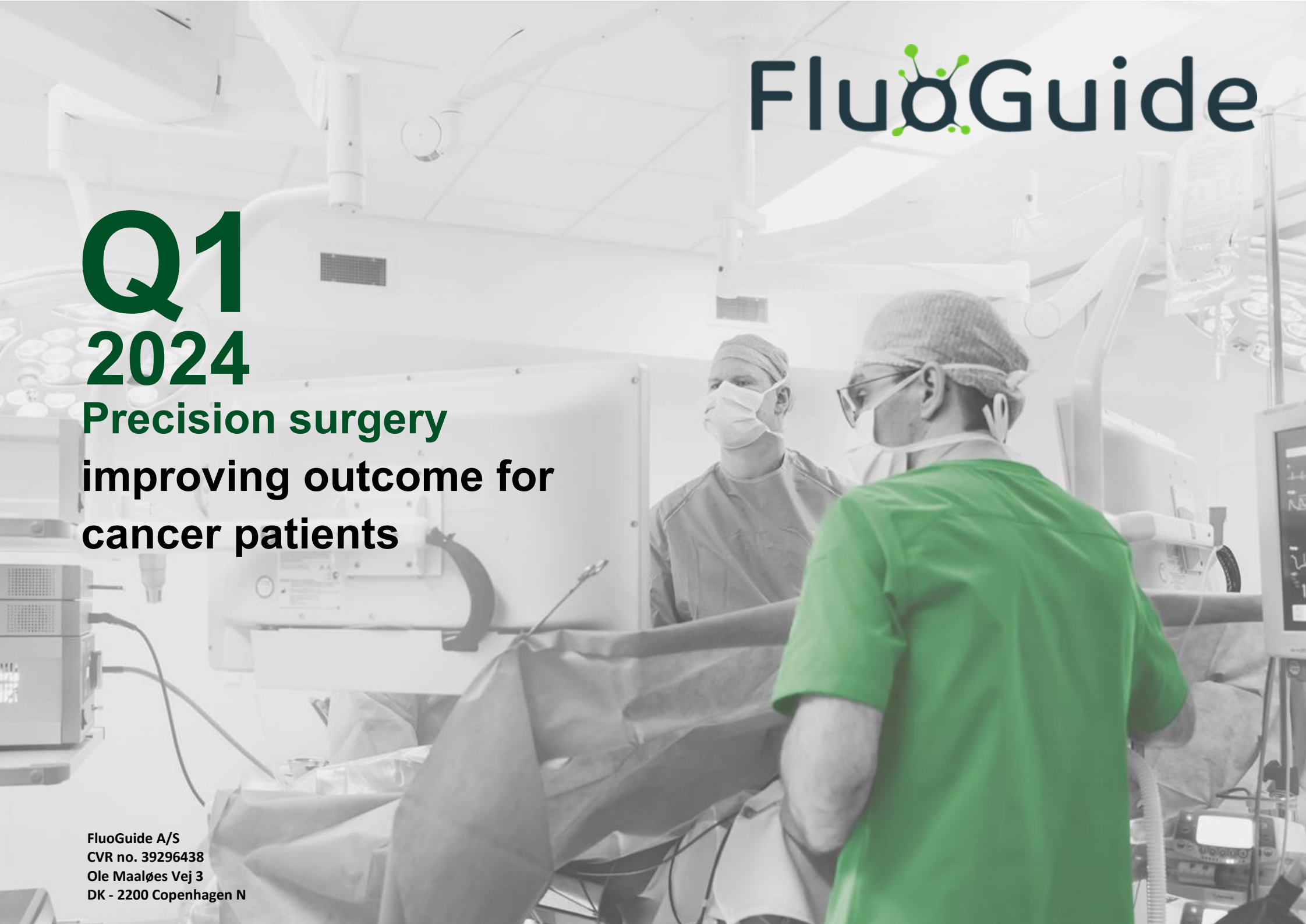


Q1 2024

Precision surgery

improving outcome for cancer patients

FluoGuide A/S
CVR no. 39296438
Ole Maaløes Vej 3
DK - 2200 Copenhagen N

IN THIS REPORT

"FluoGuide published a collaboration with Intuitive Surgical in head & neck surgery which on top of the three positive clinical study phase II results published last year supports our long-term objective of improving the outcome for patients with cancer."

- Morten Albrechtsen, CEO

COMPANY INFORMATION & MANAGEMENT REVIEW

In this document, the following definitions shall apply unless otherwise specified: “the Company” or “FluoGuide” refers to FluoGuide A/S, with CVR number 39 29 64 38. Figures in ‘()’ refer to the same period last year.

The Company

FluoGuide A/S
Ole Maaløes Vej 3
DK-2200 Copenhagen N
CVR no.: 39 29 64 38

Board of Directors

Peter Mørch Eriksen (Chairman)
Mats Thorén (Vice Chairman)
Donna Haire
Roger Gunnarsson
Andreas Kjær
Michael Engsig

Executive Management

Morten Albrechtsen, CEO
Ole Larsen, CFO

Auditors

PricewaterhouseCoopers
Statsautoriseret Revisionspartnerselskab
CVR-no. DK 33 77 12 31

NASDAQ

FluoGuide is listed on Nasdaq First North Growth Market, Sweden under the ticker symbol ‘FLUO’

FLUOGUIDE PUBLISHES ITS FIRST COLLABORATION

FluoGuide is dedicated to help patients with cancer by enhancing precision surgery. Our lead product FG001, an intraoperative fluorescent imaging agent, helps surgeons to perform more precise surgeries by illuminating the cancer in patients. FG001 continues to progress successfully through clinical development.

In the first quarter we announced the collaboration with Intuitive Surgical – a global leader in minimally invasive care and a pioneer of robotic-assisted surgery. The objective of the collaboration is to jointly test FG001 with the Intuitive Surgical technology within head & neck cancer. The collaboration supports our uPAR target approach, making cancer more visible to improve surgical accuracy. Additionally, it provides potential ways to help cancer patients in the future. For example, patients with head & neck cancer deep in the throat, who currently receive only chemo-radiotherapy due to the inaccessibility of surgical options, could now benefit from our technology. This advancement provides an alternative to chemo-radiotherapy and its associated side effects.

Our technology is versatile and offers various opportunities to help patients with many different types of cancers. Collaborations with additional surgical equipment manufacturers are anticipated and will allow for future development of treatments for patients with cancer.

Building on the three positive phase II trials in 2023, we are prioritizing advance clinical development of FG001 to guide surgery in two indications: Brain and head & neck cancers. While de-risking the phase III program in aggressive brain cancer, we are also evaluating FG001's photothermal effect in aggressive brain cancer along with potential synergies in combining this with fluorescent guided surgery in aggressive brain cancer. Trial design and timelines in brain and head & neck cancer will be communicated ongoing as they become available.

The collaboration with Intuitive Surgical in head & neck surgery on top of the three positive clinical phase II results published last year supports our long-term objective of improving the outcome for patients with cancer.

Morten Albrechtsen
CEO, FluoGuide A/S

FINANCIAL HIGHLIGHTS

KEY FIGURES	Q1 24	Q1 23	YTD 2024	YTD 2023	2023
DKK thousand	1-Jan-24 31-Mar-24	1-Jan-23 31-Mar-23	1-Jan-24 31-Mar-24	1-Jan-23 31-Mar-23	1-Jan-23 31-Dec-23
Net Revenue	-	-	-	-	-
Income before interest and tax (EBIT)	-8,345	-11,645	-8,345	-11,645	-43,924
Net result for the period	-7,521	-9,535	-7,521	-9,535	-38,377
Cash and bank	10,683	16,269	10,683	16,269	21,668
Solvency ratio (%)	*29%*	*82%*	*29%*	*82%*	*43%*
Result per share (DKK)	*-0.62*	*-0.81*	*-0.62*	*-0.81*	*-3.22*

FluoGuide had no revenue for the period and posted a net loss of DKK 7,521 thousand (DKK 9,535 thousand) for the period 1 January to 31 March 2024. The financial result for the period is in line with the Company's development plans.

For definitions of ratios, see under accounting policies.

The total number of shares as of March 31, 2024, amounted to 12,208,384 shares. The total number of shares as of March 31, 2023, amounted to 11,814,500 shares. The average number of shares in Q1 2024 amounted to 12,208,384 shares.

Q1 Highlights

- **FluoGuide provides strategic update and outlines development plans towards commercialization of FG001**
- **FluoGuide enters collaboration within robot assisted head & neck cancer surgery with Intuitive Surgical, a world leading robotic-assisted surgery company**
- **Two new board members, Donna Haire (regulatory profile) and Roger Gunnarsson (financial profile)**
- **FluoGuide selects laser system for photothermal cancer therapy with FG001**

PARTNERING STRATEGY

"Topic of the quarter" is an introduced to a relevant topic with more in depths information. A selected topic is presented in each quarterly report.

There are multiple well-established players in the surgical equipment field, and each of these represents a potential avenue for collaboration and enhancing equipment capabilities by incorporating FG001. Partnering with these well-established companies is associated with several advantages, as it will create a dual benefit for the equipment companies and FluoGuide. Moreover, it is an opportunity for market adoption and deeper market penetration of FG001 and the equipment. Many additional opportunities are expected to arise during such collaborations.

Despite the various potential partnership routes available, the goal for the coming years is to establish partnerships with specific surgical equipment manufacturers.

In Q1 2024, we announced the collaboration with Intuitive Surgical. A global leader in minimally invasive care and a pioneer of robotic-assisted surgery. Intuitive Surgical's ground-breaking technologies include the well-established da Vinci surgical system. Digital intelligence allows Intuitive Surgical to unite the advanced systems, progressive learning, and value-enhancing services to help physicians and their teams optimize care delivery to support the best surgical outcomes possible. The da Vinci already integrated fluorescence system uses near-infrared light to visualize tissue uptake of Indocyanine Green (ICG) which shares the same spectral specification as FG001.

The objective of the collaboration is jointly evaluating FG001 with the Intuitive Surgical technology within head & neck cancer.

The agreement has no initial payment and is non-exclusive. This leave space for other surgical equipment company technologies to be evaluated in the commencing of the head & neck trial, and additional similar agreements are anticipated.

With the global population of individuals aged 65 and older steadily increasing, this demographic trend is creating significant challenges for healthcare systems worldwide. The median age of cancer diagnosis is 66 years, aligning this growing elderly population with a heightened risk of developing cancer. As more people enter an age group at higher risk for cancer, there is an escalating demand for surgical interventions that are not only more precise but also more effective. Robotic systems, such as Intuitive Surgical's systems can handle more complex procedures which will expand the market for surgery. One example is patients with deeper or difficult to reach head & neck cancer which today are only rarely offered surgical treatment.

As our lead compound, FG001 fluoresces with the same spectral specifications as the approved imaging agent ICG, it can be detected by many surgical intraoperative imaging equipment available on the market today. This means that the intraoperative imaging equipment currently present in hospitals has the capability to also detect FG001.

There are many types of surgical equipment, e.g.:

- **Microscopes:** Typically used in surgeries where precision is crucial, such as in brain, but can also be used in several other types of surgeries.
- **Open Filed cameras:** Typically used in surgeries located close to a surface, such as in skin or mouth, but can also be used in several other types of surgeries.
- **Endoscopes:** Typically used in surgeries that can be done inside the body with access through body openings, such as

abdominal, urological, lung and head & neck cancers.

- **Surgical robots**: The precision required in minimally invasive surgeries, especially for head & neck and lung cancers, is greatly enhanced by robotic technology.
- **Back Table Imaging equipment:** Typically used to provide intraoperative surgical feedback of the completeness of the surgery, e.g. used in head & neck surgery but can also be used in several other types of surgeries. The use of FG001 can potentially provide more accurate and faster results than in combined use with back table imaging equipment.

Combining FG001 with these various equipment categories offer opportunities to potentially improve surgical outcomes for patients and therefore creates a range of partnering opportunities for FluoGuide.

FLUOGUIDE

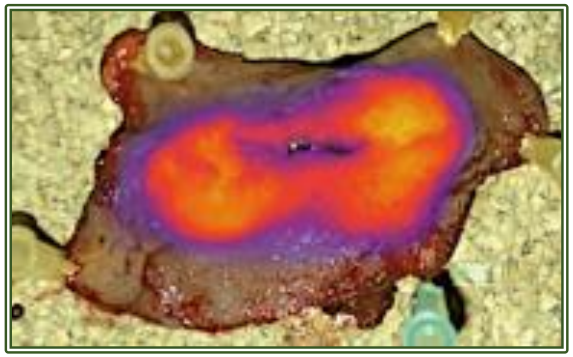
Precision surgery improving outcome for cancer patients

FluoGuide improves the outcome for cancer patients by enhancing precision in cancer surgery. FluoGuide's lead product, FG001 provides better surgical accuracy, as compared to normal white light (no usage of an imaging agent), by illuminating cancer cells in real-time during surgery. FG001 fluoresces and is designed to bind urokinase-type plasminogen activator receptor (uPAR) a protein present on the cells in the surface of the cancer and with a potential for patients with solid cancer. Enhanced surgical precision is anticipated to decrease both the incidence of local recurrence due to the ability to better evaluate resection margins after surgery and surgical complications, improving cancer treatment and outcomes for patients, while also reducing healthcare costs.

FG001 – an effective and well tolerated image agent

FluoGuide's lead product, FG001, is a uPAR targeting fluorescent imaging agent (drug)[1] that lights up the cancer work with many commonly available surgical imaging devices. It improves surgical precision by illuminating cancer cells in real-time intra-operatively which allows for better removal of tumor tissue while leaving healthy tissue unharmed. Enhanced surgical precision benefits both the patients and the health care system. Moreover, FG001 has photothermal therapy (PTT) properties, which kills cancer cells utilizing near-infrared light, and offering a direct therapeutic effect of FG001.

FG001 was first shown to be effective and well tolerated by patients undergoing surgery in phase I/II clinical trials evaluating removal of aggressive brain cancer (high grade glioma). Later, the safety and efficacy was further documented in the phase II trial in aggressive brain cancer with the clinical study endpoint (completion of surgery). FluoGuide has also reported positive topline results in two further phase II clinical trials in head & neck and lung cancers.



Patient with oral cancer where the cancer lights up on the back table after the patient received FG001 prior to surgery.

[1] · Christensen, A., Juhl, K., Persson, M., Charabi, B. W., Mortensen, J., Kiss, K., … Kjær, A. (2017). uPAR-targeted optical near-infrared (NIR) fluorescence imaging and PET for image-guided surgery in head & neck cancer: proof-of-concept in orthotopic xenograft model. Oncotarget, 8(9), 15407–15419. https://doi.org/10.18632/oncotarget.14282. · Juhl, K., Christensen, A., Persson, M., Ploug, M., & Kjaer, A. (2016). Peptide-Based Optical uPAR Imaging for Surgery: In Vivo Testing of ICG-Glu-Glu- AE105. PLoS ONE, 11(2), 1–15. https://doi.org/10.1371/journal.pone.0147428. · Juhl, K., Christensen, A., Rubek, N., Schmidt, K. K., Buchwald, C. Von, & Kjaer, A. (2019). Improved surgical resection of metastatic pancreatic cancer using uPAR targeted in vivo fluorescent guidance: comparison with traditional white light surgery. Oncotarget, 10(59), 6308–6316.

uPAR – cancer specific target expressed in over 80% of all solid cancers

uPAR is a protein present in the cells on the surface of the cancer. The expression directly correlates to the aggressiveness of the cancer and its ability to metastasize.

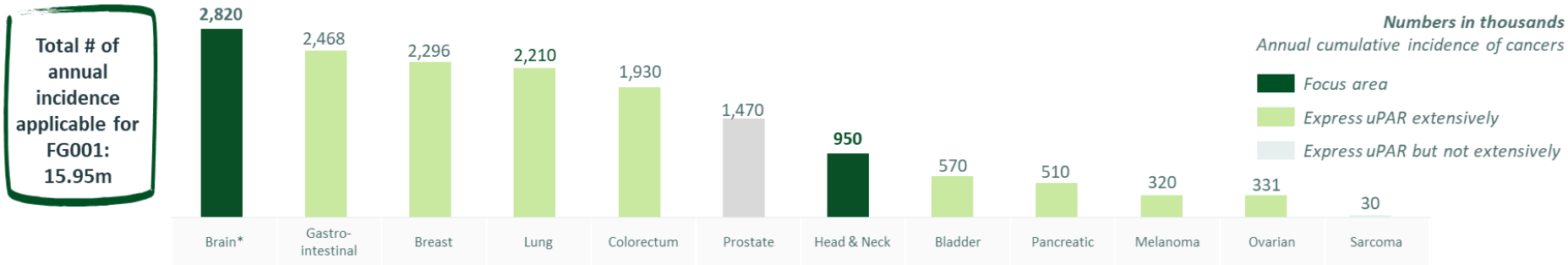
uPAR is part of a cell-bound enzyme system present on the invasive front of cancer where it degrades normal tissue to allow the cancer to spread. The protein is extensively expressed in most solid tumors, including prevalent cancer types like breast, colorectal, lung, and head & neck cancers, as well as in less common yet highly aggressive forms such as high-grade glioma and pancreatic cancer[2]. The pervasive expression of uPAR is a notable characteristic, with scientific support for its extensive presence in more than 80 % of all solid cancers.

Market – potential for most patients with solid cancer

Surgery is the cornerstone of cancer therapy. Of the 20 million new cancer patients each year worldwide, 60% will need surgery at some stage during their disease. For localized cancers, surgery is a preferred treatment with curative intent[3] [4].

Half of the patients experience local recurrence of the cancer post-surgery, with wide variation, depending on the type of cancer.

The total addressable market for FluoGuide constitutes most cancer types (solid cancers) where a selection of the 12 cancer types shown in the figure below consists of almost 16 million cancer cases each year [5].



[2] Metrangolo, V., Ploug, M., & Engelholm, L. H. (2021). The Urokinase Receptor (uPAR) as a "Trojan Horse" in Targeted Cancer Therapy: Challenges and Opportunities. Cancers, 13(21), 5376. https://doi.org/10.3390/cancers13215376

[3] World Health Organization. (2024, February 1). Global cancer burden growing, amidst mounting need for services. Retrieved from https://www.who.int/news/item/01-02-2024-global-cancer-burden-growing--amidst-mounting-need-for-services

[4] MD Anderson Cancer Center. (2024). Surgery for cancer. Retrieved from https://www.mdanderson.org/treatment-options/surgery.html

[5] International Agency for Research on Cancer. (n.d.). Cancer Tomorrow: Estimated number of deaths in 2040, all cancers, worldwide, males, all ages. Global Cancer Observatory. Retrieved May 29, 2024, from https://gco.iarc.who.int/tomorrow/en/dataviz/tables?mode=cancer&group_populations=1&multiple_populations=0&cancers=20&populations=900

Partnering

FluoGuide has entered a collaboration with Intuitive Surgical, a world leading robotic-assisted surgery company, with intraoperative imaging capabilities of fluorescent imaging agents. The collaboration is related to head & neck cancer surgery.

The objective of the collaboration is to evaluate Intuitive Surgical systems for the intraoperative near-infrared imaging of FG001 and the evaluation of surgical resection for head & neck cancer. The focus of the current agreement is to support the clinical development phase and to gather a body of evidence on Intuitive Surgical's technology platforms capabilities.

Intellectual property protection

FluoGuide has established a strong IP protection related to FG001 and, more broadly, uPAR targeted cancer imaging agents in general. Several patent families contribute to the protection of FG001. The life of the first filed patent family, issued in US and EU, lasts until 2035. The earliest patent family filed is being processed around the world and is expected to prolong the protection until 2040.

STATUS AND PLAN

FluoGuide is focusing on the development of FG001 in the two indications of aggressive brain cancer and head & neck squamous cell cancer.

Brain cancer

Overview of brain tumors

Brain tumors are abnormal cells growing inside the brain. The tumor can either be malignant (lethal for the patient) or benign (causing disability and in some instances indirectly lethal). A malignant tumor is also called cancer. Further the tumor can derive from the brain tissue or being spread from other cancers typically breast and lung cancer. Surgery is commonly used to treat patients with brain tumors and there is a need for better accuracy.

Accuracy is important for malignant cancers to remove all cancer during the first surgery while sparing as much normal tissue as possible decreasing the risk of unnecessary disability. Sparing as much normal tissue as possible is also important for benign tumor surgery to decrease the risk of unnecessary disability and to remove all the tumor during the first surgery. Benign tumors can recur although it takes a longer time than for the typical malignant brain cancer and they can in some instances develop into malignancy.

High Grade Glioma

FluoGuide has chosen aggressive brain cancer (high-grade glioma) as the first indication for development of FG001, due to the significant unmet need of these patients. Nearly all high-grade gliomas express uPAR and is an aggressive form of brain cancer that has close to 90% local recurrence rate post-surgery, translating into a very poor prognosis for most patients [6] [7]. Half of all high-grade glioma patients die within 14 months, with only 5% surviving after five years[8]. The improved precision that FG001 can offer has the potential to improved surgical outcomes for this group of patients.

Meningioma

Meningioma's are tumors that arise from the membranes surrounding the brain and spinal cord. They are mostly benign brain tumors. Meningiomas accounts for approx. half of primary non-malignant brain tumors worldwide. Of meningioma patients, an estimated 18% of patients will have malignant meningioma, and the cancer recurs locally within 5 years after their first surgery [9]. FluoGuide estimates that approx. 140,000 meningioma patients annually will undergo surgery, across US, Europe, and Asia combined.

Brain metastasis

There is a high number of cancers of other origin than the brain that metastasize to the brain. Those metastases typically come from lung and breast cancers. Patients with brain metastases frequently undergo surgery although these constitute a diverse type of cancers.

[6] Ivy Brain Tumor Center. (2023, February 24). Brain tumor recurrence. Retrieved from https://www.ivybraintumorcenter.org/blog/brain-tumor-recurrence/

[7] Smith, J. (2017). Treatment advances in glioblastoma. In Glioblastoma: Current management and treatment (pp. 150-172). Codon Publications. https://doi.org/10.15586/codon.glioblastoma.2017.ch8

[8] Tamimi, A. F., & Juweid, M. (2017). Epidemiology and outcome of glioblastoma. In Glioblastoma (pp. 143–153). https://doi.org/10.15586/codon.glioblastoma.2017.ch8

[9] Alruwaili, A. A., & De Jesus, O. (2023). Meningioma. In StatPearls. StatPearls Publishing. Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK560538/

The brain cancer market

In 2022, there were an estimated total of 2.8 million cases of brain cancer worldwide, including both malignant and non-malignant types, as well as primary and secondary tumors[10] [11] [12].

Malignant brain cancers make up approximately 22% of primary brain cancers, with about half of these being glioblastomas[13]. Non-malignant brain cancers constitute the remaining 78%[14]. Meningiomas account for approximately half of primary non-malignant brain tumors worldwide. An estimated 18% of meningioma patients will have malignant meningiomas, with cancer recurring locally within five years post-surgery. Approximately 140,000 meningioma patients undergo surgery annually across the US, Europe, and Asia.

Secondary brain cancers (brain metastases) are malignant tumors that originate in other parts of the body and spread to the brain. These metastases most come from the lungs or breasts, which together account for 71% of brain metastases[15]. In Europe, the US, and Asia[16] alone, there are an estimated 300,000 new patients with brain metastases each year[17].

Clinical data (FG001-CT-001)

The first-in-human clinical trial (FG001-CT-001) included 40 patients with suspected high-grade glioma. FG001 was very well tolerated in all patients. Based on the biopsies from the optimal dose, the specificity was 100% (fluoresces biopsies contain cancer) and the sensitivity was 79% (non-fluoresced biopsies free of cancer).

The picture shows the illumination of the brain tumor compared to surrounding healthy tissue after administration of FG001 36 mg the evening before surgery. The picture is a part of a video shown at the SNS Congress (Source: Data from phase I/II trial testing FG001 in patients with aggressive brain cancer).

[10] International Agency for Research on Cancer. (n.d.). Cancer Tomorrow: Estimated number of deaths in 2040, all cancers, worldwide, males, all ages. Global Cancer Observatory. Retrieved May 29, 2024, from https://gco.iarc.who.int/tomorrow/en/dataviz/tables?mode=cancer&group_populations=1&multiple_populations=0&cancers=20&populations=900

[11] Habbous, S., Forster, K., Darling, G., Jerzak, K., Holloway, C. M. B., Sahgal, A., & Das, S. (2021). Incidence and real-world burden of brain metastases from solid tumors and hematologic malignancies in Ontario: a population-based study. Current Oncology, 28(2), 1218-1229. https://doi.org/10.3390/curroncol28020057

[12] Ostrom, Q. T., Cioffi, G., Gittleman, H., Patil, N., Waite, K., Kruchko, C., & Barnholtz-Sloan, J. S. (2019). CBTRUS Statistical Report: Primary brain and other central nervous system tumors diagnosed in the United States in 2012–2016. Neuro-Oncology, 21(Suppl 5), v1–v100. https://doi.org/10.1093/neuonc/noz150

[13] Schaff, L. R., & Mellinghoff, I. K. (2023). Glioblastoma and other primary brain malignancies in adults: A review. JAMA, 329(9), 806-817. https://doi.org/10.1001/jama.2023.0023

[14] Alruwaili, A. A., & De Jesus, O. (2023). Meningioma. In StatPearls. StatPearls Publishing. Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK560538/

[15] Habbous, S., Forster, K., Darling, G., Jerzak, K., Holloway, C. M. B., Sahgal, A., & Das, S. (2021). Incidence and real-world burden of brain metastases from solid tumors and hematologic malignancies in Ontario: a population-based study. Neuro-Oncology Advances, 3(1), vdaa178. https://doi.org/10.1093/noajnl/vdaa178

[16] Asia constitutes of the population from India and China (categorized as the population having a daily income on >$20) combined with Japan

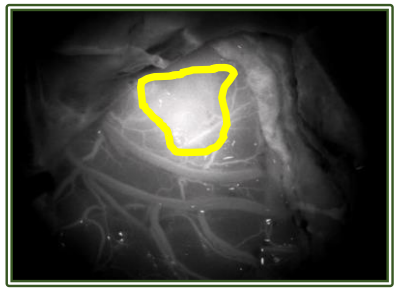
[17] Habbous, S., Forster, K., Darling, G., Jerzak, K., Holloway, C. M. B., Sahgal, A., & Das, S. (2021). Incidence and real-world burden of brain metastases from solid tumors and hematologic malignancies in Ontario: a population-based study. Current Oncology, 28(2), 1218-1229. https://doi.org/10.3390/curroncol28020057

The result of the following controlled, randomized, multi-center phase ll trial (FG001-CT-001) investigated the effect of FG001 in guiding surgery of patients with aggressive brain cancer and compared FG001's effect to 5-ALA. 5-ALA is the only imaging agent approved worldwide, including in Europe and US, for guiding surgery of aggressive brain cancer (grade III and IV glioma). The patients were randomized 1:1 to FG001 or 5-ALA. Fluorescence-guided surgery using FG001 or 5-ALA were compared to white light surgery with each patient serving as its own control. The trial was not designed to show statistical difference (superiority, non-inferiority). The results are used to guide further clinical development.

- All patients receiving FG001 (12/12) had additional cancer detected showing FG001 was superior to white light. The result for 5-ALA was 12/12.
- FG001 was safe and well tolerated in all patients with 2 related adverse events (grade 1). The result for 5-ALA was 10 related adverse events (8 grade I and 2 grade II).
- FG001 visualized tumor on dura prior to incision in 4/12 patients (deeper visualization). The result for 5-ALA was 0/12.

White light means that no product is used to guide the surgeon in removing aggressive brain cancer. Hospitals around the world use either white light

FG001



5-ALA

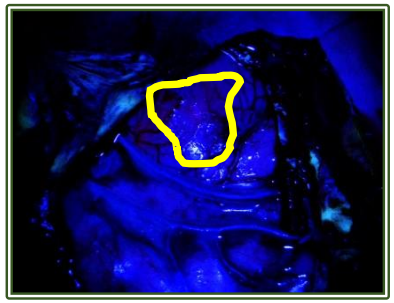


Image of the brain of a patient with high grade glioma (yellow line) having received both FG001 and 5-ALA. The image to the left is with near infrared (NIR) light switched on and the image to the right is filtered for blue light (5-ALA mode). The cancer is visible to the left (FG001) due to deeper visibility of NIR light compared to the blue image at the right (5-ALA) where the cancer is not visible[18].

[18] Abstract, 68th Scandinavian Neurosurgical Society (SNS) Congress held 14-16 May 2022 in Bergen, Norway. Presentation by Chief Surgeon Jane Skjøth Rasmussen, The Norwegian Neurosurgical Society

(no image agent), 5-ALA, or an off-label product, which has not been approved for guiding brain cancer surgery. FG001 has several technological advantages over 5-ALA. FG001 is more specific to cancer, provides deeper visibility (see image) which gives a better chance of detecting cancer and the potential for better margin resection.

Meningioma and metastasis

One patient included in the trial suspected to have high grade glioma was diagnosed with meningioma during surgery. FG001 illuminated the meningioma tissue and allowed additional meningioma tissue to be removed[19]. One patient was diagnosed with brain metastasis from a primary lung cancer which FG001 also illuminated. The trial was not designed to evaluate cancers other than high grade glioma.

Photothermal Therapy – a potential therapeutic benefit of FG001

Research has shown that when exposed to light, FG001 undergoes a process that releases energy in the form of heat. Preclinical *in vivo* data indicates that this generated heat has the potential to selectively eliminate cancer cells bound to FG001, with a notable sparing effect on surrounding normal tissue. Photothermal therapy (PTT) with FG001 has already demonstrated effect in preclinical models. Photothermal therapy has the potential to take treatment to the next level of cellular precision[20]. In March 2023 the Innovation Fund Denmark (Innovationsfonden) awarded its largest and most prestigious grant for research and development of photothermal therapy to a consortium of four highly reputed academic groups and FluoGuide. The grant valued at DKK 49.2 million was structured through a combination of a cash contribution from the Innovation Fund Denmark and a co-financing from the consortium. The grant is a significant milestone for FluoGuide in its aim to support the research and development of the optimal molecule for photothermal therapy. FG001 is a model molecule that takes information obtained from the operating room and applies it back into the discovery of novel technologies.

Plans

While de-risking the phase III clinical study program in aggressive brain cancer, FluoGuide is investigating the economic potential and synergies in combining its development of PTT in aggressive brain cancer.

During 2024, FluoGuide will assess the potential of PTT in pre-clinical models, with the intend of obtaining synergies between the development programs.

[19] Skjøth-Rasmussen, J., Azam, A., Larsen, C. C., Scheie, D., Juhl, K., & Kjaer, A. (2021). A new uPAR-targeting fluorescent probe for optical guided intracranial surgery in resection of a meningioma—a case report. Acta Neurochirurgica. https://doi.org/10.1007/s00701-021-05051-3.

[20] Simón, M., Jørgensen, J. T., Juhl, K., & Kjaer, A. (2021). The use of a uPAR-targeted probe for photothermal cancer therapy prolongs survival in a xenograft mouse model of glioblastoma. Oncotarget, 12(14), 1366–1376. https://doi.org/10.18632/oncotarget.28013

Head & neck cancer

Cancers in the head & neck region (squamous cells carcinoma in the oropharyngeal mucosa) are treated differently depending on where they are located. Localized oral cancers (lips, tongue, mouth, or upper throat) are treated surgically as the first-line treatment. If the post-surgery histology reveals incomplete surgery, the patients are offered chemo-radiotherapy. Patients with deeper or other difficult-to-reach cancers may not be offered surgery today and will only be offered chemo-radiotherapy. These difficult to reach head & neck cancers are in the larynx or pharynx.

The unmet need for oral cancer patients is to ensure that the cancer is completely removed during surgery to avoid local recurrence leading to chemo-radiotherapy. Chemo-radiotherapy gives several side effects such as cosmetic changes, teeth problems and impairment of salvia production (dry mouth).

Head & neck cancer market

Worldwide, there are about 950,000 cases of head & neck cancer each year. In Europe, the US, and Asia, there are around 260,000 cases annually. Of these, almost 40% are cancers of the lip and oral cavity, making it the most common type. The second most common type is pharynx cancer, which accounts for 32% of cases[21]. Approx. 40% of head & neck cancer patients will undergo surgery at some point, however, the specific percentage of surgery will differ depending on the location of the cancer [22].

Clinical data

The phase II trial was designed to obtain proof-of concept data. The primary endpoint was sensitivity defined as the relative number of patients where FG001 lights up the cancer confirmed by histopathology. The positive top-line result demonstrated that FG001 lit up the cancer in all 16 patients enrolled. The effect of FG001 has been very robust across a broad dose range.

Plans

FluoGuide plans the next clinical trial with FG001 in head & neck cancer with endpoints relevant for patient benefits and to support regulatory market authorization.

Other trials

FG001 has also demonstrated efficacy in lung cancer. Globally, there are 2.2 million individuals diagnosed with lung cancer annually, and 1.8 million patients die each year. Lung cancer is the second most diagnosed cancer and was the leading cause of cancer deaths in 2020[23] [24].

Colorectal and breast cancer are two other forms of cancer types that have a high frequency and where FG001 may significantly improve surgery outcomes. Additionally, FG001 is relevant in several other less frequent types of cancer.

[21] International Agency for Research on Cancer. (n.d.). Cancer Tomorrow: Estimated number of deaths in 2040, all cancers, worldwide, males, all ages. Global Cancer Observatory. Retrieved May 29, 2024, from https://gco.iarc.who.int/tomorrow/en/dataviz/tables?mode=cancer&group_populations=1&multiple_populations=0&cancers=20&populations=900

[22] Zhang, S., Zeng, N., Yang, J., He, J., Zhu, F., Liao, W., Xiong, M., & Li, Y. (2023). Advancements of radiotherapy for recurrent head and neck cancer in modern era. Radiation Oncology, 18, Article 166. https://doi.org/10.1186/s13014-023-02322-8

[23] World Health Organization. (2023, June 26). Lung cancer. Retrieved from https://www.who.int/news-room/fact-sheets/detail/lung-cancer

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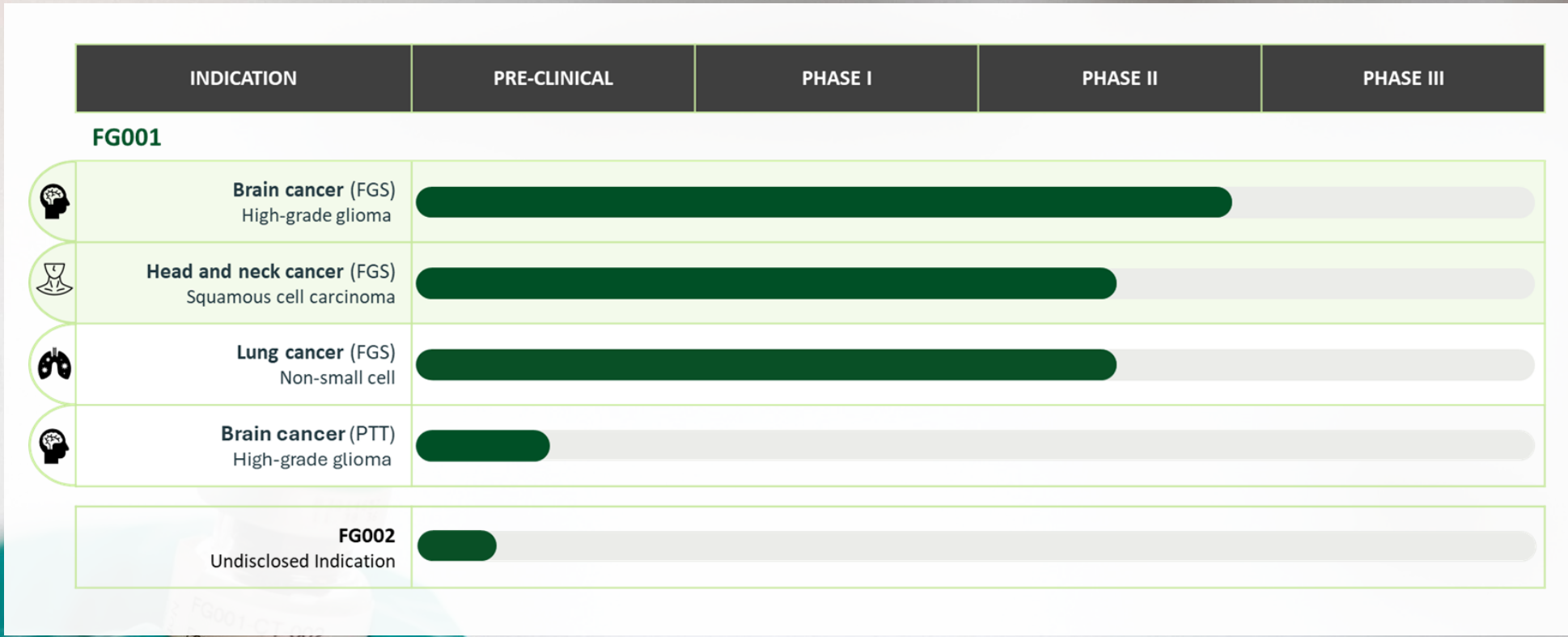
FG001 PIPELINE

FG001 is a uPAR target imaging agent designed to work with any standard intraoperative imaging device



MANAGEMENT

Board of Directors

Peter Mørch Eriksen – Chairman of the Board since 2021

Peter has more than 20 years of experience in the medtech/life science sectors, both in Denmark and internationally. He is CEO at BioPorto A/S. His extensive background includes key positions such as Vice President of Medtronic in the US and Denmark. These roles have endowed Peter with a wealth of knowledge in driving growth, executing restructuring, and securing funding in technologically advanced and complex organizations. Peter's professional foundation is in accounting, complemented by various management courses. He chairs the board of Monsenso A/S, is a board member at BioPorto A/S, chairman in AptaShape Aps and Director of PMEconsult ApS. Additionally, he contributes his expertise to the Medical Device and Diagnostics Advisory Committee of Cincinnati Children's Hospital Medical Center in Ohio, US.

Mats Thorén – Vice-Chairman of the Board since 2022

Mats brings 25 years of financial market experience, specializing in healthcare through roles in equity analysis and corporate finance. He has spent 19 years as a Healthcare investment expert, working with firms like Nalka Life Science AB and MedCap AB, and now leads Vixco Capital. Mats holds board positions at Xbrane BioPharma AB, Arcoma AB, and Herantis Pharma Oy, with past board roles at C-Rad AB, Cellartis AB, and others. His educational background includes Economics, focusing on Accounting and Financial Economics, and medical studies at the Karolinska Institute in Stockholm.

Andreas Kjær – Board member since 2018

Andreas is an MD, PhD, DMS, and professor at the University of Copenhagen as well as chief physician at Rigshospitalet, the National University Hospital of Denmark. His research is focused on molecular imaging with PET and PET/MRI in cancer and cardiovascular disease and his achievements include development of several new tracers that have reached first-in-humans clinical use. He is the holder of an ERC Advanced Grant, has published 400+ peer-review articles, and has received multiple prestigious scientific awards throughout the years. Andreas also holds an MBA from Copenhagen Business School.

Donna Haire – Board member since 2024

Donna is CEO of The Eriah Group, Inc., specializing in global regulatory, quality, clinical, and medical affairs consulting for drugs, biologics, medical devices/in vitro diagnostics, and combination products. With over 30 years in the healthcare, pharmaceutical, and medical device industries, she has extensive experience in regulatory, quality, clinical affairs, operations, business development, and R&D. Donna is currently a Board Member at Sedana Medical AB. She has served in executive roles at On Target Laboratories, Bayer, AngioDynamics, Philips Healthcare, and Medtronic. Donna was also an Adjunct Professor at the University of Akron School of Law, an AdvaMed Technical and Regulatory Board Committee Member, and a U.S. regulatory expert for international trade negotiations. She is a keynote speaker and panelist at global regulatory and compliance events.

Roger Gunnarsson – Board member since 2024

Roger is co-founder and senior advisor at Segulah Medical Acceleration, a Scandinavian growth equity investment firm. Prior to SMA, Roger worked as an international investment banker for 25 years, with a focus on healthcare for the last 18 years. Roger is recognized as a leading financial and M&A advisor in the international life science sector. Roger has a global network of contacts, across many of the world's largest healthcare corporation and smaller start-ups as well, ensuring access to relevant decision makers at potential partners.

Michael Engsig – Board member since 2023

Michael has extensive experience within the pharmaceutical industry with 20+ years of experience in both foreign capital markets and publicly listed companies. This includes a successful track record in general management, R&D, and commercial functions. Since 2019 Michael has been CEO at Nykode Therapeutics, Norway. Michael holds a M.Sc. in chemistry with a specialization in biotechnology from the Technical University of Denmark (DTU) and a graduate diploma in Business Administration (HD) from Copenhagen Business School (CBS).

Executive Management

Morten Albrechtsen – CEO since 2018

Morten Albrechtsen is an MD and BBA ('HD' in marketing, CBS). Morten is a seasoned entrepreneur with a strong medical, commercial, and financial background. The expertise is gained within a broad range of therapeutic areas and with both drugs and devices. Morten has developed and launched new health care products and concepts internationally, e.g. in Nycomed Pharma, now Takeda Pharmaceuticals Ltd., Nanovi A/S and Boehringer Ingelheim GmbH.

Ole Larsen – CFO since 2023

Ole Larsen holds a M.Sc. and is an experienced CFO with a strong history of working in various industries in both listed and unlisted companies, including Bavarian Nordic, BioPorto, Nordisk Film, and Berlingske Tidende. Ole is skilled in growth/start-ups, M&A and Corporate Finance, and has a finance professional background with a M.Sc. focused on Economics from Copenhagen Business School. Ole currently serves as member of the board at Linkfire.

Corporate Management

Andreas Kjær – CSO and CMO since 2018

Andreas Kjær is an MD, PhD, DMSc and professor at the University of Copenhagen and chief physician at Rigshospitalet, the National University Hospital of Denmark. His research is focused on molecular imaging with PET, PET/MRI and OPTICAL IMAGING in cancer and cardiovascular disease and his achievements include development of several new tracers that have reached first-in-humans clinical use. He is the holder of an ERC Advanced Grant, has published more than 400 peer-review articles and has received numerous prestigious scientific awards over the years. Andreas also has an MBA from Copenhagen Business School.

Grethe Nørskov Rasmussen – CDO since 2019

Grethe Nørskov Rasmussen holds a M.Sc. and PhD. Grethe Rasmussen is an experienced product developer with a profound understanding of CMC and former Senior Vice President Product Development at Ascendis Pharma A/S, where she worked for over 10 years. Previously, Grethe served as Vice President for Protein Science at Maxygen, Inc. and later as Managing Director for the Danish subsidiary of Maxygen. Prior to joining Maxygen, Grethe held various positions at Novo Nordisk A/S, a global healthcare company, where she contributed to research and development. Grethe holds a PhD in Biochemistry from the Danish Technical University.

Dorthe Grønnegaard Mejer - VP Clinical Development since 2020

Dorthe Grønnegaard Mejer has a M.Sc. in Pharmaceutical Sciences from Copenhagen University. She has previously held several positions across different clinical development disciplines as well as positions within clinical oncology development in other biotech companies such as Genmab, Larix, Orphazyme, and Oncology Venture.

SHAREHOLDER INFORMATION

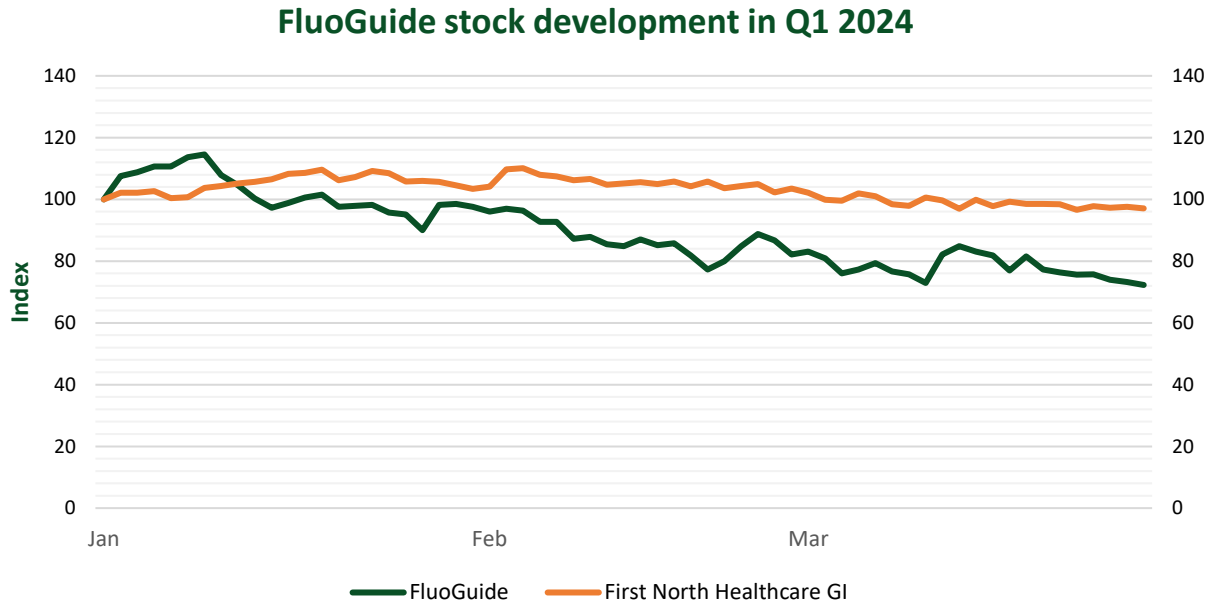
The share

The shares in FluoGuide were listed in 2019 on Spotlight Stock Market and moved from Spotlight to Nasdaq First North Growth Market, Stockholm in February 2021. The ticker is FLUO, and the ISIN code is DK0061123312.

The total number of outstanding shares as of March 31, 2024, amounted to 12,208,384 (11,814,500) shares, each with a nominal value of DKK 0.10. Each individual share entitles one vote in the company and has an equal right to the company's assets and results. There have been no changes in the number of outstanding shares, since reported in the 2023 annual report.

Share price performance in Q1 2024

At the end of Q1, the closing price for FluoGuide shares on Nasdaq First North Growth Market, Sweden was SEK 47.70 – down 27.7% since beginning of the year 2024. During the same period, the First North Health Care GI decreased by 4.9%.



The total trading volume of FluoGuide shares on Nasdaq First North Growth Market, Sweden was 790,647 in Q1 (6.7% of shares issued). By the end of Q1, FluoGuide's market capitalization was SEK 582 million against SEK 747 million at the end of 2023.

Ownership

The number of shares is always defined, however there is no complete record at any given time of all shareholders and their ownership. Based on the available information as of March 28, 2024, FluoGuide had 8,516 registered shareholders. The 20 largest shareholders owned 70.1% of the share capital.

FluoGuide has no majority shareholders.
Shareholders owning more than 15% in FluoGuide according to latest shareholding notifications are:

- Life Science ApS, a fully owned company by Board Member, CSO and CMO Andreas Kjær (17.43%)

Shareholders owning more than 10% in FluoGuide according to latest shareholding notifications are:

- Wexotec ApS, a fully owned company by CEO Morten Albrechtsen (12.20%)

Shareholders owning more than 5% in FluoGuide according to latest shareholding notifications are:

- Arbejdernes Landsbank, including withholds repositories from holding for clients
- Linc AB

Management and Board of Directors owns 34.07% of the total amount of outstanding shares.

Warrants

FluoGuide has established incentive programs for its employees, management, and Board. On February 23, 2024, the Board of Directors of FluoGuide exercised its authorization to issue new warrants by issuing 45,000 warrants to the CFO.

The warrant program is issued to ensure alignment of interests between the Company's employees, management, Board of Directors, and shareholders. The Company believes that the issue of warrants will provide motivation for the achievement of FluoGuide's short-term and long-term goals to support the Company's business strategy, sustainability, and value creation for the benefit of shareholders. As per March 31, 2024, the total number of outstanding warrants is 535,875 which represents a total dilution of 4.2 percent of the current share capital, if vested and exercised.

FINANCIAL DEVELOPMENT

Financial Development

Clinical development plays a significant role in the financial development of FluoGuide. Some of the numbers in this section show a large deviation for Q1 2024 compared to Q1 2023.

The main reason for this is that in Q1 2023, the Company was running and enrolling patients in three different clinical trials, whereas in Q1 2024, the Company has spent resources on the final analysis and study reports.

Operating income & Other operating income

Net revenue amounted to DKK 0 (DKK 0). Other operating income for the period amounted to DKK 26 thousand (DKK 66 thousand) and comprised of a grant from the Innovation Fund Denmark (Innovationsfonden) regarding a business post doc and participation in a project with Danish Life Science Cluster.

Other external expenses

For the period, other external expenses amounted to DKK 4,541 thousand (DKK 8,012 thousand). Research & development costs including IP, but excluding salaries amounted to DKK 2,013 thousand (DKK 6,427 thousand), Sales & marketing costs of DKK 205 thousand (DKK 33 thousand) and General & admin costs of DKK 2,323 thousand (DKK 1,553 thousand).

The reduction in Research & Development costs is due to the timing of the clinical trials. In Q1 2024 the study reports and final outstanding matters of the clinical trials are in process whilst in the same period last year the Company had three ongoing clinical trials with FG001 in aggressive brain cancer (HGG), lung cancer and head & neck cancer.

The increase in General & admin costs is primarily related to IT validation and timing of insurance premiums and auditor and legal fees.

Staff expenses

Staff expenses for the period amounted to DKK 3,768 thousand (DKK 3,627 thousand) and comprised:

- Wages and salaries including bonus and Board fee's DKK 3,051 thousand (DKK 3,063 thousand)
- Employee share schemes DKK 682 thousand (DKK 538 thousand)
- Other staff and social security costs DKK 35 thousand (DKK 26 thousand)

Financial items

Financial income and expenses reflect interest income/expense and currency transaction gains/losses, bank charges and interest. In Q1 2024 the financial income amounted to DKK 9 thousand (DKK 0).

In Q1 2024 the financial expenses amounted to DKK 505 thousand (DKK 57 thousand) primarily due to interest in connection with the credit facility of DKK 20 million of which DKK 10 million were drawn on March 31, 2024.

Tax

In Q1 2024, deferred tax related to tax credits from investments in research & development amounted to DKK 1,320 thousand (DKK 2,167 thousand).

Net result for the period

In Q1 2024 the net result showed a loss of DKK 7,521 thousand (loss of DKK 9,535 thousand) each reflecting the mix of variances described above. The result was in accordance with the Company's expectations for the period.

Balance sheet

As of March 31, 2024, the Company's balance was DKK 20,615 thousand (DKK 28,019 thousand).

The assets primarily consist of cash and a tax benefit related to tax credits derived from investments in research & development in 2023

and Q1 2024. The liabilities primarily consist of equity, the credit facility and working capital.

Cash and cash equivalents

As of March 31, 2024, FluoGuide's balance of cash totaled DKK 10,683 thousand (DKK 16,269 thousand) and is deposited at a national Danish bank.

As a development stage start-up life-science company, and like other similar development stage companies, the Company expects negative cash flow in 2024 from operating activities. The company is dependent on being recapitalized or selling rights to its products against cash until reaching the point where the size of the revenue surpasses the costs resulting in a positive cash flow. The activities of the company in the future will depend on proceeds obtained from capital increases, sales of rights, loans and so forth.

Equity

The total equity on March 31, 2024, amounted to DKK 5,881 thousand (DKK 22,971 thousand). The change in equity is primarily due to the realized net loss of DKK 36,363 thousand in the period April 1, 2023 – March 31, 2024, partly off-set by capital raises of DKK 17,809 thousand. As per March 31, 2024, the solidity was 29 percent (82 percent).

Current liabilities

As of March 31, 2024, the current liabilities amounted to DKK 14,165 thousand (DKK 4,978 thousand). The current liabilities primarily consist of a credit facility DKK 10,457 thousand (DKK 0) and payables of DKK 3,498 thousand (DKK 4,798 thousand).

Subsequent events

There have been no subsequent events.

Operational risks and uncertainties

The risks to and uncertainties of FluoGuide's operations are related to several factors such as development, clinical trials, regulatory, patents and other intellectual property rights, key individuals and employees, registration and licensing with agencies / governmental authorities, competitors, customers, suppliers / manufacturers, international operations, and exchange rate changes, interest rates, tax, financing needs and capital. 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 our website: www.fluoguide.com/investor/filings-archive/

Financial calendar 2024

Q2 report 2024	29 August
Q3 report 2024	28 November
Annual report 2024	27 February

All financial reports are available on FluoGuide's company page: www.fluoguide.com/investor/financial-reports

More information

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

INCOME STATEMENT AND STATEMENT OF COMPREHENSIVE INCOME

INCOME STATEMENT AND STATEMENT OF COMPREHENSIVE INCOME	Q1 24	Q1 23	YTD 2024	YTD 2023	2023
DKK thousand	1-Jan-24	1-Jan-23	1-Jan-24	1-Jan-23	1-Jan-23
	31-Mar-24	31-Mar-23	31-Mar-24	31-Mar-23	31-Dec-23
Revenue	-	-	-	-	-
Other operating income	26	66	26	66	423
Other external expenses	-4,541	-8,012	-4,541	-8,012	-29,234
Staff expenses	-3,768	-3,627	-3,768	-3,627	-14,848
Depreciation and amortization	-63	-72	-63	-72	-265
Income before interest and tax (EBIT)	-8,345	-11,645	-8,345	-11,645	-43,924
Financial income	9	0	9	0	1,824
Financial expenses	-505	-57	-505	-57	-1,777
Income before tax	-8,841	-11,702	-8,841	-11,702	-43,877
Tax on income for the period	1,320	2,167	1,320	2,167	5,500
Net result for the period	-7,521	-9,535	-7,521	-9,535	-38,377
Other comprehensive income for the period, net of tax	-	-	-	-	-
Total comprehensive income	**-7,521**	**-9,535**	**-7,521**	**-9,535**	**-38,377**

BALANCE SHEET

Assets	2024	2023	2023
DKK thousand	31-Mar-24	31-Mar-23	31-Dec-23
Non-current assets			
Aquired patents	378	378	378
Right of use assets	745	132	803
Tangible fixed assets	743	37	21
Deposit	144	112	144
Total non-current assets	2,010	659	1,346
Current assets			
Other receivables	1,099	3,405	915
Receivable corporate tax	6,820	7,667	5,500
Prepayments	2	18	180
Cash	10,683	16,269	21,668
Total current assets	18,604	27,359	28,263
Total assets	**20,615**	**28,019**	**29,609**

Equity and liabilities	2024	2023	2023
DKK thousand	31-Mar-24	31-Mar-23	31-Dec-23
Equity			
Share capital	1,221	1,181	1,221
Retained earnings	4,660	21,790	11,499
Total equity	5,881	22,971	12,720
Liabilities			
Non-current liabilities	-	-	-
Debt to credit institutions	10,457	0	10,000
Lease liabilities	211	68	205
Trade payables	2,139	3,762	4,094
Other payables	1,359	1,036	1,966
Deferred income	0	112	0
Total current liabilities	14,165	4,978	16,266
Total liabilities	14,733	5,047	16,889
Total equity and liabilities	**20,615**	**28,019**	**29,609**

STATEMENT OF CHANGES IN EQUITY

Change in Equity: Q1 24	Share-capital	Share Premium	Retained earnings	Shareholder equity
DKK thousand				
01-jan-24	1,221		11,499	12,720
Total comprehensive income for the period	-	-	-7,521	-7,521
Contribution - cash		-	-	-
Expenses in connection with capital increase		-	-	-
Employee share schemes – value of employee services			682	682
Fair value of warrants issued subsequently to right of issue			-	-
Transfer	-	-	-	-
31-mar-24	**1,221**	**-**	**4,660**	**5,881**

Change in Equity: Q1 23	Share-capital	Share Premium	Retained earnings	Shareholder equity
DKK thousand				
01-jan-23	1,181		30,787	31,968
Total comprehensive income for the period			-9,535	-9,535
Contribution - cash				-
Expenses in connection with capital increase			-	-
Employee share schemes – value of employee services			538	538
Fair value of warrants issued subsequently to right of issue			-	-
Transfer			-	-
31-mar-23	**1,181**	**-**	**21,790**	**22,971**

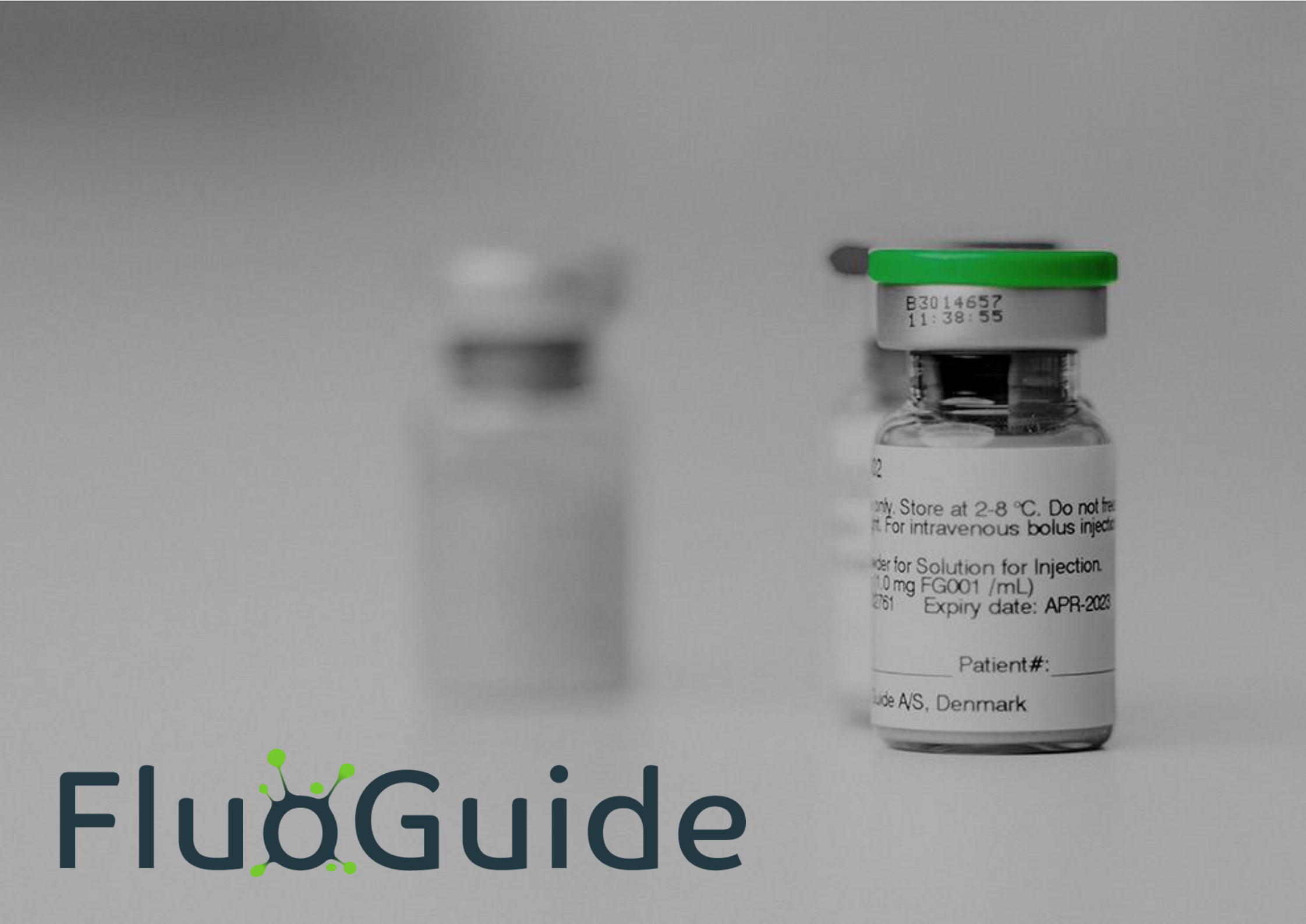
Change in Equity: YTD 2024	Share-capital	Share Premium	Retained earnings	Shareholder equity
DKK thousand				
01-jan-24	1,221		11,499	12,720
Total comprehensive income for the period	-	-	-7,521	-7,521
Contribution - cash		-	-	-
Expenses in connection with capital increase		-	-	-
Employee share schemes – value of employee services			682	682
Fair value of warrants issued subsequently to right of issue			-	-
Transfer	-	-	-	-
31-mar-24	**1,221**	**-**	**4,660**	**5,881**

Change in Equity: YTD 2023	Share-capital	Share Premium	Retained earnings	Shareholder equity
DKK thousand				
01-jan-23	1,181	-	30,787	31,969
Total comprehensive income for the period			-9,535	-9,535
Contribution - cash			-	-
Expenses in connection with capital increase				-
Employee share schemes – value of employee services			538	538
Fair value of warrants issued subsequently to right of issue			-	-
Transfer	-	-	-	-
31-mar-23	**1,181**	**-**	**21,790**	**22,972**

Change in Equity: 2023	Share-capital	Share Premium	Retained earnings	Shareholder equity
DKK thousand				
01-jan-23	1,181	-	30,787	31,969
Total comprehensive income for the period			-38,377	-38,377
Contribution - cash	39	17,770		17,809
Expenses in connection with capital increase			-84	-84
Employee share schemes – value of employee services			3,115	3,115
Fair value of warrants issued subsequently to right of issue			-1,712	-1,712
Transfer	-	-17,770	17,770	0
31-dec-23	**1,221**	**0**	**11,499**	**12,720**

CASH FLOW STATEMENTS

Cash flow	Q1 24	Q1 23	YTD 2024	YTD 2023	2023
DKK thousand	1-Jan-24	1-Jan-23	1-Jan-24	1-Jan-23	1-Jan-23
	31-Mar-24	31-Mar-23	31-Mar-24	31-Mar-23	31-Dec-23
Income before tax	-8,841	-11,702	-8,841	-11,702	-43,877
Net financial items, reversed	505	57	505	57	-47
Change in working capital	-2,568	1,421	-2,568	1,421	4,900
Depreciation and amortization	63	72	63	72	265
Adjustment for non-cash employee benefits expense - share-based payments	682	538	682	538	3,115
Cash flow from operating activities before net financials	-10,160	-9,615	-10,160	-9,615	-35,644
Net financial items paid	-505	-57	-505	-57	-1,665
Tax credit paid out	-	-	-	-	5,500
Cash flow from operating activities	-10,665	-9,672	-10,665	-9,672	-31,809
Purchase of tangible assets	-727	0	-727	0	0
Paid deposit	0	-5	0	-5	-37
Cash flow from investing activities	-727	-5	-727	-5	-37
Proceeds from capital increase	-	0	-	0	17,809
Proceeds from credit facility	457	0	457	0	10,000
Principal elements of lease payments	-50	-67	-50	-67	-225
Costs related to capital increase	-	0	-	0	-84
Cash flow from financing activities	407	-67	407	-67	27,500
Total cash flow for the period	-10,985	-9,744	-10,985	-9,744	-4,345
Cash, beginning of the period	21,668	26,013	21,668	26,013	26,013
Cash, end of the period	**10,683**	**16,269**	**10,683**	**16,269**	**21,668**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Store at 2-8 °C. Do not
For intravenous bolus
for Solution for Injection
mg FG001 /mL)
Expiry date: APR-2023
Patient#:
A/S, Denmark

FluoGuide