# INVITATION TO SUBSCRIBE FOR UNITS FLUOGUIDE A/S



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

FluoGuide now conducts a public issue of units (shares and consideration free warrants) prior to planned listing at Spotlight Stock Market. The issue proceeds of initially approximately MDKK 15.9 are primarily intended to finance a proof-of-concept Phase I/lla study with the first product FG001 as well as recruitment of a basic organization and initiation of regulatory discussions with healthcare authorities. The company's objective is to establish compassionate use sales in 2020 and launch its first product on the market in 2022/2023.







# **CEO MORTEN ALBRECHTSEN HAS THE FLOOR**

Cancer affects everyone and represents a tremendous burden on patients, families and societies. Each year more than 14 million people are diagnosed with cancer and each year over 7 million people die due to the disease. Surgery is one of the most important treatments for early cancer, and it is also the oldest and most commonly used method to treat cancer. The surgeon wishes to completely remove the cancer and cure the patient diagnosed with a localized cancer. The challenge is to distinguish the normal tissue from the cancer tissue. The surgeon will therefore remove some centimeters of normal tissue around the tumor to increase the likelihood of removing all cancer tissue. The dilemma for the surgeon is that either the location of the cancer may restrict the removal of surrounding tissue as it may cause severe side effects, or it poses a cosmetic problem to remove excessive amount of normal tissue. Furthermore, even after removal of normal surrounding tissue not all cancer are removed and in approx. 50 % of all cases, dependent on the cancer type, the disease will recur. This recurrence of cancer is a major challenge as it leads to more suffering for the patients and potential death.

Now, imagine that the surgeon could simply inject a compound and turn on a special light, making the tumor clearly visible and fluorescent, and allow the surgeon to remove the entire cancer. Even though it might sound as wishful thinking, 15 years of research in this scientific field has now made it possible to test the fluorescent concept in cancer patients. We are in the forefront of this field and we have developed a compound that, when given to patients, makes cancer tumors light up - to fluoresce. We are advancing our first product - FG001 - towards clinical development helping surgeons provide better treatment to cancer patients. FG001 consists of two building blocks, a targeting molecule and a fluorophore, that both have been proven well tolerated in humans. Our targeting molecule binds to a specific receptor named uPAR, that is extensively expressed in solid cancers. When the surgeon switches to fluorescent light during surgery, the tumor lights up. This helps the surgeon remove all of the tumor and also the local metastasis that are very hard to identify in normal light. Moreover, it also helps the surgeon to reduce the amount of normal tissue removed, and thus minimizing the potential side effects of surgery. Importantly, this new concept will also reduce the costs for the health care system, as recurring cancer increases costs in terms of using more advanced and expensive therapies, longer treatments, reoperations and more diagnostic tests applied. Everyone who have been waiting to get a diagnostic test result knows the suffering this implies on the subject and the relatives.

FG001 **fits the current workflow at hospitals.** A small amount of FG001 is simply injected into a vein prior to surgery. The majority of the fluorescent compound will quickly be removed from the body and only the molecules bound to the cancer cells will remain and help to guide the surgeon. After only 30 minutes the surgeon can switch between the standard ordinary white light and the special "night vision", where the cells fluoresce. Modern image equipment can show both images merged into one vision. In this way, the

surgeon can follow the usual procedures and simultaneously see the cancer cells, allowing the surgery to proceed until no more cancer tissue lights up. The majority of all hospitals globally have surgical equipment with the possibility to alter between normal white and fluorescent light.

FluoGuide's products have a **potential beyond cancer surgery**. Today, robotic assisted surgery is rapidly expanding, and it will likely move towards more automation which will be accelerated by guidance. In many ways, we believe that **our technology will also enable further automation of robotic surgery in the future**.

When we tested FG001 in preclinical models, we experienced a very **effective** removal of tumors. FG001 has been tested by experienced surgeons on different human cancers using the market leading Da Vinci robot, which means that we already have tested FG001 using the same study design that is needed in the pivotal clinical Phase IIb/III study, before FG001 can be used routinely in patients with cancer. The route to approval is well defined and associated with low risk compared to regular drug development. Toxicity studies will be prepared in Q2 2019. Afterwards our ambition is to submit a clinical trial application to initiate a proof-of-concept Phase I/IIa study later this year. The first results are planned to be available during H1 2020 and the top-line results from the study is expected in H2 2020. This study is a Phase I/Ila study with the objective to test safety, tolerability, optimal dose, and confirm clinical proof-of-concept in patients. After a successful Phase I/ IIa study we plan to conduct a Phase IIb/III study along with a commercial partner. The Phase IIb/III study is expected to be simpler, shorter and cheaper than a typical study for a regular drug candidate. We plan to establish compassionate use sales as early as in 2020 and market launch in a first country in 2022/2023.

#### Join us in transforming cancer surgery!



#### REFERENCE TO PROSPECTUS

All investments in financial products are associated with risks. The prospectus issued by FluoGuide contains a description of potential risks associated with the company's operations and its financial products. Before any investment decisions are made these risks should be understood, and all information in the complete prospectus should be read carefully. The prospectus is available for download on the websites of FluoGuide (www.fluoguide.com), Spotlight Stock Market (www.spotlightstockmarket.com) and Sedermera Fondkommission (www.sedermera.se).



Arne Ferstad Chairman of the Board of Directors

### **SUMMARY OF THE OFFERING**

#### **Subscription period:**

April 1st - April 15th, 2019.

#### Subscription price:

DKK 14.85 per unit. One (1) unit consists of three (3) shares and one (1) consideration free warrant of series TO 1. The price per share is thus DKK 4.95.

#### Subscription post:

The minimum subscription is 250 units, corresponding to DKK 3,737.50.

#### Issue volume and minimum limit for implementation:

The offering comprises a total of 3,224,274 shares and 1,074,758 warrants of series T0 1, initially corresponding to DKK 15,960,156.30 at the most. The minimum limit to implement the issue of units is 864,648 units, corresponding to DKK 12,840,022.80.

#### Number of shares before the issue of units:

4,000,000 shares.

#### Valuation (pre-money)\*:

Approximately MDKK 19.8.

#### **Subscription commitments:**

FluoGuide has received subscription commitments of approximately MDKK 9.9, corresponding to approximately 62 percent of the initial issue volume.

#### **Listing on Spotlight Stock Market:**

FluoGuide's shares and warrants of series T0 1 are planned to be listed on Spotlight Stock Market. The trading is planned to commence on May 7th, 2019.

#### ISIN code for the share:

DK0061123312

# **SUMMARY OF THE CONSIDERATION FREE WARRANTS**

#### **Exercise period:**

April 16th - May 7th, 2020.

#### Exercise price:

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.

#### Valuation (pre-money)\*\*:

Approximately MDKK 43.0.

#### Issue volume:

If the initial issue of units is fully subscribed, a total of 1,074,758 warrants of series TO 1 will be issued. The warrants can provide the Company a total of DKK 6,394,810.10 if all warrants are exercised.

#### ISIN code for the warrants of series TO 1:

DK0061138773

<sup>\*</sup>The valuation is based on a number of factors, including market potential and historical investments. Further information on the terms of the offer can be found under "Terms and Conditions" in the prospectus.

<sup>\*\*</sup>Dependent on a fully subscribed IPO.

## A BRIEF INTRODUCTION TO FLUOGUIDE

Cancer is one of the leading causes of death globally. Surgery is a cornerstone in treatment of localized cancer and the ambition is to completely remove the tumor in order to cure the patient. The problem is that in approx. 50% of all cases the cancer recurs locally after surgery. Recurrence of cancer leads to suffering and possible death. Incomplete surgery is also very costly for the health care system as the need for re-operation is an expensive process.

# 2019

#### **OPERATIVE OBJECTIVES**

- Prepare toxicity testing on FG001
- Initiate partnering discussions
- · CMC production partner decided
- Production process for FG001 established
- Formulation of FG001 developed
- Define FG002
- Safety of FG001 confirmed in toxicity studies
- Prepare clinical trial application for proof-ofconcept Phase I/lla study on FG001
- Initiate regulatory discussions with national, European and/or US regulatory health care authority (e.g. EMA, FDA or DMA) on FG001.
- Initiate clinical proof-of-concept Phase I/lla study on FG001
- Initiate clinical study on second indication for FG001
- First result for proof-of-concept Phase I/lla study on FG001 in first indication
- Initiate phase III production in commercial scale of ECO01
- Initiate planning of the Phase IIb/III study
- Establish compassionate use sales and/or partnering agreement of FG001
- Establish first commercial partnerships
- Initiate pre-clinical development of FG002
- Obtain result of second indication for FG001
- Define FG003
- Final result of Phase I/IIa studies
- End of Phase 2 meeting with FDA (USA) and EMA (Europe) to present the data from the Phase I/ Ila clinical trial and obtain their feedback on the Company's proposed design for the approval clinical trial needed for marketing authorization of FG001
- · Initiate pivotal clinical Phase Ilb/III study
- Submit first application for marketing authorization for FG001 assuming grant of orphan drug designation or another designation that accelerate its approval (e.g. break through status)
- Market launch in the first country of FG001
   assuming grant of orphan drug designation or
   another designation that accelerate its approval

FluoGuide develops a patented solution that is expected to reduce suffering for the patient and increase the likelihood of cure as well as reduce costs for the health care system. The first product is the compound FG001, which lights up the cancer and its invasive growth into the surrounding tissue. FG001 is made of a targeting molecule linked to a fluorophore and the components have previously indicated no or low risk of toxicity. FG001 is injected into a vein of the patient during anesthesia and binds to cells expressing uPAR, which is a protein present on the surface of the tumor. Therefore, when the surgeon switches to fluorescent light, the tumor and all local metastasis becomes visible to the surgeon. This helps the surgeon remove all the cancer and preserve normal tissue. Since FG001 is injected into the vein during anesthesia, the product fits the current workflow at hospitals. Further, FG001 is equipment independent, which means that surgeons are not restricted by which equipment is available at the hospital.

In a recently performed non-human preclinical study on eight subjects, additional metastasis were found in four of the eight subjects using FG001 and fluorescent light. This means that in half of the subjects (50 %) traditional white light surgery overlooked cancer tissue that was identified by FG001. These results demonstrate the potential of FG001 to vastly improve the likelihood of performing radical surgery (removal of all cancer) and thereby improving outcome and survival.

"The route to market approval of our products is shorter and less expensive compared to other, traditional pharmaceutical and diagnostic products."

FluoGuide's ambition is to conduct a proof-of-concept clinical trial (Phase I/ IIa) of FG001 in patients with cancer. Compassionate use sales (a treatment option that allows the use of an unapproved medicine because it is considered unethically not to) is expected by the end of 2020 provided a positive result from the proof-of-concept study with FG001. Only one additional study is anticipated necessary to obtain marketing approval for FG001 and FluoGuide plans to conduct the approval study (Phase IIb/III), which is also much simpler than a clinical trial for a regular drug candidate and needing much fewer. This means that the route to market approval is shorter and less expensive compared to other, traditional pharmaceutical and diagnostic products.

FluoGuide's products will be used at hospitals and paid for by the hospital's insurance and/or governments as well as patients. In order to sell FluoGuide's products to these target groups quickly and cost effectively, FluoGuide plans to enter distribution partnerships with companies selling drugs or medical devices to hospitals and surgeons. The company plans to establish compassionate use sales during 2020 and launch FG001 in the first country in 2022/2023. The large markets will likely accept orphan drug designation, which would mean a faster market launch with greater support from regulatory agencies and better protection.

2021

2022





#### Subscription form for subscription of units in FluoGuide A/S

Subscription period:	April 1 - April 15, 2019, 2019 until 3 p.m.						
Subscription price:	DKK 14,85 per unit						
Allocation:	Any allotment of units will be notified via a settlement note.						
Payment:	To be made in accordance with the instructions on the settlement note.						
First day of trading:	day of trading: The first day of trading in FluoGuide A/S's shares and warrants on Spotlight Stock Market is scheduled to be the 7th of May 2019.						
In an assessment of FluoGuide A/S's future development and operations, it is of great importance to consider all relevant risks. Each investor must make their own assessment of the impact of these risks by reading and understanding all available information published concerning this offer. The prospectus is available for download at www.FluoGuide.com, www.spotlightstockmarket.com or www.sedermera.se. Payment is not to be made in conjunction with the application for subscription. Any allotment is notified via a settlement note.							

#### Please note

If you wish to have your allotted shares and warrants delivered to a bank or nominee outside of Sweden or Denmark, you are required to submit with **Standard Settlement Information** (**SSI**) to Sedermera Fondkommission. The SSI can be provided to you through your bank/trustee.

Please also make sure that your bank can trade shares on Spotlight Stock Market, if you want to be able to sell or buy shares in FluoGuide A/S after first day of trading.

1. The undersigned hereby subscribes for the following number of units in FluoGuide A/S at a subscription price of DKK 14,85 per unit. The minimum subscription is 250 units, which corresponds to DKK 3 712,50.

DKK 4,95) and one (1) warrant free of payment (à DKK 0,00). The price for one (1) unit is DKK 14,85 (DKK 4,95\*3 + DKK 0,00)

Number of units			

#### 2. Please enter your securities account number where allotted shares and warrants are to be delivered:

	•									
Custody account										Bank/Trustee

Do you have a custody account with Nordnet? Please contact your bank to process your subscription directly through Nordnet.

#### 3. Do you invest regularly through Sedermera?

(ten (10) times during the last twelve (12) months, or six (6) times each year for the last five (5) years)

YES

NO

4. Subscription over 15 000 EURO?

(Please note, if you have answered the money laundry form during the last 12 months, you don't need to fill out the form again).

If the answer on question 3 or 4 is Yes, the following is required:

- 1) The money laundry form on the following page must be completed and submitted.
- 2) A verified copy of your ID (Passport) must be sent to Sedermera Fondkommission by mail to the below stated address, at the same time that the subscription form is submitted to Sedermera Fondkommission.

#### 5. Fill in your name and address information (PLEASE WRITE CLEARLY)

First name/Company	Last name	National ID number/Corp.ID.no.
Street address (or PO Box or equivalent)	Postal code	City
Street address (of PO Box of equivalent)	Postal code	City
Country (if other than Sweden)	Daytime telephone/mobile phone	E-mail (Mandatory)
		Contract note will be sent via e-mail
Place and date	Signature (authorized company signature, or guardian, if applicable)	

#### 6. By signing this subscription form I confirm the following:

- That the subscription is binding and that an incomplete or incorrect subscription form may be disregarded;
- That I have read and understand the information stated in the section "Terms and Conditions" in the prospectus;
- That I have read and accepted the information stated on the subscription form;
- That I have read the prospectus and understand the risks associated with investing in this particular financial instrument; I have observed that the offer is not addressed to persons resident in the USA, Australia, Japan, Canada, New Zealand, South Africa, Hong Kong, Switzerland, Singapore or other countries where participation requires additional prospectus, registration or other measures other than those required by Danish and Swedish law;
- That I am aware that the application is not covered by the right of return that follows from the Swedish Distant and Doorstep Sales Act or the Danish Consumer Contracts Act;
- That in signing this subscription form, I authorize Sedermera Fondkommission, at the undersigned's expense, to implement the subscription of units pursuant to the "Terms and Conditions" stated in the
  prospectus issued by the board of FluoGuide A/S in Q1 2019;
- That no amendments or additions may be made to the printed text in this subscription form;
- That the allocation of units in accordance with the subscription cannot be guaranteed;
- That I am aware that Sedermera Fondkommission will not make any assessment of whether the subscription to the instrument in question is suitable for me or the person on whose behalf I am subscribing;
- That I am aware that no customer relationship exists between Sedermera Fondkommission and the subscriber with respect to this subscription;
- That personal data supplied in connection with the assignment will be stored and processed by Sedermera Fondkommission for the purpose of administering this assignment. The data may also be used in any future mailings concerning offering documents. Personal data will be stored and processed in accordance with the General Data Protection Regulation (GDPR).

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