# Progress of the Medium-term Strategy for Precision Medicine Business

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## **Overview of Healthcare Business**









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# **Strategy for Precision Medicine Business**





# Improving Diagnostic Accuracy is Key Factor to Reducing Medical Expenses



Significant reductions in healthcare costs will be achieved by providing diagnosis that meet the individuals, since effects of medical expenditures of ¥20 trillion or more are uncertain.





#### Precision diagnostics market size: ¥4 trillion

		Genetic	: diagnosis	Pathology	Imaging		
		Hereditary	Somatic	Facilology			
Market size	Clinical	¥480 billion 2~5%	¥440 billion 30~40%	¥1.16 trillion 6~8%	¥880 billion 3~5%		
(FY19) Growth rate % (FY19-24)	Drug discovery support services	¥120 billion 70~80%	¥280 billion 16~28%	¥400 billion 10~15%	¥400 billion 6~8%		
Growth Drivers		<ul> <li>Patient awareness activities</li> <li>Global expansion</li> <li>Patient identification in drug development</li> </ul>	<ul> <li>Acquisition of reimbursement</li> <li>Discovery of new biomarkers</li> <li>Processing capacity of organizational samples</li> <li>Pair test with hereditary genetic testing</li> <li>Liquid biopsy</li> </ul>	<ul> <li>Increased use of biomarkers</li> <li>Immunostaining/Genome multi marker detection capabilities</li> <li>Digitization/Utilization of Al</li> </ul>	<ul> <li>Increase in use of biomarkers</li> <li>Molecular imaging</li> <li>Global service network</li> <li>Utilization of AI</li> </ul>		
Pharmaceutical development R&D Market size: ¥17 trillion		20 (Trillions of yen) R&D exp R&D exp R&D exp Expense 10 5 0 1980	enses in biomedicine (left axis enses in small molecular drug for getting approval of one dr 1990	) s (left axis) ug 2000 2010	(Trillions of yen) 0.2		
		Outsourcing ra	atio of R&D expenses	14% 33%	50%		



#### Multiple vs. enterprise value by company<sup>1</sup>



1. Based on latest 2021 data

2. Tempus bubble size based on valuation growth between 2019–2020; Exact Sciences CAGR excludes growth from Genomic Health acquisition

3. 2020 data

Growth Strategy for Konica Minolta Precision Medicine





# **Growth of Core Businesses**

# Gene Diagnostics Business: Ambry Genetics Inc.



		Ambry's Strengths	Growth Strategy	
Wet	Cutting-edge, large scale laboratory	<ul> <li>Massive capacity of up to 7,000 samples per day</li> </ul>	Turn third-party existing laboratories into customers	
		<ul> <li>Automated, fast and optimized workflow</li> </ul>	Provide analysis services on	
Dry	Genetic analysis		cloud	
	bioinformatics	<ul> <li>Top analysis accuracy in the industry</li> </ul>		
	Genetic mutation database	<ul> <li>Built up analysis database on 1.5 million people</li> </ul>	LATTICE	
		• Top-class data quality in the industry	Expand targets to unaffected individuals at small– and medium–sized hospitals and imaging centers	
Channels	Genetic counselors	<ul> <li>70% share of genetic counselors</li> <li>Targeting academic conters at large</li> </ul>		
	at large hospitals	hospitals		
Customers	Mainh/ill notionts		CARE Program	
	Mainly III patients	<ul> <li>60% of tests targeting ill patients</li> </ul>	Reinforce sales personnel	
Science HR	Capability to develop new products	<ul> <li>Vast improvement in diagnostic accuracy due to development of RNA</li> </ul>	Expand sales of RNA tests	
		<ul> <li>tests</li> <li>Many first NGS product in the industry</li> </ul>	Somatic and liquid	
Pricing		95% of natients are covered by insurance	biopsy development	
	insurance coverage	Premium prices are top class in industry	Insurance reimbursement requests in Japan	



# POPULATION HEALTH PLATFORM

# **Comprehensive Assessment, Risk and Education (CARE)**



### CARE Program Overview

### OPPORTUNITY

- Millions of high-risk patients unidentified
- CARE (Comprehensive Assessment Risk & Education) Fully automated solution | Revenue generation | Increase quality of patient care

### DIFFERENTIATION

- Automation of patient identification
- Platform can be applied across a health system to all specialties and disease states

# POPULATION HEALTH

- CARE for COVID launched 2020
- 500,000+ patients served
- Incremental disease state proof point





Source: Cancer statistics, NCCN Guidelines

## CARE Program <sup>™</sup> –Progress in FY2020





CARE sites' specialties: 30% Imaging Centers 20% Breast Centers **15% OBGYN** 13% Oncology **9% Family Practice** 5% High Risk 3% Internal Medicine 1% Surgical 1% Gastro 1% Urology 1% Onboarding for HRBC 1% Breast Surgeon

> Sources: 1. Data on file with Ambry Genetics 2. cdc.gov/chronicdisease/about/costs/index.htm



# +RNAinsight

# **OPPORTUNITY**

- The first RNA test in the industry
- Most progress in past 10 years in genetic testing field
- Supported for its ability to contribute to selection of appropriate clinical approach and treatment strategy for patients, and achieved approximately 200% year on year

(H1 FY19 ➡ H1 FY20)

 Currently considering acquiring eligibility for insurance reimbursement

# DIFFERENTIATION

- 9% improvement in diagnostic accuracy (decrease in false negatives)
- 5% improvement in inconsistent test results
- Achieved through bioinformatics and optimization of laboratory workflow





# Based on sophisticated medical imaging analysis technology utilizing AI, biomarkers are selected and risks in drug discovery process are significantly reduced

#### **Invicro's Strengths Growth Strategy** Deep understanding of disease and ability to specify Take opportunity to resume Medical imaging biomarkers with proprietary AI and software AD clinical trial and secure analysis capability • Experts in nuclear medicine position as leader in central nervous system (CNS) Imaging data management using cuttingmarket Imaging data edge software (iPACS) in the industry management platform Achieve high growth in World's largest AD/PD Quantification of images using TaulQ and cancer market with image database ABIQ biomarker and data management capability • IHC **Digital pathology** PK/PD using Quanticell Growth in digital pathology field based on • Imaging partner network at 2,000 places globally Quanticell technology; Imaging treatment · Familiar with laws and regulations, compliance and QA **Consider M&A targeting Project management** in different countries customer base, IP, data platforms Over 100 scientists with PhDs and MDs **Top-class scientists** Medical and data science experts Break into markets in Japan • 23 of 25 top pharmaceutical companies are clients and Asia Solid customer base Over 200 client companies, including bio companies



#### Number of Clinical Trials: Market trends



### Invicro's Backlog Trend



# Equity Market Trends: From pharmaceutical development Ventures to Biotech Companies





#### Annual Biotech\* Funding

\*Biotech: Drug Discovery Support Services and Diagnostic Tools Source: Credit Suisse, State of the CRO Industry, 19JAN21



#### Biotech\*/BioPhama Trend

# Medium-term Growth Strategy: Expansion of Diagnostic Menu



# **Oncology Somatic Product Roadmap**

Support Across the Patient Journey



# Expanding Clinical Value Through Pair Test with TOP2 & Ambry Genetics





# Medium to Long-Term Strategy: Developing Multiomics Platforms







### **Overview**

Konica Minolta precision medicine collaborates with AWS to create the next-generation of precision diagnostics

- Konica Minolta Precision Medicine, Inc. (KMPM) and Amazon Web Services, Inc. (AWS) enter into 5-year collaboration agreement
- AWS, as KMPM's preferred cloud provider, is supporting KMPM's global expansion of multi-omics platform LATTICE<sup>™</sup>\*
- Amazon has made a financial investment in KMPM
- LATTICE<sup>™</sup> is a groundbreaking integrated diagnostic data platform that combines genomics, pathology, and radiology data along with other critical information to uncover new, clinically relevant biomarkers and create the next generation of diagnostic tests





#### Konica Minolta Precision Medicine

# **KMPM**

- AWS' endorsement and support on LATTICE<sup>™</sup>(Multi-omics platform) concept
- Using AWS's latest cloud and AI technologies
- Promoting the transition from on-premises to the cloud
- Strengthening GTM to pharmaceutical companies of AWS's customers and data collaboration
- Providing bio-informatics analysis services to existing laboratories
- Promoting the shift to cloud base for CARE Program
- Promoting efficiency of KMPM genetic data storage and cost reduction of data handling (reducing IT cost per sample to 1/4)



#### Amazon Web Services, Inc.

AWS

- Precision diagnostics as the basis for realizing precision medicine
- Strengthening and accelerating innovative offerings in collaboration with KMPM (expertise and database in genetic, and healthcare imaging fields)
- Supporting to realize the global precision diagnostics through Amazon HealthLake
- Realizing cost reduction and improvement in the result of patient treatment through utilizing the AWS cloud technologies by more organizations in addition to pharmaceutical companies
- Ultimately, discovering new ways to save lives 23





Source :

1) AWS on Air 2020: AWS What's Next ft. Amazon HealthLake - YouTube <u>https://www.youtube.com/watch?v=I90EgWkb-O0</u>

2) AWS re:Invent 2020: Make sense of health data with Amazon HealthLake - YouTube https://www.youtube.com/watch?v=Ld2Uno3V4Xk

# The Ability to Analyze Enormous Amounts of Data is Essential in the Future Genetic Field.



# The genomic field requires scalable storage and computing due to increasing chronological data with wide variety.



#### Cancer whole exome sequencing



Data computational and storage needs for 1 patient = 100X Apollo 11 Mission

# LATTICE<sup>™</sup>: Multi-omics Platform





# KMPM's Differentiated Platform Becomes Cloud-based





# Customer Base and Our Proprietary Database as Barriers to Entry by Other Companies



#### **iPACS**

- 23 of top 25 pharmaceutical companies are our clients
- Over 200 companies are our clients, including biotech companies
- Increasing 2 new customers per month
- Imaging for drug discovery and clinical trial (CT、MRI、FDG-PET、PSMA-PET)
   32 thousand AD images achieved
   Proven Al-analysis (Tau<sup>IQ</sup>, Amyloid<sup>IQ</sup>)
  - Digital pathology imaging (Quanticell)
  - New biomarkers search (SPFS)
  - Pharmaceutical companies/patient collaboration (BPH)

### Ambry Variant Analyzer (AVA)

#### • Major hospital group

- Major imaging centers
- Cover 97% of insured patients through insurance company network
- Access to unaffected individuals through CARE Program

- Accumulation of analysis data for 1.5 million people
- 9500 active orders
- Highly accurate genetic analysis data from RNAs tests
- High quality analysis data by genetic counselor's translation

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### iPACS Strengths: Proprietary Database + AI Analysis Capabilities





# iPACS Strengths: Digital Pathology (Precise Analysis of Protein Expression)



# Quanticell<sup>™</sup> IHC

Phosphor-integrated Dots (PID)-based Detection Technology

#### **Key characteristics**

- Sensitivity: Brightness is 100 times higher than Quantum Dots (QDs), and elements that cannot be detected with standard IHC methods can be measured.
- Quantification: Highly precise measurements can be made at 300 times dynamic range compared to QDs
- Clarification of physiological significance: Physiological significance can be analyzed through analysis of location within the cells

#### Value for pharmaceutical companies

- Can detect low-incidence proteins that are difficult to detect (Her2, PDL-1, etc.)
- Improve patients' QOL and pharmaceutical companies' economic potential by increasing target patients



- Analysis through quantification and analytics
- Locational analysis of target particle



- Classification of specific people with diseases and identify patients with false negatives
- Analysis of location and amount of drug and target particle
- Dynamic analysis of target particle within living cell



# iPACS Strengths: Scientific Strength + Global Network







# Selected 18 priority markets by target market size and attractiveness, covering 85% of all markets.



# Diseases in Which Multi-omics Platform is Expected to be Utilized



Early Diagnosis and Improvement of Diagnostic Accuracy

## RWD: It is Important to Link Clinical and Diagnostic Information.



Global Comparison of Biobanks						
	Size/Target population	Data type	Clinical information	Data utilization		
Taiwan Biobank	<ul> <li>General citizens: 0.2 million</li> <li>Patients with chronic illness</li> </ul>	<ul> <li>Blood, urine, hematology, DNA, etc.</li> <li>Tissue of cancer patients</li> <li>With tracking</li> </ul>	<ul> <li>EMR/EHR</li> <li>Lifestyle/medical history</li> <li>With tracking</li> </ul>	• Available for both research institutions and private companies		
China National C	GeneBank ● General citizens: 1 million (China Nanjing PJT)	<ul> <li>Blood, urine, DNA, etc.</li> <li>Without tracking Each biobank exists seg</li> </ul>	<ul> <li>Lifestyle/medical history</li> <li>Without tracking parately, and there is no centralize</li> </ul>	<ul> <li>Research institutions in China only</li> <li>ed management or linkage of data.</li> </ul>		
Tohoku Medical	Megabank • General citizens: 0.16 million	<ul> <li>Blood, DNA, other body fluids, secretions, etc.</li> <li>With tracking</li> </ul>	<ul> <li>Lifestyle/medical history</li> <li>With tracking</li> </ul>	<ul> <li>Research institutions only</li> </ul>		
Genomic Englan	d • 5 million • General citizens, rare diseases and cancer patients	<ul> <li>Blood, urine, saliva, DNA, etc.</li> <li>Tissue of cancer patients</li> <li>With tracking</li> </ul>	<ul> <li>EMR/EHR</li> <li>Lifestyle</li> <li>With tracking</li> </ul>	• Available for both research institutions and private companies		
All of Us	• General citizens: 1 million	<ul> <li>Blood, urine, saliva, etc.</li> <li>With tracking</li> </ul>	<ul> <li>EMR/EHR</li> <li>Lifestyle/medical history</li> <li>With tracking</li> </ul>	<ul> <li>Research institutions only</li> </ul>		

### Source: Data from the Second Genomic Healthcare Council of the Cabinet Office, IQVIA Institute; Understanding the Global Landscape of © KONICA MINOLTA 34 Genomics Initiatives, May 2020

# **Progress of the Genomecohort Project**



### Genomecohort research\* progresses at the national level and on a large

#### enterprise basis

\*Genomecohort Study: One of the large observational study methods to investigate the relationship between cause and onset of disease

Ancestry.com	Genomics England		Million Veteran Program		China Nanjing Project		
For-Profit Company	State-Owned Company		Government Project		Government Project Target: 1 million		
Data Type: Genotyping Linked Data: Survey	Target: 5 mil	lion** /hole genome	Target: 1 million Data Type: Biological sam	ples	Turkish Genome Project		
	Linked Data: EMR/EHR		Linked Data: Clinical data		Government Project Target: 1 million ***		
AstraZeneca-MedImmur	e "All of	Us" Precision Medicine Initiative			23andMe		
<b>For-Profit Company</b> Target: 2 million Data Type: Whole exome	<b>ment Project</b> 1 million pe: Biological s Data: EMR/EHR	e <b>nt Project</b> million : Biological samples ta: EMR/EHR		For-Profit Company Current Cohort: 10 million Data Type: Genotyping Linked Data: Survey			
Genomic Health	inc.	Dubai Genomics		Т	Tohoku Medical Megabank		
<b>For-Profit Company</b> Current Cohort: 1 million Data Type: Genotyping - Sor	natic (tumor)	<b>Governmer</b> Target: "wł Data Type:	<b>Government Project (10X Initiative)</b> Target: "whole population of Dubai" Data Type: Whole genome		Public Project Farget: 0.2 million Data Type: Genotyping, Biological samples		
**Of which at least 500k will be whole genomes Public Private							

\*\*\*Planned for completion by 2023, the 100th anniversary of the founding of the modern Turkish state.

Source: IQVIA Institute; Understanding the Global Landscape of Genomics Initiatives, May 2020

### **Progress of Genomecohort Project**



Asian genomecohort studies haven't accumulated enough data considering percentage of global population (6.5M by 2025) and have high potential of most recent coming growth.



# Numerical Outlook for Growth

### Precision Medicine Business: Accelerate Sales Growth and Earnings Improvement





#### Continuous investment for growth

\*Indicator when FY2020 amount invested is set at 100

By measures	FY20	FY21	FY22	FY23	FY24	Total
Expansion of AG sales	5	55	30	5	0	95
AG R&D (including Somatic/LBx)	40	25	40	55	75	235
LATTICE	35	20	20	20	20	115
Japan	20	20	20	20	25	105
Investment amount	100	120	110	100	120	

## Focus of M&A Strategy



Enhancement of multi-omics capabilities Strengthening data science capabilities

Acceleration of sales growth

