

# 3Q 2021 – operational update

10 November 2021



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# Operational update

## **Distance to a pandemic, focus on the diabetes epidemic**

2Q 2021 was as a period of strategic adjustments and adaptations. 3Q 2021 has been a time for implementing the operational changes and adaptations necessary to ensure a solid development and progress. Our historical mission is to help people with diabetes to improve disease management. Our main objective has been to ensure control over the sensor development and to focus on the unique core technology for Continuous Glucose Monitoring (CGM).

With the Sencell technology, Lifecare aims to provide a rice-grain sized CGM device with a longevity of at least 6 months. The Sencell technology is expected to be significantly less expensive than existing CGM products. Based on the small size and long-life, the technology will to a large extent reduce the user's diabetes related waste. With this sustainable value and help, our future customers can substantially reduce their environmental footprint. Reducing the amount of “diabetes waste” is in line with the UN Sustainable Development Goals as well as the Green Declaration call-to-action announced by The Diabetes Technology Society in November 2021.

Identifying and documenting the significant cost and waste reduction that Sencell represents compared to other CGM-devices is an important priority for Lifecare going forward. Our technology represents huge potentials with respect to costs reductions and sustainability.

Lifecare aims to become the market leader for economically affordable implantable small-sized sensors with long duration of action. The product may result in a broad range of savings for CGM-users, their relatives, as well as public and private healthcare cost carriers.

# Operational update

## Progress, expectations and postponements - lessons learned during first three quarters of 2021

After a very thorough review process, the German Federal Institute for Drugs and Medical Devices (BfArM) approved Lifecares first-in-human Sencell clinical pilot study in February 2021. The changes in the regulatory guidance related to the implementation of the new EU Medical Device Regulations (MDR) were the reason the approval process took longer than expected. On the positive side, the thoroughness in the regulatory process preceded the following development steps originally planned for 2022; (1) Identification of a suitable Sterilization process and its, (2) Bioburden assessments, development of test systems and validation thereof, (3) Biocompatibility assessment of all device components and, (4) Determination of system burst pressure.

While Lifecare was ready to initiate the approved Sencell clinical pilot studies in 2Q 2021, the production of sensors for the study was suddenly interrupted by the insolvency and bankruptcy of Digital Diagnostics AG, Lifecare's key development and manufacturing partner. At that time, the financing of the Sencell development and sensor manufacturing was depending on our former German partner. Hence, we were not able to carry out the first-in-human study in 2Q 2021 as originally planned. It has been an important learning lesson for Lifecare to ensure that all future vital development should be kept inhouse to maintain control. Therefore, our consecutive restructuring, planning and preparations in 2Q and 3Q 2021 had the purpose to implement and establish a solid Lifecare-controlled infrastructure for the continued Sencell development. The end of 3Q 2021 represents the end of a challenging 12-month period for Lifecare. 4Q 2020 and 1Q 2021 were periods of high volatility in the Lifecare stock value, leading to a constant decrease throughout 2Q 2021, after Digital Diagnostics AG filed for insolvency end of March 2021.

# Operational update

## **New visual identity – new homepage**

Lifecare launched its new homepage and visual identity in 3Q 2021.

## **Acquisition of Pfützner Science & Health Institute**

Lifecare has agreed with Pfützner Science & Health Institute GmbH (PSHI) to take over the laboratory, which Lifecare up to now has contracted for evaluation and validation of the Sencell technology. This Laboratory is leading in testing and validating glucose monitoring systems in accordance with ISO15197, including regulatory system accuracy studies, user performance studies, and clinical and in-vitro interference testing. By taking over the Laboratory, Lifecare ensures reliable and effective R&D capacities. In addition, Lifecare will take advantage of the already existing contract research activities for third party customers at the laboratory, which will continue in an undisturbed fashion.

Closing of transaction is pending due to ongoing due diligence, the take-over is agreed with effect as of 1 September 2021.

# Operational update

## Share capital increase

In 3Q 2021 Lifecare engaged Carnegie AS as bookrunner and manager (the “Manager”) to advise on and effect a private placement. Two Extraordinary General Meetings were held in September as part of this process, giving the Board the necessary authorization to complete a Private Placement. Lifecare AS closed a private placement of 26,3 MNOK 5 October at market. The net proceeds will be used for: (i) Further research, development and clinical studies of the implantable sensor Sencell towards CE mark, (ii) strengthening the Company's balance sheet to ensure financial capacity and flexibility to pursue growth opportunities, (iii) working capital as well as for general corporate purposes, and (iv) continue to develop the organization and internationalize the Company. Lifecare will consider the need for additional financing in 2022. Primary insider and IR Kine Hereid participated in the private placement through her company Hereid Invest AS, and she now owns 117.647 shares in Lifecare after participating in the private placement.

## Other operational activities

Over the last year Lifecare has had a change of management, both operational and at the Board level. Former Lifecare COO and Lifecare resolved their differences in 3Q 2021 and former Lifecare COO's options have been exercised. Lifecare is happy to focus on the organization and operations going forward.

# Lifecare Nanobiosensors



To ensure access to the innovative 3D nanoprinting technology, Lifecare acquired cantiMED UG – now renamed and restructured to Lifecare NanoBioSensors GmbH.

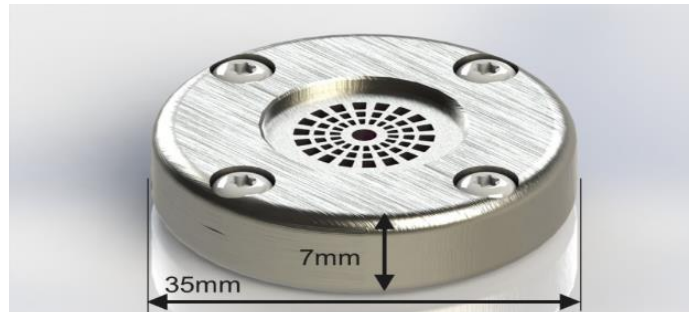
While Lifecare's core osmotic sensing technology is without size limitations, the internal pressure sensor limited the miniaturization potential. The original pressure sensing-element of Sencell was based on piezoresistive technology. The nanotechnology now licensed from the acquired company has already enabled Lifecare to print functional pressure-sensors on the nanoscale, making it possible to significantly reduce the size of the final Sencell sensor to the size of a grain of rice .

In 3Q 2021 we have also established a Lifecare NanoBioSensors office in Reutlingen (DE) with access to state-of-the-art Scanning Electron Microscopes (SEM) at the Natural and Medical Sciences Institute (NMI).

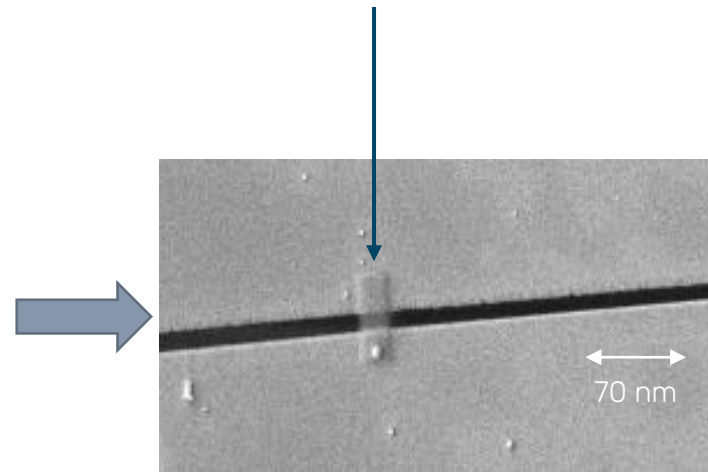
We have hired skilled and trained personnel and have invested in customized add-on equipment for the SEM to ensure production of Sencell sensors with nanoscale pressure-sensing elements. In-vitro and in-vivo testing is now planned for 1H 2022. The Lifecare NanoBioSensors operations started in 3Q 2021 with planning, preparations and alignment with various suppliers to restart the prototyping and production of Sensors for clinical trials, now fully controlled by Lifecare.

# Lifecare NanoBioSensors licensed technology is key for production of the grain-of-rice size CGM

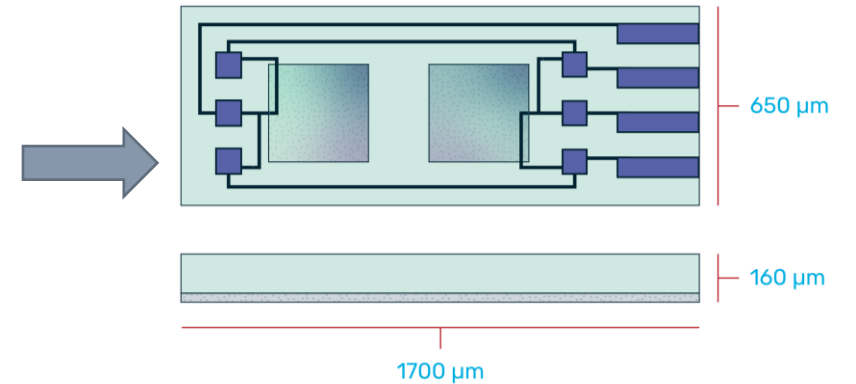
Original sensor from pre-clinical trials with piezoresistive sensing-element



Nano sensing-element detecting movement



Miniaturized sensor with nano sensing-element

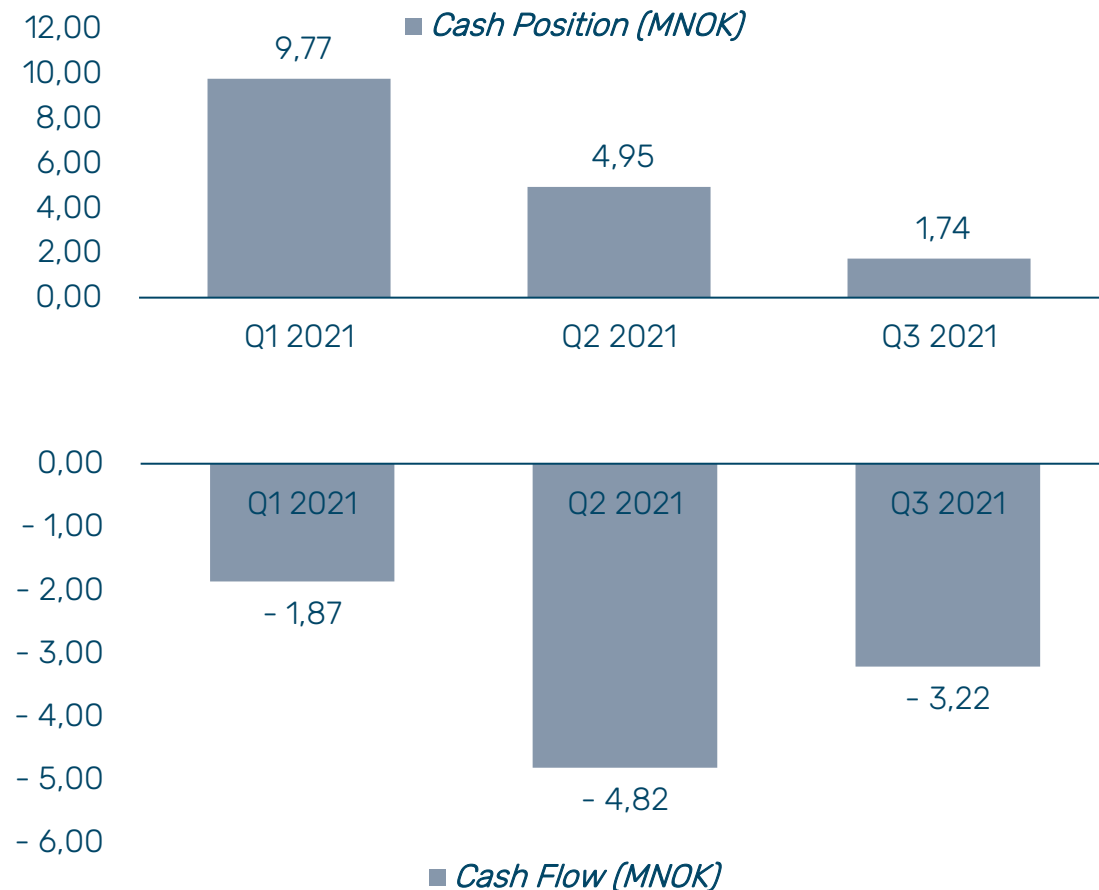




# Key Financial figures and cash flow

Financial statements 30 September 2021 – unaudited (MNOK)	YTD 2021*	YTD 2020	FY 2020
Revenue	0	0	5,4
Salaries and personnell costs	-0,6	-0,1	-0,7
<u>Other operating costs</u>	<u>-9,1</u>	<u>-3,2</u>	<u>-7,3</u>
Sum operating result	<u>-9,7</u>	<u>-3,3</u>	<u>-2,6</u>
Net finance	-0,6	-0,1	-0,2
Sum	<b>-10,3</b>	<b>-3,4</b>	<b>-2,7</b>
Equity	2,0	10,9	11,8
Total Assets	<b>9,3</b>	<b>12,9</b>	<b>15,1</b>

\* EURNOK 10,171



# Financial review

Unless otherwise stated, the key financial figures for the periods in 2021 and 2020 presented in this document relate to Lifecare Group. The Lifecare Group is Lifecare AS and Lifecare Nanobiosensors GmbH consolidated.

The company has a net loss as of 3Q 2021 of 10,3 MNOK, whereas operating expenses amount to 9,7 MNOK. The company has increased activity in the R&D section in relation to the development of chemistry solutions as expected, as well as scaling up the R&D department with key-personnel. As stated in the report of 1H 2021, Digital Diagnostics AG funded major parts of Lifecare's operational costs in 2020, enabling Lifecare to postpone the planned private placement originally planned for 2H 2020. As this agreement is no longer active, Lifecare is funding its own operating costs in 2021. A Lifecare claim towards Digital Diagnostics AG of 50 000 euro (loan given in February 2021), has now been posted in the statements as a loss. Lifecare has no further claims in relation to Digital Diagnostics AG in the balance sheet.

Primary insider and CSO Andreas Pfützner exercised through his company Islay Venture GmbH 195.498 options in 3Q 2021 alongside former COO's exercise of options. Islay Venture now owns 843.623 shares in Lifecare, with an agreed 6 month lock up period of all shares until 5 April 2022.

# Financial review

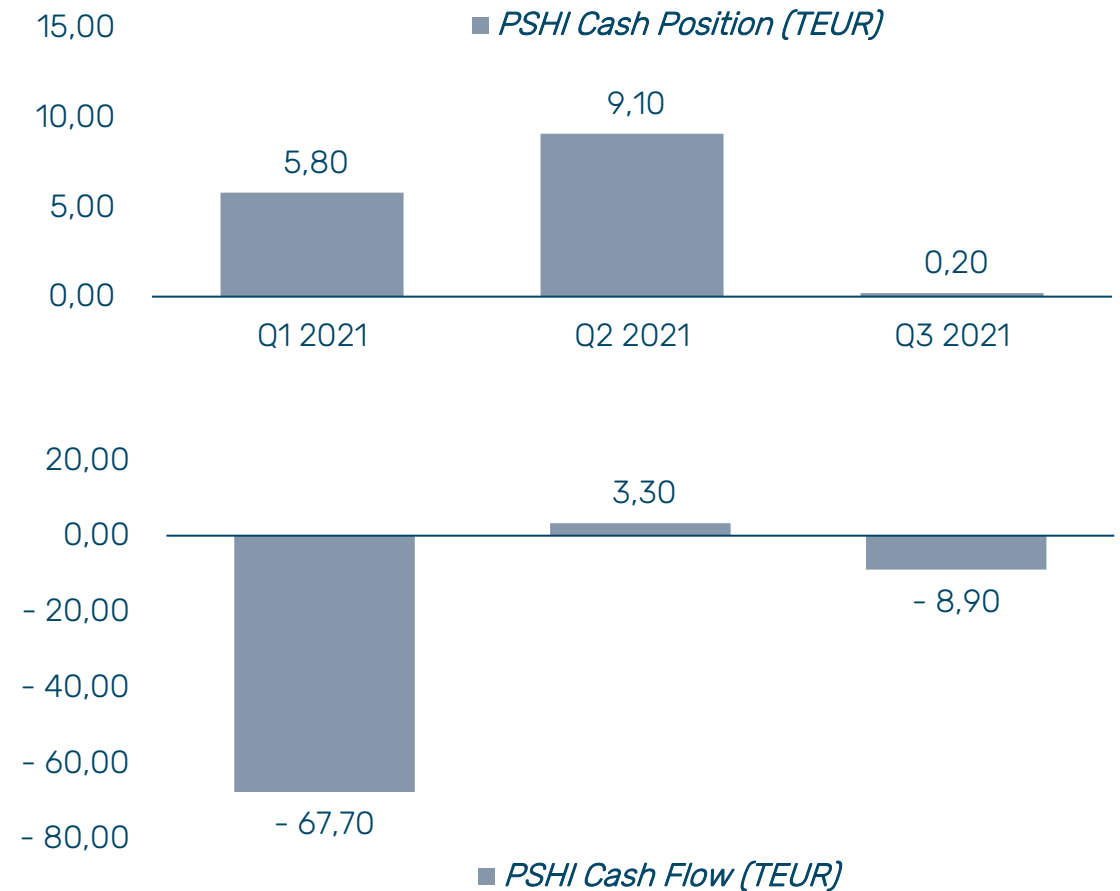
## **Pfützner Science and Health Institute**

The Lifecare acquisition of Pfützner Science and Health Institute (PSHI) is in its final stages of due diligence, and the deal will have effect as of 1 September 2021. The deal is not finalized, thereby we do not include PSHI key financial numbers in the Lifecare numbers, but the key financial figures of PSHI are presented in this report alone (slide 12). Lifecare will be taking over the existing legal entity PSHI, after a carve out of the PSHI medical clinic which continues as an own legal entity as of 1 September 2021.

The PSHI key financial figures include both the Laboratory and the Medical clinic. Approximately 60% of the revenues in the PSHI key financial figures are attributable to the laboratory and 40% to the medical clinic. The activity level in PSHI the third quarter has been higher than the first two quarters, the first two quarters as well as the financial year 2020 had a lower activity level due to the COVID-19 situation. The activity level of the third quarter is forecasted to continue in to the fourth quarter. The laboratory has currently 7 external customers with 11 development projects running. PSHI has 20 TEUR in claims towards Digital Diagnostics AG, this has not been resolved, but must be expected to have a negative outcome for the laboratory.

# Key Financial figures and cash flow - PSHI

Financial statements 30 September 2021 – unaudited (TEUR)	PSHI YTD 2021	PSHI FY 2020
Gross operating revenue	827	474
Salaries and pers.costs	-379	-375
<u>Other operating costs</u>	<u>-487</u>	<u>-520</u>
Sum operating result	<u>-33</u>	<u>-421</u>
Net finance	135	167
EBIT	102	-254
Taxes	-	88
Result	102	-165



# Outlook

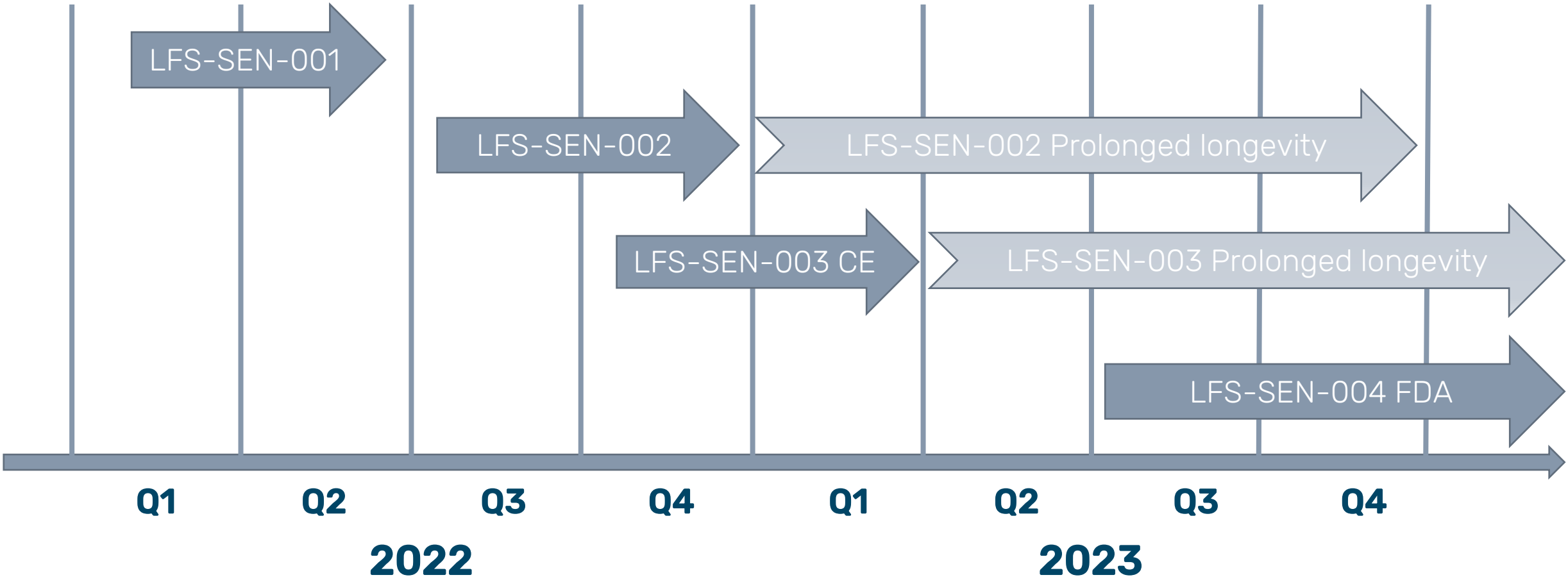
Lifecare plans to produce prototypes of the Sencell sensor in 1H 2022 at Lifecare NanoBioSensors GmbH in Reutlingen (GE). The prototypes will be subject of in-vitro testing at the PSHI Lab and the first-in-human clinical pilot study, both planned for 1H 2022.

Following the clinical pilot study our overall goal is to initiate two upscaled clinical trials in 2H 2022.

In addition to the planned clinical development to reach our aim of a small size and long-life CGM, Lifecare plans to increase the commercial focus related to the cost-saving potential Sencell represent, for people with diabetes, their relatives and next-of-kinds, public and private healthcare budgets and the global environment due to significant waste reductions compared to alternative CGM's.

In addition, Lifecares proprietary and licensed technologies represent a platform opportunity for measuring and identifying proteins and other microorganisms, both in-vitro and in-vivo. Lifecare will focus all existing recourses to develop the Sencell CGM technology but will in addition consider to initiate additional product developments on an opportunistic base through academic or industry partnerships.

# Outlook Clinical studies timeline



# Clinical studies

LFS-SEN-001

- Wired Needle Sensor
- 15 participants (10 healthy subjects & 5 patients with T1D)
- 3 days / proof of concept in humans

LFS-SEN-002

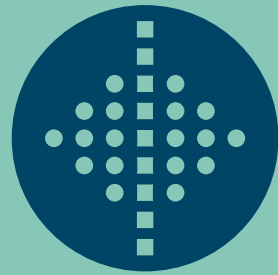
- Implanted Encapsulated Wireless Sensor
- 50 patients with type 1 or type 2 diabetes
- 3 months
- System performance + biocompatibility

LFS-SEN-003  
CE Study

- Implanted Encapsulated Wireless Sensor
- 150 patients with type 1 or type 2 diabetes
- 3 months
- System performance + biocompatibility

LFS-SEN-004  
US FDA

- Implanted Encapsulated Wireless Sensor
- 250 patients with type 1 or type 2 diabetes (non-caucasian)
- 3 months
- System performance + biocompatibility



**LIFECARE**