Team: *Dongwook Kim*, Ph.D. (Founder and CEO): more than 20 years of research experience in the biotechnology and medicinal chemistry sector for drug discovery and assay development leading to patent(s). *Contact information*: dwkim@dencoda.com, 919-428-3950.
*Alex Valencia***,** Ph.D. (Chief Technology Officer): an experienced clinical molecular geneticist who has a record of securing research funding with extensive research experience.
*Casey Krusemark***,** Ph.D. (Scientific advisor): works as an associate professor at College of Pharmacy at Purdue University. He is one of the co-inventors of DENCODA's technology.
*Consultants***:** Chelsea Bahney, Ph.D. (Steadman Philippon Institute), Steve Charlebois Ph.D. (MED institute). Chris Emery, M.D. (Indiana University Health).
Problem: Currently, more than 32 million Americans suffer from osteoarthritis, which incurred healthcare costs of ~$5 billion in 2019. These costs are high largely because physicians lack early diagnosis capabilities that would permit the prescription of preventative therapies to at-risk individuals.
Solution: DENCODA has a proprietary DNA-based protein activity assay platform (OsteoActivus™) that we will use to develop innovative, low cost, highly sensitive and multiplexed DNA-based osteoarthritis (OA) detection assays that will quantify OA biomarkers' activity levels, permit early OA detection, and open new avenues of pharmaceutical intervention. The early diagnosis benefits patients by relieving pain and lowering their healthcare costs.
Market size: The total global osteoarthritis diagnostics market size was $7 billion in 2019 and is projected to grow to $15 billion by 2025. The target market is specifically the osteoarthritis test market in the US ($3.1 billion in 2019 and is projected to grow to $5 billion by 2025).
Competition: *Sigma and R&D system*- ELISA-based kit for monitoring osteoarthritis biomarker. *Ray Biotech*- Antibody-based test for detecting osteoarthritis biomarker. *DENCODA's product,* OsteoActivus™, detects osteoarthritis biomarkers using DNA-linked probes that work in blood, urine, and other body fluids.
Business Model: DENCODA will provide a DNA-linked probe kit for the detection of biomarkers in OA. DENCODA seeks to process the assays in Clinical Laboratory Improvement Amendments (CLIA) labs, as is typical of a lab-developed test business model. The company will file for FDA clearance for the assay for more widespread adoption. Before FDA approval and concurrent efforts, DENCODA plans to conduct contract research with collaborations and/or services. After approval, the OsteoActivus™ will be sold directly to small as well as large reference clinical laboratories or via specialty distributors.
Marketing and sales: A sales team will target small to large commercial and academic clinical laboratories. DENCODA will seek partners who are interested in participating in validation studies using osteoarthritis patient samples with a goal of having a laboratory developed test at various sites. DENCODA will seek partnerships with distributors to use their established marketing strategy.
Progress to Date: The US patent for the DNA-based activity detection assays was awarded in 2021. The studies using this approach have been published in three peer-reviewed journals in 2017 and 2019. DENCODA is in the process of securing the exclusive license from Purdue University. DENCODA has completed the national NSF I-Corps program (Customer discovery) in 2021. DENCODA won an Elevate pitch competition and secured an investment ($20,000) in Nov. 2020. DENCODA was selected to enter the Purdue Boost program (earned $5,000) in Nov. 2021. DENCODA was awarded an NIH-SBIR phase I grant ($256,000) in Sept. 2022.
Future milestones: Dencoda will develop scalable MMP-1 and MMP-9 (involved in the pathogenesis of OA) activity detection assays utilizing a DNA-linked probe with sensitivities and specificities superior to existing assay platforms. *The qPCR-based assays will be our first minimal viable product*, whose intended uses will be as an OA diagnostic tool (laboratory developed test, LDT) targeting high risk populations on OA such as geriatric populations and individuals suffering from obesity.