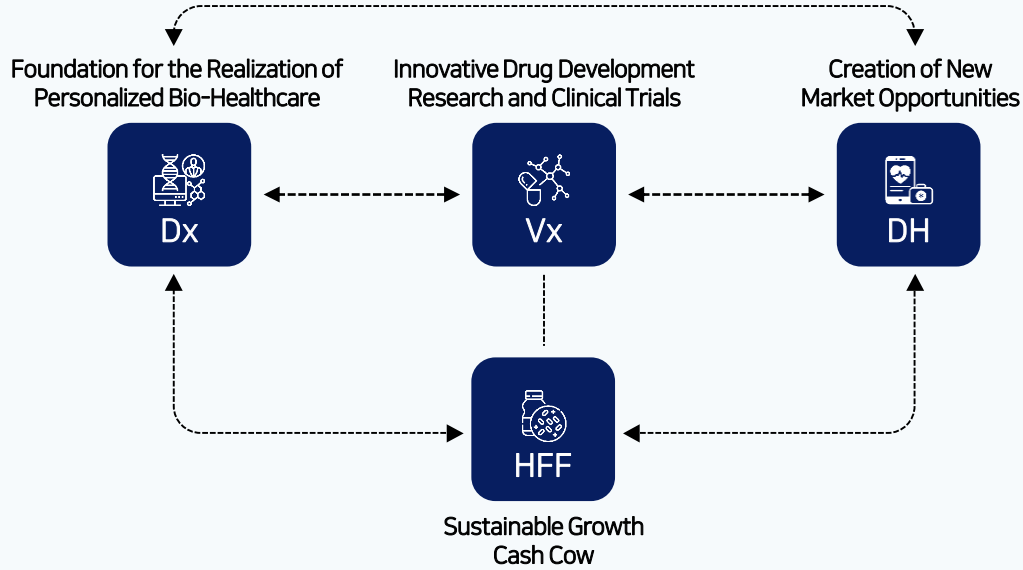
Dx&Vx

IR Letter

(Nov. 2024)

Dx&Vx Business Roadmap



Dx

Medical Diagnostics

Dx&Vx's genomic diagnostics and in vitro diagnostics contribute to reducing healthcare costs and improving treatment outcomes. Genomic diagnostic technologies enable more precise and personalized treatments, combined with new drug developments, driving innovation in the medical field. Our companion diagnostic services enhance the efficacy of both our own and third-party drug developments, minimizing side effects and facilitating the development of personalized treatment options for patients.

- Genomic Diagnostics
- In Vitro Diagnostics and CDMO
- Genomics CRO
- Companion Diagnostic Services (CliDex)

HFF

Consumer Healthcare

Using our diagnostic technologies, we provide integrated consumer healthcare solutions based on the microbiome for disease prevention, treatment, and management. Our services include health functional foods for prevention, general pharmaceuticals and prescription drugs for treatment, and products for lifestyle and hygiene management. We target the global market and continue to achieve high sales growth.

- Microbiome-based Therapeutic Adjuncts
- Nutrition Products
- Domestic and International CSO
- Functional Skincare/Personal Hygiene Products

Vx

Drug Development

Our affiliate, Oxford Vacmedix, is preparing to initiate phase 1b clinical trials both domestically and internationally for its cancer vaccine, OVM-200, and our subsidiary Avixgen is about to start phase 2 trials for a dry eye treatment. Additionally, we have a pipeline of in-house developed drugs including microbiome-based therapies, mRNA cancer vaccines, oncology antibodies, and oral obesity treatments.

- Microbiome-based Drug Development
- ROP and mRNA Cancer Vaccines
- Cancer Antibody Drugs, Synthetic Organic Drugs
- Ophthalmic Disease Treatment Drugs

DH

Digital Healthcare

Dx&Vx is on the verge of launching K-hub, a bio-pharmaceutical portal, combined with our genomic analysis platform and telemedicine services. We aim to shift from a treatment-centric to a prevention and management-focused approach in healthcare services, ultimately aiming to develop a Clinical Decision Support System (CDSS) to assist medical professionals in their decision-making.

- K-hub
- Telemedicine Services
- AI-based Drug Development Platform
- Smart Diagnostic Devices

Performance Summary for November 2024

- Launch of the revamped 'Omic-Check Microbiome Healthcare' service featuring AI-based recommendation technology.
- Medical Japan 2024 Tokyo - Introduction of 'GenomeCheck' genomic analysis services and our branded healthcare products.
- Completion of large-scale synthesis of an oral obesity treatment candidate.
- Completion of research and development of the production optimization process of body fat reduction patent probiotics.
- Completion of clinical trials for collaborative research on developing microbiome-based metabolic disorder treatments.
- Completion of site inspection for the introduction of the cancer vaccine 'OVM-200' with Oxford Vacmedix (OVM) in the UK.
- ★ Development of technology to overcome the limitations of mRNA vaccines.
- Advancement of drug development competitiveness through the proposed acquisition and merger with Avixgen.

Dx Medical Diagnostics

Launch of the revamped 'Omic-Check Microbiome Healthcare' service featuring AI-based recommendation technology

We have recently launched an enhanced version of our 'Omic-Check Microbiome Healthcare' service. This service is designed for individuals of all ages, from newborns to the elderly, and provides comprehensive analysis of the microbiome distribution and characteristics in various body sites including the gut, oral cavity, and skin. It precisely identifies beneficial microbial genomes for each individual, and recommends personalized probiotics along with optimal diets and health supplements. This approach allows for the analysis of microbial distributions linked to obesity and metabolic disorders, offering efficient management solutions. To support this, we have built a precise database utilizing information on gut probiotics from about 200 domestic clinical patients and AI image analysis technologies, and have used over 400,000 personal genomic analysis data points to complete an integrated healthcare service portfolio.

Medical Japan 2024 Tokyo - Introduction of 'GenomeCheck' genomic analysis services and our branded healthcare products

From October 9 to 11, 2024, our company participated in the Medical Japan 2024 Tokyo exhibition held in Chiba, Japan, where we engaged in partnership discussions with global enterprises. This event serves as a pivotal platform showcasing the latest products and technologies in the global healthcare industry, attracting approximately 700 companies and 20,000 attendees from around 20 countries this year. During the exhibition, we showcased a range of healthcare products, including our 'GenomeCheck' service. 'GenomeCheck' has been particularly well-received for its non-invasive prenatal testing and newborn genetic tests, standing out from competitors with a larger array of testable diseases, lower costs, and faster turnaround times. We held meetings with about 30 companies, confirming high interest in the global market and creating opportunities for business expansion in our genomic diagnostics and bio-healthcare sectors.

Vx Drug Development

Completion of large-scale synthesis of an oral obesity treatment candidate

In October 2024, our company completed the mass production of an oral obesity treatment candidate for preclinical trials. We believe we have secured compounds with significantly enhanced activity through advanced structural optimization studies, beyond what was used in activity comparison tests with global late-stage clinical benchmarks in previous research. The mass-produced compounds are slated for additional activity assessments, pharmacokinetic tests, and primate studies. We are in discussions with a Contract Research Organization (CRO) to rapidly progress additional preclinical trials and swiftly prepare for Investigational New Drug (IND) applications and clinical trials. Recently, we have also filed patents for two GLP-1 receptor agonist-based oral obesity treatments, and plan to prioritize resources to enhance our competitive position in the obesity treatment market. Following market trends, we are actively pursuing early-stage technology exports and collaborative research.

Completion of research and development of the production optimization process of body fat reduction patent probiotics

We have completed the production optimization research and development for our patented probiotic, Limosilactobacillus fermentum DX2034, which is designed to achieve optimal efficacy in reducing body fat when applied in humans. We plan to begin mass production and animal testing within this year. This strain, derived from healthy infants, has been proven safe for human use and was patented in August for its fat reduction functionality. Dr. Suwon Lee from our Microbiome Research Institute has designed and established the production optimization process for the 'Mamiai' strain at Beijing Hanmi Pharmaceuticals to meet the standards required by the China National Medical Products Administration (NMPA); 'Mamiai' has become a major revenue source for Beijing Hanmi Pharmaceuticals. We aim to complete the mass production of probiotic DX2034 within the year to commence animal testing, and intend to use it in synergy studies, potentially in combination with our already mass-produced oral obesity treatment GLP-1RA, to enhance efficacy.

Completion of clinical trials for collaborative research on developing microbiome-based metabolic disorder treatments

We have completed a collaborative clinical research study aimed at developing metabolic disorder treatments based on the microbiome. This research has been conducted since 2020 in partnership with Coree Group at Agostino Gemelli University Hospital in Rome, Italy, focusing on observing the changes in the gut microbiome of patients with type 2 diabetes and obesity. The clinical study involved a cohort of approximately 150 participants, including patients with type 2 diabetes, obese patients, patients suffering from both conditions, and healthy adults. We are currently conducting metagenomic analyses in collaboration with Professor Lorenza Putignani, a leading authority on microbiome research in Italy, and plan to collect multi-omics data through metabolomics analyses. Our goal is to identify biomarkers that can maximize the therapeutic potential for metabolic diseases. Ultimately, our main objective is to develop therapeutics based on these findings and also create microbiome-based health supplements, along with innovative biomarkers that can be used for diagnosis and prognosis monitoring.

Completion of site inspection for the introduction of the cancer vaccine 'OVM-200' with Oxford Vacmedix (OVM) in the UK

We have successfully completed the site visit and discussions for joint research with Oxford Vacmedix (OVM) and the University of Oxford regarding the introduction of the cancer vaccine 'OVM-200'. The site visit was led by our Head of Product Development, Sim Seong-nyeo, and included visits to OVM, the University of Oxford, and Eurofins. During the visit, we reviewed the patents for OVM's core technology, Recombinant Overlapping Peptide (ROP), as well as the results of the UK phase 1a clinical trials and the progress of phase 1b. We directly confirmed the excellent safety and efficacy of OVM-200. We also reviewed plans for domestic and international clinical cooperation and pharmaceutical production with both parties. Additionally, we have agreed to embark on new joint research projects with the University of Oxford to strengthen our collaborative efforts in innovative drug development. With the successful completion of this site visit, we will expedite the contract for introducing OVM's cancer vaccine, as well as swiftly advance to the next stages of clinical trials both domestically and internationally, dedicating our efforts to the commercialization of this first-in-class cancer vaccine.

★ Development of technology to overcome the limitations of mRNA vaccines

We are collaborating with Pohang University of Science and Technology to develop a groundbreaking technology, a world-first that solves one of the major drawbacks of mRNA vaccines: their inability to be stored at room temperature. Preliminary research has shown the potential for mRNA vaccines to be stored at room temperature for over a decade. This project has been selected as the inaugural task under the Korean ARPA-H program and is gaining significant attention. The success of this project is expected to enhance the stability of national healthcare systems and greatly improve global access to vaccines, thus making a substantial contribution to public health worldwide. Our company has been selected as a co-research institution for this project, 'Development of Room-Temperature Long-Term Storage mRNA Vaccine Materials and Mass Production Process Technology', led by the Korea Health Industry Development Institute under the Korean ARPA-H initiative. Supported by a total research grant of 8.5 billion KRW over five years, we will lead the validation and commercialization of the mRNA vaccines.

Currently, mRNA vaccines used in global markets require refrigeration or freezing, leading to substantial costs in the cold chain and significant distribution challenges, especially in underdeveloped countries with limited refrigeration infrastructure. Additionally, these vaccines often face issues with short shelf lives resulting in frequent disposal. The technology we are developing aims to enable long-term storage of vaccines at room temperature, reducing costs in distribution and storage and enhancing vaccine accessibility to benefit more people.

Once commercialized, this technology will allow for quick and effective responses in global health crises, strengthening national health security and laying the groundwork for rapid responses to worldwide pandemics. This will also introduce a significant shift in the global health system, presenting a new paradigm in vaccine development and distribution.

Matters concerning overall management

Advancement of drug development competitiveness through the proposed acquisition and merger with Avixgen

On October 2nd, we announced a merger with Avixgen, a company in which we hold a 62.66% stake, at a merger ratio of 1:0.2903194, resulting in a full absorption of the company. Avixgen specializes in the development of treatments for immune and inflammatory diseases. The merger aims to diversify our drug pipeline, enhance our drug development competitiveness, and increase operational efficiency. Avixgen has a pipeline that includes AVI-4015, a treatment for dry eye syndrome, and AVI-3207, a treatment for macular degeneration, both of which have completed Phase 1 clinical trials. By integrating the pipelines of both companies through the merger, we aim to diversify the stages of drug development and create a virtuous cycle where revenues from technology transfer agreements cover research and development costs. Additionally, the merger is expected to integrate Avixgen's research and operational organizations with our own, resulting in cost savings and increased managerial efficiency.

Compliance Notice