



# A novel implantable sensor for long-term continuous glucose measurement

26 Juni - 2020



**Lifecare AS is developing an implantable glucose sensor named SENCELL for long term positioning under the skin into the interstitial space.**

# Lifecare's shareholder base June 24th 2020

Dato: 24.06.2020			
Antall investorer:		2 136	
Antall aksjer:		80 925 000	
Beholdning	Prosentandel	Navn	
14 809 477	18,30025	TEIGLAND EIENDOM AS	
10 658 301	13,17059	LACAL AS	
9 440 347	11,66555	BECH INVEST AS	
7 402 700	9,14761	VERDIPAPIRFONDET NORDEA AVKASTNING	
3 147 925	3,88993	Danske Invest Norge Vekst	
2 903 742	3,58819	NORDNET LIVSFORSIKRING AS	
1 812 500	2,23973	Deutsche Bank Aktiengesellschaft	
1 636 361	2,02207	MP PENSJON PK	
1 515 152	1,87229	NORDA ASA	
1 331 355	1,64517	CIMTER AS	
1 046 000	1,29255	SANDQUIST	PATRICIA RODRIGUES DA COSTA
1 000 000	1,23571	STERNA HOLDING AS	
867 555	1,07205	DAHLER	ESPEN
720 425	0,89024	CLEARSTREAM BANKING S.A.	
710 012	0,87737	PROBE AS	
689 379	0,85187	NEXUS MARKETING	
59 691 231	73,76117		



# Increased life quality through continuous glucose measurement

Increased convenience...



Lifecare technology removes the need for daily measurements of blood glucoses through finger prick testing

...through a low-cost implantable micro-sensor...



Lifecare's micro-sensor is injected subcutaneously<sup>(1)</sup>, communicates continuously and wirelessly links to a convenient external device

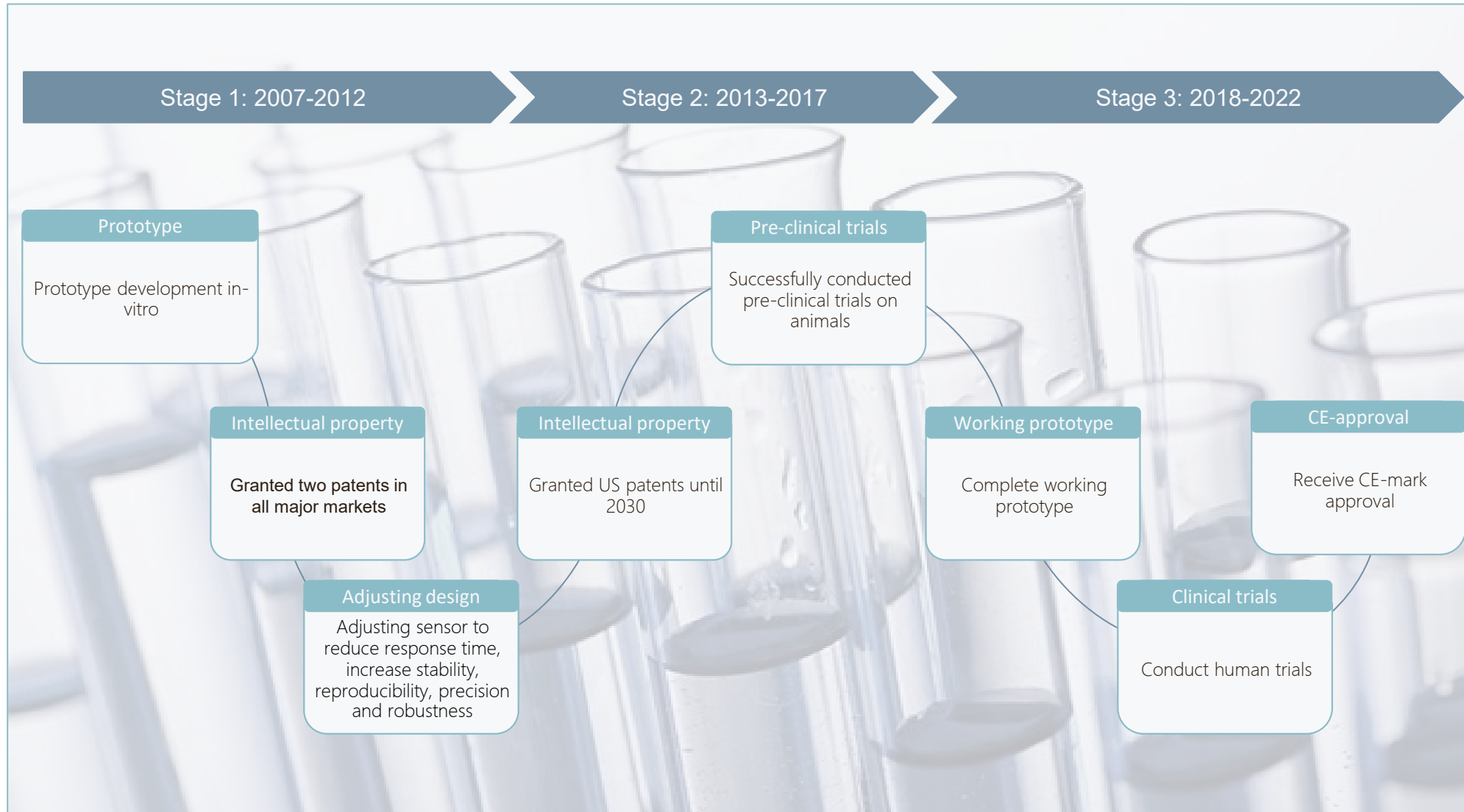
...resulting in accurate measurements and long term stability in blood sugar levels



Continuous and accurate glucose measurements prevent long term damages of poorly managed glucose levels

Note: (1) Injected in the tissue beneath the skin.

# Overall roadmap and milestones



# Development Roadmap

- **Size Reduction**
  - Former: 11,5 mm<sup>3</sup>
  - Current: 2,0 mm<sup>3</sup>
  - Future: 0.5 mm<sup>3</sup>



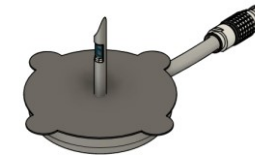
Laboratory Cell



Preclinical I



Preclinical II

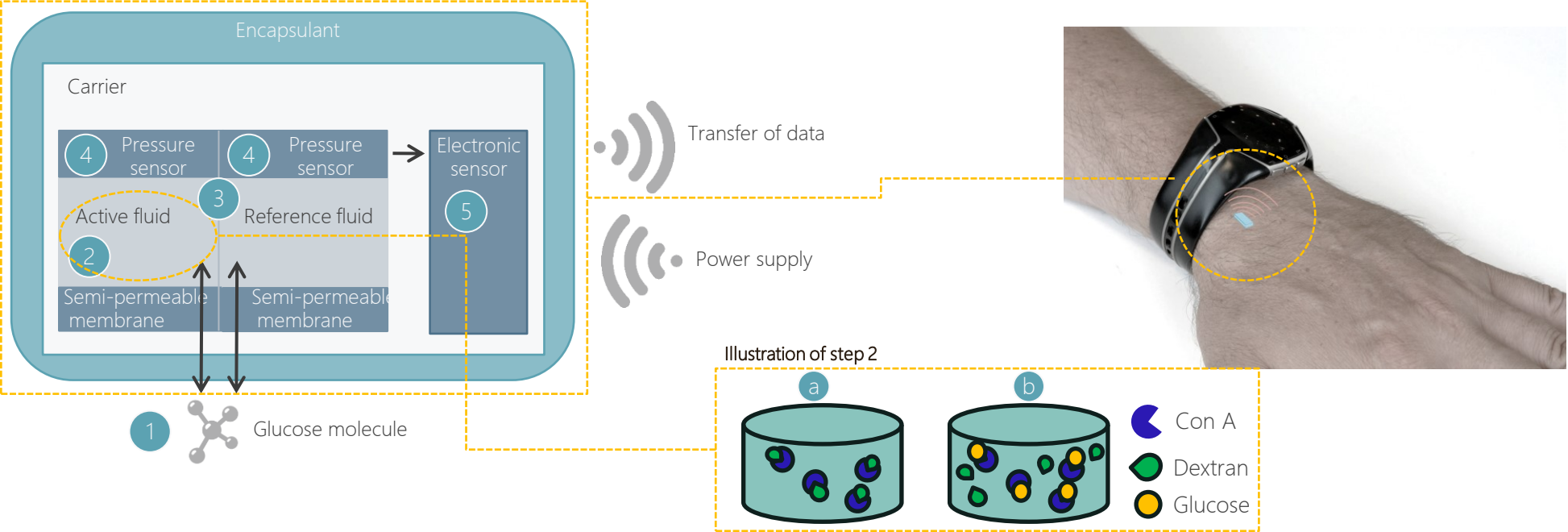


Needle Mounted



Sencell

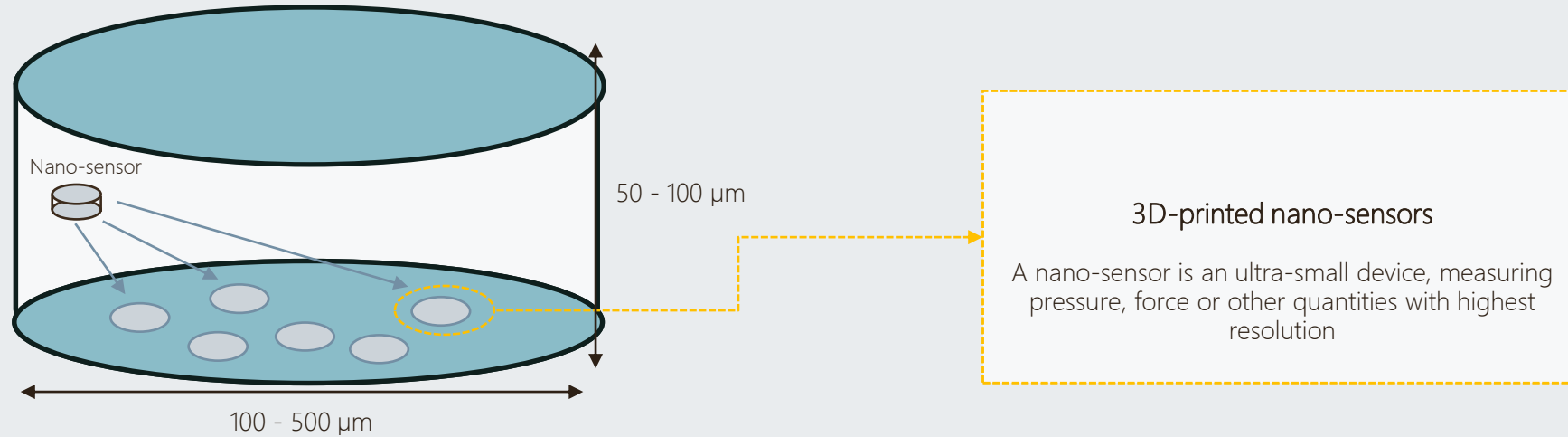
# Reading osmotic pressure variations induced by glucose level changes



- 1 Glucose molecules pass through the semi-permeable membrane and into the micro-sensor
- 2a The active fluid contains two molecules, Concanavalin A (ConA) and Dextran, which will bind together in the absence of glucose
- 2b High concentrations of glucose induce ConA and Dextran dissociation and the formation of two new molecules: ConA / glucose and Dextran
- 3 The increase in osmotic pressure, equivalent to the number of bound glucose molecules, is measured as the difference in pressure between the active and reference fluid
- 4 The pressure sensor detects the increase in the osmotic pressure
- 5 Pressure signals are conveyed to the electronic sensor and sent to an external reader

# Long term miniaturisation potential using 3D nano-printing technology

Miniaturised pressure chamber using 3D nano-printing



- Further potential in miniaturisation of Lifecare's micro-sensor using 3D-printed nano-sensors - target size 100 - 200  $\mu\text{m}$  x 200 - 1000  $\mu\text{m}$
- Several standardised pressure sensors to be placed at the bottom of the osmotic pressure chamber resulting in increased accuracy and sensitivity in pressure measurements
- Increased sensitivity allows for pressure measurements in increments of less than 0.01 mbar

- Nano-sensors offer a significant reduction in production cost
- Technology has been ranked Technology Readiness Level<sup>(1)</sup> 7 (TRL)
- 3D nano-printing process has been implemented by Zeiss in mass production processes and is e.g. considered to be the standard repair tool for high-end photomasks



# Core technology protected by patents and Freedom To Operate analysis

Double membrane patent

*2006-7*

- Composition of membranes
- A pressure sensor with a chamber on each side, where the two chambers have individual semi-permeable membranes
- Applies in USA, Canada, India, China, Japan, Norway, EPO<sup>(1)</sup>

Augmented osmotic pressure patent

*2009-10*

- Apparatus for measuring augmented osmotic pressure
- Patent applies in US
- Approved EPO

Chemistry

- Active fluid composition and method of production and method of production of active fluid, which can be used in a sensor for measurement of glucose concentrations in fluids
- Pending (Norway)

Dual sensor patent

- Implantable sensor with two chambers, each with a pressure sensor
- Pending

3D print nanosensor patent

- Global exclusive licence agreement



According to Harold Schnitzer Diabetes Health Center US presented at Diabetes Technology Meeting US 2017", this is what the diabetes patient wants for a CGM (continuous glucose measurement) device;

- # 1) Simple & Affordable ✓ # 1)
- # 2) Covered by insurance # 2)
- # 3) Long wear time ✓ # 3)
- # 4) High usability with integration ✓ # 4)
- # 5) Excellent accuracy ✓ # 5)
- # 6) No calibration required ✓ # 6)
- # 7) No interference ✓ # 7)
- # 8) Inconspicuous (not readily visible to others) ✓ # 8)
- # 9) Safe & comfortable ✓ # 9)
- # 10) Accessible data ✓ # 10)

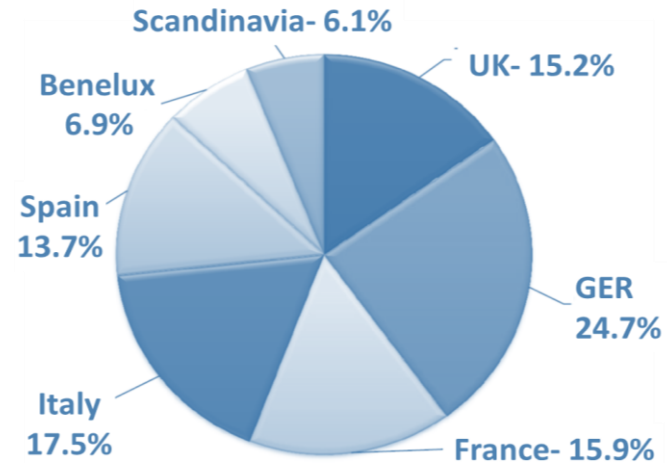


Fig. 2.2 EU SMBG market geographical segmentation (adapted from 127).

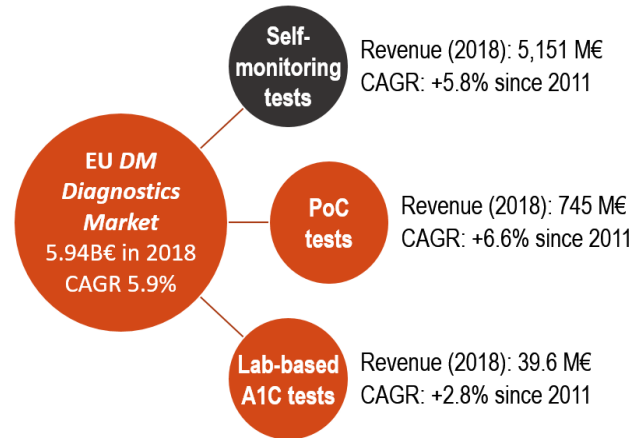
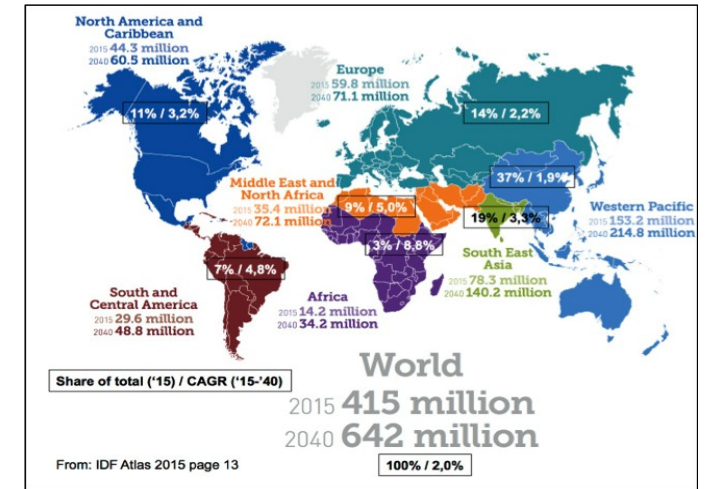


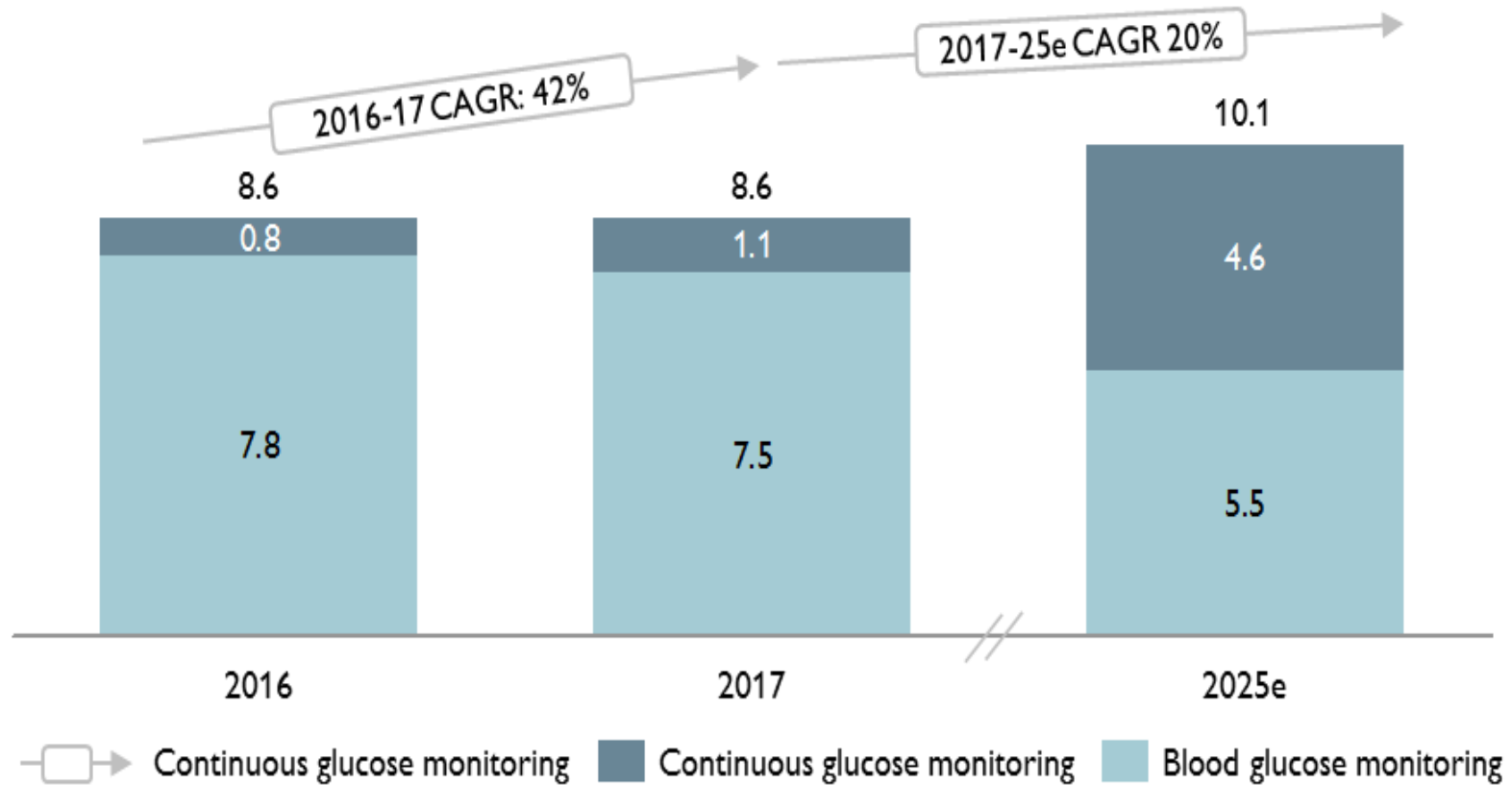
Figure 14: European market potential in 2018

Fig - Global and regional spread of diabetes (IDF) ('15-'40)



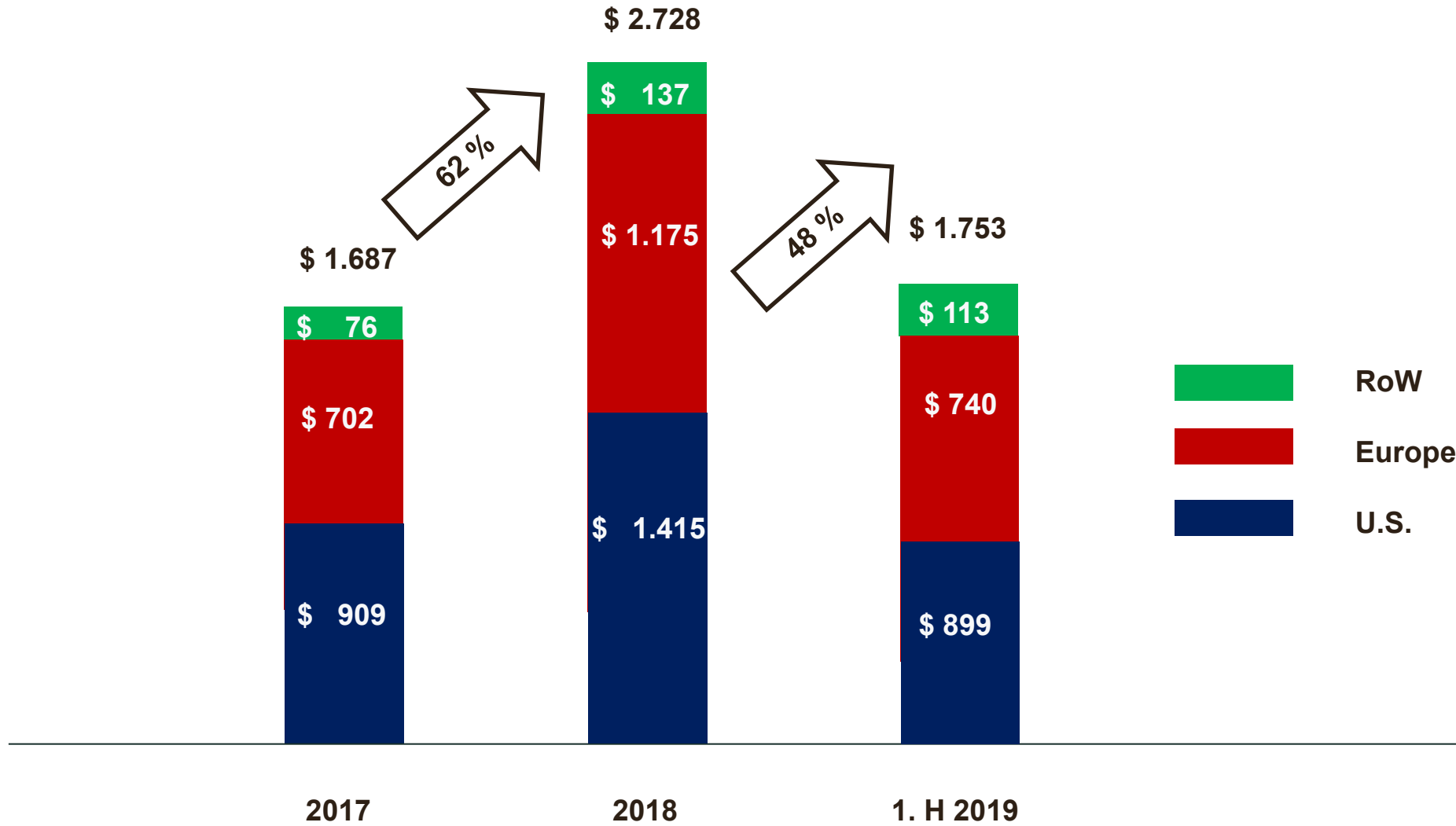
**Market potential and trends:** the global market for Diabetes Therapeutics and Diagnostics should reach €144 Billion by 2021, up from €116 Billion in 2016 (4.4% CAGR), including devices and PoC solutions as well as medication and other therapeutics. Within the large DM market, monitoring and diagnosis devices/systems represent close to 11%, expected to account for €16 billion globally, by 2021 (9.1% CAGR).

# Blood Glucose Measurement (BGM) versus Continuous Glucose Monitoring CGM





### Continuous Glucose Monitoring (CGM) - sales in Mill \$



# Lifecare Team

**Rune Frisvold**  
COO



- Managing Director of Lifecare since 2012
- Previously held senior management, operational and director positions in leading enterprises
- Managed and participated in major national and international companies and projects
- MBA / Usa

**Prof. Andreas Pfützner**  
CSO



- Managing director of Pfützner Health & Science Institute, Diabetes Center and Practice
- CEO of ikfe GmbH Mainz Germany
- Prof. of Applied Clinical Research
- 25 years of pharmaceutical and device development experience

**DR. Sanja Ramljak**  
Scientific Project Manager



- Former Director, Research Laboratory of IFKE
- Post Doc at German Primate Centre
- PhD in Molecular Biology, University of Göttingen
- Specialized in clinical and lab studies for the assessment of the accuracy of blood glucose meters

**Dr. Konstantin Kloppstech**  
VP Technology



- CEO of DEVmedical UG, Oldenburg Germany
- Head of Technology for MEMS/NEMS Sensor Development for Medical and Industrial Sensor Solutions 2016-2019
- PhD at the Department of Physics in Sensor Development for Fundamental Research at University of Oldenburg, 2011-2015

**Dr. rer. nat. Frank Flacke**  
VP R&D



- Previously global Medical Director Devices in the diabetes division at Sanofi
- Held management positions in several biotech and technology companies
- Over 20 years of experience in the pharma and medtech business

**Prof. Dr. Michael Huth**  
Consultant



- Professor for experimental solid state physics
- Stefan Lyson professor of physics
- Member Board of Trustees Beilstein-Institut, Frankfurt am Main
- Member Scientific Advisory Board Frankfurt Institute of Advanced Studies
- Member Scientific Advisory Board Austrian Centre for Electron Microscopy and Nanoanalysis
- Member Senate of the Goethe University, Frankfurt am Main
- 170 peer-reviewed publications

# Scientific Advisory Board

## **Prof. David C. Klonoff**

*Chairman, Scientific Advisory Board*



- Clinical professor of Medicine, UCSF
- Editor-in-chief, DST
- Medical Director, INST
- Chairman, i.a. DTM and ADA
- Chaired i.e. FDA, NASA, US army, NIH, NSF
- Consulting i.e. Sanofi, Google and Insulin
- Spoken to the US Congressional Diabetes Caucus, and White House Health Roundtable, and spoken at the European Parliament.

## **Prof. Lutz. Heinemann**

*Member, Scientific Advisory Board*



- Partner and Scientific Consultant, Profil
- Co-editor, DST
- Published 160 research articles
- Awarded "Leadership in Diabetes Technology"
- Charing the EU founded project "AP at home"

## **Prof. Kåre Birkeland**

*CMO, Scientific Advisory Board*



- Professor of Internal Medicine and Endocrinology, University of Oslo
- Senior consultant in Endocrinology, Dep. of Transplantation Medicine, Rikshospitalet, Oslo University Hospital
- Chairman Advisory Board, Norwegian Diabetes Association

# Sanofi-Aventis Groupe – A global health leader



A SIGNIFICANT VALIDATION OF LIFECARE'S TECHNOLOGY, IP,  
AND SCIENTIFIC AND BUSINESS CREDIBILITY



*Lifecare has undergone a complex and robust evaluation and due diligence process from Sanofi scientists and business department, including a detailed review of the product development plan and its funding*



*Sanofi has also evaluated the commercial aspects of Lifecare's Sencell relative to Sanofi's present and future product portfolio and the competitive landscape*



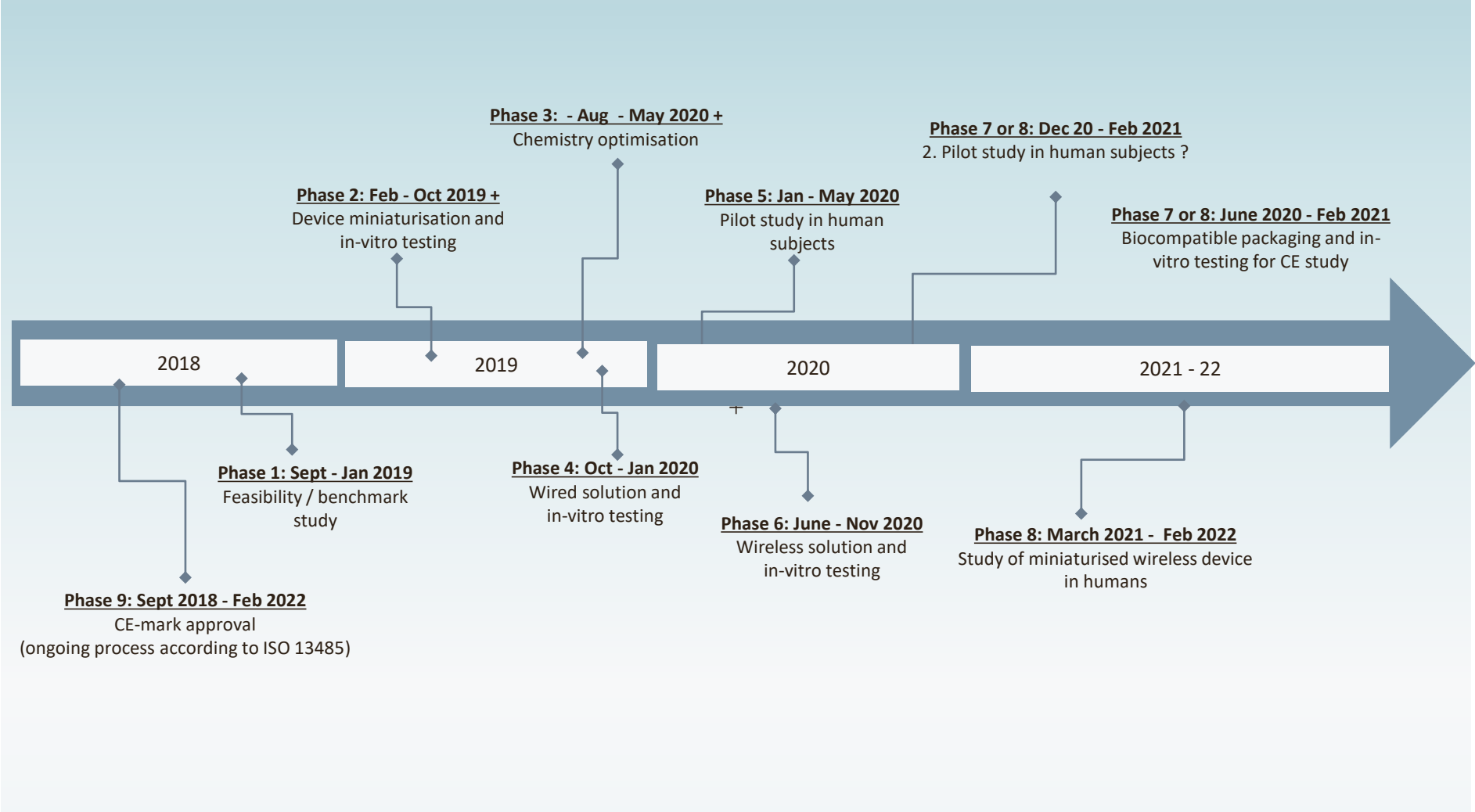
*Sanofi will pay EUR 290,000 in four instalments with EUR 190,000 was paid on the initiation of the first phase*

## Sanofi-Aventis Groupe at a glance

- Sanofi-Aventis Groupe is a global life science company
- Engages in the research, production and distribution of pharmaceutical products and operates through the following business segments: Pharmaceuticals, Human Vaccines, and Animal Health
- 44 new pharmaceutical molecular entities in the R&D pipeline with 50% coming from partnerships and collaborations
- One of the key priorities of the company is to provide access to healthcare for underserved populations
- A Bill & Melinda Gates Foundation partner
- Revenue of EUR 33.8bn in 2016



# Detailed roadmap and milestones



# First Human Clinical Trial

## Timelines:

IRB and BfARM submission:	Feb 7th, 2020
Deficiency Report received:	Feb. 14th, 2020
Review response expected by	Mid/End March 2020
Approval expected by	Mid/End April 2020
First Patient in and first results by	May 2020
Last patient out by	tbd

**Covid19 har medført mindre forsinkelser i det korte bildet, samtidig som vi har innspart noe tid i det lengre bildet.**



Lifecare AS has established a joint venture with Digital Diagnostics AG in Germany.

Lifecare AS has a 25% ownership in Digital Diagnostics AG

Digital Diagnostics (DD) will finance the remaining costs of completing the development of Lifecare's implantable continuous glucose sensor named Sencell.

In return, Lifecare AS will give Digital Diagnostics AG non-exclusive and non-competitive license agreement for use of Lifecare AS' technology.

Digital Diagnostics will explore how Lifecare's technology can be used outside the field of glucose monitoring and data collection, such as in e-health, big data and lifestyle technologies

Lifecare AS keeps all its rights to its existing IP and has exclusive right to future IP within our filed of use.



Additional technological development by Digital Diagnostics AG has the goal to rapidly develop a new type of sensor device that can be used for immediate tests for the new SARS coronavirus.

*In comparison to currently available rapid tests, the SARS-CoV-2 MEMS 5 Minute Test™ directly detects the virus over the entire course of the infection and can be read immediately, without the need for a laboratory.*

**The technological development by Digit is based on the IP and technology from Lifecare**

Lifecare's partner Digital Diagnostics AG detects corona virus with rapid test, seeks FDA approval and aims to deliver units starting in July



Takk for  
oppmerksomheten!

<https://www.lifecare.no/>

[rune.frisvold@lifecare.no](mailto:rune.frisvold@lifecare.no)

901 36 063



<https://www.diabetes.no/om-diabetes/diabetes-type-1/>

<https://www.diabetes.no/om-diabetes/diabetes-type-2/>

<https://www.youtube.com/watch?v=YnycU8iYqKU>