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

August 3, 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	
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Scheduled Date to File Quarterly Report	August 4, 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 June 30, 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	%
Q2 FY 2023	3,178	(34.8)	(49)	–	66	(95.4)	(79)	–
Q2 FY 2022	4,873	–	1,372	–	1,447	–	1,108	–

(Note) Comprehensive income: Q2 FY 2023 (80) million yen [– %]
Q2 FY 2022 1,108 million yen [– %]

	Earnings per Share	Diluted Earnings per Share
	Yen	Yen
Q2 FY 2023	(2.02)	–
Q2 FY 2022	28.71	28.32

(Note) Diluted earnings per share is not stated above 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 2023 (as of June 30, 2023)	9,206	8,378	88.1
FY 2022 (as of December 31, 2022)	10,433	8,506	77.6

(Reference) Shareholders' equity: Q2 FY 2023 (as of June 30, 2023) 8,112 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	6,477	(35.3)	(331)	–	(219)	–	(370)	–	(9.34)

(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 2023	39,840,556 shares	FY 2022	39,603,606 shares
(ii) Total number of treasury shares at the end of the period	Q2 FY 2023	86,594 shares	FY 2022	85,268 shares
(iii) Average number of shares during the period (cumulative)	Q2 FY 2023	39,606,729 shares	Q2 FY 2022	38,592,106 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.

Index of the attachment

1. Qualitative Information on Quarterly Financial Results

(1) Business results

Progress in the Company's business for the first six 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 is used.

Conversion to the RI administration has proceeded smoothly, with nearly 90% of medical institutions switching to RI administration as of the end of June 2023.

Net sales of TREAKISYM® for Q1 totaled 3,178,665 thousand yen (-34.8% 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 2,522,844 thousand yen (-4.4% year on year). This amount includes research and development expenses of 1,203,998 thousand yen (+19.3% year on year).

As a result, operating loss was 49,731 thousand yen (versus an operating profit of 1,372,472 thousand yen for the same period in FY 2022) and ordinary profit was 66,941 thousand yen (versus 1,447,214 thousand yen for the same period in FY 2022). Loss attributable to owners of parent amounted to 79,850 thousand yen (versus a profit attributable to owners of parent of 1,108,091 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, 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.

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 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 potential uses for 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 (intravenous formulation) (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 is prioritizing global development of BCV (primarily in Japan, the U.S., and Europe), targeting disseminated adenovirus (AdV) infections occurring after hematopoietic stem cell transplantation. 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. In May 2023, this study established human POC for BCV. This trial is currently underway, and as of June 30, 2023, 27 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. Furthermore, in June 2023, results of its research collaboration with NCCS on BCV ware presented at the 17th International Conference on Malignant Lymphoma (ICML) in Lugano, Switzerland.

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 BCV in 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 August 2023, the Group appointed Stephane Berthier, PharmD as CEO and President of SymBio Pharma USA, Inc., 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 June 30, 2023, stood at 9,206,561 thousand yen. Current assets totaled 8,151,680 thousand yen, mainly consisting of 6,076,026 thousand yen in cash and deposits, 1,094,009 thousand yen in accounts receivable-trade, and 440,054 thousand yen in merchandise and finished goods. Non-current assets were 1,054,880 thousand yen, mainly consisting of 582,970 thousand yen in deferred tax assets and 179,992 thousand yen in software.

Total liabilities were 828,511 thousand yen. Current liabilities totaled 824,806 thousand yen, mainly consisting of 554,505 thousand yen in accounts payable-other. Non-current liabilities were 3,705 thousand yen, consisting of 3,705 thousand yen in liabilities for retirement benefits.

Total net assets stood at 8,378,049 thousand yen. This includes 17,597,351 thousand yen in capital stock, 17,572,242 thousand yen in capital surplus, and 265,184 thousand yen in share acquisition rights.

As a result, the equity ratio was 88.1%.

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

Although the impact of generic bendamustine products were generally in line with our expectations, delays in treatment of malignant lymphoma continued due to COVID-19, despite the downgrading of the severity of COVID-19 status as an infectious disease. As a result, compared with the previously announced forecast, the forecast of net sales was revised downward by 523 million yen, to 6,477 million yen.

While we are prioritizing R&D investment for our ongoing global development of BCV, we have reviewed expenses and reduced selling, general and administrative expenses to reduce the impact of the decrease in sales, resulting in an operating loss of 331 million yen, an ordinary loss of 219 million yen (compared to 351 million yen in the previously announced forecast due to foreign exchange gains on foreign currency denominated assets). Forecasted net loss attributable to owners of the parent remains 331 million yen, which is unchanged from the previously announced forecast, with the impact of foreign exchange gains set off by an increase in deferred income taxes.

2. Quarterly Consolidated Financial Statements and Primary Notes

(1) Quarterly consolidated balance sheet

(Unit: thousands of yen)

	FY 2022 (as of December 31, 2022)	Q2 FY 2023 (as of June 30, 2023)
Assets		
Current assets		
Cash and deposits	6,282,554	6,076,026
Accounts receivable–trade	2,084,915	1,094,009
Merchandise and finished goods	293,757	440,054
Semi-finished goods	175,170	–
Prepaid expenses	209,886	203,229
Other	266,422	338,360
Total current assets	9,312,706	8,151,680
Non-current assets		
Property, plant and equipment		
Buildings, net	40,670	38,519
Tools, furniture and fixtures, net	28,339	23,269
Total property, plant and equipment	69,009	61,789
Intangible assets		
Software	222,204	179,992
Software in progress	–	2,200
Total intangible assets	222,204	182,192
Investments and other assets		
Deferred tax assets	744,728	582,970
Leasehold and guarantee deposits	84,698	227,927
Total investments and other assets	829,427	810,898
Total non-current assets	1,120,641	1,054,880
Total assets	10,433,347	9,206,561
Liabilities		
Current liabilities		
Accounts payable–trade	46,633	-
Accounts payable–other	1,163,721	554,505
Income taxes payable	401,066	171,955
Provision for product changeover	16,331	–
Other	296,118	98,345
Total current liabilities	1,923,870	824,806
Non-current liabilities		
Liabilities for retirement benefits	3,385	3,705
Total non-current liabilities	3,385	3,705
Total liabilities	1,927,255	828,511

(Unit: thousands of yen)

	FY 2022 (as of December 31, 2022)	Q2 FY 2023 (as of June 30, 2023)
Net assets		
Shareholders' equity		
Share capital	17,548,459	17,597,351
Capital surplus	17,523,357	17,572,242
Retained earnings	(28,889,486)	(26,969,336)
Treasury shares	(88,154)	(88,764)
Total shareholders' equity	8,094,176	8,111,492
Accumulated other comprehensive income		
Foreign currency translation adjustment	243	1,372
Total accumulated other comprehensive income	243	1,372
Share acquisition rights	411,672	265,184
Total net assets	8,506,092	8,378,049
Total liabilities and net assets	10,433,347	9,206,561

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

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

(Unit: thousands of yen)

	Q2 FY 2022 (from January 1, 2022 to June 30, 2022)	Q2 FY 2023 (from January 1, 2023 to June 30, 2023)
Net sales	4,873,695	3,178,665
Cost of sales	863,247	705,552
Gross profit	4,010,448	2,473,112
Selling, general and administrative expenses	2,637,976	2,522,844
Operating profit (loss)	1,372,472	(49,731)
Non-operating income		
Interest income	29	149
Foreign exchange gains	168,142	130,604
Other	–	776
Total non-operating income	168,171	131,529
Non-operating expenses		
Commission expenses	47,590	7,964
Share issuance costs	45,302	977
loss on retirement of fixed assets	536	5,915
Total non-operating expenses	93,429	14,857
Ordinary profit	1,447,214	66,941
Extraordinary income		
Gain on reversal of share acquisition rights	106,401	96,891
Total extraordinary income	106,401	96,891
Profit before income taxes	1,553,615	163,833
Income taxes - current	185,950	81,925
Income taxes - deferred	259,574	161,757
Total income taxes	445,524	243,683
Profit (loss)	1,108,091	(79,850)
Profit attributable to non-controlling interests	–	–
Profit (loss) attributable to owners of parent	1,108,091	(79,850)

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

(Unit: thousands of yen)

	Q2 FY 2022 (from January 1, 2022 to June 30, 2022)	Q2 FY 2023 (from January 1, 2023 to June 30, 2023)
Profit	1,108,091	(79,850)
Accumulated other comprehensive income		
Foreign currency translation adjustment	(61)	(1,129)
Total other comprehensive income	(61)	(1,129)
Comprehensive income	1,108,029	(80,979)
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	1,108,029	(80,979)
Comprehensive income attributable to non-controlling interests	–	–

(3) Quarterly consolidated statement of cash flows

(Unit: thousands of yen)

	Q2 FY 2022 (from January 1, 2022 to June 30, 2022)	Q2 FY 2023 (from January 1, 2023 to June 30, 2023)
Cash flows from operating activities		
Profit before income taxes	1,553,615	163,833
Depreciation	48,380	48,389
Amortization of guarantee deposits	669	669
Share-based payment expenses	49,339	47,950
Increase (decrease) in provision for retirement benefits	192	320
Increase (decrease) in provision for product changeover	(163,107)	(16,331)
Interest income	(29)	(149)
Foreign exchange losses (gains)	(289,630)	(167,115)
Commission expenses	47,590	7,964
Share issuance costs	45,302	977
Gain on reversal of share acquisition rights	(106,401)	(96,891)
Loss on retirement of non-current assets	536	5,915
Decrease (increase) in trade receivables	836,453	990,905
Decrease (increase) in inventories	47,745	28,873
Decrease (increase) in prepaid expenses	(34,705)	6,656
Increase/decrease in consumption taxes payable/consumption taxes refund receivable	(363,569)	(186,611)
Increase (decrease) in trade payables	(53,623)	(46,633)
Increase (decrease) in accounts payable–other	94,171	(612,160)
Decrease (increase) in other current assets	(303,641)	(71,937)
Increase (decrease) in other current liabilities	(113,856)	(32,716)
Other	156,280	–
Subtotal	1,451,712	71,909
Interest and dividends received	29	149
Commitment fees paid	(47,590)	(5,712)
Income taxes paid	(240,360)	(289,481)
Net cash provided by (used in) operating activities	1,163,790	(223,135)
Cash flows from investing activities		
Purchase of property, plant and equipment	(2,034)	–
Purchase of intangible assets	(4,407)	(6,450)
Payments of leasehold and guarantee deposits	–	(143,898)
Proceeds from refund of leasehold and guarantee deposits	432	–
Net cash provided by (used in) investing activities	(6,009)	(150,349)
Cash flows from financing activities		
Proceeds from issuance of shares resulting from exercise of share acquisition rights	103	236
Proceeds from issuance of share acquisition rights	13,760	–
Payments for issuance of shares	(38,193)	(907)
Proceeds from issuance of shares	662,000	–
Purchase of treasury shares	(1,052)	(638)
Proceeds from disposal of treasury shares	81	21
Net cash provided by (used in) financing activities	636,699	(1,287)
Effect of exchange rate change on cash and cash equivalents	137,585	168,244
Net increase (decrease) in cash and cash equivalents	1,932,065	(206,527)
Cash and cash equivalents at beginning of period	3,860,106	6,282,554
Increase in cash and cash equivalents resulting from inclusion of subsidiaries in consolidation	13,637	–
Cash and cash equivalents at end of period	5,805,810	6,076,026

(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 2023, the Company issued new shares due to the exercise of some of share acquisition rights pertaining to the 33rd, 43rd, 48th, 49th, 52nd, and 53rd warrants. As a result, share capital increased by 48,891 thousand yen and capital surplus increased by 48,891 thousand yen. The total value of treasury shares increased 610 thousand yen as a result of share repurchases.

The disposal of treasury shares in response to the request to sell shares by shareholders of less-than-one unit of shares led to a decrease of 28 thousand yen in the total value of treasury shares and a decrease of 6 thousand yen in other capital surplus.

As a result, as of June 30, 2023, consolidated share capital was 17,597,351 thousand yen, capital surplus was 17,572,242 thousand yen, and the total value of treasury shares was 88,764 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)

None to be reported.