SymBio Pharmaceuticals Limited

Summary of Consolidated Financial Statements for the First Six Months of Fiscal Year Ending December 31, 2024 [Japanese GAAP]

August 1 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	Corporate Officer and Chief Financial Officer	Shigetaka Natsukuri	TEL +81-3-5472-1125
Scheduled Date to File Quarterly Report	August 2, 2024	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 Six Months of FY 2024 (January 1, 2024 to June 30, 2024)

(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	%
Q2 FY 2024	1,284	(59.6)	(1,719)	–	(1,481)	–	(1,541)	–
Q2 FY 2023	3,178	(34.8)	(49)	–	66	(95.4)	(79)	–

(Note) Comprehensive income: Q2 FY 2024 (1,528) million yen [－%]
Q2 FY 2023 (80) million yen [– %]

	Earnings per Share	Diluted Earnings per Share
	Yen	Yen
Q21 FY 2024	(34.75)	–
Q2 FY 2023	(2.02)	–

(Note) Diluted earnings per share is not stated due to recording of a net loss per share, despite the potential dilution of shares.

(2) Consolidated Financial Position

	Total Assets	Net Assets	Equity Ratio
	Millions of yen	Millions of yen	%
Q2 FY 2024 (as of June 30, 2024)	7,241	6,447	85.0
FY 2023 (as of December 31, 2023)	8,170	7,209	84.9

(Reference) Shareholders' equity: Q2 FY 2024 (as of June 31, 2024) 6,156 million yen
FY 2023 (as of December 31, 2023) 6,932 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 2023	–	0.00	–	0.00	0.00
FY 2024	–				
FY 2024 (Forecast)		0.00	–	0.00	0.00

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

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

(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	2,623	(53.1)	(3,702)	–	(3,524)	–	(3,628)	–	(84.15)

(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)	Q2 FY 2024	45,908,581 shares	FY 2023	42,278,081 shares
(ii) Total number of treasury shares at the end of the period	Q2 FY 2024	89,484 shares	FY 2023	87,720 shares
(iii) Average number of shares during the period (cumulative)	Q2 FY 2024	44,358,869 shares	Q2FY 2023	39,606,729 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 Appendix.

Appendix

Index

1. Qualitative Information on Quarterly Financial Results

(1) Business results

Progress of business of the Company and subsidiary ("the Group") for the first six months of the fiscal year under review is as follows.

(i) Business results for the period under review

Currently, TREAKISYM® 100mg/4mL ready-to-dilute liquid formulation (TREAKISYM® RTD) is approved for rapid injection (RI) administration. RI shortens the infusion time from 60 to 10 minutes, benefitting both patients and healthcare providers. Compared to freeze-dried formulations, TREAKISYM® RTD eliminates the need for manual reconstitution and significantly reduces preparation time. RI administration has the further benefit of reduced infusion volume (from 250 ml to 50 ml), meaning a lower volume of saline solution is used.

As of the end of June 2024, more than 90% of medical institutions had converted to RI administration.

Regarding sales activities, market share erosion due to generic products is gradually continuing. On the other hand, the negative impact on prescriptions of bendamustine due to concerns about prolonged or severe infection during or after bendamustine treatment has been gradually easing. Reflecting these factors the situation is progressing according to plan against the earnings forecast, net sales were 1,284,426 thousand yen (a reduction of 59.6% year on year).

Selling, general and administrative expenses totaled 2,715,755 thousand yen (up 7.6% year on year). This amount includes research and development expenses of 1,531,833 thousand yen (up 27.2% year on year).

As a result, operating loss was 1,719,487 thousand yen (versus an operating loss of 49,731 thousand yen for the same period in FY 2023) and ordinary loss was 1,481,369 thousand yen (versus an ordinary profit 66,941 thousand yen for the same period in FY 2023). Loss attributable to owners of parent amounted to 1,541,241 thousand yen (versus a loss attributable to owners of parent of 79,850 thousand yen for the same period in FY 2023).

In February 2022, generic bendamustine products from four companies were approved for manufacturing and two of these products started to be sold in Japan within the year. 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, Towa Pharmaceutical Co., Ltd. (head office: Osaka) and Pfizer Japan Inc. (head office: Tokyo), seeking an injunction against the manufacture and sale of the products and compensation for damages arising from the infringement. This proceedings in both cases are ongoing. As of August 2024, other three companies were marketing generic drugs.

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 six months of FY 2024, we conducted the following research and development activities.

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

Post-transplant infectious disease area

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 the treatment of adenovirus infection in immunocompromised patients, such as those who have had hematopoietic stem cell transplantation or organ transplantation. In March 2021, the group submitted an Investigational New Drug (IND) Application to the U.S. Food and Drug Administration (FDA) to initiate a Phase II a clinical trial for the treatment of adenovirus infection and infectious diseases, primarily in pediatric patients (including adults). in immunocompromised patients with adenovirus (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, and subsequent oral presentations were given at other major conferences, including the 2024 U.S. Tandem Meetings in February 2024, and the 50th Annual Meeting of the European Society for Blood and Marrow

Transplantation (EBMT) in April 2024. 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 Phase II a clinical trial in the U.S. for patients with cytomegalovirus infection after hematopoietic stem cell transplantation started in May 2024, with the first patient enrolled in June 2024, and the trial is ongoing.

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. 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.

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 verify the antiviral activity of BCV in a mouse model of polyomavirus infection. In July 2024, the first report of the study's findings was published in the journal mBio with new findings.

Hematology and Oncology

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 poster presented 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 April 2024, the anti-tumor effect of brincidofovir on B-cell lymphoma was presented orally at the AACR Annual Meeting 2024, held in San Diego, California. In addition, a poster presentation on the anti-tumor effect of BCV on peripheral T-cell lymphoma (PTCL) was made at the European Hematology Association (EHA 2024 Hybrid Congress) held in Madrid, Spain, in June 2024

Other Areas

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 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.

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 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.

In March 2024, the group established a subsidiary, SymBio Pharma Ireland Limited (Dublin, Ireland), after which orphan drug designations for the prevention of adenovirus and cytomegalovirus infections in immunocompromised patients were transferred to the subsidiary from Emergent BioSolutions Ltd.

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

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.

(c) 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®).

In April 2024, Onconova Therapeutics and Trawsfynydd Therapeutics, Inc. merged to form Traws Pharma, Inc. (head office: Pennsylvania, U.S.).

(iii) Business outside Japan

In April 2024, the Group appointed John Houghton as CEO and President of SymBio Pharma USA, Inc., 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 our global development plan for IV BCV, further accelerate development in Europe, the U.S., Japan, and the U.K., and develop activities to achieve commercialization.

(iv) Licensing of new drug candidates

As a biopharmaceutical company with profitability and growth potential, the Group will promote the global development of BCV, an antiviral drug introduced in 2019, and will continue to evaluate promising new drug candidates .Through these efforts, the Group aims to create medium-to long-term business value.

(2) Summary of financial position

Total consolidated assets at the end of the second quarter of the current fiscal year stood at 7,241,090 thousand yen. Current assets totaled 7,196,297 thousand yen, mainly consisting of cash and deposits of 6,358,711 thousand yen, accounts receivable of 463,912 thousand yen, and merchandise and finished goods of 87,543 thousand yen. Noncurrent assets totaled 44,793 thousand yen is leasehold and guarantee deposits.

Total liabilities were 793,102 thousand yen. Current liabilities totaled 789,078 thousand yen, mainly consisting of 649,195 thousand yen in accounts payable-other. Non-current liabilities were 4,024 thousand yen, for retirement benefits accounted.

Total net assets totaled 6,447,988 thousand yen. This includes 18,328,911 thousand yen in capital stock, 18,303,783 thousand yen in capital surplus, and 291,484 thousand yen in share acquisition rights.

As a result, the equity ratio was 85.0%.

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

There are no changes to the forecast for the fiscal year ending December 31, 2024 at this time.

2. Quarterly Consolidated Financial Statements and Primary Notes

(1) Quarterly consolidated balance sheet

(Unit: thousands of yen)

	FY 2023 (as of December 31, 2023)	Q2 FY 2024 (as of June 30, 2024)
Assets		
Current assets		
Cash and deposits	6,517,007	6,358,711
Accounts receivable–trade	913,094	463,912
Merchandise and finished goods	231,650	87,543
Prepaid expenses	119,271	147,367
Other	301,504	138,762
Total current assets	8,082,526	7,196,297
Non-current assets		
Investments and other assets		
Leasehold and guarantee deposits	87,716	44,793
Total investments and other assets	87,716	44,793
Total non-current assets	87,716	44,793
Total assets	8,170,243	7,241,090
Liabilities		
Current liabilities		
Accounts payable	853,825	649,195
Income taxes payable	18,474	98,048
Provision for office transfer	16,784	—
Other	67,540	41,835
Total current liabilities	956,625	789,078
Non-current liabilities		
Liabilities for retirement benefits	3,709	4,024
Total non-current liabilities	3,709	4,024
Total liabilities	960,334	793,102

(Unit: thousands of yen)

	FY 2023 (as of December 31, 2023)	Q2 FY 2024 (as of June 30, 2024)
Net assets		
Shareholders' equity		
Share capital	17,952,692	18,328,911
Capital surplus	17,927,584	18,303,783
Retained earnings	(28,852,303)	(30,393,161)
Treasury shares	(89,122)	(89,473)
Total shareholders' equity	6,938,849	6,150,060
Accumulated other comprehensive income		
Foreign currency translation adjustment	(5,985)	6,444
Total accumulated other comprehensive income	(5,985)	6,444
Share acquisition rights	277,044	291,484
Total net assets	7,209,909	6,447,988
Total liabilities and net assets	8,170,243	7,241,090

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

Quarterly consolidated statement of income for the first six months of FY 2024

(Unit: thousands of yen)

	Q2 FY 2023 (from January 1, 2023 to June 30, 2023)	Q2 FY 2024 (from January 1, 2024 to June 30, 2024)
Net sales	3,178,665	1,284,426
Cost of sales	705,552	288,158
Gross profit	2,473,112	996,267
Selling, general and administrative expenses	2,522,844	2,715,755
Operating loss	(49,731)	(1,719,487)
Non-operating income		
Interest income	149	13,420
Foreign exchange gains	130,604	249,132
Other	776	615
Total non-operating income	131,529	263,168
Non-operating expenses		
Commission expenses	7,964	7,410
Share issuance costs	977	17,640
Loss on disposal of fixed assets	5,915	–
Total non-operating expenses	14,857	25,050
Ordinary profit (loss)	66,941	(1,481,369)
Extraordinary income		
Gain on reversal of share acquisition rights	96,891	12,216
Total extraordinary income	96,891	12,216
Extraordinary loss		
Impairment loss	–	56,956
Total extraordinary loss	–	56,956
Profit (loss) before income taxes	163,833	(1,526,109)
Income taxes - current	81,925	15,231
Income taxes - deferred	161,757	–
Total income taxes	243,683	15,231
Loss	(79,850)	(1,541,341)
Loss attributable to non-controlling interests	–	–
Loss attributable to owners of parent	(79,850)	(1,541,341)

Quarterly consolidated statement of comprehensive income for the first six months of FY 2024

(Unit: thousands of yen)

	Q2 FY 2023 (from January 1, 2023 to June 30, 2023)	Q2 FY 2024 (from January 1, 2024 To June 30, 2024)
Loss	(79,850)	(1,541,341)
Accumulated other comprehensive income		
Foreign currency translation adjustment	(1,129)	12,913
Total other comprehensive income	(1,129)	12.913
Comprehensive income	(80,979)	(1,528,427)
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	(80,979)	(1,528,427)
Comprehensive income attributable to non-controlling interests	–	–

(3) Quarterly consolidated statement of cash flows

(Unit: thousands of yen)

	Q2 FY 2023 (from January 1, 2023 to June 30, 2023)	Q2 FY 2024 (from January 1, 2024 to June 30, 2024)
Cash flows from operating activities		
Loss before income taxes	163,833	(1,526,109)
Depreciation	48,389	–
Amortization of guarantee deposits	669	–
Impairment loss	–	56,956
Share-based payment expenses	47,950	50,213
Increase (decrease) in provision for retirement benefits	320	315
Increase (decrease) in provision for product changeover	(16,331)	–
Increase (decrease) in provision for office transfer expenses	–	(16,784)
Interest income	(149)	(13,420)
Foreign exchange losses (gains)	(167,115)	(215,270)
Commission expenses	7,964	7,410
Share issuance costs	977	17,640
Gain on reversal of share acquisition rights	(96,891)	(12,216)
Loss on retirement of non-current assets	5,915	–
Decrease (increase) in trade receivables	990,905	449,181
Decrease (increase) in inventories	28,873	144,106
Decrease (increase) in prepaid expenses	6,656	(50,429)
Increase/decrease in consumption taxes payable/consumption taxes refund receivable	(186,611)	(25,227)
Increase (decrease) in trade payables	(46,633)	-
Increase (decrease) in accounts payable–other	(612,160)	(217,063)
Decrease (increase) in other current assets	(71,937)	151,044
Increase (decrease) in other current liabilities	(32,716)	19,195
Subtotal	71,909	(1,180,456)
Interest and dividends received	149	25,117
Commitment fees paid	(5,712)	(23,953)
Income taxes refund(paid)	(289,481)	44,668
Net cash provided by (used in) operating activities	(223,135)	(1,134,626)
Cash flows from investing activities		
Purchase of property, plant and equipment	–	(8,787)
Purchase of intangible assets	(6,450)	(9,356)
Payments of leasehold and guarantee deposits	(143,898)	-
Proceeds from refund of leasehold and guarantee deposits	–	42.923
Net cash provided by (used in) investing activities	(150,349)	24,778
Cash flows from financing activities		
Proceeds from issuance of shares resulting from exercise of share acquisition rights	236	30
Payments for issuance of shares	(907)	(5,142)
Proceeds from issuance of shares		728,850
Purchase of treasury shares	(638)	(379)
Proceeds from disposal of treasury shares	21	8
Net cash provided by (used in) financing activities	(1,287)	723,367
Effect of exchange rate change on cash and cash equivalents	168,244	228,184
Net increase (decrease) in cash and cash equivalents	(206,527)	(158,295)
Cash and cash equivalents at beginning of period	6,282,554	6,517,007
Cash and cash equivalents at end of period	6,076,026	6,358,711

(4) 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 six months of FY 2024, the Company issued new shares due to the exercise of some of share acquisition rights pertaining to the 41rd, 49rd, 53rd and 55th warrants. As a result, share capital increased by 11,794 thousand yen and capital surplus increased by 11,794 thousand yen. The total value of treasury shares increased 379 thousand yen as a result of share repurchases and decreased by 28 thousand yen as a result of the disposal. In addition, the Company received payment for the third-party allotment of new shares from EVO FUND on February 7, March 18, and April 19,2024, increasing capital stock by 364,425 yen and capital surplus by 364,425 thousand yen.

As a result, as of June 30, 2024, consolidated share capital was 18,328,911 thousand yen, capital surplus was 18,303,783 thousand yen, and the total value of treasury shares was 89,473 thousand yen.

(Significant subsequent events)

None to be reported.