SymBio Pharmaceuticals Limited

Summary of Financial Statements for the Fiscal Year Ended December 31, 2023 [Japanese GAAP] (Consolidated)

February 8, 2024

Company Name	**SymBio Pharmaceuticals Limited**	Listing: Tokyo Stock Exchange	
Securities Code	4582	URL: https://www.symbiopharma.com/	
Representative	Representative Director, President and Chief Executive Officer	Fuminori Yoshida	
Contact Person	Executive Vice President, Corporate Officer and Chief Financial Officer	Takaaki Fukushima	TEL +81-3-5472-1125
Ordinary Annual General Meeting of Shareholders	March 22, 2024	Date of Dividend Payment (plan)	—
Scheduled Date to File Securities Report	March 22, 2024		

Supplementary materials for the financial statements: Yes [No]

Holding of earnings performance review: [Yes] No (For securities analysts and institutional investors)

(Amounts of less than one million yen are rounded down.)

1. Business Results for FY 2023 (January 1, 2023 to December 31, 2023)

(1) Consolidated Operating Results (Percentages indicate year-on-year changes.)

	Net Sales		Operating Profit		Ordinary Profit		Profit attributable to owners of parent	
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
FY 2023	5,589	(44.1)	(811)	—	(736)	—	(1,962)	—
FY 2022	10,008	—	1,963	—	1,999	—	1,179	—

(Note) Comprehensive income: FY 2023 (1,956) million yen (-%)
FY 2022 1,179 million yen (-%)

	Earnings per Share	Diluted Earnings per Share	Ratio of Profit to Equity (ROE)	Ratio of Ordinary Profit to Total Assets (ROA)	Ratio of Operating Profit to Net Sales
	Yen	Yen	%	%	%
FY 2023	(49.19)	—	(26.1)	(7.9)	(14.5)
FY 2022	30.20	29.77	14.6	19.2	19.6

(Reference) Equity in net income of affiliated companies: FY 2023 — million yen
FY 2022 — million yen

(Note) The Group began preparing consolidated financial statements from FY 2022 with the start of operations at SymBio Pharma USA Inc. Return on equity and the ordinary profit rate to total assets for the fiscal year ended December 31, 2022 were calculated on the basis of the year-end equity and total assets respectively since the fiscal year ended December 31, 2022 is the first fiscal year that consolidated financial statements were prepared for.

(2) Consolidated Financial Position

	Total Assets	Net Assets	Equity Ratio	Net Assets per Share
	Millions of yen	Millions of yen	%	Yen
FY 2023 (as of December 31, 2023)	8,170	7,209	84.9	164.32
FY 2022 (as of December 31, 2022)	10,433	8,506	77.6	204.83

(Reference) Shareholders' equity: FY 2023 (as of December 31, 2023) 6.938 million yen
FY 2022 (as of December 31, 2022) 8,094 million yen

(3) Consolidated 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
FY 2023	(1,94)	(376)	680	6,517
FY 2022	1,614	(47)	627	6,282

2. Dividends

	Annual Dividend per Share					Total Dividends	Payout Ratio (Consolidated)	Ratio of Dividends to Net Assets (Consolidated)
	1st Quarter	2nd Quarter	3rd Quarter	Fiscal Year End	Full Year			
	Yen	Yen	Yen	Yen	Yen	Millions of yen	%	%
FY 2022	—	0.00	—	0.00	0.00	—	—	—
FY 2023	—	0.00	—	0.00	0.00	—	—	—
FY 2024 (Forecast)	—	0.00	—	0.00	0.00		—	

3. Earnings Forecasts for FY 2024 (January 1, 2024 to December 31, 2024)

(Percentages indicate year-on-year changes.)

	Net Sales		Operating Profit		Ordinary Profit		Profit attributable to owners of parent		Earnings per Share
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Yen
Full Year	3,641	(34.9)	(2,837)	—	(2,867)	—	(2,870)	—	(71.93)

Notes:

(1) Changes in significant subsidiaries during the period: Yes ・ [No]

(Transfer of specified subsidiary accompanying a change in the scope of consolidation)
New: SymBio Pharma USA, Inc.
Removed: None

(2) Changes in accounting policies, changes in accounting estimates and restatements after error corrections

(a) Changes in accounting policies due to revision of accounting standards: [Yes] ・ No

(b) Changes in accounting policies due to other reasons: Yes ・ [No]

(c) Changes in accounting estimates: Yes ・ [No]

(d) Restatements after error corrections: Yes ・ [No]

(3) Number of issued shares (common stock)

(i) Total number of issued shares at the end of the period (including treasury shares)	FY 2023	42,278,081 shares	FY 2022	39,603,606 shares
(ii) Total number of treasury shares at the end of the period	FY 2023	87,720 shares	FY 2022	85,268 shares
(iii) Average number of shares during the period (cumulative)	FY 2023	39,902,249 shares	FY 2022	39,046,821 shares

* Summaries of financial statements are not subject to audit through certified public accountants or auditing corporations.

* Explanation regarding the appropriate use of earnings forecasts and other matters

All forecasts presented in this document, including earnings forecasts, are based on the information currently available to the Company and assumptions judged to be reasonable. Actual results may differ substantially from these forecasts due to various factors. Regarding the assumptions on which the Company's earnings forecasts are based and their usage, please refer to section 1-(4) " Future outlook," on Page 5 of the attachment.

Index of the attachment

1. Overview of Business Results, etc. 2
(1) Overview of business results for the fiscal year under review 2
(2) Overview of financial position for the fiscal year under review 4
(3) Overview of cash flows for the fiscal year under review 5
(4) Future outlook 5
(5) Pipeline 6
2. Basic Views on Selection of Accounting Standards 7
3. Consolidated Financial Statements and Primary Notes 8
(1) Consolidated balance sheet 10
(2) Consolidated statements of income and consolidated statements of comprehensive income 11
Consolidated statements of comprehensive income 11
(3) Consolidated statements of changes in equity 12
(4) Consolidated statements of cash flows 14
(5) Notes to consolidated financial statements 15
(Notes to going concern assumptions) 15
(Changes in accounting policies) 15
(Segment information) 15
(Per share information) 15
(Significant subsequent events) 17

1. Overview of Business Results, etc.

(1) Overview of business results for the fiscal year under review

Progress in the Company's business for the fiscal year under review is as follows.

(i) Business results for the period under review

In December 2020, the Group began selling TREAKISYM® (generic name: bendamustine hydrochloride or bendamustine hydrochloride hydrate) through its own sales organization, and the Company achieved its most important milestone for FY2021, which was to attain profitability.

To achieve nationwide distribution, we have entered into distribution agreements with Suzuken Co., Ltd. and Toho Pharmaceutical Co., Ltd. We are also working with S.D. Collabo Co., Ltd. and have established two logistics centers, one in eastern and one in western Japan. Additionally, by deploying drug information personnel across the country, we have established a system that allows us to provide more scientific information to healthcare providers..

In February 2022 (FY2022), the Group obtained approval of a partial change to our marketing authorization of the ready-to-dilute (RTD) liquid formulation of TREAKISYM® to add rapid infusion (RI) administration. The RTD formulation of TREAKISYM® is a liquid formulation that does not require manual reconstitution, significantly reducing preparation time. RI administration reduces the infusion time from 60 minutes to 10 minutes, benefiting both patients and healthcare providers. In addition, the reduction in infusion volume of RI from 250 ml to 50 ml means a lower volume of saline solution is used.

As of the end of December 2023, more than 90% of medical institutions had converted to RI administration.

Prescriptions for bendamustine in combination with rituximab ("BR therapy") and in combination with rituximab and polatuzumab vedotin (genetical recombination) ("Pola-BR therapy") for rr/DLBCL continue to be lower due to the spread of novel coronavirus variants and other infectious diseases and the concern of some physicians that patients with hematological malignancies, especially malignant lymphoma patients, may be at risk of prolonged or more severe infection during or after bendamustine treatment. Net sales were 5,589,708 thousand yen (down 44.1% year-on-year).

Selling, general and administrative expenses totaled 5,222,681 thousand yen (-7.3% year on year). This amount includes research and development expenses of 2,638,234 thousand yen (+3.3% year on year).

Operating loss was 811,668 thousand yen (versus an operating profit of 1,963,625 thousand yen for the same period in FY 2022) and ordinary loss was 736,130 thousand yen (versus an ordinary profit of 1,999,878 thousand yen for the same period in FY 2022). Loss attributable to owners of parent was 1,962,817 thousand yen (versus profit attributable to owners of parent of 1,179,238 thousand yen for the same period in FY 2022), impacted by the reversal of deferred tax assets of 744,728 thousand yen in income taxes-deferred and recognized an Impairment loss,etc. of 560,590 thousand yen as a result of examining "Accounting Standard for Impairment of Fixed Assets". In February 2022, generic bendamustine products from four companies were approved for manufacturing and two of these products started to be sold in Japan. Given the potential infringement of the patents related to TREAKISYM® in Japan which are exclusively licensed to the Company from Eagle Pharmaceuticals, Inc (head office: New Jersey, U.S.; hereinafter "Eagle"), the Company in coordination with Eagle notified four generic makers of potential patent infringement and, in December 2022, commenced litigation against the makers of the generic products, Pfizer Japan Inc. (head office: Tokyo) and Towa Pharmaceutical Co., Ltd. (head office: Osaka) , seeking an injunction against the manufacture and sale of the products and compensation for damages arising from the infringement. The litigations are ongoing and the Company is diligently taking appropriate steps to preserve its rights.

Segment information has been omitted as the Group operates within a single segment, which includes the research and development, manufacturing, and marketing of pharmaceutical drugs and other related activities.

(ii) Research and development activities

During the FY 2023, we conducted the following research and development activities.

(a) Anticancer agents: SyB L-0501 (FD formulation), SyB L-1701 (RTD formulation), and SyB L-1702 (RI administration)
(generic name: bendamustine hydrochloride or bendamustine hydrochloride hydrate, trade name: TREAKISYM®)

In February 2022, clinical trials on the safety of RI administration were completed and a partial change to our marketing authorization was approved to permit the use of RI injection for all indications approved for the RTD formulation.

The Group continues to actively conduct further research on TREAKISYM®, such as ongoing joint research with the University of Tokyo and Kyoto University, to explore new potential uses and development of the drug.

(b) Anticancer agents: SyB L-1101 (intravenous formulation) and SyB C-1101 (oral formulation) (generic name: rigosertib sodium)

Rigosertib is in-licensed from Onconova Therapeutics, Inc. (head office: Pennsylvania, U.S.). The Group is collaborating with the University of Tokyo to conduct research to identify new potential indications or applications for the drug either alone or in combination with other existing drugs (including TREAKISYM®).

(c) Antiviral drug: SyB V-1901 (intravenous formulation) (generic name: Brincidofovir [BCV])

With a view to global expansion, the Group is developing brincidofovir (SyB V-1901, hereinafter "IV BCV" and "Oral BCV", respectively), an antiviral drug in-licensed from Chimerix, Inc. with their broad activity against double-stranded DNA viruses (dsDNA viruses). The Group is conducting joint research with leading research facilities in Japan and overseas. Global clinical trials will be considered and implemented based on the scientific findings of the research.

The Group is prioritizing the global development of BCV IV, focusing on Japan, the United States, and Europe, for the treatment of adenovirus infection in immunocompromised patients, such as those who have had hematopoietic stem cell transplantation or organ transplantation. In March 2021, we submitted an Investigational New Drug (IND) Application to the U.S. Food and Drug Administration (FDA) to initiate a Phase II clinical trial for the treatment of adenovirus infection and infectious diseases, primarily in pediatric patients (including adults). in immunocompromised patients with adenovirus (AdV) infection

The Group is prioritizing global development of BCV (primarily in Japan, the U.S., and Europe), targeting disseminated adenovirus (AdV) infections occurring after hematopoietic stem cell transplantation or organ transplantation. In March 2021, the Group filed an Investigational New Drug (IND) application with the FDA to conduct a Phase II clinical trial in immunocompromised patients (primarily pediatric but also adults) suffering from AdV infection. In April 2021, the program was granted Fast Track designation by the FDA, and in May 2023, this study established human POC for BCV. Positive data demonstrating the efficacy of the study was presented orally at the 65th Annual Meeting of the American Society of Hematology in December 2023. Additionally, a patent for the use of BCV for the treatment of adenovirus infection and infectious diseases based on these results was granted and registered in Japan in January 2024.

The Group submitted clinical trial notifications for a Phase II study of IV BCV in patients with BK virus (BKV) infection after kidney transplantation to the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan and the Therapeutic Goods Administration (TGA) of Australia, in May and August 2022, respectively. BKV infection after kidney transplantation is a disease with serious consequences for the recipient, the donor, the medical practitioner, and society, due to the risk of impaired renal function and loss of the transplanted kidney (graft loss). The investigational drug was administered to the first subject in December 2022. Although the trial was planned to be completed in 2025, due to enrollment delays, we will discuss modifications to the protocol will researchers.

The Group is also investigating the use of BCV to treat multiple sclerosis, an intractable disease that has recently been shown to be associated with Epstein-Barr virus (EBV). In August 2022, the Company entered into a collaboration agreement with the National Institute of Neurological Disorders and Stroke (NINDS), part of the U.S. National Institutes of Health (NIH), for the transfer of materials to evaluate the antiviral effect of BCV in EBV. In March 2023, the Company entered into a Cooperative Research and Development Agreement (CRADA) for BCV with NINDS for research to verify the efficacy of BCV as an anti-viral therapeutic for EBV in the treatment of multiple sclerosis, and to obtain necessary data with a view to future clinical trials. In October 2023 , the results of the research were presented by Dr. Maria Chiara Monaco at the 9th Joint ECTRIMS-ACTRIMS Meeting in Milan, Italy. In April 2023, the Company entered into a CRADA with the National Institute of Allergy and Infectious Diseases (NIAID), part of NIH in the U.S., to investigate the efficacy of BCV in the treatment of EBV associated lymphoproliferative diseases.

Among dsDNA viruses, polyomaviruses are known to cause serious diseases through their infection. As existing antiviral drugs show little efficacy, a high medical need exists for the development of an effective treatment. In November 2022, the Group entered into Material Transfer Agreement with Penn State College of Medicine whereby the Group will provide BCV for use in a non-clinical study to evaluate the efficacy of BCV in a mouse model of polyomavirus infection.

Some dsDNA viruses, such as herpes simplex virus type 1 (HSV1) and varicella zoster virus (VZV), are directed against cranial nerve tissues. Recent research has advanced on the involvement of the reactivation of those viruses in various serious diseases of the nervous system, including Alzheimer's disease. In December 2022, the Group entered into a Sponsored Research Agreement with Tufts University to conduct research to evaluate the efficacy of BCV in a HSV infection model using a 3D (three-dimensional)

brain model developed by Tufts University.

In addition to its strong antiviral effect, BCV also is expected to have an antitumor effect, and the Group is exploring BCV's potential in indications such as EBV-positive lymphoma, refractory brain tumors, and other cancers, through research collaborations with the National Cancer Centre Singapore (NCCS) and the University of California San Francisco (UCSF) Brain Tumor Center. In December 2022, the results of collaborative research with NCCS on the therapeutic efficacy of BCV in the treatment of NK/T-cell lymphoma, for which no effective treatment is currently available, were presented by Dr. Jason Chan at the 64th American Society of Hematology (ASH) Annual Meeting in New Orleans. Additionally, in June 2023, the results of its research collaboration with NCCS on BCV were presented at the 17th International Conference on Malignant Lymphoma (ICML) in Lugano, Switzerland.

In September 2022, Chimerix announced the close of the sale of its brincidofovir business to Emergent BioSolutions (headquartered in Maryland, USA). The sale does not affect our exclusive worldwide license of the rights for development, manufacturing, and marketing of BCV in all indications except orthopox diseases.

(iii) Business outside Japan

In August 2023, the Group appointed Stephane Berthier, PharmD, as CEO and President of SymBio Pharma USA, Inc., and in September 2023, appointed Nkechi Azie, MD, to the Group management team as Global Chief Medical Officer (CMO) to further strengthen the Group's global development structure and make SymBio Pharma USA, Inc. the driving force for our international clinical trials as we move forward with global development of BCV.

(iv) Licensing of new drug candidates

The Group continues to evaluate promising new drug candidates for in-licensing. Through these efforts, the Group aims to create medium-to long-term business value.

(2) Summary of financial position

Total consolidated assets as of September 31, 2023, stood at 8,170,243 thousand yen. Current assets totaled 8,082,526 thousand yen, mainly consisting of 6,517,007 thousand yen in cash and deposits, 913,094 thousand yen in accounts receivable-trade, and 231,650 thousand yen in merchandise and finished goods. All fixed assets were impaired at the end of the current period as a result of a review of revenue projections. In addition, the security deposit and guarantee money for the new head office due to the relocation were also impaired at 87,716 thousand yen as a result of restoration costs.

Total liabilities were 960,334 thousand yen. Current liabilities totaled 956,625 thousand yen, mainly consisting of 853,825 thousand yen in accounts payable-other. Non-current liabilities were 3,709 thousand yen, consisting of 3,709 thousand yen in liabilities for retirement benefits.

Total net assets stood at 7,209,909 thousand yen. This includes 17,952,692 thousand yen in capital stock, 17,927,584 thousand yen in capital surplus, and 277,044 thousand yen in share acquisition rights.

As a result, the equity ratio was 84.9%.

(3) Overview of cash flows for the fiscal year under review

Cash and cash equivalents (hereinafter, "net cash") stood at 6,517,007 thousand yen as of December 31, 2023

Cash flows during the fiscal year under review and their causes are as follows.

(Cash flows from operating activities)

Net cash provided by operating activities was 194,685 thousand yen. The key drivers were 1,195,387 thousand yen in loss before income taxes and a decrease of 1,171, 821 thousand yen in receivable-trade. Cash outflows were mainly due to an decrease of 212,814 thousand yen in consumption taxes receivable, an increase of 237,277 thousand yen in inventory.

(Cash flows from investing activities)

Net cash used in investing activities was 376,696 thousand yen, mainly attributable to purchase of fixed assets of 204,250 thousand yen and intangible assets of 28,547 thousand yen.

(Cash flows from financing activities)

Net cash provided by financing activities was 680,160 thousand yen, mainly attributable to proceed from issuance of shares of 692,400 thousand yen. in proceeds from issuance of shares.

	18th Term FY 2022	19th Term FY 2023
Equity ratio (%)	77.6	84.9
Equity ratio on a fair market value basis (%)	243.6	127.55
Debt redemption period (years)	―	―
Interest coverage ratio	―	―

Equity ratio: Equity (total shareholders' equity)/total assets
Equity ratio on a fair market value basis: Total market value of common stock/total assets
Debt redemption period: Interest-bearing debt/cash flows from operating activities
Interest coverage ratio: Cash flows from operating activities/interest payments
(Notes) 1. As the Group began preparing consolidated financial statements in FY2022, figures for FY2021 and earlier are not presented.
2. Total market value is calculated based on the number of shares issued, excluding treasury shares.
3. Debt redemption period and interest coverage ratio are not available due to the absence of interest payments in FY 2022.

(4) Future outlook

The Group expects net sales for FY 2024 to decrease to 3,641 million yen, a decrease of 34.9% compared to FY 2023. While the Group aims to further expand the market share of TREAKISYM®, net sales have been impacted due to the significant reduction in NHI drug price as a result of TREAKISYM® being excluded from the new drug creation premium and the impact of generic products on TREAKISYM® sales. In addition, the Group initiated litigation against two manufacturers of generic versions of TREAKISYM® based on patent infringement. As the litigations are ongoing, the potential impact of the lawsuits on net sales is not reflected.

Regarding research and development, we will continue the global development of IV BCV for treatment of AdV infection and continue to explore development for other indications through joint research with academia with the aim of enhancing long-term corporate value. The Group expects R&D expenses to increase to 3,207 million yen in FY 2024 (compared to 2,638 million yen in FY 2023).

As a result, for the fiscal year ending December 31, 2024, the Group forecasts net sales of 3,641 million yen, operating loss of 2,837 million yen, ordinary loss of 2,867 million yen, and loss attributable to owners of parent of 2,870 million yen.

(5) Pipeline

The Group currently has the following pipeline products under development: SyB L-0501, SyB L-1101, SyB C-1101, SyB L-1701, SyB L-1702, and SyB V-1901. The Group will continue to in-license candidate drugs to further expand and build its pipeline portfolio with a balanced risk–return trade-off.

(i) [Anticancer agents: SyB L-0501 (FD formulation), SyB L-1701 (RTD formulation), SyB L-1702 (RI injection), (generic name: bendamustine hydrochloride or bendamustine hydrochloride hydrate, trade name: TREAKISYM®)]

Bendamustine hydrochloride (the generic name), the active pharmaceutical ingredient of TREAKISYM®, is an anticancer agent that has been in use for a number of years in Germany under the trade name of Ribomustin® for the treatment of non-Hodgkin's lymphoma, multiple myeloma, and chronic lymphocytic leukemia. The Group decided to in-license this product because there is currently no effective medication for the indications of recurrent/refractory low-grade non-Hodgkin's lymphoma and mantle cell lymphoma. These are underserved therapeutic areas aligned with the Group's corporate mission and also fall within one of the Group's targeted therapeutic fields (hematologic cancer). Astellas Deutschland GmbH, a German subsidiary of Astellas Pharma Inc., is the worldwide licensor of bendamustine hydrochloride.

The Group licensed from Astellas Deutschland GmbH with exclusive rights for the development and commercialization of bendamustine hydrochloride in Japan, China, South Korea, Singapore, and Taiwan. In Japan, the drug was approved for the indications of recurrent/refractory low-grade non-Hodgkin's lymphoma and mantle cell lymphoma in October 2010, and was launched under the trade name TREAKISYM® in December 2010. In December 2015, the Group filed a partial change application to include the additional target indications of first-line treatment of low-grade non-Hodgkin's lymphoma and mantle cell lymphoma, and chronic lymphocytic leukemia. The Group obtained approval for the indication of chronic lymphocytic leukemia in August 2016 and of first-line treatment of low-grade non-Hodgkin's lymphoma and mantle cell lymphoma in December 2016. In May 2020, the Group submitted a partial change application to include the indication of recurrent/refractory diffuse large B-cell lymphoma (r/r DLBCL), and obtained approval in March 2021. In order to maximize the business value of TREAKISYM® by further promoting product life cycle management, the Group concluded an exclusive license agreement with Eagle Pharmaceuticals in September 2017 to develop, market, and sell Eagle's ready-to-dilute ("RTD") liquid formulation injection and rapid infusion ("RI") administration products in Japan. The Group obtained approval for the RTD formulation in September 2020, and launched the product in January 2021. For the RI injection, the Group filed a partial change application in May 2021. In February 2022, we obtained approval of a partial change to our marketing authorization enable the use of RI administration for all indications for which RTD is approved. We will continue joint research with academia, including ongoing research with the University of Tokyo and Kyoto University, to explore new potential uses and development possibilities for Treakisym®.

(ii) [Anticancer agents: SyB L-1101 (intravenous formulation) and SyB C-1101 (oral formulation) (generic name: rigosertib sodium)]

Rigosertib is an anticancer agent with a unique type of multikinase inhibitory activity. It is currently being developed in the U.S., Europe, and elsewhere by a U.S. company, Onconova Therapeutics, Inc. ("Onconova"), for the target indications of myelodysplastic syndromes ("MDS"). MDS is the pre-pathological state for malignant tumors of blood cells, which has shown increasing numbers of patients in recent years; it frequently affects elderly people; and it is a refractory disease, with a high probability of developing into leukemia.

No effective medication is available yet, especially for recurrent/refractory MDS, and it therefore constitutes an underserved therapeutic area. In July 2011, the Group signed a license agreement with Onconova, obtaining the exclusive right to develop and commercialize rigosertib in Japan and South Korea. Based on this agreement, the Group had developed the intravenous rigosertib formulation for the target indication of recurrent/refractory higher-risk MDS and the oral formulation for the target indication of first-line higher-risk MDS (in combination with azacitidine).

Through joint research with the University of Tokyo, we are exploring new indications for rigosertib in combination with other drugs, including TREAKISYM®.

(iii) [Antiviral drug: SyB V-1901 (generic name: brincidofovir [BCV])]

In September 2019, the Group concluded an exclusive global licensing agreement for antiviral drug brincidofovir ("BCV") with Chimerix Inc. Under this agreement, the Group acquired the exclusive rights for the worldwide development, marketing, and manufacture of BCV for all human indications, excluding orthopox viruses.

The Group is prioritizing the global development of BCV, targeting adenovirus (AdV) infections in immunocompromised

patients, including patients who have had hematopoietic stem cell transplantation—a niche area with a high unmet medical need, and a Phase II clinical trial of BCV IV is currently being conducted.

Based on the knowledge and insight on the safety and efficacy of BCV obtained from the clinical trial of IV BCV for treatment of AdV infections, the Group will investigate the effectiveness of BCV in treating various other dsDNA virus infections following hematopoietic stem cell transplantation and aim to expand target indications to include multiviral infections. BK virus (BKV) infection after kidney transplantation is a disease with serious consequences due to the risk of impaired renal function and loss of the transplanted kidney (graft loss). The Group has commenced a Phase II clinical trial in patients infected with BKV after kidney transplantation and the investigational drug was administered to the first patient in Australia In December 2022. In clinical studies conducted by Chimerix in Europe and the U.S., Oral BCV has been shown to have broad antiviral activity against dsDNA viruses. Oral BCV's antiviral activity against dsDNA viruses suggests that IV BCV may also be safe and effective in the prevention and treatment of various viral infections following hematopoietic stem cell transplantation.

In December 2020, Chimerix announced that the FDA had accepted its NDA for Oral BCV for the treatment of smallpox, and the NDA was approved by the FDA in June 2021.

2. Basic Views on Selection of Accounting Standards

Over the near term, the Group will prepare its financial statements based on Japanese generally accepted accounting principles (GAAP), taking into account the inter-period comparability of financial statements and comparability across companies.

In terms of the application of International Financial Reporting Standards (IFRS), the Group will take appropriate measures in light of the existing circumstances in Japan and overseas.

3. Consolidated Financial Statements and Primary Notes

(1) Consolidated balance sheet

(Unit: thousands of yen)

	FY 2022 (as of December 31, 2022)	FY 2023 (as of December 31, 2023)
Assets		
Current assets		
Cash and deposits	6,282,554	6,517,007
Accounts receivable–trade	2,084,915	913,094
Merchandise and finished goods	293,757	231,650
Semi-finished goods	175,170	-
Stored goods	452	380
Advance payments	252,745	271,516
Prepaid expenses	209,886	119,271
Other	13,224	29,607
Total current assets	9,312,706	8,082,526
Non-current assets		
Property, plant and equipment		
Buildings, net	40,670	-
Tools, furniture and fixtures, net	28,339	-
Construction in progress	-	-
Total property, plant and equipment	69,009	-
Intangible assets		
Software	222,204	-
Software in progress	-	-
Total intangible assets	222,204	-
Investments and other assets		
Deferred tax assets	744,728	-
Leasehold and guarantee deposits	84,698	87,716
Total investments and other assets	829,427	87,716
Total non-current assets	1,120,641	87,716
Total assets	10,433,347	8,170,243
Liabilities		
Current liabilities		
Accounts payable–trade	46,633	-
Accounts payable–other	1,163,721	853,825
Provision for office transfer expenses	-	16,784
Income taxes payable	401,066	18,474
Provision for product changeover	16,331	-
Other	296,118	67,540
Total current liabilities	1,923,870	956,625
Non-current liabilities		
Liabilities for retirement benefits	3,385	3,709
Total non-current liabilities	3,385	3,709
Total liabilities	1,927,255	960,334

(Unit: thousands of yen)

	FY 2022 (as of December 31, 2022)	FY 2023 (as of December 31, 2023)
Net assets		
Shareholders' equity		
Share capital	17,548,459	17,952,692
Capital surplus	17,523,357	17,927,584
Retained earnings	(26,889,486)	(28,852,303)
Treasury shares	(88,154)	(89,122)
Total shareholders' equity	8,094,176	6,938,849
Accumulated other comprehensive income		
Foreign currency translation adjustment	243	(5,985)
Total accumulated other comprehensive income	243	(5,985)
Share acquisition rights	411,672	277,044
Total net assets	8,506,092	7,209.909
Total liabilities and net assets	10,433,347	8,170,243

(2) Consolidated statements of income and consolidated statements of comprehensive income

Consolidated statements of income

(Unit: thousands of yen)

	FY 2022 (from January 1, 2022 to December 31, 2022)	FY 2023 (from January 1, 2023 to December 31, 2023)
Net sales	10,008,338	5,589,708
Cost of sales	2,408,434	1,178,694
Gross profit	7,599,904	4,411,013
Selling, general and administrative expenses	5,636,278	5,222,681
Operating profit (loss)	1,963,625	(811,668)
Non-operating income		
Interest income	98	11,972
Foreign exchange gains	136,179	117,106
Other	2,925	3,711
Total non-operating income	139,204	132,789
Non-operating expenses		
Commission expenses	56,543	12,728
Share issuance costs	45,867	11,478
Provision for office relocation expenses	-	25,176
Loss on retirement of fixed assets	540	7,868
Total non-operating expenses	102,951	57,252
Ordinary profit	1,999,878	(736,130)
Extraordinary income		
Gain on reversal of share acquisition rights	106,401	101,333
Total extraordinary income	106,401	101,333
Extraordinary loss		
Impairment loss		560,590
Total extraordinary loss		560,590
Profit before income taxes	2,106,279	(1,195,387)
Income taxes - current	396,010	22,700
Income taxes - deferred	531,030	744,728
Total income taxes	927,041	767,429
Profit (loss)	1,179,238	(1,962,817)
Profit attributable to non-controlling interests	-	-
Profit (loss) attributable to owners of parent	1,179,238	(1,962,817)

Consolidated statements of comprehensive income

(Unit: thousands of yen)

	FY 2022 (from January 1, 2022 to December 31, 2022)	FY 2023 (from January 1, 2023 to December 31, 2023)
Profit	1,179,238	(1,962,817)
Accumulated other comprehensive income		
Foreign currency translation adjustment	198	6,228
Total other comprehensive income	198	6,228
Comprehensive income	1,179,437	(1,956,588)
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	1,179,437	(1,956,588)
Comprehensive income attributable to non-controlling interests	–	–

(3) Consolidated statements of changes in equity

FY 2022 (from January 1, 2022 to December 31, 2022)

(Unit: thousands of yen)

	Shareholder's equity				
	Share capital	Capital surplus	Retained earnings	Treasury shares	Total Shareholder's equity
Balance at beginning of period	17,157,628	17,132,501	(27,975,902)	(86,045)	6,228,181
Cumulative effect of changes in accounting policies			(92,822)		(92,822)
Restated balance	17,157,628	17,132,501	(28,068,725)	(86,045)	6,135,358
Changes during period					
Issuance of new shares	331,000	331,000			662,000
Issuance of new shares (exercise of share acquisition rights)	59,831	59,831			119,662
Profit attributable to owners of parent			1,179,238		1,179,238
Purchase of treasury shares				(2,165)	(2,165)
Disposal of treasury shares		24		56	81
Net changes of items other than shareholders' equity					
Total changes during period	390,831	390,856	1,179,238	(2,108)	1,958,817
Balance at end of period	17,548,459	17,523,357	(26,889,486)	(88,154)	8,094,176

	Accumulated other comprehensive income		Share acquisition rights	Total net assets
	Foreign currency translation adjustment	Total accumulated other comprehensive income		
Balance at beginning of period	44	44	519,099	6,747,325
Cumulative effect of changes in accounting policies				(92,822)
Restated balance	44	44	519,099	6,654,502
Changes during period				
Issuance of new shares				662,000
Issuance of new shares (exercise of share acquisition rights)				119,662
Profit attributable to owners of parent				1,179,238
Purchase of treasury shares				(2,165)
Disposal of treasury shares				81
Net changes of items other than shareholders' equity	198	198	(107,426)	(107,228)
Total changes during period	198	198	(107,426)	1,851,589
Balance at end of period	243	243	411,672	8,506,092

FY 2023 (from January 1, 2023 to December 31, 2023)

(Unit: thousands of yen)

	Shareholder's equity				
	Share capital	Capital surplus	Retained earnings	Treasury shares	Total Shareholder's equity
Balance at beginning of period	17,548,459	17,523,357	(26,889,486)	(88,154)	8,094,176
Restated balance					
Changes during period	346,200	346,200			692,400
Issuance of new shares	58,032	58,032			116,065
Issuance of new shares (exercise of share acquisition rights)			(1,962,817)		(1,962,817)
Profit attributable to owners of parent				(996)	(996)
Purchase of treasury shares		(6)		28	21
Disposal of treasury shares					
Net changes of items other than shareholders' equity					
Total changes during period	404,232	404,226	(1,962,817)	(968)	(1,155,326)
Balance at end of period	17,952,692	17,927,584	(28,852,303)	(89,122)	6,938,849

	Accumulated other comprehensive income		Share acquisition rights	Total net assets
	Foreign currency translation adjustment	Total accumulated other comprehensive income		
Balance at beginning of period	243	243	411,672	8,506,092
Restated balance				
Changes during period				692,400
Issuance of new shares				116,065
Issuance of new shares (exercise of share acquisition rights)				(1,962,817)
Profit attributable to owners of parent				(996)
Purchase of treasury shares				4,919
Disposal of treasury shares				21
Net changes of items other than shareholders' equity	(6,228)	(6,228)	(134,627)	(140,856)
Total changes during period	(6,228)	(6,228)	(134,627)	(1,296,183)
Balance at end of period	(5,985)	(5,985)	277,044	7,209,909

(4) Consolidated statements of cash flows

(Unit: yen in thousands)

	FY 2022 (from January 1, 2022 to December 31, 2022)	FY 2023 (from January 1, 2023 to December 31, 2023)
Cash flows from operating activities		
Profit before income taxes	2,106,279	(1,195,387)
Depreciation	98,092	96,005
Amortization of guarantee deposits	1,339	2,381
Impairment loss	-	560,590
Share-based remuneration expenses	104,731	82,497
Increase (decrease) in provision for retirement benefits	609	324
Increase (decrease) in provision for product changeover	(171,081)	(16,331)
Increase (decrease) in provision for office transfer expenses	-	16,784
Interest income	(98)	(11,972)
Foreign exchange losses (gains)	(370,416)	(132,415)
Commission expenses	56,543	12,728
Share issuance cost	45,867	11,478
Gain on reversal of share acquisition rights	(106,401)	(101,333)
Loss on retirement of non-current assets	540	7,868
Decrease (increase) in trade receivables	62,594	1,171,821
Decrease (increase) in inventories	(82,746)	237,277
Decrease (increase) in prepaid expenses	(64,874)	90,614
Increase/decrease in consumption taxes payable/consumption taxes refund receivable	(270,711)	(212,814)
Decrease (increase) in other current assets	(89,984)	(23,384)
Increase (decrease) in notes and accounts payable–trade	(23,050)	(46,633)
Increase (decrease) in accounts payable–other	685,306	(310,273)
Increase (decrease) in other current liabilities	(105,844)	(66,344)
Others	157,769	(1,700)
Subtotal	2,034,463	(171,781)
Interest and dividends received	98	274
Commitment fee paid	(56,543)	(12,029)
Income taxes paid	(363,776)	(354,711)
Net cash provided by (used in) operating activities	1,614,241	(194,685)
Cash flows from investing activities		
Purchase of property, plant and equipment	(2,034)	(204,250)
Purchase of intangible assets	(45,524)	(28,547)
Leasehold and guarantee deposits	-	(143,898)
Proceeds from refund of leasehold and guarantee deposits	432	-
Net cash provided by (used in) investing activities	(47,127)	(376,696)
Cash flows from financing activities		
Proceeds from issuance of shares resulting from exercise of share acquisition rights	146	274
Proceeds from issuance of share acquisition rights	13,760	-
Payments for issuance of shares	(45,837)	(11,538)
Proceeds from issuance of shares	662,000	692,400
Purchase of treasury shares	(2,165)	(996)
Proceeds from disposal of treasury shares	81	21
Net cash provided by (used in) financing activities	627,985	680,160
Effect of exchange rate change on cash and cash equivalents	213,710	125,673
Net increase (decrease) in cash and cash equivalents	2,408,809	234,452
Cash and cash equivalents at beginning of period	3,860,106	6,282,554
Increase in cash and cash equivalents resulting from inclusion of subsidiaries in consolidation	13,637	-
Cash and cash equivalents at end of period	6,282,554	6,517,007

(5) Notes to consolidated financial statements

(Notes to going concern assumptions)

None to be reported.

(Accounting policy changes)

The Company has applied the "Accounting Standard for Fair Value Measurement" (ASBJ Statement No. 31; June 17, 2021; hereinafter "Fair Value Measurement Standard") from the beginning of the first quarter of FY 2023.

In applying the Fair Value Measurement Standard, the Company has followed the transitional treatment prescribed in the transitional measures provided for in paragraph 27-2 of the Implementation Guidance on Accounting Standard for Fair Value Measurement and will apply the new accounting standard prescribed by the Fair Value Measurement Standard, prospectively.

The adoption of this accounting standard has no effect on the quarterly consolidated financial statements.

(Segment information)

Segment information is omitted since the Group operates within a single segment, which includes the research and development, manufacturing, and marketing of pharmaceutical drugs and other related activities.

(Per share information)

	FY 2022 (from January 1, 2022 to December 31, 2022)	FY 2023 (from January 1, 2023 to December 31, 2023)
Net assets per share	204.83 yen	164.32 yen
Net income per share	30.20 yen	(49.19 yen)
Dilutive net income per share	29.77 yen	—

(Notes) The basis of the calculation of basic earnings per share and diluted earnings per share is as follows.

	FY 2022 (from January 1, 2022 to December 31, 2022)	FY 2023 (from January 1, 2023 to December 31, 2023)
Basic earnings per share		
Profit attributable to owners of parent (thousands of yen)	1,179,238	(1,962,817)
Amount not attributable to common shareholders (thousands of yen)	—	—
Profit attributable to owners of parent of common stock (thousands of yen)	1,179,238	(1,962,817)
Average number of common stock during the fiscal year (shares)	39,046,822	39,902,249
Diluted earnings per share		
Adjustment of profit attributable to owners of parent (thousands of yen)	—	—
Increase in shares of common stock (shares)	558,585	344,572
(Of which, share acquisition rights) (shares)	(558,585)	(344,572)
Outline of dilutive shares not included in the calculation of diluted earnings per share because they have no dilutive effect	1 types of share acquisition rights (20,000 units) in accordance with the Companies Act Article 236, 238, and 239.	1 types of share acquisition rights (20,000 units) in accordance with the Companies Act Article 236, 238, and 239.

Basic calculation of net assets per share

	FY 2022 (from January 1, 2022 to December 31, 2022)	FY 2023 (from January 1, 2023 to December 31, 2023)
Total net assets (thousand of yen)	8,506,092	7,209,909
Amount deducted from total net assets (thousand of yen)	411,672	277,044
(Of which stock acquisition rights) (thousand of yen)	(411,672)	(277,044)
(Of which, noncontrolling interests) (thousand of yen)	(-)	(-)
Net assets related to common stock at the end of the period (thousand of yen)	8,094,419	6,932,864
Number of shares of common stock used in the calculation of net assets per share at the end of the period (shares)	39,518,338	42,190,361

(Significant subsequent events)

(Execution of agreement establishing share issuance program and issuance of new shares by way of third-party allotment)

On October 6, 2023 (the "Initial Press Release"), the Company announced that the Company's Board of Directors, at a meeting held on the same date, had resolved to enter into an agreement with EVO FUND (the "Allottee") to set up an equity issue program (the "Agreement to Set up an Equity Issue Program"), and based on the equity issue program established under the Agreement to Set up an Equity Issue Program (the "Program"), to issue new shares in five tranches (shares issued to the Allottee, whether individually or collectively, under the Program are referred to as the "Shares").

The Company is authorized to issue up to a total of 6,000,000 ordinary shares by way of third-party allotment to the allottees in the period from 25 October 2023 to 3 April 2024, with ordinary shares to be issued by way of a total of five allotments, from the first to the fifth allotment.

As at the date of submission, the new shares to be issued by way of third-party allotment are as follows.

(3rd allotment)

The payment was completed on February 7, 2024.

1	Class and Numbers Shares Offered	1,200,000 common shares
2	Issue Price	230 yen per share
3	Capital inclusion amount	115 yen per share
4	Total Issue Price	276,000,000 Yen
5	Increases in Capital Stock and Legal Capital Surplus	138,000,000 Yen
6	Allotment resolution date	January 22, 2024
7	Deadline for Application	February 7, 2024
8	Due Date of Payment	February 7, 2024
9	Allottee	EVO FUND
10	Specific uses	(1) Development funds for antiviral drug brincidofovir (direct expenses) (2) Development funds for antiviral drug brincidofovir (indirect expenses) (3) Investment in new in-licensing and M&A for the purpose of securing long-term growth opportunities.

(4th allotment) *Note 1

1	Class and Numbers Shares Offered	1,200,000 common shares
2	Issue Price	To be determined *Note 2
3	Capital inclusion amount	The amount to be contributed to capital stock shall be half the upper limit of an increase in capital stock under Article 14, Paragraph 1, of the Rules of Corporate Accounting (with any fractional amounts less than one yen resulting from such calculation rounded up). The increase in the legal surplus shall be the upper limit of an increase in capital stock less the amount of the increase in capital stock.
4	Total Issue Price	To be determined.
5	Increases in Capital Stock and Legal Capital Surplus	To be determined.
6	Allotment resolution date	February 29, 2024 *Note 3
7	Deadline for Application	March 18, 2024
8	Due Date of Payment	March 18, 2024 *Note 3
9	Allottee	EVO FUND
10	Specific uses	(1) Development funds for antiviral drug brincidofovir (direct expenses (2) Development funds for antiviral drug brincidofovir (indirect expenses) (3) Investment in new in-licensing and M&A for the purpose of securing long-term growth opportunities.

(5th allotment) *Note 1

1	Class and Numbers Shares Offered	1,200,000 common shares
2	Issue Price	To be determined
3	Capital inclusion amount	The amount to be contributed to capital stock shall be half the upper limit of an increase in capital stock under Article 14, Paragraph 1, of the Rules of Corporate Accounting (with any fractional amounts less than one yen resulting from such calculation rounded up). The increase in the legal surplus shall be the upper limit of an increase in capital stock less the amount of the increase in capital stock.
4	Total Issue Price	To be determined.
5	Increases in Capital Stock and Legal Capital Surplus	To be determined.
6	Allotment resolution date	April 3, 2023 *Note 3
7	Deadline for Application	April 19, 2024
8	Due Date of Payment	April 19, 2024 *Note 3
9	Allottee	EVO FUND

10	Specific uses	(1) Development funds for antiviral drug brincidofovir (direct expenses (2) Development funds for antiviral drug brincidofovir (indirect expenses) (3) Investment in new in-licensing and M&A for the purpose of securing long-term growth opportunities.

*Note 1. The number of shares for each of the 4th through 5th allotments will range from 1,200,000 shares to 2,500,000 shares, and the total will not exceed the 6,000,000 shares stipulated for issuance under the Program. The actual number will be determined by the Allottee notifying the Company prior to the date of the resolution by the Board of Directors for each allotment (the "Allotment Resolution Date").

*Note 2. The issue price for each allotment will be the amount equal to the simple average of the closing price of common shares of the Company announced by the Tokyo Stock Exchange, Inc. (the "TSE") during the 10 trading days up to and including the day immediately preceding the Allotment Resolution Date (rounded off to the first decimal place). (However, if there is no closing price for any of the 10 trading days, the Allotee may decide whether to include such a day in the calculation of the issue price.)

*Note 3. The Allotment Resolution Date and the due date of payment may be changed, if agreed upon by the Company and the Allottee. If such changes occur, the Company will withdraw the securities registration statement allotment and submit a new securities registration statement.