shares for the first quarter 2020 was 8,057,832 shares (4,733,333). The average number of shares for the period from 1 January 2019 to 31 December 2019 was 6,475,565 shares (688,179). Note that the number of shares in the Company after the end of the period, through exercise of the warrants serie TO 1, has increased to 10,555,268 shares registered on 18 May 2020.*

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

HIGHLIGHTS DURING Q1

- European patent granted "uPAR targeting peptide for use in peroperative optical imaging of invasive cancer" (EP3193945)
- Excellent results published on FluoGuide's FG001 guided surgical removal of cancer
- Safety study initiated for FG001
- Directed share issue strengthened FluoGuide's ownership, and is expected to shorten the time to market for FG001
- FluoGuide is shortlisted for an EU grant

HIGHLIGHTS AFTER Q1

- Warrants of series TO 1 subscribed by 100% - 97.4% before guarantors and 2.6% by guarantors
- FluoGuide secures a pipeline of uPAR targeting products
- FluoGuide A/S is awarded Best IPO in 2019 by the independent IPO Guide
- FG001 has completed all toxicity studies successfully

CEO HAS THE FLOOR

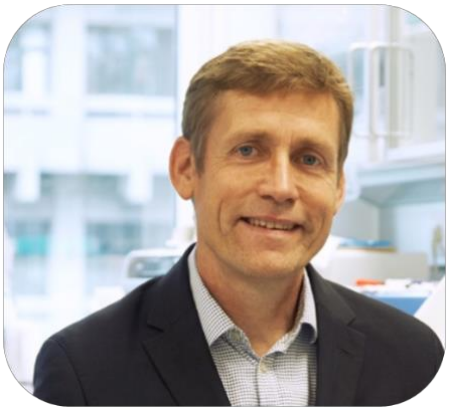
The current COVID-19 pandemic has had significant global impact and increased uncertainty for all businesses. However, FluoGuide has not been negatively impacted by the effects of COVID-19 to date, and we remain determined to maintain our timelines and stay on track towards our goal of improving outcomes in surgical oncology.

The European patent on our lead product, FG001, was granted in January. The US patent from the same family was granted in 2018. It is the most foundational patent type ('composition of matter'), protecting both the product and its uses. FG001 is covered under this patent family until 2034, providing FluoGuide ample time to develop and commercialize the product.

Early in first quarter, we shared excellent results from a preclinical study demonstrating that FG001 has the potential to significantly improve surgeons' ability to identify and remove additional local metastases in pancreatic cancer. The data confirms FG001's potential in indications outside of glioblastoma.

Our financial position has improved as a result of a directed share issue in February and a successful warrant exercise subsequent to the first quarter close (May), which provided the company with approximately DKK 11.6 million and DKK 6.4 million (before issuing costs), respectively. The funds will facilitate the pursuit of our strategy to transform FluoGuide from a preclinical company into a late clinical-stage organization in 2021, with a broadened pipeline of products and indications. With this capital injection, we also expect to accelerate clinical development and shorten the time to market for FG001.

Another important confirmation of our progress came subsequent to the first quarter (May), with Affärsvärlden's annual IPO Awards, where FluoGuide won both the 2019 share price development award in the micro-cap category, as well as an honorary quality award.



Affärsvärlden's IPO Guide reviewed a total of 42 listings, based on pre-IPO and post-IPO analysis, and recognized FluoGuide as exemplary.

During first quarter, all preclinical toxicity studies needed to support the testing of FG001 in the first clinical trial in humans, was completed. The results from the preclinical toxicity studies on FG001 were analyzed subsequent to the first quarter close (May) and confirmed our belief that FG001 will be well tolerated in humans. Manufacturing for the clinical supply of FG001 has also been completed, with only the final release and labeling outstanding.

Preparation of the application for our first clinical trial is ongoing. In May, we had a consultation with the Danish Medicines Agency and received positive feedback and endorsement of our plans for the study. We anticipate submitting the clinical trial application in June and initiating the study this fall. The time from the first patient enrollment to trial results is short for FG001 compared to typical drug studies for a number of reasons, most particularly because only a single dose is needed, and the blinding lies in the light used why the results can be reported ongoing. We will therefore regularly report on the results of this study during 2020. The clinical study is planned completed during first half 2021.

During the quarter we have initiated the discussion of the design of the entire FG001 clinical program, leading to a marketing authorization, with both national and international investigators. Consultations with the EMA and FDA are also planned once clinical data is available, so that we can optimize feedback from regulatory authorities on the development of FG001.

Detailed work on how to expand FG001's use beyond glioblastoma and how to bring FG001 to market quickly and safely have also been initiated, with the constant goal of maximizing benefit to patients, physicians and shareholders.

"Our enthusiasm thus far has been quite high, but Q1 increased our optimism even further. We look forward to the next quarters and to delivering on many significant milestones."

Morten Albrechtsen – CEO, FluoGuide A/S

BEST IPO 2019

On 15 May 2020 Affärsvärlden's IPO Guiden ('IPO Guide') announced that FluoGuide won the 2019 share price development award in the micro-cap category and also received the honorary quality award. The IPO Guide is an independent analysis group that has reviewed all Swedish IPOs since 2017. In 2019, they reviewed 42 Swedish listings and ranked them by both quality and price development. IPO Guide applies a rigorous pre-IPO and post-IPO analysis identifying critical issues with the aim of contributing to the quality of the IPO sector in Sweden.

Affärsvärlden's IPO Guiden devided the companies into three goupes depending on marked capitalization. FluGuide was grouped in the micro-cap and of the 13 companies analyzed by Affärsvärlden's IPO Guide, 5.2 flags were identified on average, compared to only 2 flags for FluoGuide. FluoGuide's share price increased with 353% from its IPO to the end of the first 12 months post-listing. This compared to an average of 29% for FluoGuide's peers.

FLUOGUIDE

The primary focus of FluoGuide A/S (Spotlight Stock Market: FLUO) is to maximize surgical outcomes in oncology. FluoGuide's first product, FG001, does this by improving the precision of surgery by illuminating cancer cells.

FluoGuide's primary focus is to maximize surgical outcomes in oncology. The Company's first product, FG001, is designed to improve surgical precision by illuminating cancer cells intraoperatively. The improved precision enabled by FluoGuide's products has a dual benefit – it reduces both the frequency of local recurrence post-surgery and lessens surgical sequelae. Ultimately, these improvements will improve a patient's chance of achieving a complete cure and will lower system-wide healthcare costs. The Company is planning a proof-of-concept clinical study (phase I/IIa) to demonstrate the effect of FG001 in patients with glioblastoma.

FG001 is an innovative and patent protected product that illuminates cancer

FG001

FluoGuide's first product is designed to allow surgeons to clearly delignate cancer from normal tissue during surgery through a novel uPAR-targeted luminescent technology. During standard white light procedures, surgeons are faced with the challenging task of completely removing all cancerous tissue while saving normal tissue. The increased precision enabled by FG001 decreases the risk of leaving malignant cells behind, reducing the risk of local recurrence and maximizing outcomes.

How it works

FG001 is made of a cancer-targeting molecule linked to a fluorophore. The targeting molecule binds to the urokinase-type plasminogen activator receptor (uPAR), which is extensively expressed on the surface of most types of solid cancer cells. This binding identifes the cancer through fluorescence during surgery.

Seamless integration

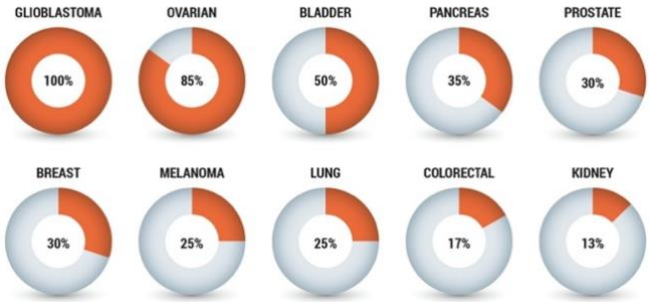
FG001 is injected while the patient undergoes anesthesia, so it does not disrupt standard surgical workflows. Furthermore, use of FG001 does not require specific equipment, reducing the cost and complexity of integrating FG001 into the operating environment.

The challenge of local recurrence post-surgery

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, during which the surgeon uses sight and palpation to find and delineate cancer from normal tissue. Because this is difficult, the average recurrence rate is approximately 50%, with wide variation, depending on the type of cancer.

Percent local recurrence after surgery [1]

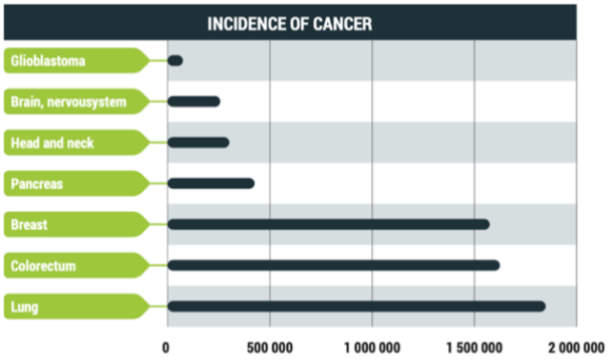


Significant potential for FG001

FluoGuide has chosen glioblastoma for the initial indication of FG001 due to the significant unmet need in this segment of patients. Nearly all glioblastomas express uPAR and glioblastoma is an aggressive form of brain cancer that has a nearly 100% local recurrence rate post-surgery, translating into a very poor prognosis. Half of all glioblastoma patients die within 14 months, with only 5% surviving after 5 years [2]. The improved precision that FG001 can bring to glioblastoma surgery has the potential to dramatically improve patient outcomes.

While glioblastoma is the initial indication for FG001, there is tremendous opportunity to address other solid cancers as well because uPAR is extensively expressed in most aggressive cancers. Preclinical studies have confirmed the effect of FG001 in glioblastoma, 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 colorectal cancer.

Incidence rates of solid tumor cancers[3]



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

FG001's route to market

Active fluorescent targeting products are regulated as pharmaceutical products following imaging agent guidelines set out by health authorities, which must approve the products' safety and efficacy. Broad commercialization of FluoGuide's products will be contingent on such approvals, which in the USA and Europe are granted by FDA and EMA, respectively.

FluoGuide has developed high-quality production procedures required for human use of products following Good Manufacturing Practice (GMP) requirements. Although both the targeting molecule and the fluorophore have been demonstrated to be well tolerated in humans, FG001 has undergone a comprehensive safety testing program in preparation for human clinical studies.

Early commercialization is important for patients

FluoGuide's ambition for FG001 is to initiate compassionate use sales – a process by which a therapy that has not yet been approved can be used because withholding it would be considered unethical. These sales would be contingent on positive results from the proof-of-concept clinical study of FG001, which will be initiated during the summer of 2020.

High concentration of FluoGuide's potential customers

FluoGuide's products will be used in hospitals, paid for either by patient insurance or by governments through the hospital payment system. The key customers will be surgeons as the key decision-makers in the hospitals. The ability to focus on leading hospitals with a specialized neurosurgical practice provides an opportunity for FluoGuide to directly serve customers in targeted geographies.

Intellectual property 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 and in the EU
FILED: 2014
EXPIRES: 2034
OWNER: FluoGuide A/S

FG001 has a direct and comparatively short path to market

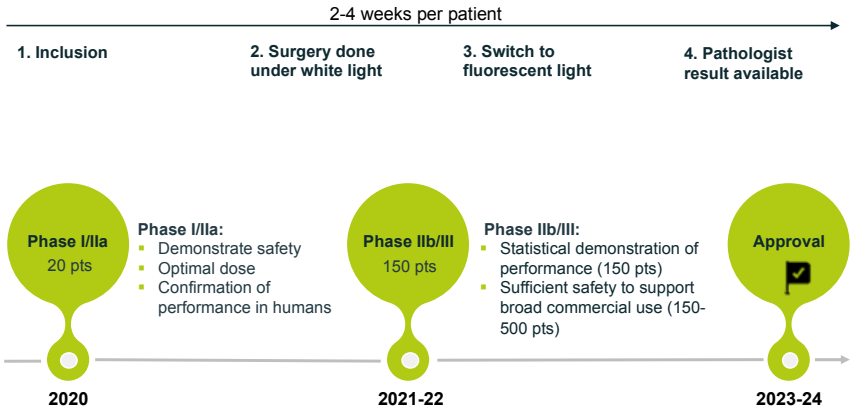
Classified as an imaging agent within medicinal product regulation

First indication (glioblastoma) qualifies for orphan drug designation

Clinical studies are straightforward and require few patients

- **Clear endpoint:** At least one additional local lesion detected
- **No/small placebo arm**: Fewer patients needed
- **Short time frame**: Enrollment to surgery
- **Single blind**: Initial results known after the first few patients
- **No competition for patients:** Treatment can be done in addition to other treatments

Clinical trial design and regulatory milestones



MAXIMIZE SURGICAL OUTCOMES

FluoGuide A/S provides solutions for maximizing surgical outcomes through intelligent targeting. FG001 is the Company's lead product, representing just the beginning of FluoGuide's potential.

uPAR – broadly expressed, highly selective to delineate cancer

uPAR's robust scientific foundation

uPAR is a protein present on the surface of cancer cells that directly correlates to the aggressiveness of the cancer. uPAR is part of a cell-bound enzyme system present on the aggressive invasive forefront of cancer where it breaks down normal tissue to allow the cancer to spread. uPAR is therefore an optimal target to delineate cancer from normal tissue. 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 glioblastoma, 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.

Pipeline

The Innovation Fund Denmark awarded a Grand Solution grant titled, "FluoGuide: an optical probe to guide cancer surgeons" to FluoGuide's Chief Scientific Officer, Andreas Kjaer in 2017. This EUR 1.39 million grant will run until the end of 2021 and gives FluoGuide the first right to new inventions in its field that may arise from the grant project.

Partnerships

In parallel with the development of FG001, FluoGuide is exploring commercial partnerships to accelerate value creation based on this novel product. Such partnerships cover a wide range of activities such as equipment integration during clinical development, exploring novel surgical equipment, investigating new uses of FG001 or other new products, and post-approval commercialization.

Tremendous opportunity to transform surgical outcomes

The market for new surgical products is significant – it is estimated that surgical costs account for more than 5% of GDP (Gross Domestic Product) in the USA and Europe.

FluoGuide's products will be used in hospitals by surgeons, providing both a clear payment path and a natural concentration of the potential customer base, allowing FluoGuide to market directly to these customers in targeted regions.

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 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 per year who suffer from glioblastoma in the USA and Europe.

Expanding to the broader mission to realize the vast potential of uPAR to guide cancer surgery, FluoGuide's second objective is to accelerate the development of FG001 for indications beyond glioblastoma and to begin to develop second generation products. These could include enhanced precision and luminescence to further improve cancer detection through uPAR targeting fluorophores.

In January 2020 the Company announced a directed issue to strengthen its ownership, accelerate the development of FG001 and initiate implementation of its new product strategies designed to transform FluoGuide into a company with a robust pipeline of products for multiple indications by the end of 2020, and a pivotal study (phase IIb/III) underway in 2021.

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

References:

1 Cancer Recurrence Statistics, Nov-2018

2 Tamimi, A. F. et al. (2017). Epidemiology and Outcome of Glioblastoma. Glioblastoma, 143–153. https://doi.org/10.15586/codon.glioblastoma.2017.ch8

3 http://gco.iarc.fr/today/home

FINANCIAL DEVELOPMENT

Operating income and operating results
The operating income and result for Q1 of 2020 were as expected. Net revenue amounted to DKK 0 (0) and the operating result was KDKK -3,088 (-953). The operating result was as expected as the Company is currently conducting development activities.

Balance sheet and solidity
The total equity at 31 March 2020 was KDKK 12,863 (-547). The solidity as per 31 March 2020 was 88% (-10%).

Cash flow and investments
The total cash flow in Q1 2020 was KDKK 8,687 (4,658). There were no investments during the period.

Financial calendar

Q2 and half-year report:	14 August 2020
Q3 report:	20 November 2020
Q4 and year-end report 2020:	26 February 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 March 2020 amounted to 9,455,268 shares (4,000,000). The average number of shares for the first quarter 2020 was 8,057,832 shares (4,733,333). The average number of shares for the period from 1 January 2019 to 31 December 2019 was 6,475,565 shares (688,179). Note that the number of shares in the Company after the end of the period, through exercise of the warrants serie TO 1, has increased to 10,555,268 shares registered on the 18 May 2020. Every share equals the same rights to the Company's assets and results.

Shareholders per 28 May 2020	Number of shares	Votes and capital
Flagged		
Life Science IVS *	2,124,891	20.2%
Wexotec ApS **	1,487,394	14.1%
Linc AB	718,500	6.8%
Management and board of directors		
Grethe Nørskov Rasmussen ***	373,185	3.5%
Arne Ferstad ****	254,218	2.4%
PME HOLDING APS *****	131,297	1.2%
Micaela Sjökvist ****	57,678	0.5%
Shomit Ghose****	39,810	0.4%
Other sharehodlers		
Others	5,343,053	50.7%
TOTAL	10,530,026	100.0%

(The figures are from the share book of the Company and to the best of the knowledge of the Company)

* *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.*

Lock-up

Life Science IVS (Andreas Kjaer) and Wexotec ApS (Morten Albrechtsen) prolonged their lock-up of 100% of their shares until 31 December 2020 in relation to the directed issue in February 2020.

Warrants

There are no outstanding warrants in FluoGuide.

Accounting policy

The financial statements for the first 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 2019.

This year-end report has been prepared using unchanged accounting policies for recognition and measurement as the Annual Report for 2019.

Operational risks and uncertainties regarding covid-19

The current COVID-19 pandemic has had significant global impact and increased uncertainty for all businesses. However, FluoGuide has not been negatively impacted by the effects of COVID-19 to date, and remain determined to maintain our timelines and stay on track towards our goal of improving outcomes in surgical oncology. The Board of Directors and Executive Management are constantly monitoring the development in the COVID-19 situation as any other factor that can impact the Company to be prepared to take adequate and swift measures to secure development of the Company.

Other 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

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

SUBMISSION OF Q1 REPORT

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

Copenhagen
29 May 2020
The Board of Directors

INCOME STATEMENT AND STATEMENT OF COMPREHENSIVE INCOME

Income Statement ('000 DKK)	Q1 2020 01/Jan/20 31/Mar/20	Q1 2019 01/Jan/19 31/Mar/19	2019 01/Jan/19 31/Dec/19
Revenue	0	0	0
Other operating income	150	0	100
Other operating expenses	-3,543	-74	-8,880
Staff expenses	-530	-368	-1,864
Operating loss before net financials	-3,923	-442	-10,644
Financial costs	45	-511	-1,062
Loss before tax	-3,878	-953	-11,706
Tax on loss for the period	790	0	2,053
Net loss for the period	-3,088	-953	-9,653
Other comprehensive income for the period, net of tax	0	0	0
Total comprehensive income	**-3,088**	**-953**	**-9,653**

BALANCE SHEET

Balance Sheet ('000 DKK)	2020 31/Mar/20	2019 31/Mar/19	2019 31/Dec/19
Assets			
Total non-current assets	389	0	389
Tax receivables	2,843	0	2,053
Other receivables	239	0	325
Prepayments	128	512	127
Cash at bank	11,031	4,717	2,344
Total current assets	14,241	5,229	4,849
Total assets	**14,630**	**5,229**	**5,238**
Equity and liabilities			
Equity			
Share capital	946	50	722
Share premium	24,701	400	13,516
Retained earnings	-12,784	-997	-9,696
Total equity	12,863	-547	4,542
Liabilities			
Total long term liabilities	0	0	0
Convertible loan	0	4,801	0
Trade payables	1,767	975	696
Other payables	0	0	0
Total current liabilities (short-term)	1,767	5,776	696
Total liabilities	1,767	5,776	696
Total equity and liabilities	**14,630**	**5,229**	**5,238**

STATEMENT OF CHANGES IN EQUITY

Change in Equity: Q1 2020 (KDKK)	Share-capital	Share Premium	Retained earnings	Shareholders equity
01/Jan/20	722	13,516	-9,696	4,542
				0
Paid in capital	223	11,378		11,601
Capital contribution				0
Costs relating to contribution		-192		-192
Net result Q1-20			-3,088	-3,088
31/Mar/20	945	24,702	-12,784	12,863

Change in Equity: Q1 2019 (KDKK)	Share-capital	Share Premium	Retained earnings	Shareholders equity
01/Jan/19	50	0	-43	7
				0
Paid in capital	350	50		400
Capital contribution				0
Costs relating to contribution		0		0
Net result Q1-20			-953	-953
Rounding difference				-1
31/Mar/19	400	50	-996	-547

Change in Equity: 2019 (KDKK)	Share-capital	Share Premium	Retained earnings	Shareholders equity
1/Jan/19	50	0	-43	7
Paid in capital	556	10,043		10,599
Capital contribution	116	5,645	0	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

CASH FLOW STATEMENT

Cash flow ('000 DKK)	Q1 2020 01/Jan/20 31/Mar/20	Q1 2019 01/Jan/19 31/Mar/19	2019 01/Jan/19 31/Dec/19
Loss before tax	-3,878	-953	-11,706
Financial expenses, reversed	-45	511	1,062
Change in working capital	1,158	-48	192
Cash flow from operating activities before net financials	-2,765	-490	-10,452
Financial expenses paid	45	-53	-102
Cash flow from operating activities	-2,720	-543	-10,554
Cash flow from investing activities	0		-389
Cash capital increase	11,601	400	10,599
Contribution		0	0
Convertible loan		4,801	4,801
Transaction cost, cash capital increase	-194	0	-2,172
Cash flow from financing activities	11,407	5,201	13,228
Total cash flow from the period	8,687	4,658	2,285
Cash, beginning of the period	2,344	59	59
Cash, end of the period	**11,031**	**4,717**	**2,344**

FluoGuide

Intelligent surgical targeting

www.fluoguide.com