SymBio Pharmaceuticals Limited

Summary of Consolidated Financial Statements for the First Three Months of Fiscal Year Ending December 31, 2023 [Japanese GAAP]

April 27, 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	Executive Corporate Officer and Chief Financial Officer	Takaaki Fukushima	TEL +81-3-5472-1125
Scheduled Date to File Quarterly Report	April 28, 2023	Date of Dividend Payment (plan)	–

Supplementary materials for the quarterly financial statements: Yes ・ No

Holding of quarterly earnings performance review: Yes ・ No

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

1. Business Results for the First Three Months of FY 2023 (January 1, 2023 to March 31, 2023)

(1) Consolidated Operating Results (cumulative) (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	%
Q1 FY 2023	1,544	(33.3)	51	(89.9)	48	(89.9)	4	(97.3)
Q1 FY 2022	2,315	–	509	–	478	–	163	–

(Note) Comprehensive income: Q1 FY 2023 4 million yen [(97.2)%]
Q1 FY 2022 163 million yen [– %]

	Earnings per Share	Diluted Earnings per Share
	Yen	Yen
Q1 FY 2023	0.11	0.11
Q1 FY 2022	4.25	4.18

(2) Consolidated Financial Position

	Total Assets	Net Assets	Equity Ratio
	Millions of yen	Millions of yen	%
Q1 FY 2023 (as of March 31, 2023)	9,356	8,533	87.0
FY 2022 (as of December 31, 2022)	10,433	8,506	77.6

(Reference) Shareholders' equity: Q1 FY 2023 (as of March 31, 2023) 8,139 million yen
FY 2022 (as of December 31, 2022) 8,094 million yen

2. Dividends

	Annual Dividend per Share				
	1st Quarter	2nd Quarter	3rd Quarter	Fiscal Year End	Full Year
	Yen	Yen	Yen	Yen	Yen
FY 2022	–	0.00	–	0.00	0.00
FY 2023	–				
FY 2023 (Forecast)		0.00	–	0.00	0.00

(Note) Revision of dividend forecasts most recently announced: Yes ・ No

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

(Percentages indicate year-on-year changes.)

	Net Sales		Operating Profit (Loss)		Ordinary Profit (Loss)		Profit (Loss) attributable to owners of parent		Earnings (Loss) 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)

(Note) Revision of earnings forecasts most recently announced: Yes ・ No

Notes:

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

(Transfer of specified subsidiary accompanying a change in the scope of consolidation)

New: None

Removed: None

(2) Application of special accounting treatment in preparing the quarterly financial statements: Yes ・ No

(3) 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

(4) Number of issued shares (common stock)

(i) Total number of issued shares at the end of the period (including treasury shares)	Q1 FY 2023	39,693,656 shares	FY 2022	39,603,606 shares
(ii) Total number of treasury shares at the end of the period	Q1 FY 2023	85,844 shares	FY 2022	85,268 shares
(iii) Average number of shares during the period (cumulative)	Q1 FY 2023	39,530,266 shares	Q1 FY 2022	38,392,424 shares

* Summary of the quarterly financial statements is not subject to quarterly reviews by certified public accountants or accounting 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 determined by the Company 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. Qualitative Information on Quarterly Financial Results (3) Explanation of consolidated earnings forecast and other forward-looking information" on Page 4 of the attachment.

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1. Qualitative Information on Quarterly Financial Results

(1) Business results

Progress in the Company's business for the first three months of 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.

The Group has established a highly productive salesforce consisting of qualified medical representatives nationwide. As our medical representatives have expertise in hematology and are deployed nationally, they are capable of effectively addressing the local needs of institutions in each region in the country. 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.

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. The RTD formulation of TREAKISYM® is a liquid formulation that eliminates the need for manual reconstitution and significantly reduces preparation time. RI administration has the further advantage of reducing the infusion time to 10 minutes, benefiting both patients and healthcare providers. In addition, the reduction in infusion volume of RI means a lower volume of saline solution and accordingly the amount of water and 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 March 2023.

Net sales of TREAKISYM® for Q1 totaled 1,544,813 thousand yen (-33.3% year on year), impacted by postponed purchases in anticipation of NHI price revision, continuing downward trend in drug usage per case with the COVID-19 pandemic, the impact of generic bendamustine products launched in June 2022, and the temporary sales increase in the same period last year due to the increase in distribution inventory following the switch from freeze-dried (FD) to RTD.

Selling, general and administrative expenses totaled 1,192,011 thousand yen (-14.2% year on year). This amount includes research and development expenses of 549,848 thousand yen (+10.8% year on year).

As a result, operating profit was 51,246 thousand yen (versus 509,200 thousand yen for the same period in FY 2022) and ordinary profit was 48,326 thousand yen (versus 478,616 thousand yen for the same period in FY 2022). Profit attributable to owners of parent amounted to 4,455 thousand yen (versus 163,171 thousand yen for the same period in FY 2022).

In February 2022, generic bendamustine products were approved for manufacturing and marketing 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.

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 first three months of 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®)

For the RI administration, 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 continues to actively conduct further research on TREAKISYM®, such as ongoing 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.), 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 bendamustine).

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

The Group obtained the exclusive license to brincidofovir from Chimerix Inc. (head office: North Carolina, U.S.; hereinafter "Chimerix") in September 2019. In September 2022, Emergent BioSolutions Inc. (head office: Maryland, U.S.) completed its acquisition of the exclusive worldwide rights to brincidofovir from Chimerix. The Group's exclusive worldwide license to develop, manufacture, and market BCV for all indications except orthopox virus infections (including smallpox and monkeypox) will not be affected.

The Group prioritizing global development of BCV (primarily in Japan, the U.S., and Europe), targeting disseminated adenovirus (AdV) infections occurring after hematopoietic stem cell transplantation. In March 2021, the Group filed an Investigational New Drug (IND) application with the FDA to conduct a Phase II clinical trial in patients (primarily pediatric but also adults) suffering from AdV infections. This development program was granted Fast Track designation by the FDA in April 2021. As of March 31, 2023, 22 patients were enrolled.

In addition, the Group submitted a clinical trial notification for a Phase II study in patients infected with BK virus (BKV) infection 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. 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.

In light of the drugs' broad effectiveness against double-stranded DNA (dsDNA) viruses, the Group is also collaborating with leading research institutions both in Japan and overseas to study BCV's potential use in the treatment of various other diseases.

Among dsDNA viruses, polyomaviruses are known to cause serious diseases through their infection. As existing antiviral drugs show little efficacy, there is a high level of medical need 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.

In addition to having 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.

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 National Institutes of Health (NIH) in the U.S., for the transfer of materials to evaluate the antiviral effect of BCVin EBV. In March 2023, The Company has entered into a Cooperative Research and Development Agreement (CRADA) for BCV with NINDS. The purpose of the CRADA is 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 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.

Some dsDNA viruses, such as HSV1 and VZV, are directed against cranial nerve tissues. In recent years, 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 herpes simplex virus (HSV) infection model using a 3D (three-dimensional) brain model established by Tufts University.

(iii) Business outside Japan

In 2022, the Group appointed Dr. Carolyn Yanavich, President and Chief Operating Officer of SymBio Pharma USA, Inc., as Chief Development Officer, to further expand 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 our global development plan for 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 March 31, 2023, stood at 9,356,741 thousand yen. Current assets totaled 8,302,192 thousand yen, mainly consisting of 5,939,570 thousand yen in cash and deposits, 1,334,011 thousand yen in accounts receivable-trade, 386,831 thousand yen in merchandise and finished goods, and 168,578 thousand yen in semi-finished goods. Non-current assets were 1,054,548 thousand yen, mainly consisting of 701,908 thousand yen in deferred tax assets and 201,453 thousand yen in software.

Total liabilities were 823,181 thousand yen. Current liabilities totaled 819,505 thousand yen, mainly consisting of 529,672 thousand yen in accounts payable-other. Non-current liabilities were 3,676 thousand yen, consisting of 3,676 thousand yen in liabilities for retirement benefits.

Total net assets stood at 8,533,560 thousand yen. This includes 17,568,878 thousand yen in capital stock, 17,543,776 thousand yen in capital surplus, and 394,087 thousand yen in share acquisition rights.

As a result, the equity ratio was 87.0%.

(3) Explanation of consolidated earnings forecasts and other forward-looking information

No revision was made to the earnings forecasts for FY 2023 as of the date of this document.

2. Quarterly Consolidated Financial Statements and Primary Notes

(1) Quarterly consolidated balance sheet

(Unit: thousands of yen)

	FY 2022 (as of December 31, 2022)	Q1 FY 2023 (as of March 31, 2023)
Assets		
Current assets		
Cash and deposits	6,282,554	5,939,570
Accounts receivable–trade	2,084,915	1,334,011
Merchandise and finished goods	293,757	386,831
Semi-finished goods	175,170	168,578
Prepaid expenses	209,886	198,033
Other	266,422	275,167
Total current assets	9,312,706	8,302,192
Non-current assets		
Property, plant and equipment		
Buildings, net	40,670	39,594
Tools, furniture and fixtures, net	28,339	25,631
Total property, plant and equipment	69,009	65,226
Intangible assets		
Software	222,204	201,453
Software in progress	–	1,597
Total intangible assets	222,204	203,050
Investments and other assets		
Deferred tax assets	744,728	701,908
Leasehold and guarantee deposits	84,698	84,363
Total investments and other assets	829,427	786,271
Total non-current assets	1,120,641	1,054,548
Total assets	10,433,347	9,356,741
Liabilities		
Current liabilities		
Accounts payable–trade	46,633	68,015
Accounts payable–other	1,163,721	529,672
Income taxes payable	401,066	53,531
Provision for product changeover	16,331	–
Other	296,118	168,285
Total current liabilities	1,923,870	819,505
Non-current liabilities		
Liabilities for retirement benefits	3,385	3,676
Total non-current liabilities	3,385	3,676
Total liabilities	1,927,255	823,181

(Unit: thousands of yen)

	FY 2022 (as of December 31, 2022)	Q1 FY 2023 (as of March 31, 2023)
Net assets		
Shareholders' equity		
Share capital	17,548,459	17,568,878
Capital surplus	17,523,357	17,543,776
Retained earnings	(28,889,486)	(26,885,030)
Treasury shares	(88,154)	(88,470)
Total shareholders' equity	8,094,176	8,139,154
Accumulated other comprehensive income		
Foreign currency translation adjustment	243	318
Total accumulated other comprehensive income	243	318
Share acquisition rights	411,672	394,087
Total net assets	8,506,092	8,533,560
Total liabilities and net assets	10,433,347	9,356,741

(2) Quarterly consolidated statement of income and consolidated statement of comprehensive income

Quarterly consolidated statement of income for the first three months of FY 2023

(Unit: thousands of yen)

	Q1 FY 2022 (from January 1, 2022 to March 31, 2022)	Q1 FY 2023 (from January 1, 2023 to March 31, 2023)
Net sales	2,315,992	1,544,813
Cost of sales	417,901	301,555
Gross profit	1,898,090	1,243,257
Selling, general and administrative expenses	1,388,889	1,192,011
Operating profit (loss)	509,200	51,246
Non-operating income		
Interest income	22	142
Foreign exchange gains	17,010	2,992
Total non-operating income	17,032	3,135
Non-operating expenses		
Commission expenses	47,319	5,712
Share issuance costs	298	343
Total non-operating expenses	47,617	6,055
Ordinary profit	478,616	48,326
Extraordinary income		
Gain on reversal of share acquisition rights	–	2,496
Total extraordinary income	–	2,496
Profit before income taxes	478,616	50,823
Income taxes - current	76,119	3,547
Income taxes - deferred	239,325	42,820
Total income taxes	315,444	46,367
Profit	163,171	4,455
Profit attributable to non-controlling interests	–	–
Profit attributable to owners of parent	163,171	4,455

Quarterly consolidated statement of comprehensive income for the first three months of FY 2023

(Unit: thousands of yen)

	Q1 FY 2022 (from January 1, 2022 to March 31, 2022)	Q1 FY 2023 (from January 1, 2023 to March 31, 2023)
Profit	163,171	4,455
Accumulated other comprehensive income		
Foreign currency translation adjustment	239	75
Total other comprehensive income	239	75
Comprehensive income	163,410	4,531
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	163,410	4,531
Comprehensive income attributable to non-controlling interests	–	–

(3) Notes to quarterly consolidated financial statements

(Notes to going concern assumptions)

None to be reported.

(Notes in case of significant changes to shareholders' equity)

In the first three months of FY 2023, the Company issued new shares due to the exercise of some of share acquisition rights pertaining to the 44th, 49th, 52nd, and 53rd warrants. As a result, share capital and capital surplus each increased by 20,419 thousand yen. The total value of treasury shares increased 315 thousand yen as a result of share repurchases.

As a result, as of March 31, 2023, consolidated share capital was 17,568,878 thousand yen, capital surplus was 17,543,776 thousand yen, and the total value of treasury shares was 88,470 thousand yen.

(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 three months 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.

(Significant subsequent events)

1. Issuance of the 59th warrant (stock options)

On April 14, 2023, the Company issued and granted share acquisition rights in the form of stock options to four directors (excluding directors who are Audit & Supervisory Committee Members) as indicated below. This issuance of share acquisition rights was pursuant to a resolution approved by the Board of Directors on March 23, 2023.

Number of share acquisition rights	3,160 units
Class and number of shares to be issued upon the exercise of share acquisition rights	79,000 common shares
Issue price of share acquisition rights and total issue amount	Issue price: 11,000 yen Total issue amount: 34,760,000 yen
Amount to be paid in for share acquisition rights	Amount to be paid in per share: 440 yen As the amount to be paid for the stock acquisition rights is provided to the recipient in lieu of compensation, each recipient is required to waive his or her claim to the corresponding amount of compensation against the Company.
Exercise price of share acquisition rights	Exercise price per share: 1 yen
Exercise period of share acquisition rights	From March 24, 2026 to March 23, 2033
Conditions for the exercise of share acquisition rights	(1) Individuals to whom these share acquisition rights are granted must hold a position as a director or employee of the Company or with an affiliate to exercise these rights. However, this will not apply to directors at the Company or its affiliates who have left their positions due to expiry of their terms of offices, employees at the Company or its affiliates who have retired as a result of reaching retirement age or directors or employees at the Company or its affiliates who have been deemed to have left their positions or retired amicably by the Board of Directors. (2) Other conditions will be established in the Share Acquisition Rights Allocation Agreement concluded between the Company and the employees.
Increase in share capital in case of the issuance of shares through the exercise of share acquisition rights	Increase in share capital related to the issuance of shares through the exercise of share acquisition rights shall equal to one half of the maximum amount by which share capital can be increased as calculated in accordance with Article 17 of the Ordinance on Company Accounting. Any fraction less than one yen shall be rounded up to the nearest one yen.
Matters regarding transfer of share acquisition rights	Transfers will require approval from the Board of Directors.

2. Issuance of the 60th warrant (stock options)

On April 14, 2023, the Company issued and granted share acquisition rights in the form of stock options to 110 employees as indicated below. This issuance of share acquisition rights was based on a resolution by the Board of Directors on March 23, 2023.

Number of share acquisition rights	10,801 units
Class and number of shares to be issued upon the exercise of share acquisition rights	270,025 common shares
Issue price of share acquisition rights and total issue amount	Issue price: 11,000 yen Total issue amount: 118,811,000 yen
Amount to be paid in for share acquisition rights	Exercise price per share: 440 yen As the amount to be paid for the stock acquisition rights is provided to the recipient in lieu of compensation, each recipient is required to waive his or her claim to the corresponding amount of compensation against the Company.
Exercise price of share acquisition rights	Exercise price per share: 1 yen
Exercise period of share acquisition rights	From March 24, 2026 to March 23, 2033
Conditions for the exercise of share acquisition rights	(1) Individuals to whom these share acquisition rights are granted must hold a position as a director or employee of the Company or with an affiliate to exercise these rights. However, this will not apply to directors at the Company or its affiliates who have left their positions due to expiry of their terms of offices, employees at the Company or its affiliates who have retired as a result of reaching retirement age or directors or employees at the Company or its affiliates who have been deemed to have left their positions or retired amicably by the Board of Directors. (2) Other conditions will be established in the Share Acquisition Rights Allocation Agreement concluded between the Company and the directors.
Increase in share capital in case of the issuance of shares through the exercise of share acquisition rights	Increases in share capital related to the issue of shares through the exercise of share acquisition rights shall be equal to one half of the maximum amount by which share capital can be increased as calculated in accordance with Article 17 of the Ordinance on Company Accounting. Any fraction less than one yen shall be rounded up to the nearest one yen.
Matters regarding transfer of share acquisition rights	Transfers will require approval from the Board of Directors.