

Financial Results for the Third Quarter of Fiscal Year Ending December 31, 2012 [Japan GAAP] (Non-consolidated)

November 9, 2012

Company name:	Symbio Pharmaceuticals Limited	Listing:	Osaka Securities Exchange
Securities code:	4582	URL	http://www.symbiopharma.com/
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Supplementary materials for the financial statements:	No		
Presentation to explain for the financial statements:	No		

(Million yen – rounded down, unless otherwise stated)

1. Business Results for the Third Quarter of Fiscal 2012 (January 1, 2012 to September 30, 2012)

(1) Business results (cumulative) (Percentage figures represent changes from the same quarter of the previous fiscal year)

	Net sales		Operating profit		Ordinary profit		Quarterly net profit	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%
3rd Quarter Fiscal 2012	1,518	16.2	-1,238	—	-1,256	—	-1,259	—
3rd Quarter Fiscal 2011	1,306	—	-1,757	—	-1,766	—	-1,775	—

	Quarterly net profit per share	Diluted quarterly net profit per share
	Yen	Yen
3rd Quarter Fiscal 2012	-65.84	—
3rd Quarter Fiscal 2011	-131.65	—

(Notes) 1. Despite the issuance of stock acquisition rights, information in connection with diluted quarterly net profit per share is not disclosed due to quarterly net loss per share.

2. As the Company started to compile quarterly financial statements in the first quarter of Fiscal 2011, the changes from the same quarter of the previous fiscal year are not disclosed for the second quarter of Fiscal 2011.

(2) Financial position

	Total assets	Net assets	Equity ratio
	Million yen	Million yen	%
3rd Quarter Fiscal 2012	5,645	5,364	94.7
Fiscal 2011	7,256	6,605	91.0

(Reference) Shareholders' equity 3rd Quarter Fiscal 2012 5,346 million yen Fiscal 2011 6,605 million yen

2. Dividends

	Annual dividend per share				
	1st quarter end	2nd quarter end	3rd quarter end	Fiscal year end	Full year
	Yen	Yen	Yen	Yen	Yen
Fiscal 2011	—	0.00	—	0.00	0.00
Fiscal 2012	—	0.00	—		
Fiscal 2012 (forecast)				0.00	0.00

(Note) Revision of forecast of dividends during this quarter: No

3. Forecast of Financial Results for Fiscal 2012 (January 1, 2012 to December 31, 2012)

(Percentage figures represent changes from the previous fiscal year)

	Net sales		Operating profit		Ordinary profit		Net profit		Net profit per share
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
Full year	1,966	4.4	-1,844	—	-1,858	—	-1,862	—	-97.33

(Note) Revision of forecast of financial results during this quarter: Yes

* Explanatory notes

(1) Special accounting treatments for quarterly financial statements: No

(2) Changes in accounting policies and estimates and retrospective corrections

(i) Changes in accounting policies due to revisions of accounting standards: No

(ii) Changes in accounting policies other than those noted in 1.: No

(iii) Changes in accounting estimates: No

(iv) Retrospective corrections: No

(3) Number of issued shares (common shares)

(i) Number of issued shares at the end of period (including treasury shares)	3rd Quarter Fiscal 2012	19,130,900shares	Fiscal 2011	19,130,900shares
(ii) Number of treasury shares at the end of period	3rd Quarter Fiscal 2012	75shares	Fiscal 2011	75shares
(iii) Average number of shares during the period (cumulative quarterly periods)	3rd Quarter Fiscal 2012	19,130,825shares	3rd Quarter Fiscal 2011	13,483,900shares

* Quarterly review procedures

Review procedure for quarterly financial statements is underway based on Financial Instruments and Exchange Act at the timing of this disclosure.

* Information regarding proper use of financial forecast and other important matters

Any forward-looking statements in this material including forecast of financial results are estimates based on information available at the time and certain assumptions that the management believes reasonable. Actual results may differ substantially from such forecasts due to various factors. Please refer to “(3) Forecast of financial results” in “1. Management’s Discussion and Analysis on the Quarterly Financial Results” on page 2 in the attachment to this quarterly business report for the assumptions for forecast of financial results and notes for its proper use.

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1. Management's Discussion and Analysis on the Quarterly Financial Results

(1) Business results analysis

The Company's business progressed during the first six months of Fiscal 2012 as follows:

1. Domestic

In Japan, the Company sells an anticancer drug SyB L-0501 (the generic name: bendamustine hydrochloride, the trade name: TREAKISYM®) through the business partner Eisai Co., Ltd. (hereinafter "Eisai") for the indications of relapsed/refractory indolent non-Hodgkin's lymphoma (NHL) and mantle cell lymphoma (MCL) since December 2010.

Three different series of clinical trials are underway for TREAKISYM® at present for multiple extended indications. The registration of trial cases was completed last year for Phase II clinical trials (collaborative trials in Japan and South Korea) for the indication of relapsed/refractory aggressive non-Hodgkin's lymphoma and we performed analyses and evaluations of data from clinical trials and consulted with the Pharmaceuticals and Medical Devices Agency (hereinafter "the Agency") in April 2012 prior to the application for approval.

However, we received the Agency's comment that the data we had obtained were regarded insufficient for the application for approval at that point in time. We decided to postpone the application for approval originally planned for the current fiscal year respecting the Agency's comment.

In Phase II clinical trials under discussion, we conducted trials in treated patients with relapsed/refractory aggressive non-Hodgkin's lymphoma at a total of 25 facilities in Japan and South Korea for the purpose of assessing the efficacy and safety of SyB L-0501 in combination with rituximab. 63 cases were registered in these trials, of which 59 cases were analyzed. The results showed high efficacy with the overall response rate (ORR) of 62.7% and the complete response (CR) rate of 37.3%. The median progression-free survival (PFS) was 200 days, suggesting the possibility of improving recuperation for patients with relapsed/refractory non-Hodgkin's lymphoma. Side-effects were clinically controllable and the therapy was applicable to elderly patients.

Detailed results of the trials were presented by Dr. Michinori Ogura from Nagoya Daini Red Cross Hospital at the annual meeting of the American Society of Clinical Oncology (ASCO) held in Chicago in June 2012.

Results of the trial were also presented by a few other doctors, including Dr. Kensei Tobinai, from National Cancer Center Central Hospital, at the 74th Annual Meeting of the Japanese Society of Hematology held in October, 2012.

We will decide on the future development plan discussing with the business partner Eisai.

Patient enrollment in the Phase II trial for untreated indolent non-Hodgkin's lymphoma and mantle cell lymphoma, and in the Phase II trial for relapsed/refractory multiple myeloma achieved 66 out of 67 and 16 out of 44 target patients, respectively, as of September 30, 2012.

As for an anticancer drug SyB L-1101 (the intravenous form, the generic name: rigosertib), the application for domestic Phase I clinical trials in Japan was accepted in March 2012 for the indication of relapsed/refractory myelodysplastic syndrome (MDS), a hematologic cancer. The first series of patient enrollment was done in June 2012 and we initiated domestic Phase I clinical trials.

In September, 2012, Onconova Therapeutics, Inc. (hereinafter "Onconova") announced that they have entered into a license agreement with Baxter International Inc. for the European right to rigosertib. With this alignment, we expect commercialization of rigosertib in the US and Europe to accelerate and increase the possibility of NDA approval / launch of rigosertib in our licensed territories, Japan and Korea. where we have the exclusive right to develop and commercialize rigosertib using data generated in the overseas..

Patient enrollment for the Phase II clinical trial of SyB D-0701, a transdermal antiemetic patch indicated for radiotherapy-induced nausea and vomiting (RINV), is ongoing with 181 out of 189 target patients enrolled as of September, 2012 (patient enrollment to be completed in October, 2012).

2. Overseas

The business partner InnoPharmax Inc. (Taiwan) started to sell SyB L-0501 in Taiwan in February 2012. The sales were close to the plan in Singapore and South Korea, where we sell the product through Eisai as in Japan.

3. Business results

As a result of aforementioned developments, net sales totaled 1,518,446 thousand yen (an increase by 16.2% from the same period of the previous fiscal year) in the first nine months of the current fiscal year due to the product sales of SyB L-0501 in Japan and Asian countries.

Selling, general and administrative expenses totaled 1,723,580 thousand yen (an decrease by 20.7% from the same period of the previous fiscal year), which comprised research and development cost of 1,062,048 thousand yen (an decrease by 33.5% from the same period of the previous fiscal year) for clinical trials of SyB L-0501 for multiple indications, clinical trials of SyB D-0701, and preparations for clinical trials of SyB L-1101 as well as selling, general and administrative expenses of 661,531 thousand yen (an increase by 15.0% from the same period of the previous fiscal year).

As a result, we posed operating loss of 1,238,704 thousand yen in the first nine months of the current fiscal year (compared to operating loss of 1,757,759 thousand yen in the same period of the previous fiscal year). Non-operating expenses of 23,600 thousand yen were recorded mainly due to foreign exchange loss, resulting in ordinary loss of 1,256,757 thousand yen and net quarterly loss of 1,259,647 thousand yen (compared to losses of 1,766,967 and 1,775,148 thousand yen in the same period of the previous fiscal year, respectively).

Segment information is not disclosed as our business consists of a single line of business, namely drug research and development, manufacture and sales, and other related activities.

(2) Financial position analysis

Total assets stood at 5,645,325 thousand yen at the end of the third quarter of the current fiscal year, a decrease of 1,610,768 thousand yen from the previous fiscal year end. Current assets stood at 5,569,867 thousand yen, a decrease of 1,608,524 thousand yen from the previous fiscal year end, reflecting a decrease of cash and deposits by 1,689,693 thousand yen due mainly to expenditures for research and development costs and selling, general and administrative expenses, while marketable securities increased by 300,666 thousand yen. Fixed assets decreased to 75,457 thousand yen by 2,244 thousand yen from the previous fiscal year end.

Liabilities stood at 280,676 thousand yen, a decrease of 369,853 thousand yen from the previous fiscal year end, reflecting a decrease of account payables of 289,652 thousand yen mainly due to the purchase of TREAKISYM®.

Net assets stood at 5,364,648 thousand yen, a decrease of 1,240,915 thousand yen from the previous fiscal year end due to quarterly net loss of 1,259,647 thousand yen. This results in a increase of capital-to-asset ratio by 3.7 percentage points from the previous fiscal year end to 94.7%.

(3) Forecast of financial results

The sales forecast for FY2012 is expected to be 1,966 million yen, 372 million yen lower than budget. For SyB D-0701, our antiemetic patch, data analysis will not be completed until the first half of next year. due to the time required for completion of patient registration, Thus, there is no possibility of out-licensing product rights for SyB D-0701 this year, decreasing the sales forecast with no upfront revenue on contracts for SyB D-0701 and fluctuation in the number of vials per delivery for TREAKISYM®, our oncology product being marketed in Japan.

While the reduction in SG&A costs have exceeded expectations with the use of cost-saving measures, we expect to register 1,862 million yen as net loss due to lower sales.

*Any forward-looking statements in this material, including the forecast of financial results, are estimates based on information available at the time and certain assumptions that the management believes to be reasonable. Actual results may differ substantially from such forecasts due to various factors.

2. Other Summary Information (Explanatory Notes)

(1) Additional information

(Application of Accounting Standard for Accounting Changes and Error Corrections and its Implementation Guidance) “Accounting Standard for Accounting Changes and Error Correction” (ASBJ Statement No. 24, December 4, 2009) and “Implementation Guidance on Accounting Standard for Accounting Changes and Error Corrections” (ASBJ Guidance No. 24, December 4, 2009) are applied to any accounting changes and error corrections for prior reporting periods that are made after the beginning of the first quarter of Fiscal 2012.

3. Quarterly Financial Statements

(1) Quarterly balance sheet

(Unit: Thousand yen)

	Fiscal 2011 (December 31, 2011)	3rd Quarter Fiscal 2012 (September 30, 2012)
Assets		
Current assets		
Cash and deposits	4,558,714	2,869,020
Accounts receivable	162,409	156,881
Marketable securities	1,952,533	2,253,200
Merchandise and finished goods	207,467	—
Prepaid expenses	79,038	121,417
Advances	124,589	131,921
Other	93,638	37,425
Total current assets	7,178,392	5,569,867
Fixed assets		
Tangible fixed assets		
Building (net)	2,468	2,684
Fixtures and equipment (net)	14,938	12,459
Total tangible fixed assets	17,407	15,144
Intangible fixed assets		
Software	9,541	8,930
Lease assets	3,189	2,702
Total intangible fixed assets	12,730	11,633
Investments and other assets		
Long-term prepaid expenses	24,300	18,979
Fixed leasehold deposits and security deposits	23,264	29,700
Total investments and other assets	47,564	48,680
Total fixed assets	77,702	75,457
Total assets	7,256,094	5,645,325
Liabilities		
Current liabilities		
Trade accounts payable	308,953	19,300
Other accounts payable	277,898	176,512
Income taxes payable	19,073	8,943
Other	39,821	71,889
Total current liabilities	645,746	276,646
Long-term liabilities		
Allowance for retirement benefits	2,092	1,844
Other	2,691	2,186
Total long-term liabilities	4,783	4,030
Total liabilities	650,529	280,676

(Unit: Thousand yen)

	Fiscal 2011 (December 31, 2011)	3rd Quarter Fiscal 2012 (September 30, 2012)
Net assets		
Shareholders' equity		
Capital stock	6,024,610	6,024,610
Capital surplus	5,994,610	5,994,610
Earned surplus	(5,413,091)	(6,638,323)
Treasury shares	(17)	(17)
Total shareholders' equity	6,606,110	5,346,463
Appraisal and conversion variance, etc.		
Other marketable securities appraisal variance	(546)	12
Total appraisal and conversion variance, etc.	(546)	12
Stock acquisition rights	—	18,172
Total net assets	6,605,564	5,364,648
Total liabilities and net assets	7,256,094	5,645,325

(2) Quarterly income statement
 (Nine months ended September 30)

(Unit: Thousand yen)

	First nine months of Fiscal 2011 (From January 1, 2011 to September 30, 2011)	First nine months of Fiscal 2012 (From January 1, 2012 to September 30, 2012)
Net sales	1,306,894	1,518,446
Cost of sales	891,549	1,033,570
Gross profit	415,345	484,875
Selling, general and administrative expenses	2,173,104	1,723,584
Operating (loss)	(1,757,759)	(1,238,704)
Non-operating income		
Interest income	693	1,275
Interest on securities	1,864	2,347
Refunded consumption tax	—	654
Dividends income of insurance	1,044	1,122
Income from subvention	51,891	—
Other	21	147
Total non-operating income	55,514	5,547
Non-operating expenses		
Interest expense	664	128
Fees	16,828	8,107
New share issuance expense	7,000	—
Foreign exchange loss	18,155	15,045
IPO preparation costs	22,074	—
Other	—	320
Total non-operating expenses	64,723	23,600
Ordinary (loss)	(1,766,967)	(1,256,757)
Extraordinary loss		
Loss on disposal of fixed assets	—	39
Impact of application of accounting standard for asset retirement obligations	5,331	—
Total extraordinary loss	5,331	39
Quarterly (loss) before tax	(1,772,298)	(1,256,797)
Corporate tax, local inhabitant tax, and local enterprise tax	2,850	2,850
Total income tax	2,850	2,850
Quarterly net (loss)	(1,775,148)	(1,259,647)

(3) Explanatory note regarding the assumption of the Company as going concern

None to be reported.

(4) Explanatory note regarding significant fluctuation in the shareholders' equity

None to be reported.

(5) Important subsequent events

None to be reported.