CASR NANOBODIES
A NOVEL TREATMENT PARADIGM FOR CHRONIC KIDNEY DISEASE

CHRONIC KIDNEY DISEASE (CKD)

CLINICAL STAGES OF CKD

- Stage 1: Normal kidney function
- Stage 2: Mild kidney damage
- Stage 3: Moderate kidney damage
- Stage 4: Severe kidney damage
- Stage 5: End-stage renal disease (ESRD)

AGE

- CKD GLOBAL PREVALENCE
  - ALL: 1 in 7
  - 65-74: 1 in 10
  - >75: 1 in 5

TOTAL POPULATION

- 1 in 7
- 1 in 10
- 5 in 10

SIXTH LEADING CAUSE OF DEATH WORLDWIDE

COSTS OF CKD DO NOT INCLUDE:

- $4.34 B TOTAL ESTIMATED ANNUAL COSTS (2026)
- $43 B DRUG MARKET (2026)
- $190 B GLOBAL MARKET (2026)
- $120 B KIDNEY DISEASE MARKET (2026)
- $131 B KIDNEY DISEASE MARKET (2026)
- $33 B GLOBAL MARKET (2026)

FINANCIAL BURDEN ON SICK LEADING CAUSE OF DEATH

IN DEATH

NANOBODY

IN VIVO

TARGET

IMMUNIZATION

AND SELECTION

NANOBODY IDENTIFICATION

TARGET VALIDATION

NANOBODY OPTIMIZATION

IN VITRO PROOF OF CONCEPT

IN VIVO PROOF OF CONCEPT

PRECLINICAL SAFETY STUDIES

CLINICAL STUDIES

MARKET

Technology Description
We have developed a novel class of biologics (nanobodies) that target the calcium sensing receptor (CaSR) as treatment paradigm for chronic kidney disease (CKD) with secondary hyperparathyroidism. Currently, secondary hyperparathyroidism (SHPT) is treated with a small molecule drug class ‘calcimetics’ that target CaSR. However, the use of these drugs is limited due to severe side effects in patients. Our solution to overcome these side effects is CaSR-targeting nanobodies. Nanobodies are small variable domain fragments of single-domain antibodies derived from llamas offering several advantages compared to conventional antibodies. Thus, nanobodies are excellent tools to therapeutically modulate receptors, as they exhibit high target affinity and selectivity, and as conjugates offer an excellent avenue for tissue- and disease-specific modulation of the target to reduce adverse side effects.

Intellectual Property Rights
CaSR nanobodies are patented under patent application EP19211709.1

Current State
We have identified and characterized monovalent nanobodies in vitro to determine mode-of-action at target, and delineated nanobody-binding epitopes. We have developed humanized nanobody-Fc conjugates to improve circulatory half life and target coverage, and bivalent nanobodies to improve pharmacology for the target. Moreover, we have explored the potential of combination therapy using nanobodies and calcimetics. Our next step is to test nanobodies and nanobody conjugates in pre-clinical in vivo models and further improve their pharmacokinetic and pharmacodynamic properties.

Business opportunity and Call to action
Our proof of concept is supported by the NNF Pioneer Innovator, LF Experiment, DFF Research project J grants (6M DKK in total).
We seek further investment to form a spin-out company from the University of Copenhagen. Funding will be used to test our lead drug candidate in pre-clinical models, progression towards a clinical stage ready molecule, and to strengthen our management team.

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