

Notice: This is a translation of a notice in Japanese and is made solely for the convenience of foreign shareholders.  
In the case of any discrepancy between the translation and the Japanese original, the latter shall prevail.

[Translation]



## Financial Results Second Quarter of Fiscal Year Ending March 31, 2023

Our desire is to understand medical needs, to promote development in the medical setting and to contribute to innovation in the medical field.

Dec 6, 2022

- This document contains forward-looking statements. These statements are based on assumptions made at the time the statements are made regarding future events and trends, and there can be no assurance that such assumptions will prove accurate. Furthermore, such statements are not guarantees of future results and involve risks and uncertainties. Please note that actual results may differ materially from those discussed in the forward-looking statements due to changes in the environment and other factors.
- Factors that may affect the actual results described above include, but are not limited to, domestic and international economic conditions and trends in our related industries.
- The information contained in this document regarding other companies is quoted from publicly available information, etc. Renaissance has not verified and does not guarantee the accuracy or appropriateness of such information.
- The information in this document is subject to change without prior notice.
- In the event of any discrepancy between this document and the "Financial Results for the Second Quarter of the Fiscal Year Ending March 31, 2023 [Japanese GAAP] (Non-Consolidated)" (Summary), the contents of the Summary shall prevail.

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## Company Profile

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**We devote ourselves to research and development of various modalities (pharmaceuticals, medical devices, artificial intelligence (AI), etc.) in the medical setting to solve problems in the medical field, and create new medical care to enable people to enjoy lifelong health, both physically and mentally.**



- ❑ Solving the healthcare challenges of an aging population
- ❑ Focus on research on women's and children's diseases.

## Aging-related diseases

### Non-communicable diseases (NCDs)

Cancer • Diabetes • Respiratory diseases •  
Cardiovascular diseases

Chronic myeloid leukemia (pharmaceuticals)

New coronavirus pneumonia  
(pharmaceuticals)

Malignant melanoma (pharmaceuticals)

Interstitial pneumonia (pharmaceuticals)

Angiosarcoma (pharmaceuticals)

Systemic sclerosis (pharmaceuticals)

Non-small cell lung cancer (pharmaceuticals)

Diabetes (pharmaceuticals, AI)

Respiratory (AI)

Chronic dialysis (AI)

Dysphagia (AI)

Peritoneal dialysis (fiberscope, medical device)

## Female and pediatric diseases

Premenstrual dysphoric disorders (pharmaceuticals)

Climacteric disorder (pharmaceuticals)

Autism spectrum disorder (pharmaceuticals)

FGF23-associated hypophosphatemic rickets  
(pharmaceuticals)

Pediatric Metabolic Disorder (diagnostic)

Pediatric developmental disorder (AI)

Breast cancer (AI)

## Our Strengths

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# Large Number of Development Pipeline

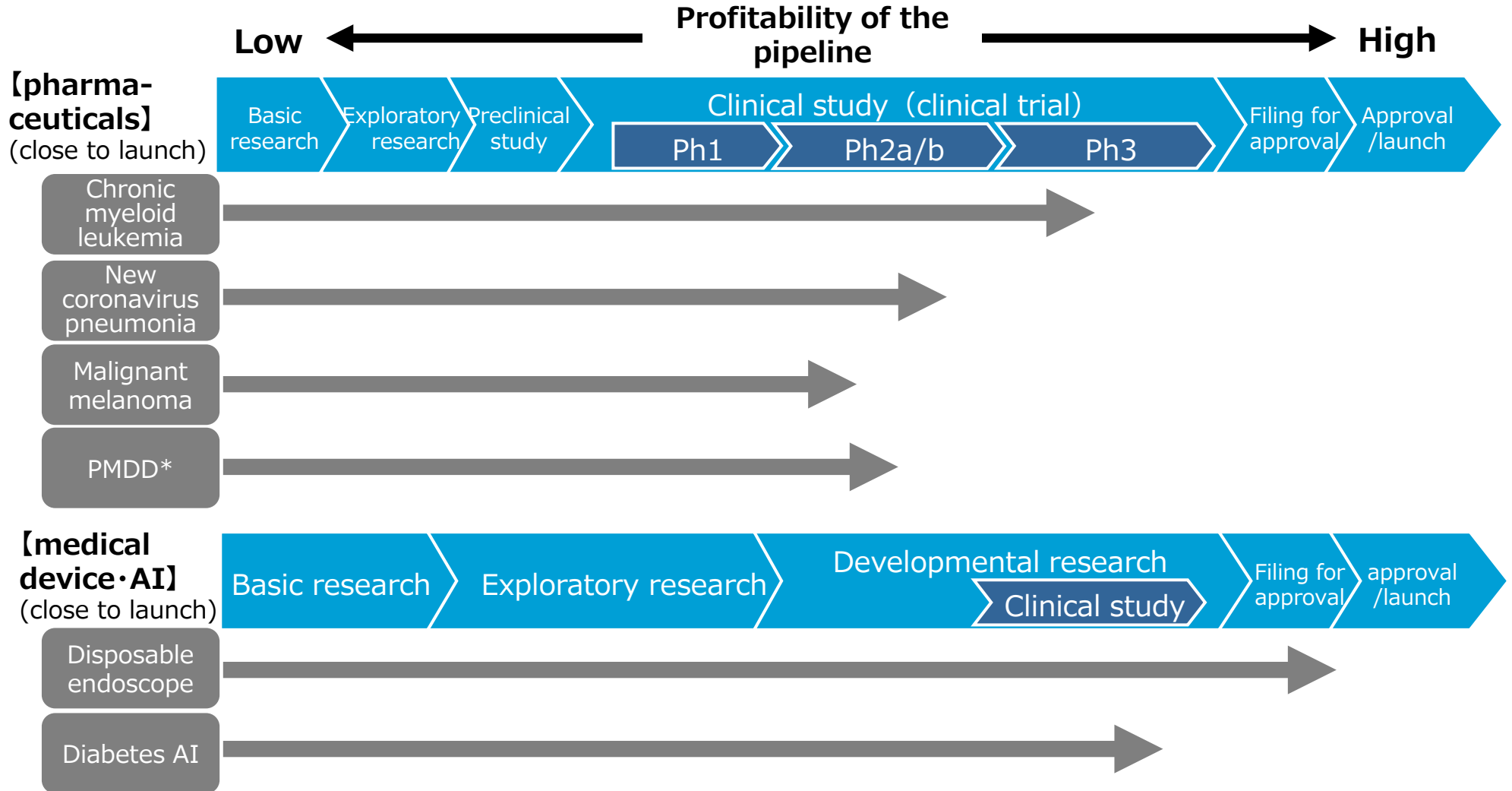
The number of our most recent clinical trial is seven (7).  
We started the Ph3 trials for chronic myeloid leukemia this fiscal year.

Period	Track record		scheduled
	FY2022	FY2023	FY2024
Pipeline in clinical stage	<b>6</b>	<b>7</b>	<b>10</b>
content	Ph3	<ul style="list-style-type: none"> <li>Chronic myeloid leukemia</li> </ul>	Chronic myeloid leukemia
	Ph2	<ul style="list-style-type: none"> <li>New coronavirus pneumonia (Japan/the US/Turkey)</li> <li>Malignant melanoma</li> <li>Premenstrual dysphoric disorders</li> <li>Autism spectrum disorder</li> </ul>	<ul style="list-style-type: none"> <li>Malignant melanoma</li> <li>Premenstrual dysphoric disorders</li> <li>Angiosarcoma</li> <li>Non-small cell lung cancer</li> <li>Systemic sclerosis</li> </ul>
	Ph1		<ul style="list-style-type: none"> <li>Alopecia (Eirion)</li> </ul>
	Other clinical study		<ul style="list-style-type: none"> <li>FGF23-associated hypophosphatemic rickets</li> </ul>



# Integrated R&D from Basic Research to Filing for Approval

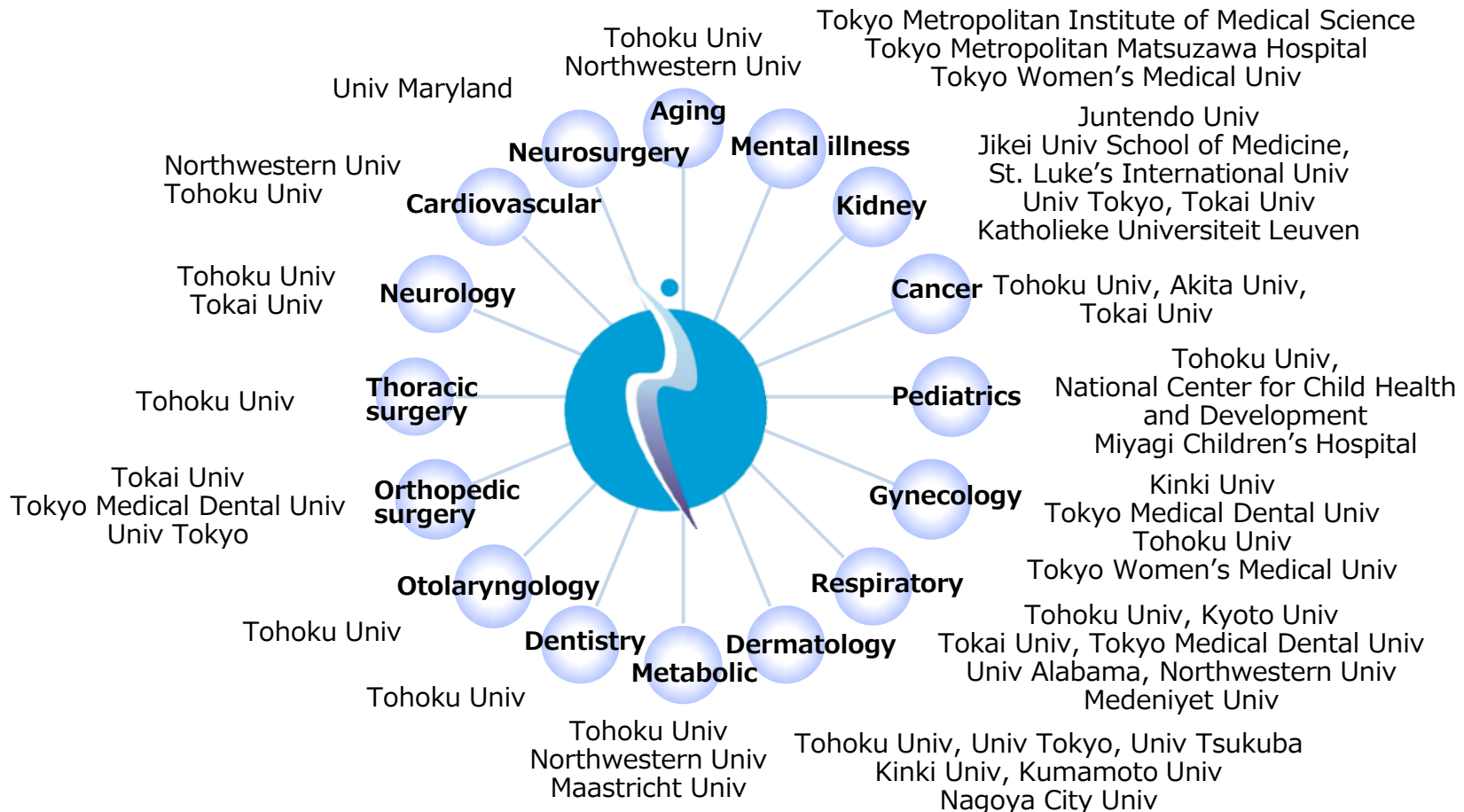
Ensuring the important seeds will be implemented by the integrated R&D  
 Increasing the profitability of our pipeline compared to other companies (e.g., increase royalty)



\*PMDD: Premenstrual dysphoric disorders

# Network with Many Medical Departments and Institutions

Based on our experience in investigator-initiated clinical trials, a broad network is built with a large number of medical institutions and departments for a variety of indications. This extensive network is one of our major strengths over our competitors.



## Our strengths : Efficient R&D

- Large development pipeline
- Conducting integrated development from basic research to clinical development
- Development for various indications through networking with numerous medical departments

## R&D while minimizing out-of-pocket research expenses

- Cooperation with External Organizations → Seed acquisition, drug repositioning, minimizing in-house resources
- Leveraging investigator-initiated clinical trials → Conducting difficult clinical trials, acceleration of development, and reduction of development costs
- Utilization of public funds such as Japan Agency for Medical Research and Development (AMED) → minimizing out-of-pocket expense

# Utilization of Public Funds

Our development pipeline has so far received approximately 3 billion yen in grants from AMED and other public institutions, which is a major factor in our low out-of-pocket expenses for R&D.

Category	Development pipeline		Public fund	fund (billion yen)
Pharmaceutical	PAI-1 inhibitor	Chronic myeloid leukemia	Ministry of Education, Culture, Sports, Science and Technology (MEXT) Japan Science and Technology Agency (JST) Japan Agency for Medical Research and Development (AMED) (- Ph3, scheduled to complete in March 2026)	1.08
		New coronavirus pneumonia	AMED (Ph2a - Ph2b, scheduled to complete in March 2023)	0.60
		Malignant melanoma	AMED (Ph2, scheduled to complete in March 2024)	0.30
	Pyridoxamine	PMS/PMDD	AMED (Ph2, Scheduled to complete in December 2023)	0.38
		Autism spectrum disorder	AMED (2017 - 2019)	0.18
	Medical device	Disposable ultrafine endoscope	MEXT (2015 - 2016)	0.13
AI	AI for supporting diabetes treatment	AMED (Scheduled to complete in March 2025)	0.38	

**total 3.05**

(Note) The full amount of the above funds will not be credited to Renascience, but as total research expenses.

# Progress of Pipeline Development

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Modality	Indication	Progress
PAI-1 inhibitor	Chronic myeloid leukemia	<b>Ph3 ongoing</b>
	New coronavirus pneumonia (Japan)	<b>Ph2b completed The study report in March 2023</b>
	Malignant melanoma	Ph2 ongoing
	Interstitial pneumonia	Preclinical stage
	FGF23-associated hypophosphatemic rickets	<b>Clinical study ongoing</b>
	Angiosarcoma	<b>Ph2 in preparation</b>
	Non-small cell lung cancer	<b>Ph2 in preparation</b>
	Systemic sclerosis	<b>Ph2 in preparation</b>
	Alopecia	Ph1 in preparation
Pyridoxamine	Autism spectrum disorder	Analysis of Ph2 results Seeking partners
	PMS/PMDD	Ph2 ongoing <b>AMED support obtained to promote the enrollment</b>
	Climacteric disorder	Clinical study in preparation

Modality	Indication	Progress	
Ultrafine endoscope	Peritoneal dialysis	<b>Filed for approval</b>	
Artificial intelligence (AI)	Respiratory function diagnostics	Developmental stage	
	Support for chronic dialysis system	Developmental stage	
	Support for diabetes treatment	Developmental stage <b>Adopted as an AMED project</b>	
	Assessment of swallowing function	<b>Developmental stage</b>	
	Pediatric developmental disability	Exploratory stage	
	Pathology of breast cancer	Research stage	
	diagnostics	Phenylketonuria	Exploratory stage

(note)   : supported by AMED  
**Bold** : significant progress



# Treatment for Chronic Myeloid Leukemia (CML)

Proof-of-Concept (POC) was obtained in the Ph2b study.  
 A Ph3 investigator-initiated clinical trial was initiated in August 2022, and the clinical development is ongoing with the aim of submitting the regulatory filing in FY2027.

Modality	Code	Indication	Developmental stage						Collaboration	Partner
			Research	Pre-clinical	Ph1	Ph2	Ph3	Filing /Approval		
Small molecule PAI-1 inhibitor	RS5614	Chronic myeloid leukemia (CML)					<b>Ph3 ongoing</b>		Twelve (12) institutions including Tohoku Univ	TBD
							Scheduled to complete in the FY 2026			

## Progress in this FY and Results to date

### March 2021

- Completed the Ph2b study
- Obtained POC in combination with anticancer agent
  - Efficacy: DMR(\*) achievement rate 33.3% (Anticancer agent alone: 8% - 12%)
  - Safety: Excellent safety and tolerability after 1 year of administration

### March 2022

- Adopted in AMED program "Practical Application of Innovative Cancer Therapy"

### August 2022

- Started a Ph3 investigator-initiated clinical trial

(\*) A condition in which the cancer-causing gene cannot be detected even with highly sensitive testing methods.

## Future plans

### FY2026

- The Ph3 investigator-initiated clinical trial to be completed (Ph3 study design)
  - Placebo-controlled double-blind study
  - Number of subjects: 60
  - Primary endpoint: maintenance of DMR for 2 years
  - Duration: 4 years (1 year for enrollment, 1 year for achieving DMR, 2 years for maintaining DMR)



### FY2027

- Aiming for regulatory filing



# Treatment for COVID-19 Pneumonia

The Ph2b study completed in October 2022  
The study report to be completed in March 2023

Modality	Code	Indication	Developmental stage						Collaboration	Partner
			Research	Pre-clinical	Ph1	Ph2	Ph3	Filing /Approval		
Small molecule PAI-1 inhibitor	RS5614	New coronavirus pneumonia				<b>Japan: Ph2b</b> completed Oct 2022 the report to be completed in March 2023 			Twenty (20) institutions including Tohoku Univ  Northwestern Univ Medeniyet Univ	 Daiichi-Sankyo

## Progress in this FY and Results to date

## Future plans

### June 2021

- Started a Ph2b study
  - Adopted in AMED program of “Research Program for Emerging and Re-emerging Infectious Disease”
  - The Investigator-initiated clinical trial has been conducted at 20 medical institutions in Japan

### October 2022

- The Ph2b study completed

### November 2022

- Extended the Option agreement with Daiichi Sankyo

### March 2023

- The study report of the Ph2b study to be completed





# Immune Checkpoint Inhibitor (Melanoma, Non-small cell lung cancer)

For melanoma, a Ph2 study is now well underway and is scheduled to be completed in March 2024.  
For non-small cell lung cancer, a Ph2 investigator-initiated clinical trial is currently being prepared.

Modality	Code	indication	Developmental stage					Collaboration	Partner
			Research	Pre-clinical	Ph1	Ph2	Ph3		
Small molecule PAI-1 inhibitor	RS5614	Malignant melanoma				Ph2 ongoing Scheduled to complete in March 2024		Six (6) institutions including Tohoku Univ	TBD
		Non-small cell lung cancer				Ph2 in preparation		Five (5) institutions including Hiroshima Univ	TBD

## Progress in this FY and Results to date

### [Malignant Melanoma]

#### May 2021

- Adopted in AMED program of "Translational Research Program"

#### July 2021

- Started a Ph2 investigator-initiated clinical trial
  - Open-label, number of subjects: 40

### [Non-small cell lung cancer]

#### October 2022

- Signed a collaboration agreement with Hiroshima University.

## Future plans

### [Malignant Melanoma]

#### March 2024

- The Ph2 investigator-initiated clinical trial to be completed.

### [Non-small cell lung cancer]

- A Ph2 investigator-initiated clinical trial



# Premenstrual Syndrome (PMS) / Premenstrual Dysphoric Disorder (PMDD)

Ph2 investigator-initiated clinical trial underway with support from AMED  
Scheduled to be completed in December 2023 after accelerating patient enrollment through the addition of the clinical trial sites and clinical trial advertisements.

Modality	Code	indication	Developmental stage						Collaboration	Partner
			Research	Pre-clinical	Ph1	Ph2	Ph3	Filing /Approval		
Small molecule Pyridoxamine	RS8001	PMS/PMDD				Ph2			Eight (8) institutions including Kinki Univ	ASKA Pharmaceutical

## Progress in this FY and Results to date

### December 2019

- Adopted in AMED program of "Cyclic Innovation of Clinical Empowerment (CiCLE)"
- Option agreement signed with ASKA Pharmaceutical Co Ltd.

### November 2020

- Started the Ph2 investigator-initiated clinical trial

### September 2021 and July 2022

- The interim evaluation by AMED
  - AMED decided to continue the project in both evaluations

## Future plans


- Continuing the measures to accelerate patient enrollment
  - Additional sites for clinical trials: 2 sites in FY2021, more sites in FY2022
  - Utilization of the volunteer panels
  - Advertisement of the clinical trial
  - Educational seminars by physicians

### December 2023

- The Ph2 investigator-initiated clinical trial to be completed

# Disposable Ultrafine Endoscope (for Peritoneal Dialysis)

Filed for regulatory approval for the fiberscope in August 2022.  
This will be our first product

Modality	Code	Indication	Developmental stage			Collaboration	Partner
			Exploratory	Development	Commercialization		
Medical device	RS9001	Peritoneal dialysis (ultrafine endoscope)			<b>Regulatory filing in August 2022</b>  (preceding application of the fiberscope)	Four (4) institutions including Tohoku Univ	Major Medical Products Manufacturer in the US

## Progress in this FY and Results to date

### June 2021

- First milestone received from our licensee

### August 2022

- Submitted the regulatory filing for the fiberscope

### September 2022

- Executed a collaboration agreement with HI-LEX Corporation and HI-LEX Medical
- Started joint development of a guide catheter with HI-LEX Medical

## Future plans

- Regulatory approval and insurance reimbursement of the fiberscope
- Development of guide catheter in collaboration with HI-LEX Corporation and HI-LEX Medical

### FY2024

- Scheduled to apply for "Minor Modification Procedure for Partial Change of Medical Device" with the addition of a guide catheter



# AI for Supporting Diabetes Treatment

In January 2022, Successfully built an AI that can predict insulin dosage with high accuracy. Received a grant from AMED from this fiscal year, aiming to file for regulatory approval in FY2026.

Modality	Code	Indication	開発ステージ			Collaboration	Partner
			Exploratory	Development	Commercialization		
AI	RSAI03	Support for diabetes treatment		<b>Developmental research ongoing</b> AI developmental research to be completed in 2023 Clinical trials scheduled to start in 2023		Tohoku Univ NEC NES	TBD

## Progress in this FY and Results to date

## Future plans

### January 2022

- Built "DM-SAiL," an artificial intelligence (AI) capable of predicting insulin dosage, using inpatient data (1,000 cases) from Tohoku University Hospital (Department of Diabetes and Metabolism)
- DM-SAiL" can predict insulin dosage with an error of 2 units (high accuracy) from insulin dosages by diabetologists.

### April 2022

- Adopted in AMED program of "Innovation in Medical Engineering (Development and Commercialization Project)".

### November 2022

- Executed a memorandum of understanding with NEC Solution Innovator, Ltd.

- Further improvement of AI prediction accuracy
- System development
- Clinical study

### In 2023

- AI developmental research to be completed; clinical trials to begin

### FY2026

- Aiming for regulatory filing



# AI for Supporting Chronic Dialysis System / AI for Assessment of Swallowing Function

AI for supporting chronic dialysis: AI is already acquired to accurately predict blood pressure drop during dialysis. Collaboration with Nipro.

AI for assessment of swallowing function: AI that analyzes voice data has been developed, and a system to assist diagnosis of swallowing function is under development.

Modality	Code	Indication	Developmental stage			Collaboration	Partner
			Exploratory	Development	Commercialization		
AI	RSAI02	Support for chronic dialysis system		Developmental research ongoing Scheduled to complete in FY2024		Fifteen (15) institutions including St. Luke Int Univ NEC NES	
	RSAI04	Assessment of swallowing function		Developmental research ongoing Scheduled to complete in FY2025		Tohoku Univ NEC NES	TBD

## Progress in this FY and Results to date

### [Chronic Dialysis Support]

- Acquired AI capable of predicting sudden decrease of blood pressure (below 20 mmHg) during dialysis with high accuracy of AUC0.91 based on dialysis medical data of 3,000 cases (800,000 dialysis sessions).

### May 2022

- Extension of the collaboration agreement with Nipro

### [Assessment of swallowing function]

- Completed an exploratory analysis using data from 150 healthy subjects to confirm baseline (sex, age, individual, text, etc.) of healthy voice

## Future plans

### [Chronic Dialysis Support]

- Development of AI to Predict Blood Pressure Decrease during Dialysis in Real Time
- Addition of function to predict safe water removal during dialysis

**FY2024:** Developmental research to be completed

### [Assessment of Swallowing Function]

- Developmental research using data on elderly patients with impaired swallowing function

**FY2025:** Development research to be completed

## Forecast of Profitability

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# Outlook of Profitability: Pharmaceuticals

The estimated market size of our drug candidates ranges from several billion to several tens of billions of yen in Japan, and from several hundred billion to one trillion yen when overseas markets are included. In these markets, there are currently no competing products.

## Market size

(as of May 2022)

Pipeline		Patients in the Therapeutic Target Segment		Estimated Market Size (TAM/billion yen)	Features of Our Products
Chronic myeloid leukemia	Japan	8,000		<b>11.5</b>	<ul style="list-style-type: none"> <li>Expected to be curative in combination with anticancer agents</li> <li>There is no product in clinical development with the similar action.</li> </ul>
	The US	32,000		<b>256</b>	
New coronavirus pneumonia	Japan	84,000		<b>5.6</b>	<ul style="list-style-type: none"> <li>An oral medicine for the treatment of lung injury</li> <li>Currently no competing oral medicines for treatment of lung injury</li> </ul>
	The US	3,100,000		<b>1,150</b>	
Immune check-point inhibitor	Mela-noma	Japan	3,200	<b>1.3</b>	<ul style="list-style-type: none"> <li>A small molecule medicine with immune checkpoint inhibitory action (similar to existing antibody therapeutics)</li> <li>Oral</li> <li>Currently, there are no marketed or developed oral immune checkpoint inhibitors.</li> </ul>
		The US	80,000	<b>179</b>	
	Lung cancer	Japan	131,000	<b>52.8</b>	
		The US	223,000	<b>500.1</b>	
PMS/PMDD	Japan	1,620,000		<b>47.4</b>	<ul style="list-style-type: none"> <li>Extremely safe</li> <li>Potentially first approved medicine in this disease where unapproved medicines, such as oral contraceptives and antidepressants are used</li> </ul>
	The US	4,010,000		<b>653.3</b>	

The market size of medical devices and AI that are close to launch is several hundred million to several billion yen in Japan, and there are currently no competing products in the market.

## Market size

(as of May 2022)

pipeline	Patients in the Therapeutic Target Segment		Estimated Market Size (TAM/billion yen)	Features of Our Products
Ultrafine endoscope (peritoneal dialysis)	Japan	Patient number: 9,000	<b>0.2 – 1.5</b>	<ul style="list-style-type: none"> <li>• Allowing observation of intraperitoneal condition through catheters in peritoneal dialysis patients</li> <li>• Currently no competitive products</li> </ul>
AI for supporting diabetes treatment	Japan	Patient number : 100,000 Medical institution : 7,100	<b>4.2</b>	<ul style="list-style-type: none"> <li>• Predicting insulin dosage with the same accuracy as diabetologists</li> <li>• Currently no competitive products</li> </ul>
AI for supporting chronic dialysis system	Japan	Patient number : 340,000 Medical institution : 4,400	<b>2.6</b>	<ul style="list-style-type: none"> <li>• Predicting sudden decrease of blood pressure during dialysis and optimal amount of water removal to improve patient prognosis and to efficiently utilize human resources in dialysis hospitals.</li> <li>• Currently no competitive products</li> </ul>



## Financial Results

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# Financial Results (FY2023 2Q)

Profit and loss statement (million yen)	FY2023			Major details of 2Q results
	Annual budget	2Q	Ratio %	
Operating revenue	<b>90</b>	<b>20</b>	<b>22%</b>	Upfront Payment in RSAI02, support for Chronic Dialysis System
Business cost	–	–	–	–
Business expenses	–	<b>172</b>	–	–
R&D expenses	–	<b>59</b>	–	Clinical trial costs for RS8001_PMS/PMDD, RS5614_CML
others	–	<b>113</b>	–	Personnel expenses, outsourcing expenses, etc.
Operating loss	△ <b>542</b>	△ <b>152</b>	<b>28%</b>	–
Ordinary loss	△ <b>542</b>	△ <b>152</b>	<b>28%</b>	–
Net loss	△ <b>542</b>	△ <b>153</b>	<b>28%</b>	–



# Financial Results (FY2023 2Q)

Renaissance

Balance sheet (million yen)	FY2022	FY2023	GAP	Major factors for increase or decrease
	4Q	2Q		
Current assets	<b>2,428</b>	<b>2,393</b>	<b>△34</b>	–
cash and bank deposit	<b>2,386</b>	<b>2,344</b>	<b>△42</b>	Payments for research and development, labor costs, etc.
others	<b>41</b>	<b>48</b>	<b>7</b>	–
Fixed assets	<b>9</b>	<b>9</b>	<b>△0</b>	–
Total assets	<b>2,438</b>	<b>2,402</b>	<b>△35</b>	–
Current liabilities	<b>37</b>	<b>57</b>	<b>19</b>	Receipt of funds from AMED
Fixed liabilities	<b>199</b>	<b>297</b>	<b>98</b>	Increase in long-term debt from AMED
Total liabilities	<b>237</b>	<b>355</b>	<b>117</b>	–
capital stock	<b>1,036</b>	<b>1,036</b>	<b>–</b>	–
capital surplus	<b>1,518</b>	<b>1,518</b>	<b>–</b>	–
retained earnings	<b>△354</b>	<b>△508</b>	<b>△153</b>	Net loss for the quarter
Total net assets	<b>2,200</b>	<b>2,047</b>	<b>△153</b>	–
Total liabilities and net assets	<b>2,438</b>	<b>2,402</b>	<b>△35</b>	–

Cash flow Statement (million yen)	FY2023	Major factors for 2Q results
	2Q	
Cash flows from operating activities	△ <b>139</b>	Income (decrease) before income taxes, increase (decrease) in advances received
Cash flows from investing activities	△ <b>0</b>	Expenditures for the acquisition of property and equipment
Cash flows from financing activities	<b>98</b>	Proceeds from long-term debt
Net increase (decrease) in cash and cash equivalents	△ <b>42</b>	—
Cash and cash equivalents at beginning of year	<b>2,005</b>	—
Cash and cash equivalents at the end of the 2Q	<b>1,963</b>	—