# **Precision medicine** business growth strategies



# **Precision medicine business strengths and market forecast**

Advancements are being made in personalized medical care in the U.S. and other countries in the face of population aging and other issues that have prompted a need for improved quality of life and reduced healthcare costs for people around the world. Precision medicine is currently a more than \$40 billion market worldwide, and is expected to grow 16% annually on average\*1 and is receiving increasing attention from investors. Companies are accelerating growth investment with the realization that gaining a competitive advantage in these markets depends greatly on how much diagnostic and analysis data can be collected and how guickly.

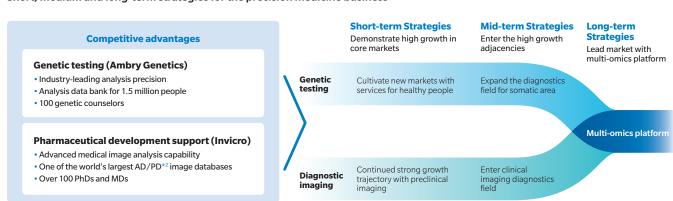
Against this backdrop, Konica Minolta Group operates the precision medicine business, utilizing the genetic analysis, organ image analysis, and high sensitive tissue testing technologies owned by U.S.-based Ambry Genetics, Invicro, and Konica Minolta, respectively. By analyzing the human body at the molecular level and performing high precision stratification, these technologies facilitate proper patient dosing and treatment and help boost clinical trial and pharmaceutical development success rates.

Because of their rarity throughout the world, companies with technologies for analyzing genes, organs, and proteins enjoy a competitive strength. Ambry Genetics and Invicro, in particular, have a first-rate technology suite and track record in the U.S. market, where precision medicine is making advancements.

Guided by short term, medium-term, and long-term strategies, Konica Minolta Group will maximize its strengths. In the short- to mid-term, we will focus on strengthening two core businesses—Ambry Genetics' genetic testing services and Invicro's image analysis services—and aiming for upgrading and expanding our services. Looking to mid- to long-term, we will bring together the bioscience and informatics technologies of these two companies to realize a multi-omics analysis service, which involves comprehensively analyzing the molecules in the human body, and provide this service to the world through a cloud-based platform. We plan to actively grow our businesses through such strategies.

\*1 Source: BCC Research (2021). Biomarkers: Technologies and Global Markets

#### Short, medium and long-term strategies for the precision medicine business



<sup>\*2</sup> AD: Alzheimer's disease, PD: Parkinson's disease

# Short-term Strategy: Growth of Core Businesses

### **Expand scope of genetic testing services to** non-patients

Ambry Genetics has created many services new to the industry, which includes being the first to commercialize RNA testing. With a state-of-the-art, large-scale laboratory capable of processing 7,000 samples a day, the company continues to grow by providing genetic testing services for patients with cancer.

With a view to expanding the number of people receiving genetic testing to include non-patients, in 2019 Ambry Genetics launched its CARE Program<sup>™</sup>, a genetic testing services for people receiving regular health checkups. There are currently several million people in the U.S. who have not been tested for cancer yet at high risk, 650,000 tests were conducted in 2019, and the NCCN (National Comprehensive Cancer Network) Guidelines estimates that approx. 32 times that number of people—21 million—require testing. As genetic testing provided by healthcare providers to non-patients is a new market with few competitors, Ambry Genetics is expanding the service at a rapid pace.

Through the CARE Program, healthcare providers identify individuals with high hereditary cancer risk through Web-based interviews. They then recommend tests for high-risk individuals, who thereafter receive undergo counseling and tests at a hospital.

Based on the results, healthcare providers then propose cancer screening plan individually customized for the individual. Using IT, healthcare providers provide thorough support from recommending to the tests to educating individuals and conducting follow-ups. The user base has seen continued growth since the service was launched, increasing twofold between January and October 2020.

In April 2021, the CARE Program was also launched in Japan. Working with Seirei Social Welfare Community, which runs a number of hospitals in the country, we will roll out this service in stages throughout Japan.

## **Expanding pharmaceutical development support** services in the central nervous system and cancer fields

Using advanced image analysis technologies powered by Al, Invicro provides pharmaceutical development support services that identify biomarkers, improve clinical trial efficiency, and decrease pharmaceutical development process risk. The company excels in services for the central nervous system, in particular, and boasts one of the world's largest image databases for Alzheimer's and Parkinson's diseases.

The number of clinical trials for Alzheimer's began to grow in

2020, and Invicro is focusing on leveraging this favorable opportunity to boost its track record. At the same time, the company is enhancing its pharmaceutical development support in the cancer field by applying its data management expertise and technologies developed through its central nervous system research.

Although Invicro currently provides services to mainly pharmaceutical companies, in the future it will broaden its service lineup for clinical settings.

#### **Message from a Business Partner**

The Seirei Social Welfare Community has sought to achieve early detection of cancer and provide preventive treatment by conducting "personalized screenings based on gene mutation." By combining high-quality, precision technologies derived from Ambry Genetics' scientific findings with Seirei's know-how in providing healthcare and screenings, we have developed the SEIREI-CARE Program,



Japan's first genetic diagnostics service. The benefits of this program are the ability to determine whether an individual has hereditary breast cancer or ovarian cancer risk through AI (chatbot) interviews, instead of face-to-face interviews to ask about individuals' medical and family histories that have previously been conducted by doctors, nurses, certified genetic counselors, and other healthcare professionals. Furthermore, I believe this program gives everyone accurate knowledge of genetic cancers and facilitates better awareness and education about hereditary cancers. We are also considering expanding the program to cover other cancers such as colorectal, prostate, and pancreatic cancers, as well as dementia. By getting as many people as possible to use this program, we hope to help people achieve a healthier, higher quality of life. We look forward to further R&D efforts by Konica Minolta and Ambry Genetics in order to grow this program into the future.

#### Takanori Fukuda

Director, Senior Executive Director, and Health Business Department Manager, Seirei Social Welfare Community

#### The CARE Program, a genetic testing service for healthy people / unaffected individuals



#### Medical interview

Learn one's own risk through e-mail and medical interview app

#### **Educational activities**

Learn accurate information about hereditary diseases and appropriate response to one's own risks

# For high-risk individuals Follow-up

#### **Genetic diagnostics**

Receive genetic counseling and genetic testing at appropriate medical institution

Receive appropriate medical management and relative response

# Medium-term Strategy: Expansion of Diagnostic Menu

## Expanding genetic testing services to cover nonhereditary cancers

Genetic testing for cancer has typically targeted hereditary cancers. In recent years, however, it has become possible to receive genetic tests for non-hereditary cancers, as well, due to advances in medicine and technologies, and companies are stepping up competition to develop such tests. The market for genetic testing for non-hereditary cancers conducted in clinical settings is expected to grow significantly between FY2019 and FY2024: 30-40% compared to the 2-5% for hereditary cancer tests.

Ambry Genetics will take this opportunity to commercialize genetic testing services for non-hereditary cancers. The company will achieve differentiated services by launching liquid biopsies (tests using blood, etc.) for diagnosis and treatment and highprecision RNA liquid biopsies in short- to mid-term. Liquid biopsies are useful not only for diagnosing cancer risk but also when following up on treatment. As such, they can comprehensively support patients from the early detection stage through to recurrence prevention.

Ambry Genetics was the first to commercialize many services in the industry, and by using this strength it will build a groundbreaking testing service in the field of non-hereditary cancers, as well.

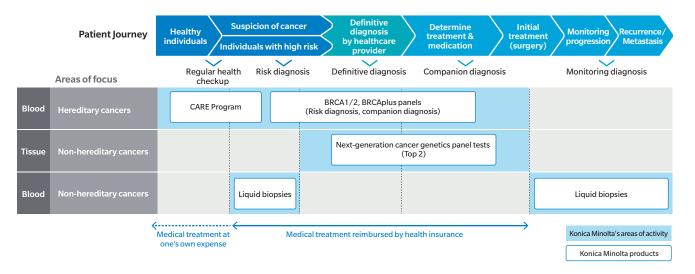
## Working with research institutes to develop a cancer gene panel inspection

To strengthen its genetic testing for non-hereditary cancers, Konica Minolta is working with the University of Tokyo and

National Cancer Center Japan to develop a cancer gene panel inspection.

This inspection detects numerous gene mutations all at once. The goal of this effort is to bring together the advanced detection and analysis technologies of these two institutions with Ambry Genetics' expertise and establish a means of conducting an inspection of unprecedented precision and performance. This inspection will allow for identifying previously unidentifiable gene mutations and accumulating extensive inspection data, which will lead to improved data analysis precision and further support for pharmaceutical development and diagnoses. This next-generation panel inspection is slated to hit the market in or after 2022.

#### Areas of focus for Konica Minolta in oncogene testing



# **Message from a Development Partner**

The University of Tokyo is working with Konica Minolta to commercialize the Todai OncoPanel, a proprietary cancer gene panel test, and further improve its performance. The Todai OncoPanel is one of the world's most state-of-the-art twin panels for analyzing both DNA (750 genes) and RNA (1418 genes). It allows for calculating scores related to gene mutation, amplification, and drug sensitivity, and for quantifying fusion genes, transcript variant, and gene expression level, all in one panel.

By collaborating with Konica Minolta Group, it will become possible to integrate diagnostic imaging that includes pathologies with genetic diagnostic technologies, and we expect to be able to bring world-leading next-generation precision medicine to the global market.

#### Katsutoshi Oda

Professor, Graduate School of Medicine, Division of Integrative Genomics, The University of Tokyo

# Medium to Long-Term Strategy: Multi-omics Platforms

# Providing a next-generation diagnosis platform through Group synergy

Multi-omics analysis is garnering attention as a key aspect of personalized medicine going forward. A method of analyzing various substances within the human body, including genes and proteins, all at once rather than individually, it can further enhance the quality of disease prevention, diagnosis, and treatment.

Konica Minolta Group has launched LATTICE<sup>TM</sup>, a next-generation diagnostics platform that performs multi-omics analysis. Powering LATTICE is an expansive database built up by Ambry Genetics and Invicro.

In addition to analysis data for 1.5 million cancer patients, Ambry Genetics possesses precision genetic analysis data from RNA tests and high-quality analysis data provided by genetic counselors. This data is at the top of its class worldwide both in quality and quantity. Invicro has a vast store of data that includes image data for pharmaceutical development and clinical testing, as well as digital pathology images.

LATTICE has a plan to create its own unique value by pairing a wide range of medical information with the data of gene, pathology, and medical images within Konica Minolta Group and analyzing it all using Al.

# Working with Amazon Web Services (AWS) to help achieve personalized medicine care worldwide

To operate LATTICE, Konica Minolta works with U.S.-based AWS, using the company's wide-ranging services and high-security cloud to provide services useful for pharmaceutical development, clinical trials, diagnosis, and treatment to hospitals and pharmaceutical companies around the world.

We have also signed contracts with third-party laboratories worldwide to provide consulting services for genetic analysis. Having a worldwide network of contracted laboratories would bring much more data into LATTICE, improving diagnosis accuracy and allowing us to provide even more useful information for

pharmaceutical development and clinical trials.

The principle target diseases are breast, prostate, and lung cancers, as well as Alzheimer's disease. With breast cancer, for example, since a patient's condition can be identified using only X-ray images currently, using LATTICE as well to add genetic information to an analysis enables earlier detection and more effective treatment

We have received investment from AWS for this groundbreaking platform and will coordinate with the company over the next five years. Along with diagnoses and treatment in clinical settings, through LATTICE we are aiming to further contribute to discovering new biomarkers, developing new treatment methods, and accelerating pharmaceutical development.

#### **Message from a Business Partner**

One of the cornerstones of precision medicine is precision diagnostics, and we are excited to collaborate with Konica Minolta Precision Medicine, Inc. to enhance and accelerate their innovative offerings and help deliver precision diagnosis at a global scale using Amazon HealthLake. We're seeing a renaissance in the healthcare and life sciences industry as more organizations leverage cloud technology on AWS to uncover new ways to reduce cost, improve patient outcomes, and ultimately save lives.

#### Taha Kass-Hout

Director of Machine Learning, Amazon Web Services, Inc.

#### Next-generation diagnosis platform "LATTICE"



# Collect data from laboratories worldwide

