SymBio Pharmaceuticals Limited

Summary of Financial Statements for the Fiscal Year Ended December 31, 2022 [Japanese GAAP] (Consolidated)

February 9, 2023

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	Corporate Officer and Chief Financial Officer	Takaaki Fukushima	TEL +81-3-5472-1125
Ordinary Annual General Meeting of Shareholders	March 23, 2023	Date of Dividend Payment (plan)	—
Scheduled Date to File Securities Report	March 23, 2023		

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

(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 2022	10,008	—	1,963	—	1,999	—	1,179	—
FY 2021	—	—	—	—	—	—	—	—

(Note) Comprehensive income: FY 2022 1,179 million yen (-%)
FY 2021 — 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 2022	30.20	29.77	14.6	19.2	19.6
FY 2021	—	—	—	—	—

(Reference) Equity in net income of affiliated companies: FY 2022 — million yen
FY 2021 — million yen

(Note) The Group began preparing consolidated financial statements from FY 2022 with the start of operations at SymBio Pharma USA. As a result, figures for FY 2021 as well as year-on-year comparisons against FY 2021 have not been provided. 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 2022 (as of December 31, 2022)	10,433	8,506	77.6	204.83
FY 2021 (as of December 31, 2021)	—	—	—	—

(Reference) Shareholders' equity: FY 2022 (as of December 31, 2022) 8,094 million yen
FY 2021 (as of December 31, 2021) — million yen

(Note) The Group began preparing consolidated financial statements from FY 2022, and hence figures for FY 2021 have not been provided.

(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 2022	1,614	(47)	627	6,282
FY 2021	—	—	—	—

(Note) The Group began preparing consolidated financial statements from FY 2022, and hence figures for FY 2021 have not been provided.

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 2021	—	0.00	—	0.00	0.00	—	—	—
FY 2022	—	0.00	—	0.00	0.00	—	—	—
FY 2023 (Forecast)	—	0.00	—	0.00	0.00		—	

3. Earnings Forecasts for FY 2023 (January 1, 2023 to December 31, 2023)

(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	7,000	(30.1)	(331)	—	(351)	—	(370)	—	(9.48)

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 2022	39,603,606 shares	FY 2021	38,457,206 shares
(ii) Total number of treasury shares at the end of the period	FY 2022	85,268 shares	FY 2021	82,618 shares
(iii) Average number of shares during the period (cumulative)	FY 2022	39,046,821 shares	FY 2021	38,313,220 shares

(Reference) Non-consolidated Financial Statements for Fiscal 2022

1. Business Results for FY 2022 (January 1, 2022 to December 31, 2022)

(1) Non-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 2022	10,008	21.2	1,972	94.1	2,001	99.9	1,186	(41.6)
FY 2021	8,256	176.4	1,016	—	1,001	—	2,032	—

	Earnings per Share	Diluted Earnings per Share
	Yen	Yen
FY 2022	30.37	29.95
FY 2021	53.04	52.32

(2) Non-consolidated Financial Position

	Total Assets	Net Assets	Equity Ratio	Net Assets per Share
	Millions of yen	Millions of yen	%	Yen
FY 2022 (as of December 31, 2022)	10,410	8,511	77.8	204.95
FY 2021 (as of December 31, 2021)	8,452	6,745	73.7	162.26

(Reference) Shareholders' equity: FY 2022 (as of December 31, 2022) 8,099 million yen

FY 2021 (as of December 31, 2021) 6,226 million yen

* 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 "1. Overview of Business Results, etc. (4) Future outlook," on Page 5 of the attachment.

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1. Overview of Business Results, etc.

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

(Business results for the fiscal year under review)

From the fiscal year ended December 31, 2022, the Group began preparing consolidated financial statements in connection with the commencement of full-fledged operations at its wholly-owned U.S.-based subsidiary, SymBio Pharma USA, Inc. (President: Carolyn Yanavich), which serves as a strategic base for our global operations as a specialty pharmaceutical company. As reference, we have provided year-on-year comparisons with the non-consolidated financial statements in the same period last year, since there have been no substantial changes in our business composition.

(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. This was a critical step of the Group to attain profitability in FY 2021, which was a top priority for the fiscal year.

The Group has assigned medical representatives nationwide to establish a highly productive salesforce that can identify local needs and plan detailed proposals. We also deployed hematology experts in each region of operation to provide information in a more scientific manner. To achieve nationwide distribution, we have entered into distribution agreements with Suzuken Co., Ltd. and Toho Pharmaceutical Co., Ltd. with both companies as exclusive distributors. We are also working with S.D. Collabo Co., Ltd. and have established two logistics centers, one in Eastern Japan and the other in Western Japan.

In February 2022, the Group obtained approval for a partial change to the marketing authorization of the ready-to-dilute (RTD) liquid formulation of TREAKISYM® to add rapid infusion (RI) administration. Compared to the freeze-dried (FD) formulation, the RTD formulation of TREAKISYM® reduces the time required for the complicated dissolution process. RI administration further reduces the infusion time to 10 minutes, relieving the burden on both patients and healthcare providers. The reduction in infusion volume lowers the volume of saline solution and accordingly the amount of salt (sodium chloride) used.

Conversion to the RI administration proceeded smoothly, with over 80% of medical institutions switching to RI administration as of the end of December 2022.

As a result, net sales totaled 10,008,338 thousand yen (+21.2% year on year). Despite sales activities being constrained by delays in treatment and continued restrictions on facility visits due to the spread of COVID-19, net sales rose due to the approval for the use of TREAKISYM® in the bendamustine-rituximab (BR) therapy and in polatuzumab vedotin plus bendamustine-rituximab (Pola+BR) therapy to treat recurrent/refractory diffuse large B-cell lymphoma (r/r DLBCL).

Selling, general and administrative expenses totaled 5,636,278 thousand yen (+1.1% year on year). This amount includes research and development expenses of 2,554,799 thousand yen (+47.2% year on year).

As a result, operating profit was 1,963,625 thousand yen (versus 1,016,001 thousand yen in the same period of FY 2021) and ordinary profit was 1,999,878 thousand yen (versus 1,001,133 thousand yen in the same period of FY 2021). Profit attributable to owners of parent amounted to 1,179,238 thousand yen (versus 2,032,203 thousand yen in the same period of FY 2021, due in part to the recording of 1,275,759 thousand yen in deferred tax assets). As cumulative total sales of the RTD formulation of TREAKISYM® reached 11,000,000 thousand yen in FY 2022, the Group booked 550,000 thousand yen in sales milestone payments to Eagle Pharmaceuticals, Inc. (head office: New Jersey, U.S.; hereinafter “Eagle”) under cost of sales.

In February 2022, generic versions of TREAKISYM® were approved for manufacturing and marketing in Japan. Given the potential infringement of Eagle’s patents related to TREAKISYM® in Japan which are exclusively licensed to the Company, the Company in coordination with Eagle notified four generic makers of potential patent infringement and requested they take appropriate measures to avoid such infringement. In December 2022, Eagle and the Company commenced the litigation seeking an injunction against the manufacture and sale of Pfizer’s and Towa’s generic version of TREAKISYM® and compensation for damages arising from the infringement.

Segment information has been 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.

(ii) Research and development activities

During the fiscal year under review, we conducted the following research and development activities in each of our development

pipelines.

(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®)

For the RI administration, the Group completed clinical studies on safety and a partial change application was approved in February 2022, enabling the use of RI injection for all approved indications of the RTD formulation in-licensed from Eagle.

The Group will actively conduct further research on TREAKISYM®, such as ongoing clinical research with Saitama Medical University and joint research with Kyoto University, to explore new possibilities of the drug.

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

For rigosertib in-licensed from Onconova Therapeutics, Inc. (head office: Pennsylvania, U.S.; hereinafter "Onconova") and TREAKISYM®, the Group is searching for new indications as well as new applications for the drugs used in combination with each other or with other existing drugs, through joint research and the offering of academia-industry collaborative courses with the University of Tokyo.

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

In the development of the intravenous and oral formulations of antiviral drug brincidofovir (SyB V-1901; hereinafter "BCV IV" and "BCV Oral") , in-licensed from Chimerix Inc. (head office: North Carolina, U.S.; hereinafter "Chimerix") with a view to global rollout, the Group has been carrying out joint research with top research institutions of each specialized field in Japan and overseas in light of the drugs' broad effectiveness against dsDNA viruses.

The Group has decided to prioritize the global development of BCV IV primarily in Japan, the U.S., and Europe, targeting disseminated AdV infections occurring after hematopoietic stem cell transplantation, a niche area with a high unmet medical need. In March 2021, the Group filed an Investigational New Drug (IND) application with the FDA to conduct a Phase II clinical trial primarily in pediatric patients suffering from AdV infections (also including adults). This development program was granted Fast Track designation by the FDA in April 2021, and the investigational drug was administered to the first patient in August 2021. As of December 31, 2022, 20 patients were enrolled.

BK virus (BKV) infection after kidney transplantation is a disease with serious consequences for the recipient, the donor, the medical practitioner, and the society, due to the risk of impaired renal function and loss of the transplanted kidney (graft loss). The Group submitted a clinical trial notification for a global Phase II study in patients infected with BKV after kidney transplantation to the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan in May 2022 and filed another notification with the Therapeutic Goods Administration (TGA) of Australia in August 2022, and the investigational drug was administered to the first patient in December 2022.

The Group is also looking to develop BCV to treat multiple sclerosis, an intractable disease that has recently been proven to be associated with Epstein-Barr virus (EBV). In August 2022, the Group entered into a collaboration agreement with the National Institute of Neurological Disorders and Stroke (NINDS), part of the National Institutes of Health (NIH) in the U.S., for the transfer of materials for evaluation of BCV's potential antiviral effect on EBV.

Among double-stranded DNA viruses (dsDNA), polyomaviruses are known to cause serious diseases through their infection. As existing antiviral drugs show little efficacy, the development of an effective treatment is eagerly awaited. 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 double-stranded DNA viruses, such as HSV1 and VZV, are directed against cranial nerve tissues and are known to cause serious diseases, including Alzheimer's disease, in various cranial nerve areas due to infection caused by their reactivation. In December 2022, the Group entered into a Sponsored Research Agreement with Tufts University to conduct joint research on BCV. This joint research is a nonclinical study that will evaluate the efficacy of BCV in a herpes simplex virus (HSV) infection model using a 3D (three-dimensional) brain model established by Tufts University.

In addition to having its strong antiviral effect, BCV also is expected to have an antitumor effect, and the Group is exploring new indications such as EBV-positive lymphoma, refractory brain tumors, and other cancers via research collaborations with the National Cancer Centre Singapore (NCCS) and 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 Yongsheng Chan at the 64th American Society of Hematology (ASH) Annual Meeting in New Orleans.

In September 2022, Chimerix announced that it has completed the closing of the sale of BCV to Emergent BioSolutions Inc. (head office: Maryland, U.S.). The Group's exclusive worldwide development, manufacturing, and marketing rights to BCV for all indications except orthopox virus infections (including smallpox and monkeypox) will not be affected.

(iii) Business outside Japan

The Group appointed Dr. Carolyn Yanavich, President and Chief Operating Officer of SymBio Pharma USA, Inc., as Chief Development Officer of the Group to further expand our global development structure and make SymBio Pharma USA, Inc. as the driving force behind the international clinical trials, spearheading and accelerating the global development plan for BCV.

(iv) Licensing of new drug candidates

The Group is moving ahead with global development of brincidofovir, an antiviral drug in-licensed in 2019. At the same time, the Group continues to evaluate new drug candidates for potential in-licensing. Through these efforts, the Group aims to create medium- to long-term business value as a profitable biopharmaceutical company with growth potential.

(2) Overview of financial position for the fiscal year under review

(Assets, liabilities, net assets, and cash flows)

Total consolidated assets as of December 31, 2022 stood at 10,433 ,347 thousand yen. Current assets totaled 9,312,706 thousand yen, mainly consisting of 6,282,554 thousand yen in cash and deposits, 2,084,915 thousand yen in accounts receivable-trade, 293,757 thousand yen in merchandise and finished goods, and 175,170 thousand yen in semi-finished goods. Non-current assets amounted to 1,120,641 thousand yen, mainly consisting of 744,728 thousand yen in deferred tax assets and 222,204 thousand yen in software.

Total liabilities stood at 1,927,255 thousand yen. Current liabilities totaled 1,923,870 thousand yen, mainly consisting of 1,163,721 thousand yen in accounts payable-other. Non-current liabilities amounted to 3,385 thousand yen, consisting of 3,385 thousand yen in liabilities for retirement benefits.

Total net assets stood at 8,506,092 thousand yen. This mainly breaks down as 17,548,459 thousand yen in capital stock, 17,523,357 thousand yen in capital surplus, and 411,672 thousand yen in share acquisition rights.

As a result, the equity ratio was 77.6%.

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

Cash and cash equivalents (hereinafter, “net cash”) stood at 6,282,554 thousand yen as of December 31, 2022.
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 1,614,241 thousand yen. The key drivers were 2,106,279 thousand yen in profit before income taxes and a decrease of 62,594 thousand yen in receivable-trade. Cash outflows were mainly due to an increase of 270,711 thousand yen in consumption taxes receivable, an increase of 82,746 thousand yen in inventory.

(Cash flows from investing activities)

Net cash used in investing activities was 47,127 thousand yen, mainly attributable to purchase of intangible assets of 45,524 thousand yen.

(Cash flows from financing activities)

Net cash provided by financing activities was 627,985 thousand yen, mainly attributable to proceed from issuance of shares of 662,000 thousand yen. in proceeds from issuance of shares.

	18th Term FY 2022
Equity ratio (%)	77.6
Equity ratio on a fair market value basis (%)	243.6
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 2023 to decrease by 30.1% from FY 2022 to 7,000 million yen. While the Group aims to further expand the market share of TREAKISYM®, reduction in NHI drug prices and impact of generic products on sales of TREAKISYM® are expected. In addition, the Group initiated litigation against the makers of the generic versions of TREAKISYM® based on patent infringement. As the litigation process is not expected to conclude for some time, , potential impact of the lawsuits on net sales is not included.

Regarding research and development, in addition to the global Phase II clinical trial for treatment of AdV infection with BCV IV that started in 2021, the global Phase II clinical trial for treatment of post renal transplant BKV infection with BCV IV that started in 2022 will be in full operation. Furthermore, in order to develop new indications through joint research with academia and to evaluate new drug development candidates with the aim of enhancing long-term corporate value, the Group expects R&D expenses to increase to 3,380 million yen in FY 2023 (compared to 2,554 million yen in FY 2022), following the increase in FY 2022.

As a result, for the fiscal year ending December 31, 2023, the Group forecasts net sales of 7,000 million yen, operating loss of 331 million yen, ordinary loss of 351 million yen, and loss attributable to owners of parent of 370 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.

The license agreement concluded with Astellas Deutschland GmbH concerning the rights in Japan and other Asian countries for the freeze-dried formulation of anticancer agent bendamustine has expired.

(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 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).

The oral formulation of rigosertib was shown to be effective and safe when administered in combination with azacitidine in a Phase I/II clinical trial in first-line higher-risk MDS patients conducted by Onconova in the U.S. The Group commenced a Phase I clinical trial in Japan to confirm the safety of high-dose monotherapy and tolerance in Japanese patients in Japan in June 2017, and completed patient enrollment in June 2019.

With the aim of maximizing the business value of rigosertib and TREAKISYM®, the Group is conducting joint research with the University of Tokyo to investigate the efficacy of the drugs used in combination with each other as well as with other existing drugs and to look for new indications.

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

On September 2019, the Group concluded an exclusive global licensing agreement for antiviral drug brincidofovir ("BCV")

with Chimerix 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 has decided to prioritize the global development of BCV, targeting adenovirus (AdV) infections occurring after 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 trials targeting 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., BCV Oral has been shown to have strong antiviral activity against a broad range of viruses. BCV Oral's antiviral activity against a range of dsDNA viruses suggests that BCV IV 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 BCV Oral as a medical countermeasure against smallpox; the NDA was approved 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)
Assets	
Current assets	
Cash and deposits	6,282,554
Accounts receivable–trade	2,084,915
Merchandise and finished goods	293,757
Semi-finished goods	175,170
Supplies	452
Advance payments	252,745
Prepaid expenses	209,886
Other	13,224
Total current assets	9,312,706
Non-current assets	
Property, plant and equipment	
Buildings	64,931
Accumulated depreciation	(24,260)
Buildings, net	40,670
Tools, furniture and fixtures	73,159
Accumulated depreciation	(44,819)
Tools, furniture and fixtures, net	28,339
Total property, plant and equipment	69,009
Intangible assets	
Software	222,204
Total intangible assets	222,204
Investments and other assets	
Deferred tax assets	744,728
Leasehold and guarantee deposits	84,698
Total investments and other assets	829,427
Total non-current assets	1,120,641
Total assets	10,433,347

(Unit: thousands of yen)

	FY 2022 (as of December 31, 2022)
Liabilities	
Current liabilities	
Accounts payable–trade	46,633
Accounts payable–other	1,163,721
Income taxes payable	401,066
Provision for product changeover	16,331
Other	296,118
Total current liabilities	1,923,870
Non-current liabilities	
Liabilities for retirement benefits	3,385
Total non-current liabilities	3,385
Total liabilities	1,927,255
Net assets	
Shareholders' equity	
Share capital	17,548,459
Capital surplus	17,523,357
Retained earnings	(26,889,486)
Treasury shares	(88,154)
Total shareholders' equity	8,094,176
Accumulated other comprehensive income	
Foreign currency translation adjustment	243
Total accumulated other comprehensive income	243
Share acquisition rights	411,672
Total net assets	8,506,092
Total liabilities and net assets	10,433,347

(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)
Net sales	10,008,338
Cost of sales	2,408,434
Gross profit	7,599,904
Selling, general and administrative expenses	5,636,278
Operating profit	1,963,625
Non-operating income	
Interest income	98
Foreign exchange gains	136,179
Other	2,925
Total non-operating income	139,204
Non-operating expenses	
Commission expenses	56,543
Share issuance costs	45,867
Other	540
Total non-operating expenses	102,951
Ordinary profit	1,999,878
Extraordinary income	
Gain on reversal of share acquisition rights	106,401
Total extraordinary income	106,401
Profit before income taxes	2,106,279
Income taxes - current	396,010
Income taxes - deferred	531,030
Total income taxes	927,041
Profit	1,179,238
Profit attributable to non-controlling interests	—
Profit attributable to owners of parent	1,179,238

Consolidated statements of comprehensive income

(Unit: thousands of yen)

	FY 2022 (from January 1, 2022 to December 31, 2022)
Profit	1,179,238
Other comprehensive income	
Foreign currency translation adjustment	198
Total other comprehensive income	198
Comprehensive income	1,179,437
(Comprehensive income attributable to)	
Comprehensive income attributable to owners of parent	1,179,437
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

(4) Consolidated statements of cash flows

(Unit: yen in thousands)

	FY 2022 (from January 1, 2022 to December 31, 2022)
Cash flows from operating activities	
Profit before income taxes	2,106,279
Depreciation	98,092
Amortization of guarantee deposits	1,339
Share-based remuneration expenses	104,731
Increase (decrease) in provision for retirement benefits	609
Increase (decrease) in provision for product changeover	(171,081)
Interest income	(98)
Foreign exchange losses (gains)	(370,416)
Commission expenses	56,543
Share issuance cost	45,867
Gain on reversal of share acquisition rights	(106,401)
Loss on retirement of non-current assets	540
Decrease (increase) in trade receivables	62,594
Decrease (increase) in inventories	(82,746)
Decrease (increase) in prepaid expenses	(64,874)
Increase/decrease in consumption taxes payable/consumption taxes refund receivable	(270,711)
Decrease (increase) in other current assets	(89,984)
Increase (decrease) in notes and accounts payable–trade	(23,050)
Increase (decrease) in accounts payable–other	685,306
Increase (decrease) in other current liabilities	(105,844)
Others	157,769
Subtotal	2,034,463
Interest and dividends received	98
Commitment fee paid	(56,543)
Income taxes paid	(363,776)
Net cash provided by (used in) operating activities	1,614,241
Cash flows from investing activities	
Purchase of property, plant and equipment	(2,034)
Purchase of intangible assets	(45,524)
Proceeds from refund of leasehold and guarantee deposits	432
Net cash provided by (used in) investing activities	(47,127)
Cash flows from financing activities	
Proceeds from issuance of shares resulting from exercise of share acquisition rights	146
Proceeds from issuance of share acquisition rights	13,760
Payments for issuance of shares	(45,837)
Proceeds from issuance of shares	662,000
Purchase of treasury shares	(2,165)
Proceeds from disposal of treasury shares	81
Net cash provided by (used in) financing activities	627,985
Effect of exchange rate change on cash and cash equivalents	213,710
Net increase (decrease) in cash and cash equivalents	2,408,809
Cash and cash equivalents at beginning of period	3,860,106
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

(5) Notes to consolidated financial statements

(Notes to going concern assumptions)

None to be reported.

(Changes in accounting policies)

(Application of Accounting Standard for Revenue Recognition)

The Group has applied the "Accounting Standard for Revenue Recognition" (ASBJ Statement No. 29; March 31, 2020; hereinafter "Revenue Recognition Standard") from the beginning of the fiscal year under review. As a result of the application of this standard, revenue will be recognized in the amount expected to be received in exchange for the promised goods or services at the time control of the promised goods or services is transferred to the customer.

Under the previous accounting standard, for transactions where the total amount of consideration the Group is entitled to in exchange for the transfer of promised goods or services, i.e., the transaction price, is likely to be reduced after a contract is signed with the customer, the Group revised the transaction price once the amount to be reduced was fixed. However, under the new accounting standard, the Group makes a reasonable estimate of the variable amount and subtracts it from the transaction price at the time the goods or services are transferred to the customer. Further, under the previous accounting standard, the Group accounted for expected sales returns by recording provisions for sales returns in the amount equivalent to gross profit; however, in accordance with the provisions regarding variable consideration, the Group no longer recognizes revenue at the time of sale and records refund liabilities as "other" under the current liabilities section of the balance sheet.

The Group has followed the transitional treatment prescribed in the provision of Paragraph 84 of the Revenue Recognition Standard, and has applied the new accounting standard from the opening balance of retained earnings of the fiscal year under review, whereby the cumulative effect of retrospective application of the new accounting standard prior to the beginning of the fiscal year under review is added to or deducted from the beginning balance of retained earnings.

As a result, in the consolidated statements of income for the fiscal year under review, net sales increased by 62,962 thousand yen, operating profit and ordinary profit increased by 62,962 thousand yen, respectively, and profit before income taxes increased by 62,962 thousand yen. In addition, the balance of retained earnings at the beginning of the period decreased by 92,822 thousand yen.

(Application of Accounting Standard for Fair Value Measurement)

The Group has applied the "Accounting Standard for Fair Value Measurement" (ASBJ Statement No. 30; July 4, 2019; hereinafter "Fair Value Measurement Standard") from the beginning of the fiscal year under review.

In applying the Fair Value Measurement Standard, the Group has followed the transitional treatment prescribed in the provision of Paragraph 19 of the Fair Value Measurement Standard and Paragraph 44-2 of the "Accounting Standard for Financial Instruments" (ASBJ Statement No. 10; July 4, 2019), 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 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)	
Net assets per share	204.83 yen
Net income per share	30.20 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)
Basic earnings per share	
Profit attributable to owners of parent (thousands of yen)	1,179,238
Amount not attributable to common shareholders (thousands of yen)	—
Profit attributable to owners of parent of common stock (thousands of yen)	1,179,238
Average number of common stock during the fiscal year (shares)	39,046,822
Diluted earnings per share	
Adjustment of profit attributable to owners of parent (thousands of yen)	—
Increase in shares of common stock (shares)	558,585
(Of which, share acquisition rights) (shares)	(558,585)
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.

(Significant subsequent events)

None to be reported.