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]

May 12, 2022

Financial Results for the Fiscal Year Ended March 31, 2022 [Japanese GAAP] (Non-consolidated)

Company name	Renascience Inc	Listed exchange	East
Code No.	4889		
Representative	(President & CEO)	Koji Naito	
Contact Person	(Director, CFO)	Kazuhiro Ikeda	
Scheduled date of the ordinary general meeting of shareholders		June 29, 2022	
Scheduled date of dividend payment commencement		--	
Scheduled date of securities report submission		June 30, 2022	
Preparation of supplementary explanatory documents for financial results		no	
Financial results briefing session		no	

1. Results for the fiscal year ended March 31, 2022 (April 1, 2021 to March 31, 2022)

(Millions of yen, rounded down to the nearest million)

(1) Operating results (Percentages represent year-on-year changes)

	Operating revenue		Operating profit		Ordinary income		Net income for the year	
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
Year ending March 2022	139	△33.6	△210	-	△241	-	△254	-
Year ending March 2021	209	191.3	△86	-	△90	-	△100	-

	Net income per share	Net income per share (diluted)	Current net profit rate of own capital	Ratio of Ordinary Income to Total Assets	Net Sales Operating income ratio
	Yen sen	Yen sen	%	%	%
Year ending March 2022	△22.33	-	△18.4	△13.8	△151.3
Year ending March 2021	△10.19	-	△16.9	△8.7	△41.1

(Reference) Gain (loss) on equity method investment: year ending March 31, 2022 -- million yen; year ending March 31, 2021 -- million yen

(note)

1. Net income per share-fully diluted is not shown in the above table, because net income per share was negative although there are residual shares.
2. The Company conducted a 300-for-1 stock split of shares of common stock on June 1, 2021, and net loss per share is calculated on the assumption that the stock split was conducted at the beginning of the previous fiscal year.
3. The "Accounting Standard for Revenue Recognition" (ASBJ Statement No. 29, March 31, 2020) and others have been applied from the beginning of the fiscal year under review, and the figures for the fiscal year ended March 31, 2022 are after the application of the said accounting standards and others.

(2) Financial conditions

	Total assets	Net assets	Own capital ratio	Net assets per share
	Millions of yen	Millions of yen	%	Yen Sen
Year ending March 2022	2,438	2,200	90.3	173.14
Year ending March 2021	1,066	561	52.6	57.01

(Reference)
Own capital 2,200 millions of yen in a year ending March 2022 561 millions of yen in a year ending March 2021

Note: The "Accounting Standard for Revenue Recognition" (ASBJ Statement No. 29, March 31, 2020) and others are applied from the beginning of the fiscal year under review, and the figures for the fiscal year ended March, 2022 are after the application of the said accounting standard and others.

(3) Cash flows

	Cash flows from operating activities	Cash flows from investing activities	Cash flows from financing activities	Cash and cash equivalents at end of period
	Millions of yen	Millions of yen	Millions of yen	Millions of yen
Year ending March 2022	△230	△0	1,591	2,005
Year ending March 2021	△89	△1	135	644

2. Dividends

	Annual dividend					Total dividends (Total)	Dividend payout ratio	Net assets Dividend ratio
	End of 1st quarter	End of 2nd quarter	End of 3rd quarter	End of term	Total amount			
	Yen sen	Yen sen	Yen Sen	Yen Sen	Yen sen	Millions of yen	%	%
Year ending March 2021	-	0.00	-	0.00	0.00	-	-	-
Year ending March 2022	-	0.00	-	0.00	0.00	-	-	-
Year ending March 2023 (Forecast)	-	0.00	-	0.00	0.00		-	

3. Forecast for the fiscal year ending March, 2023 (April 1, 2022 to March 31, 2023)

(Percentages represent changes from the same period of the previous fiscal year.)

	Operating revenue		Operating profit		Ordinary income		Net income for the year		Net income per share
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Yen sen
Ful business year	90	△34.8	△542	-	△542	-	△542	-	△42.70

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Notes

(1) Changes in accounting policies, changes in accounting estimates, and restatement of prior period financial statements after error corrections

① Changes in accounting policies due to revisions of accounting standards, etc. : yes
② Changes in accounting policies other than ① above : none
③ Changes in accounting estimates : none
④ Restatement : none

(2) Number of shares issued and outstanding (common stock)

① Number of shares outstanding at end of period (Including treasury stock)
② Number of treasury stock at end of period
③ Average number of shares during the period

①	Year ending March 2022	12,711,700 shares	Year ending March 2021	9,849,000 shares
②	Year ending March 2022	- shares	Year ending March 2021	- shares
③	Year ending March 2022	11,389,120 shares	Year ending March 2021	9,819,082 shares

(Notes)

1. The Company issued 600 new shares by way of third-party allotment with a payment date of April 6, 2021.
2. The Company conducted a 300-for-1 stock split of shares of common stock on June 1, 2021, and the number of shares issued and outstanding (common stock) is calculated on the assumption that the stock split was conducted at the beginning of the previous fiscal year.
3. The Company issued 2,240,000 new shares in connection with its listing on the Tokyo Stock Exchange Mothers on September 24, 2021.
4. The Company has issued 442,700 new shares by way of third-party allotment in connection with the secondary offering by way of over-allotment with a payment date of October 26, 2021.

※ The financial results are not subject to audit by a certified public accountant or auditing firm.

※ Explanation of the appropriate use of earnings forecasts and other special notes

(Cautionary statement regarding forward-looking statements, etc.)

The forward-looking statements, including earnings forecasts, contained in these materials are based on information currently available to the Company and assumptions deemed to be reasonable, and are not intended to be a promise by the Company that they will be achieved. Actual results may differ materially from these forecasts due to various factors. Please refer to "1. Overview of Business Results, etc. (5) Outlook for the Future" in the attached material.

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1. Overview of Business Results, etc.

(Company Profile)

The Company will continue to contribute to the creation of medical innovation by working with physicians to research and develop various modalities (pharmaceuticals, medical devices, artificial intelligence (AI) solutions, etc.) to solve problems in the medical field, thereby creating new medical treatments that enable people to enjoy lifelong health in both mind and body. The Company is working to resolve issues of medical or social importance, such as aging-related diseases (cancer, diabetes, respiratory diseases, and cardiovascular diseases), diseases of women and children, and new coronavirus infections.

A summary of operating results, financial position, cash flows and research and development activities for the fiscal year under review is as follows.

(1) Summary of Business Results for the Fiscal Year Ended March, 2022

Operating revenue for the fiscal year under review was 139,333 thousand yen due to the receipt of upfront payment for RSAI02 Support for Chronic Dialysis System, the recording of a milestone revenue for RS9001 Disposable Ultrafine Endoscope, the recording of a milestone revenue for RSAI01 Respiratory Function Diagnostic System, the recording of contract research revenue for RS5614 COVID-19 program, and the recording of a contract research revenue for RS5614 Melanoma program, etc. Operating loss amounted to 210,839 thousand yen, mainly due to the recording of business expenses of 291,810 thousand yen, including research and development expenses of 82,713 thousand yen for RS8001 PMS/PMDD and RS5614 COVID-19. Ordinary loss amounted to 241,769 thousand yen, including the recording of stock issuance expenses of 25,532 thousand associated with the listing on the Tokyo Stock Exchange. Net loss was 254,292 thousand yen, including the recording of 11,318 thousand yen in impairment loss on patent rights related to RS8001 Schizophrenia.

As the Company operates in a single business segment, segment information has been omitted.

(2) Summary of Financial Position

(Assets)

Current assets at the end of the current fiscal year increased by 1,385,503 thousand yen to 2,428,148 thousand yen from 1,042,644 thousand yen at the end of the previous fiscal year. This was mainly due to an increase of 1,360,872 thousand yen in cash and deposits, mainly due to the issuance of shares in connection with the listing on the Mothers market of the Tokyo Stock Exchange in September 2021.

Fixed assets at the end of the current fiscal year decreased by 14,108 thousand yen to 9,880 thousand yen from 23,988 thousand yen at the end of the previous fiscal year. This was mainly due to the recording of 11,318 thousand yen in impairment loss on patents related to RS8001 Schizophrenia.

As a result, total assets increased by 1,371,395 thousand yen to 2,438,028 thousand yen from 1,066,632 thousand yen at the end of the previous fiscal year.

(Liabilities)

Current liabilities at the end of the current fiscal year increased by 8,493 thousand yen to 37,942 thousand yen from 29,449 thousand yen at the end of the previous fiscal year. This was mainly due to an increase of 14,325 thousand yen in income taxes payable.

Long-term liabilities at the end of the fiscal year under review decreased by 276,421 thousand yen to 199,228 thousand yen from 475,650 thousand yen at the end of the previous fiscal year. This was due to the repayment of 380,000 thousand yen in long-term loans borrowed from financial institutions as collateral funds for the CiCLE project related to RS8001 PMS/PMDD using a part of the funds raised through the listing and, on the other hand, long-term loans payable increased by 103,578 thousand yen due to the receipt of research and development funds for the CiCLE project to RS8001 PMS/PMDD.

As a result, total liabilities decreased by 267,927 thousand yen to 237,171 thousand yen from 505,099 thousand yen at the end of the previous fiscal year.

(Net assets)

Net assets at the end of the current fiscal year increased by 1,639,323 thousand yen to 2,200,857 thousand yen from 561,533

thousand yen at the end of the previous fiscal year. This was mainly due to an increase of 946,808 thousand yen in capital stock and capital reserve, respectively, as a result of the issuance of shares in connection with the listing on the Mothers section of the Tokyo Stock Exchange in September 2021.

(3) Summary of Cash Flows for the Year Ended March, 2022

Cash and cash equivalents ("cash") at the end of the current fiscal year increased by 1,360,872 thousand yen to 2,005,816 thousand yen from 644,944 thousand yen at the end of the previous fiscal year.

The status of each cash flow and the main factors of fluctuation during the fiscal year under review are as follows.

(Net cash provided by (used in) operating activities)

Net cash used in operating activities for the fiscal year under review was 230,492 thousand yen (89,255 thousand yen in the previous fiscal year). This was mainly due to the recording of a net loss before income taxes of 253,088 thousand yen, stock issuance expenses of 25,532 thousand yen, and an increase in prepaid expenses of 24,462 thousand yen.

(Net cash provided by (used in) investing activities)

Net cash used in investing activities for the current fiscal year was 296 thousand yen (1,719 thousand yen in the previous fiscal year). This was mainly due to the expenditure of 1,164 thousand yen for the acquisition of tangible fixed assets, while an income of 867 thousand yen was recorded from the collection of guarantee deposits.

(Net cash provided by (used in) financing activities)

Net cash provided by financing activities in the current fiscal year was 1,591,662 thousand yen (135,650 thousand yen in the previous fiscal year). This was due to the posting of proceeds of 1,868,083 thousand yen from the issuance of stock and proceeds of 103,578 thousand yen from long-term loans payable, while 380,000 thousand yen was used for the repayment of long-term loans payable.

(4) Research and Development Activities

The Company is pursuing research and development of multiple pipelines across a variety of modalities, including pharmaceuticals, medical devices, and medical solutions utilizing artificial intelligence (AI).

a. RS5614 (PAI-1 inhibitor)

(a) Chronic myeloid leukemia (CML)

The late phase II investigator-initiated clinical trial was conducted in 33 patients with chronic phase CML using RS5614 in combination with a tyrosine kinase inhibitor (TKI) to confirm that the cumulative rate of deep molecular response (DMR: no detectable cancer-causing gene) achieved during 48 weeks after the start of RS5614 treatment (*1) was significantly higher than that in the historical control, to examine the pharmacokinetics, and to confirm the safety of RS5614 when used in combination with TKI for a long period of time (started in August 2019 and the clinical study report completed in March 2021). Eleven out of 33 patients achieved DMR, and the cumulative DMR achievement rate at 48 weeks was 33.3%, which was significantly higher than the historical control (8-12%) with TKI alone (POC obtained). In particular, the cumulative DMR achievement rate reached 50.0% in patients treated with TKIs for 3-5 years. In addition, no serious adverse events causally related to the therapeutic agent were observed after one year of long-term treatment with RS5614.

Based on the results of the late phase II study, the Company held preliminary consultations with the Pharmaceuticals and Medical Devices Agency (PMDA) in June and August 2021, and face-to-face consultations in November and December 2021, and finalized a placebo-controlled, double-blind (*2) phase III clinical trial protocol to evaluate the efficacy of the combination of TKI and RS5614 in patients with chronic phase CML. The phase III study is scheduled to begin in the first half of fiscal year 2022 and will enroll 60 patients with chronic phase CML who have been on TKI treatment for at least three years but less than five years. The study will evaluate whether the combination of the investigational agent RS5614 with TKI significantly increases the maintenance rate of DMR over two years compared to TKI alone. The phase III clinical trial, which was submitted to the Japan Agency for Medical Research and Development (AMED) by the Company's collaborator; Tohoku University, has

been adopted as a "Practical Application of Innovative Cancer Medicine" for fiscal 2022 (The Company is also participating as a sharing research organization).

(*1) DMR achievement rate: Current treatment of chronic phase CML requires lifelong use of expensive TKIs, but it has recently been shown that some patients who achieved DMR, the deepest therapeutic effect, and maintain it for a certain period do not relapse even after TKI discontinuation (maintenance of treatment-free remission; TFR). To date, the cumulative 1-year (48-week) DMR achievement rate published for existing TKIs is 8-12% (historical control). DMR maintenance is defined as the achievement of DMR for a specified period.

(*2) Double-blind: A clinical trial method in which the subject patients are randomly divided into two groups, one to receive the study drug (RS5614 in this case) and the other to receive the control drug (placebo with no effect in this case), and both groups receive the drugs simultaneously under the condition that neither physicians nor patients know which will be administered. This method is used to avoid the possibility of deliberate actions by physicians, such as administering the study drug to patients who are expected to benefit from it, or the possibility of preconceived notions that the drug should be effective being reflected in the evaluation. The results of each group are compared and evaluated to determine if the study drug is effective.

(b) Acute respiratory distress syndrome associated with novel coronavirus infection (COVID-19)

The Company is developing an oral medicine for the treatment of interstitial pneumonia associated with COVID-19 by focusing on RS5614's ability to improve pulmonary microthrombosis, fibrosis, emphysema, and lung (epithelial) protection. An early phase 2 investigator-initiated clinical study was conducted as an open-label study (non-blinded) since fall in 2020, and the clinical study report was completed in June 2021. There were no notable adverse events, and all 26 patients who were hospitalized for lung disorders and administered the investigational drug were discharged from the hospital without incidents.

A late phase 2 investigator-initiated clinical study is ongoing with a placebo control. In March 2021, the study was selected for the AMED's Research Program to “Promote the Development of Innovative Drugs for Emerging and Re-emerging Infectious Diseases" (with Tohoku University as the representative research organization and the Company as a sharing organization). Based on a preliminary meeting with the PMDA conducted in April 2021, a study protocol was finalized and the clinical trial was initiated in June 2021. This is a multicenter, placebo-controlled study involving 20 universities and other medical institutions in Japan. If patient enrollment progresses smoothly, the clinical trial was scheduled to be completed by the end of March 2022, with the clinical study report to be completed in June of the same year. However, since October 2021, the number of patients infected with novel coronavirus has declined sharply and the number of subjects enrolled in the clinical trials has decreased significantly, so we reviewed the planned number of patients to be enrolled at the clinical trial sites and decided to extend the clinical trial period until December 2022. Although the number of patients infected with novel coronavirus began to increase again due to the sixth wave, the rate of severe disease was low despite the high infection rate of the Omicron strain, and enrollment of patients with novel coronavirus pneumonia (moderate disease and hospitalized patients) did not increase significantly (as of March 2022, 70 cases has been enrolled).

In the U.S., a phase II investigator-initiated clinical trial is being conducted at Northwestern University with a similar protocol. Due to the severity of novel coronavirus infection in the U.S., it has been difficult to obtain consent for the study in which placebo is administered as a control (only about 5% of hospitalized patients agreed to participate), and patient enrollment has been delayed. The trial at Northwestern University will be temporarily suspended and resumption of the trial will be considered after confirming the results of the preceding trial in Japan. The study is listed as "suspended" in the clinical trial information database (Home - ClinicalTrials.gov) (Study To antagonize Plasminogen Activator Inhibitor-1 in Severe COVID-19 - Full Text View - ClinicalTrials.gov).

In addition, we completed an early phase II open-label, investigator-initiated clinical trial at Medeniyet University in the Republic of Turkey to confirm the safety of the drug. We prepared to conduct a double-blind study in patients with novel coronavirus pneumonia (moderate disease, outpatients), but since there are few severe cases of current Omicron strain infection, and it is difficult to conduct the study with the designed endpoint (hospitalization rate), we decided to consider restarting the study after confirming the results of the preceding Japanese study as in the United States.

On December 25, 2020, the Company entered into an option agreement with the first negotiation rights, with Daiichi Sankyo Company, Limited on therapeutic applications for lung diseases including COVID-19 pneumonia and lung injuries. At the time of the agreement, an early phase II investigator-initiated clinical trials were ongoing (the late phase II investigator-initiated clinical trials were yet to be determined) and the option period was set to expire one year later on December 31, 2021. In

October 2021, we concluded a memorandum of understanding to extend the option period to June 2022 in conjunction with the implementation of the late phase II investigator-initiated clinical trials.

(c) Malignant melanoma (melanoma)

Based on RS5614's ability to regulate immune checkpoint molecules and activate the cancer immune system, a phase II investigator-initiated clinical trial to confirm its efficacy and safety as a treatment for melanoma is currently underway since July 2021 (scheduled to be completed in March 2024).

This clinical trial was funded by the AMED "Translational Research Program Seeds C" (Tohoku University as a representative research organization, and the Company as a sharing organization) in May 2021, and the open-label study is being conducted in collaboration with six universities: Tohoku University, University of Tsukuba, Tokyo Metropolitan Komagome Hospital, Kinki University, Nagoya City University, and Kumamoto University. Patients will receive RS5614 in combination with nivolumab at a dose of 120-180 mg once daily for 8 weeks to evaluate efficacy and safety.

As of March 2022, case enrollment is progressing steadily and has reached 20 cases, half of the target.

(d) Prevention and treatment of interstitial lung disease caused by anticancer drugs

Based on the results of non-clinical studies suggesting that RS5614 improves interstitial lung diseases (interstitial pneumonia and pulmonary fibrosis), the Company plans to collaborate with Kyoto University to investigate whether RS5614 can prevent interstitial lung diseases, a side effect of anticancer drugs.

The Company is now making necessary preparations for clinical trials with Kyoto University.

(e) FGF23-associated hypophosphatemic rickets

RS5614 can accelerate the degradation of FGF23, suggesting that it may improve the condition of FGF23-associated hypophosphatemic rickets. The certified review board (CRB) of Tokyo Medical and Dental University approved the application of the study in November 2021, and preparations are underway for the clinical study, including the production of the study drug. The study is scheduled to start in fiscal 2022 as a clinical research (target number of patients: 5).

(f) RS5441 (PAI-1 inhibitor) for alopecia

A phase I study is under preparation by the licensee, Eirion Therapeutics Inc in the US (scheduled to be conducted in 2022).

(g) Exploratory research for new indications of RS5614 (PAI-1 inhibitor)

Based on the findings that RS5614 activates the cancer immune system, the Company has started to investigate new indications for cancer immunotherapy other than melanoma. Specifically, in collaboration with Tohoku University, the Company plans basic and clinical research on angiosarcoma and cutaneous T-cell lymphoma (CTCL) (*1), which are rare diseases. The Company also plans studies on interstitial lung disease associated with systemic scleroderma (*2).

(*1) Angiosarcoma and cutaneous T-cell lymphoma (CTCL): Angiosarcoma is a type of skin cancer, especially angiosarcoma of the scalp, which is rare (about 2.5 cases per 1 million people), but it is extremely malignant and progresses rapidly, with a disease-free survival rate of less than 20% at 5 years. Standard treatment has not been established. Cutaneous T-cell lymphoma (CTCL) is a malignant lymphoma of the skin that originates from T cells, one of the cells responsible for immunity. CTCL is also a rare cancer with an estimated total number of 2500 patients in Japan and 170 patients affected annually. In the advanced stage of the disease, the tumor invades and metastasizes that result in aggravations of the disease as well as infections, which can lead to death. A new treatment method based on cancer immunotherapy has been suggested for those cancers.

(*2) Systemic scleroderma: Systemic scleroderma is an intractable disease of unknown cause that results in fibrosis of multiple organs in addition to skin hardening. The most common cause of death with this disease is interstitial lung disease (interstitial pneumonia and pulmonary fibrosis), which is found in 50-60% of the patients and has a significant impact on life expectancy.

b. RS8001 (pyridoxamine)

(a) Autism spectrum disorder

A placebo-controlled, randomized, double-blind, parallel-group study was conducted in patients with autism spectrum

disorder with irritability, in order to explore and evaluate the efficacy and safety of pyridoxamine and to determine the appropriate target patient population, dosage and administration, and endpoints. The study was completed in May 2021, and the clinical study report was finalized in June 2021.

There were no major safety issues, and the drug was well tolerated. In terms of efficacy, the high-dose group showed the greatest improvement in the primary efficacy endpoint, the mean change in the ABC-J excitability subscale score at the final evaluation (*1), but no statistically significant difference was observed in the dose-response relationship or in comparison to the placebo group. In order to evaluate the efficacy of this drug more appropriately, issues that need to be considered, especially in psychiatric disorders, were identified, such as the selection of target patients and the development of a clinical trial plan that reduces the placebo effect (e.g., the placebo lead-in method (*2), in which the placebo effect is observed in advance). As the number of patients and the clinical trial system required to reduce the placebo effect to show a significant difference could be examined in a large-scale clinical trial, The Company has decided to secure a partner company and consider the possibility of licensing-out the product.

(*1) ABC-J Excitability subscale score mean change: An efficacy evaluation scale used as a global standard method to evaluate the efficacy of drug treatment in autism spectrum disorder. ABC-J is a Japanese translation of the Abnormal Behavior Checklist (ABC).

(*2) Placebo lead-in method: Placebo does not contain active ingredients, but psychological effects may improve disease symptoms (placebo effect). Therefore, we may employ a study design in which subjects take a placebo for a certain period of time before receiving the active drug, and subjects with a large placebo effect are not asked to participate in the study.

(b) Premenstrual syndrome (PMS) and premenstrual dysphoric mood disorder (PMDD))

In FY2019, the Company was selected for the AMED's Cyclic Innovation for Clinical Empowerment (CiCLE) project and received a grant from AMED. A phase II investigator-initiated clinical trial (placebo lead-in, placebo-controlled, double-blind, 3-arm comparative study with a target number of 105 patients) is ongoing at Kinki University, Tohoku University, Tokyo Medical and Dental University, and Tokyo Women's Medical University (started in November 2020 and scheduled to end in December 2023).

We started the clinical trial in November 2020, earlier than the original schedule of February 2021. However, the number of patient visits decreased due to the impact of the spread of new coronavirus infection, so we asked the Seiwa-kai Hayakawa Clinic to join the project in the first half of fiscal 2021 in order to promote the patient enrollment. In addition, as part of our advertising and awareness-raising activities, we created in-hospital posters and educational booklets, and the coordinating investigator conducted a webinar for pharmacists in March 2021 hosted by the NPO Healthy Aging Projects for Women (HAP). Furthermore, in the latter half of fiscal 2021, the jMOG Tanabe Women's Clinic also joined the study as a study site and we are continuing to take measures to promote case registration, including the use of volunteer panels* and holding open lectures by the investigators and others to raise disease awareness in collaboration with NPOs.

We reported the interim achievement of evaluation milestones and future progress to AMED, and AMED approved the continuation of this clinical trial grant in September 2021.

(*) Volunteer panel: A registration system for people who wish to participate in clinical trials operated by clinical trial support companies and organizations.

(c) Schizophrenia

In 2020, a late phase II schizophrenia study (double-blind, placebo-controlled study in approximately 100 patients) by Kowa Company, Ltd (Kowa), our licensee, was completed. Although some negative symptom items showed improvement in the sub-analysis, no clear difference was observed between the placebo group and the active drug group in the total score of the negative symptom scale of the Positive and Negative Symptom Scale (PANSS) (*), which was the primary endpoint, and Kowa intends not to develop pyridoxamine further for schizophrenia.

(*) Positive and Negative Symptom Scale (PANSS): A 30-item rating scale designed primarily to assess the overall mental status of schizophrenia.

(d) Menopause syndrome

We have prepared a clinical study of RS8001 as a treatment for the two major symptoms of menopause (hot flashes* and depression) at Tokyo Medical and Dental University (25 active drug and 25 placebo). In September 2021, the preliminary interview for Advanced Medical Care B by the Ministry of Health, Labour and Welfare was completed, and in November of the same year, an application to the certified review board (CRB) of Tokyo Medical and Dental University was approved. Preparations for the clinical study, including the manufacturing of the test drug, have been completed, and the study is scheduled to begin in fiscal 2022 as a placebo-controlled, double-blind clinical study (placebo lead-in method, target number of patients: 50).

(*) Hot flashes: Flushing, hot flashes, and sweating in the upper body occur as typical symptoms of menopause.

c. RS9001 (disposable ultrafine endoscope)

In peritoneal dialysis (*1), a tube is always inserted into the peritoneum to inject dialysis fluid. In May 2020, the Company, in collaboration with Tohoku University and other universities, has developed an ultrafine endoscope (about 1 mm in diameter) that can be inserted through this thin tube to non-invasively observe the inside of the abdominal cavity without a need for laparotomy or laparoscopy. The Company signed a license agreement with Baxter Healthcare Corporation (Baxter), a leading U.S. pharmaceutical and medical device company and a leader in peritoneal dialysis treatment, to co-develop and commercialize the endoscope, and is currently preparing to file for regulatory approval.

Due to the delay in negotiations between Baxter and the manufacturer of the guide catheter (*2), the Company agreed with Baxter to apply for approval only with the fiberscope (*3) (without the guide catheter as an accessory). We are now preparing for the filing. In addition, the first milestone payment was received in June 2021 following the execution of a supply agreement between the fiberscope manufacturer and Baxter.

(*1) Peritoneal dialysis: This method uses one's own body's peritoneum (the thin membrane covering the stomach, intestines and other organs) as a dialysis apparatus. When the abdominal cavity is filled with dialysis fluid injected through a tube (catheter), waste products in the blood, unnecessary urinary toxins, electrolytes and excess water move into the dialysis fluid and the blood is cleaned.

(*2) Guide catheter (disposable): Used in combination with a fiberscope; it can make the tip of the fiberscope controlled easily. It is possible to observe the peritoneal conditions with the fiberscope alone, but using a guide catheter improves operability.

(*3) Fiberscope (Disposable): The main body of a disposable ultrafine endoscope. The tip is about 1 mm in diameter and passes through a tube that is inserted in the abdomen.

d. Development of medical solutions using artificial intelligence (AI)

(a) RSAI01 (Respiratory function diagnostic system)

Spirometry* is the most important test for respiratory disease and respiratory function, but it is not widely used. This is because it is difficult for non-specialists to judge whether the test was performed correctly and to interpret the output results (flow volume curve), in addition to the fact that the cooperation of the subject (patient) (forced breathing) is required. The development of a system that allows non-specialists to easily interpret the results is an important medical issue for the diagnosis and early treatment of respiratory diseases. The Company is currently developing an AI to interpret flow volume curves with Kyoto University and NEC Solution Innovator, Ltd. and in July 2020, the Company signed a joint development and commercialization agreement (license agreement) with Chest M.I. Inc (Chest), and received an upfront payment. Having developed an initial AI model capable of differential diagnosis of respiratory diseases, the Company received a milestone payment under an agreement with Chest in October 2021. We plan to increase the prediction accuracy by improving the "quantity" and "quality" of medical data and develop it for commercialization.

(*) Spirometry: A physiological test for respiratory function that measures the amount of breath a subject exhales and the time it takes to exhale. It is an important test for the diagnosis of chronic obstructive pulmonary disease (COPD) and other lung diseases.

(b) RSAI02 (Support for chronic dialysis system)

Hemodialysis is a life-supporting renal replacement therapy for patients with chronic renal failure. Blood pressure drops during dialysis occur as high as 5-10%, but there is no medical device to predict blood pressure drop. Dialysis hospitals are facing a shortage of medical staff, i.e.; one doctor and only a few nurses and clinical engineers for dozens of patients, and when a drop in blood pressure occurs in some patients, the staff is overburdened with the task of raising blood pressure and caring for the patients. The Company acquired medical data (patient information, dialysis information, and examination information) on 3,000 subjects (800,000 dialysis cycles) from St. Luke's International Hospital and 15 private dialysis treatment facilities, and developed an AI (DCCN: Dual-Channel Combiner Network) based on a deep-learning engine to predict sudden blood pressure drops that occur during dialysis. In May 2021, the Company entered into a collaboration agreement with Nipro Corporation, a global hemodialysis medical device manufacturer. We will continue to develop the AI to increase its accuracy and functionality, such as improving the accuracy by examining clinical parameters, improving the AI to learn from individual patients (P-DCCN), and adding a function to predict the safe amount of water removal during dialysis in addition to detecting blood pressure drops during dialysis.

(c) RSAI03 (Support for diabetes treatment)

Insulin therapy is necessary to strictly control blood glucose levels in diabetes patients and to prevent diabetic complications. However, the safe range of doses of insulin is narrow and overdosing results in hypoglycemia, so the optimal types and the doses must be carefully controlled for each patient. On the other hand, since diabetes specialists account for less than 2% of all physicians and are geographically unevenly distributed, diabetes patients currently do not always see diabetes specialists but rather often see a non-specialist physician.

In January 2022, the Company completed the analysis of the data from approximately 1,000 patients (approximately 1,080,000 clinical parameters) admitted to Tohoku University Hospital, and have been developing an AI that can predict insulin dosage within a few units of error from the dosage prescribed by the specialists. By utilizing SAiL (Skill Acquisition Learning; an AI algorithm based on deep learning) we have now obtained an AI that can predict insulin doses with an error of only around 2 units. In the future, we plan to further increase the prediction accuracy by improving the "quantity" and "quality" of medical data, and conduct clinical trials for practical use. This research has been selected for the AMED's “Innovation in Medical Engineering (Development and Commercialization Project)” in April 2022, and will be supported by the AMED for three years from fiscal year 2022.

In November 2021, the Company concluded a collaboration agreement with Nipro Corporation.

(d) RSAI04 (Diagnosis of pronunciation and swallowing Function)

Aspiration is the cause of about 70% of pneumonia, which is the leading cause of death in an aging society. Early detection of dysphagia is important to prevent aspiration pneumonia, but current swallowing evaluation methods, such as endoscopic swallowing and fluoroscopic swallowing, are very burdensome for patients.

The Company has focused on the possibility of predicting swallowing function from conversation, because the organs used in swallowing and conversation have many parts in common, such as the tongue, oral cavity, and pharynx, and the Company is developing a new AI that can evaluate swallowing dysfunction from speech data during conversation.

In collaboration with several departments of Tohoku University (Department of Otorhinolaryngology, Department of Dentistry, and Department of Rehabilitation Medicine, School of Biomedical Engineering) and NEC, the Company will develop an AI that can detect differences between the pronunciation of healthy people and that of patients by analyzing all frequencies of the sounds spoken by patients visiting the Swallowing Treatment Center at Tohoku University Hospital using an AI engine specialized for analyzing time-series data (time-series model-free analysis). The AI engine will detect differences between the pronunciation of healthy people and that of patients, and develop an AI to diagnose the decline in swallowing function.

(e) RSAI06 (Diagnostics for pediatric developmental disabilities (dyslexia))

Dyslexia, one of the learning disabilities in children, is a phonological processing disorder, which can lead to poor school performance and truancy, but it is a disorder that can lead to a normal life with early detection and appropriate training. There

is an urgent need to develop a simple and accurate diagnostic method to provide appropriate early help, but currently there is no good diagnostic method.

Since there is a correlation between dyslexia and children's oral reading errors and speed, the Company is developing an AI to diagnose dyslexia. The AI detects abnormal values that deviate from the normal range by capturing voices as frequencies and treating them as time-series data. The data from a child developmental survey conducted by the Tohoku Medical Megabank Organization* and the oral reading data from children diagnosed with dyslexia at Tohoku University Hospital and several other medical institutions will be used in this project. With a simple diagnosis system based on speech data, it will be possible to detect the presence or absence of a disability in a short period of time, such as during regular health checkups, and this will lead to early support for those affected.

(*) Tohoku Medical Megabank Organization: Established to build futuristic medicine and tackle earthquake reconstruction, the organization is building a biobank that combines medical and genomic information while working to rebuild local healthcare and support health in areas affected by the Great East Japan Earthquake (established in 2012).

e. Diagnostic agent: Blood phenylalanine assay kit

Phenylketonuria can cause severe symptoms such as delayed intellectual development if not treated properly, and almost all affected children were detected at an early stage when postnatal mass screening tests were introduced in 1977. Treatment of phenylketonuria requires a proper diet to limit phenylalanine and regular checkups at a medical institution, but detailed dietary management cannot be achieved with blood samples taken every few months.

The Company is developing a system to measure blood phenylalanine levels easily and accurately at home in collaboration with Tohoku University. The aim is to make this new testing system available as a kit and to link it to insurance reimbursement for self-management. If self-measurement becomes possible at any time at home, as in the case of self-glucose control in diabetic patients, detailed dietary management for patients with phenylketonuria can be realized.

In May 2021, the Company filed a patent application jointly with Tohoku University for the diagnostic, and in June 2021, we had a meeting with the PMDA for consultation.

(5) Outlook for the future

(Business revenue)

Business revenue for the next fiscal year (April 1, 2022 to March 31, 2023) is expected to be 90 million yen from milestone incomes related to AI medical solutions and grant incomes related to projects adopted by AMED (e.g., RS5614 CML, RS5614 Melanoma, and RSAI03 Support system for diabetes treatment).

In addition to the above, upfront and milestone payments are expected for some pipeline products. However, considering the progress of clinical trials and the uncertainty of licensing negotiations, we believe that it is not appropriate to include all of the upfront and milestone payments expected at this stage in the forecast for the single fiscal year. We plan to clarify the outlook in a timely manner as earnings become more visible.

Reference: Drug Discovery Biotechs (Tokyo Stock Exchange)
https://www.jpx.co.jp/listing/others/risk-info/tvdivq0000001rss-att/nlsgeu000000xf3f.pdf

(Business expenses)

Business expenses for the next fiscal year are expected to be 631 million yen.

The pipeline development policy for the next fiscal year is to promote investigator-initiated clinical trials in Japan and overseas for the launch of pharmaceutical products and to further promote AI projects for securing a stable revenue and early establishment of the brand. In order to steadily develop these pipelines, we expect to utilize funds raised through the listing of our shares in addition to grants from AMED-adopted projects, and expect to significantly increase R&D expenses compared to the previous year.

As a result of the above, we forecast business revenue of 90 million yen (a decrease of 34.8% from the previous fiscal year), operating loss of 542 million yen (loss of 210 million yen in the previous fiscal year), ordinary loss of 542 million yen (loss of 241 million yen in the previous fiscal year) and net loss of 542 million yen (loss of 254 million yen in the previous fiscal year) for the full

year.

2. Basic Policy on Selection of Accounting Standards

For the time being, the Company's policy is to prepare its financial statements in accordance with Japanese GAAP, taking into consideration the comparability of financial statements from period to period and the comparability among enterprises. The Company's policy is to adopt International Financial Reporting Standards (IFRSs) as appropriate, taking into consideration various conditions in Japan and overseas.

3. Financial Statements and Notes

(1) Balance Sheet

(Unit: Thousands of yen)

	Previous fiscal year (March 31, 2021)	Current fiscal year (March 31, 2022)
Assets		
Current assets		
Cash and bank deposit	1,025,641	2,386,513
Prepaid expenses	7,327	31,173
The others	9,675	10,461
Total current assets	1,042,644	2,428,148
Fixed assets		
Tangible fixed assets		
Buildings and accompanying facilities, net	992	869
Tools, furniture and fixtures, net	2,589	2,760
Total property, plant and equipment	3,581	3,630
Intangible fixed assets		
Patent rights	13,258	-
Software	18	-
Total intangible fixed assets	13,277	-
Investments and other assets		
Capital	10	10
Long-term prepaid expenses	962	1,210
The others	6,156	5,029
Total investments and other assets	7,129	6,249
Total fixed assets	23,988	9,880
Total assets	1,066,632	2,438,028

(Unit: Thousands of yen)

	Previous fiscal year (March 31, 2021)	Current fiscal year (March 31, 2022)
Liabilities		
Current liabilities		
Arrearage	26,373	20,659
Unpaid expenses	2,428	2,431
Unpaid income taxes	290	14,615
Deposit (received)	357	235
Total current liabilities	29,449	37,942
Fixed liabilities		
Long-term debt	475,650	199,228
Total long-term liabilities	475,650	199,228
Total liabilities	505,099	237,171
Total net assets		
Capitals		
Capital stock	90,000	1,036,808
Capital surplus		
Capital reserve	510,425	1,457,233
Other capital surplus	61,162	61,162
Total capital surplus	571,587	1,518,395
Retained earnings		
Other retained earnings		
Retained earnings brought forward	△100,054	△354,346
Total retained earnings	△100,054	△354,346
Total shareholders' equity	561,533	2,200,857
Total net assets	561,533	2,200,857
Total liabilities and net assets	1,066,632	2,438,028

(2) Profit and Loss Statement

(Unit: Thousands of yen)

	Previous fiscal year (From April 1, 2020 to March 31, 2021)	Current fiscal year (From April 1, 2021 to March 31, 2022)
Operating revenue	209,802	139,333
Business cost	29,977	58,363
Gross profit	179,825	80,970
Business expenses	265,950	291,810
Operating loss (△)	△86,125	△210,839
Non-operating income		
Interest income	43	20
Profit on currency exchange	1,100	-
Grant income	1,735	-
Miscellaneous income	22	42
Total non-operating income	2,901	63
Non-operating expenses		
Interest expense	7,504	5,366
Foreign exchange loss	-	94
Stock issuance expenses	-	25,532
Total non-operating expenses	7,504	30,993
Ordinary loss (△)	△90,728	△241,769
Extraordinary loss		
Impairment loss	-	11,318
Loss on disposal of fixed assets	28	-
Special retirement allowance	9,000	-
Total extraordinary loss	9,028	11,318
Loss before income tax (△)	△99,757	△253,088
Corporate, inhabitant and enterprise taxes	296	1,204
Total income taxes	296	1,204
Net loss (△)	△100,054	△254,292

(3) Statement of Changes in Net Assets

Previous fiscal year (April 1, 2020 to March 31, 2021)

(Unit: Thousands of yen)

	capital stock							Total net assets
	Capital stock	Capital surplus			Retained earnings		Capital stock total amount	
		Capital reserve	The other capital surplus	Capital surplus total amount	Other retained earnings: Retained earnings brought forward	Retained earnings total amount		
Balance at the beginning of current period	496,175	490,425	-	490,425	△365,012	△365,012	621,587	621,587
Changes of items during the period								
Issuance of new shares	20,000	20,000		20,000			40,000	40,000
Reduction of capital	△426,175		426,175	426,175			-	-
Compensation for a deficit			△365,012	△365,012	365,012	365,012	-	-
Net loss (△)					△100,054	△100,054	△100,054	△100,054
Total changes of items during the period	△406,175	20,000	61,162	81,162	264,958	264,958	△60,054	△60,054
Balance at the end of current period	90,000	510,425	61,162	571,587	△100,054	△100,054	561,533	561,533

Current fiscal year (From April 1, 2021 to March 31, 2022)

(Unit: Thousands of yen)

	capital stock							Total net assets
	Capital stock	Capital surplus			Retained earnings		Capital stock total amount	
		Capital reserve	The other capital surplus	Capital surplus total amount	Other retained earnings: Retained earnings brought forward	Retained earnings total amount		
Balance at the beginning of current period	90,000	510,425	61,162	571,587	△100,054	△100,054	561,533	561,533
Changes of items during the period								
Issuance of new shares	946,808	946,808		946,808			1,893,616	1,893,616
Net loss (△)					△254,292	△254,292	△254,292	△254,292
Total changes of items during the period	946,808	946,808	-	946,808	△254,292	△254,292	1,639,323	1,639,323
Balance at the end of current period	1,036,808	1,457,233	61,162	1,518,395	△354,346	△354,346	2,200,857	2,200,857

(4) Statements of Cash Flows

(Unit: Thousands of yen)

	Previous fiscal year (From April 1, 2020 to March 31, 2021)	Current fiscal year From April 1, 2021 to March 31, 2022)
Cash flows from operating activities		
Income (△) before income taxes	△99,757	△253,088
Depreciation expense	2,868	3,074
Impairment loss	-	11,318
Interest income	△43	△20
Interest expense	7,504	5,366
Loss on disposal of fixed assets	28	-
Special retirement allowance	9,000	-
Stock issuance expenses	-	25,532
Decrease (increase) in prepaid expenses	△4,245	△24,462
Increase (decrease) in unpaid liabilities	22,058	△5,713
Increase (decrease) in unpaid expenses	△755	three
Decrease (increase) in other assets	△517	△ 561
Increase (decrease) in other liabilities	△2,919	13,292
The others	△5,724	△212
Subtotal	△72,504	△225,470
Interest income received	43	20
Interest payments	△7,504	△4,749
Income taxes paid	△290	△293
Special retirement payments	△9,000	-
Cash flows from operating activities	△89,255	△230,492
Cash flows from investing activities		
Payments for purchase of property, plant and equipment	△1,010	△1,164
Proceeds from collection of guarantee deposits	-	867
Payments for guarantee deposits	△110	-
Payments for purchase of long-term prepaid expenses	△599	-
Cash flows from investing activities	△1,719	△296
Cash flows from financing activities		
Proceeds from issuance of stock	40,000	1,868,083
Proceeds from long-term debt	95,650	103,578
Repayment of long-term debt	-	△380,000
Cash flows from financing activities	135,650	1,591,662
Net increase (decrease) in cash and cash equivalents	44,675	1,360,872
Cash and cash equivalents at beginning of year	600,269	644,944
Cash and cash equivalents at end of year	644,944	2,005,816

(5) Notes to Financial Statements

(Notes on Premise of Going Concern)

None

(Change in Accounting Policy)

(Application of Accounting Standard for Revenue Recognition, etc.)

The Company adopted the "Accounting Standard for Measurement of Inventories" (ASBJ Statement No. 9, March 31, 2008) and others from the beginning of the fiscal year under review, and recognized revenue at the amount expected to be received in exchange for the promised goods or services when control of the goods or services is transferred to the customer.

The Company's revenues are primarily derived from up-front, milestone and royalty income from agreements for the development and out-licensing of pharmaceuticals, medical devices and medical solutions, and the specific revenue recognition criteria are as follows

Upfront revenue is recognized when the Company enters into agreements for the development and out-licensing of pharmaceuticals, medical devices and medical solutions, and grants development and marketing rights to third parties.

Milestone revenues are recognized when contractually defined milestones are achieved.

Royalty income is the consideration calculated based on the sales revenue of the licensee partner, and revenue is recognized when the sales revenue of the partner is generated or the performance obligation is satisfied, whichever is later.

The Company has followed the transitional treatment prescribed in the proviso of Paragraph 84 of the Accounting Standard for Revenue Recognition, and the cumulative effect of retrospective application of the new accounting policy prior to the beginning of the current fiscal year is added to or deducted from retained earnings brought forward at the beginning of the current fiscal year, and the new accounting policy is applied from such beginning balance.

As a result, there was no effect on the balance of retained earnings at the beginning of the period and the adoption of this accounting standard did not have a material impact on the Company's consolidated financial statements.

(Application of Accounting Standard for Measurement of Fair Value)

The Company adopted the Accounting Standard for Fair Value Calculation, etc. from the beginning of the fiscal year under review and applied the new accounting policy prescribed by the Accounting Standard for Fair Value Calculation, etc. in accordance with Paragraph 19 of the Accounting Standard for Fair Value Calculation and Paragraph 44-2 of the Accounting Standard for Financial Instruments (ASBJ Statement No. 10, July 4, 2019). In accordance with the treatment, the Company will apply the new accounting policies prescribed by the Accounting Standard for Fair Value Calculation and others prospectively.

This change has no impact on the financial statements.

(Segment Information, etc.)

Segment information is omitted because the Company's business is a single segment consisting solely of the development and sale of pharmaceuticals, medical devices and other products, and is therefore immaterial.

(Equity in Earnings (Losses) of Affiliates, etc.)

None

(Per Share Information)

	Previous fiscal year (From April 1, 2020 to March 31, 2021)	Current fiscal year (From April 1, 2021 to March 31, 2022)
Net assets per share	57.01 yen	173.14 yen
Net loss per share	△10.19 yen	△22.33 yen

(note)

1. Diluted net income per share is not shown in the above table, because net income per share was negative although there are residual shares.
2. The Company conducted a 300-for-1 stock split of shares of common stock on June 1, 2021, and per share information is calculated on the assumption that the stock split was conducted at the beginning of the previous fiscal year. The per share information is calculated on the assumption that the stock split was conducted at the beginning of the previous fiscal year.
3. Basis for calculation of net loss per share is as follows.

item	Previous fiscal year (From April 1, 2020 to March 31, 2021)	Current fiscal year (From April 1, 2021 to March 31, 2022)
Net loss per share		
Net loss (△) (thousand yen)	△100,054	△254,292
Amount not attributable to common shareholders (thousand yen)	-	-
Net loss (△) related to common stock (thousand yen)	△100,054	△254,292
Average number of shares of common stock during the period (shares)	9,819,082	11,389,120
Outline of potential shares not included in the calculation of diluted net income per share due to the absence of dilutive effects	3 types of stock acquisition rights (Number of stock acquisition rights: 85)	3 types of stock acquisition rights (Number of stock acquisition rights: 55)

4. Basis for calculation of net assets per share is as follows.

item	Previous fiscal year (March 31, 2021)	Current fiscal year (March 31, 2022)
Total net assets (Thousands of yen)	561,533	2,200,857
Amount deducted from total net assets (thousand yen)	-	-
Net assets related to common stock at the end of the period (thousand yen)	561,533	2,200,857
Number of shares of common stock used in the calculation of net assets per share at the end of the fiscal year (shares)	9,849,000	12,711,700

(Significant Subsequent Events)

On April 20, 2022, the Company's development of artificial intelligence (AI) to predict insulin dosage for diabetes patients was adopted by the Japan Agency for Medical Research and Development (AMED) as a fiscal 2022 project for the "Innovation in Medical Engineering (Development and Commercialization)". In this project, the Company will conduct clinical research aiming for regulatory approval of the RSAI03 Diabetes treatment support system with a research grant from the AMED. The project is scheduled to run for three years from the fiscal year ending March 31, 2023 to the fiscal year ending March 31, 2025.

The earnings impact of the adoption of the Project has already been factored into the earnings forecast for the fiscal year ending March 31, 2023, which is included in the Summary of Consolidated Financial Statements.