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July 12, 2024

Non-consolidated Financial Results for the Three Months Ended May 31, 2024 [Japanese GAAP]

Company name: TMS Co., Ltd.
Listing: Tokyo Stock Exchange
Securities code: 4891
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Scheduled date to file quarterly securities report: July 12, 2024
Scheduled date to commence dividend payments: –
Preparation of supplementary material on quarterly financial results: None
Holding of quarterly financial results briefing: None

(Yen amounts are rounded down to millions, unless otherwise noted.)

1. Non-consolidated financial results for the three months ended May 31, 2024 (from March 1, 2024 to May 31, 2024)

(1) Non-consolidated operating results (cumulative)

(Percentages indicate year-on-year changes.)

	Operating revenue		Operating income		Ordinary income		Net income	
Three months ended	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
May 31, 2024	–	–	(223)	–	(223)	–	(247)	–
May 31, 2023	–	–	(151)	–	(148)	–	(148)	–

	Basic earnings per share	Diluted earnings per share
Three months ended	Yen	Yen
May 31, 2024	(6.15)	–
May 31, 2023	(4.07)	–

Notes: 1. The Company began disclosing the non-consolidated financial results for the first three months of the fiscal year starting from the fiscal year ended February 29, 2024. Therefore, the year-on-year changes for the three months ended May 31, 2023 are not shown.
2. Diluted earnings per share is not stated because, although potential shares existed, a basic loss per share was recorded.

(2) Non-consolidated financial position

	Total assets	Net assets	Equity-to-asset ratio
As of	Millions of yen	Millions of yen	%
May 31, 2024	3,326	3,213	96.1
February 29, 2024	3,554	3,457	96.9

Reference: Equity
As of May 31, 2024 ¥3,197 million
As of February 29, 2024 ¥3,445 million

2. Cash dividends

	Annual dividends per share				
	First quarter-end	Second quarter-end	Third quarter-end	Fiscal year-end	Total
	Yen	Yen	Yen	Yen	Yen
Fiscal year ended February 29, 2024	–	0.00	–	0.00	0.00
Fiscal year ending February 28, 2025	–				
Fiscal year ending February 28, 2025 (Forecast)		0.00	–	0.00	0.00

Note: Revisions to the forecast of cash dividends most recently announced: None

3. Forecast of non-consolidated financial results for the fiscal year ending February 28, 2025 (from March 1, 2024 to February 28, 2025)

The forecast of non-consolidated financial results for the fiscal year ending February 28, 2025 has not been presented as it is difficult to reasonably calculate the forecast for financial results. For details concerning the reasons, business policy, estimated costs, etc. for the fiscal year ending February 28, 2025, please refer to “(3) Explanation of earnings forecasts and other forward-looking statements” under “1. Qualitative information regarding financial results for the three months ended May 31, 2024” on page 4 of the attached material.

*** Notes**

(1) Adoption of accounting treatment specific to the preparation of quarterly financial statements: Yes

Note: For details, please refer to "Adoption of accounting treatment specific to the preparation of quarterly financial statements" under "(3) Notes to quarterly financial statements" of "2. Quarterly financial statements and significant notes thereto" on page 7 of the attached material.

(2) Changes in accounting policies, changes in accounting estimates, and restatement

(i) Changes in accounting policies due to revisions to accounting standards and other regulations: None

(ii) Changes in accounting policies due to other reasons: None

(iii) Changes in accounting estimates: None

(iv) Restatement: None

(3) Number of issued shares (common shares)

(i) Total number of issued shares at the end of the period (including treasury shares)

As of May 31, 2024	40,304,367 shares
As of February 29, 2024	40,304,367 shares

(ii) Number of treasury shares at the end of the period

As of May 31, 2024	10 shares
As of February 29, 2024	10 shares

(iii) Average number of shares outstanding during the period (cumulative from the beginning of the fiscal year)

Three months ended May 31, 2024	40,304,357 shares
Three months ended May 31, 2023	36,574,880 shares

* Quarterly financial results reports are exempt from quarterly review conducted by certified public accountants or an audit corporation.

* Proper use of earnings forecasts, and other special matters

Caution regarding forward-looking statements and others

The forward-looking statements, including earnings forecasts, contained in these materials are based on information currently available to the Company and on certain assumptions deemed to be reasonable. Consequently, any statements herein do not constitute assurances regarding actual results by the Company. Actual financial results may differ significantly from the forecasts for various reasons. For the suppositions that form the assumptions for earnings forecasts and cautions concerning the use thereof, please refer to "(3) Explanation of earnings forecasts and other forward-looking statements" of "1. Qualitative information regarding financial results for the three months ended May 31, 2024" on page 4 of the attached material.

Attached Material

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1. Qualitative information regarding financial results for the three months ended May 31, 2024

(1) Explanation of operating results

In the previous fiscal year, our clinical stage pipeline products increased from one to three. During the first three months of this fiscal year (March 1, 2024 - May 31, 2024), we made steady progress in our pipeline products and made efforts to further expand the pipeline through both internal and external sources.

The following is the summary of each clinical-stage pipeline product.

(i) TMS-007-related activities

TMS-007 (JX10) is a member of the *Stachybotrys microspora* triprenyl phenol (SMTP) compound family, a large family of small molecules derived from fungus *S. microspora*, and has been developed for the treatment of acute cerebral infarction. It has dual mechanisms in restoring blood flow through plasminogen-mediated thrombolysis and anti-inflammatory effects by the inhibition of soluble epoxide hydrolase (sEH). Because of its unique feature of the dual mechanisms of action, TMS-007 is considered to have advantages over other drugs and drug candidates for this indication with limited treatment options despite the life-threatening serious condition.

In the previous placebo-controlled randomized phase 2a clinical trial conducted by the Company in Japan, TMS-007 showed encouraging results. Subjects for the trial were patients who could not be treated with existing drugs (t-PA) which should be administered within 4.5 hours after onset of symptoms but could be treated with TMS-007 within 12 hours after symptom onset (average 9.5 hours in the TMS-007 group). TMS-007 showed an excellent safety profile with no cases of symptomatic intracranial hemorrhage with worsening on the National Institutes of Health Stroke Scale (NIHSS) of four points or more reported (0% in the TMS-007 group vs. 2.6% in the placebo group). As for the efficacy, TMS-007 demonstrated a statistically significant difference in the outcome of the patients measured by the modified Rankin Scale (mRS), a gold standard used for the outcome measure in acute cerebral infarction clinical trials.

Currently, the Company has the exclusive rights to develop and commercialize TMS-007 in Japan and the right to receive milestone payments and royalties from Ji Xing Pharmaceuticals (Hong Kong) Limited (hereinafter, "JIXING") for development and sales worldwide, excluding Japan. During the first quarter, we cooperated with JIXING to prepare the initiation of the next clinical trials.

In addition to activities related to the clinical development, a patent related to the SMTP compounds was granted in Japan in May 2024 for "an agent for treating or preventing cerebral hemorrhage and a method for treating or preventing cerebral hemorrhage using said agent," which was granted in the US in May 2021.

(ii) JX09-related activities

JX09 is an oral, small-molecule aldosterone synthesis inhibitor indicated for the treatment of patients with treatment-resistant or uncontrolled hypertension. As aldosterone synthesis inhibitors for hypertension treatment, it is considered important to selectively inhibit the aldosterone synthase CYP11B2 but not the closely related CYP11B1 (cortisol synthase). Given that JX09 has shown high selectivity to CYP11B2, it is considered to have the potential to be the best-in-class compound.

The Company has been granted the exclusive rights to develop and market JX09 in Japan by JIXING. The phase 1 clinical trial is currently being conducted by JIXING in healthy subjects in Australia. The Company is considering a plan to play a role in future global trials by conducting studies in Japan.

(iii) TMS-008 related activities

TMS-008 is one of the SMTP family compounds that exhibits anti-inflammatory effects by inhibiting sEH with little pro-thrombolytic activity, and is being developed for acute kidney injury and cancer cachexia. TMS-008 has a potential to be indicated for a wide range of inflammatory diseases.

The exclusive worldwide development and marketing rights have been granted by JIXING for certain TMS-008 indications.

During the three months ended May 31, 2024, efforts were made to prepare the initiation of the phase 1 clinical trial in Japan. This study is a first-in-human, dose-escalation trial of TMS-008 to evaluate the

pharmacokinetics, pharmacodynamics, and safety of TMS-008 in healthy adult males. The first administration was completed after the end of this reporting period.

(iv) Pipeline expansion-related activities

During the three months ended May 31, 2024, the Company has made substantial efforts in research and development to expand its pipeline through internal and external initiatives.

With regard to the internal initiatives, the Company continued to search for novel sEH inhibitors by leveraging the Company's knowledge and experience on the enzyme accumulated through development of SMTP compounds. To achieve this goal, the Company has been taking multiple approaches including optimization of AI-generated compounds and screening of a natural compound library. From these activities, promising candidate compounds were discovered, and further characterization of the novel compounds is ongoing. As a part of pipeline expansion, additional indications for which TMS-008 could be developed were investigated.

With regard to the external initiatives, the Company continued to search for and evaluate early-stage programs being developed in academic research institutions and biopharma companies. Two seed-stage products developed at Hokkaido University have been undergoing exclusive evaluation. Following the careful assessments from a number of different perspectives, we entered into a license agreement for one of the programs on July 3, 2024, after the end of the first quarter. Through this agreement, TMS obtained an exclusive worldwide license for a drug candidate (TMS-010) indicated for the treatment of spinal cord injury.

As a result of these activities, operating expenses for the three months ended May 31, 2024 totaled ¥223,250 thousand, which included ¥154,173 thousand in research and development expenses, mainly for TMS-008, and ¥69,077 thousand in other selling, general and administrative expenses.

Based on these results, operating loss was ¥223,250 thousand (compared to operating loss of ¥151,762 thousand in the same period of the previous fiscal year), ordinary loss was ¥223,808 thousand (compared to ordinary loss of ¥148,619 thousand in the same period of the previous fiscal year), and net loss was ¥247,670 thousand (compared to net loss of ¥148,856 thousand in the same period of the previous fiscal year).

As the Company operates a single segment of drug development business, operating results by segment are omitted.

(2) Explanation of financial position

Assets

Total assets as of the end of the first quarter were ¥3,326,260 thousand, a decrease of ¥228,493 thousand from the end of the previous fiscal year.

This was mainly due to a decrease of ¥190,597 thousand in cash and deposits mainly due to payments for operating expenses.

Liabilities

Total liabilities as of the end of the first quarter were ¥113,216 thousand, an increase of ¥15,526 thousand from the end of the previous fiscal year.

This was mainly due to an increase of ¥17,014 thousand in accounts payable - other, including those payable to contractors, in line with an increase in research and development expenses.

Net assets

Net assets as of the end of the first quarter were ¥3,213,044 thousand, a decrease of ¥244,020 thousand from the end of the previous fiscal year.

This was mainly due to a decrease of retained earnings, resulting from the recording of ¥247,670 thousand in net loss.

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

The Company's policy for future outlook is to postpone the disclosure of its earnings forecasts for the time being. It is difficult to carry out earnings forecasts right now, since the Company is presently at a stage of implementing upfront investment to advance research and development without having products brought to market, and its financial results are influenced significantly by milestone revenue and other external events. Once the Company is in the position of being able to forecast stable revenue from royalty and other recurrent revenue, it will disclose its earnings forecasts.

In the fiscal year ending February 28, 2025, the Company will work toward the development of each pipeline product at the clinical stage, adding TMS-007 and JX09, for which we have newly acquired the rights in Japan, to TMS-008, which has been under development for some time. In addition, it will work to expand its pipeline by 1) searching for candidate compounds for sEH inhibitors, leveraging its drug discovery expertise, and 2) introducing early-stage programs from academia, research institutions, and biopharma companies.

In light of this, operating expenses for the fiscal year ending February 28, 2025 are expected to be as follows.

- Research and development expenses are expected to be in the range of ¥750 million to ¥1,100 million.
- Other selling, general and administrative expenses are expected to be in the range of ¥300 million to ¥400 million.

2. Quarterly financial statements and significant notes thereto

(1) Quarterly balance sheet

(Thousands of yen)

	As of February 29, 2024	As of May 31, 2024
Assets		
Current assets		
Cash and deposits	3,446,630	3,256,032
Supplies	–	178
Advance payments to suppliers	32,658	27,433
Prepaid expenses	17,367	24,060
Consumption taxes refund receivable	54,925	15,368
Other	–	15
Total current assets	3,551,581	3,323,088
Non-current assets		
Property, plant and equipment	0	0
Investments and other assets	3,172	3,172
Total non-current assets	3,172	3,172
Total assets	3,554,754	3,326,260
Liabilities		
Current liabilities		
Accounts payable - other	32,853	49,867
Accrued expenses	39,206	42,915
Income taxes payable	14,195	5,844
Provision for bonuses	2,956	12,019
Other	8,478	2,569
Total current liabilities	97,689	113,216
Total liabilities	97,689	113,216
Net assets		
Shareholders' equity		
Share capital	1,506,650	1,506,650
Capital surplus	2,682,793	2,682,793
Retained earnings	(744,106)	(991,777)
Treasury shares	(2)	(2)
Total shareholders' equity	3,445,335	3,197,664
Share acquisition rights	11,729	15,380
Total net assets	3,457,065	3,213,044
Total liabilities and net assets	3,554,754	3,326,260

(2) Quarterly statement of income

(Cumulative)

(Thousands of yen)

	Three months ended May 31, 2023	Three months ended May 31, 2024
Operating revenue	–	–
Operating expenses		
Research and development expenses	76,927	154,173
Other selling, general and administrative expenses	74,834	69,077
Total operating expenses	151,762	223,250
Operating loss	(151,762)	(223,250)
Non-operating income		
Subsidy income	3,202	–
Interest on tax refund	–	27
Miscellaneous income	–	13
Total non-operating income	3,202	40
Non-operating expenses		
Foreign exchange losses	59	598
Total non-operating expenses	59	598
Ordinary loss	(148,619)	(223,808)
Extraordinary losses		
Impairment losses	–	23,624
Total extraordinary losses	–	23,624
Loss before income taxes	(148,619)	(247,433)
Income taxes	237	237
Net loss	(148,856)	(247,670)

(3) Notes to quarterly financial statements

Notes on premise of going concern

Not applicable.

Notes when there are significant changes in amounts of shareholders' equity

Not applicable.

Adoption of accounting treatment specific to the preparation of quarterly financial statements

Calculation of tax expenses

The Company calculates tax expenses by rationally estimating the effective tax rate after applying the tax effect on income before income taxes for the fiscal year including the first quarter of the year ending February 28, 2025, and multiplying income before income taxes by the estimated effective tax rate. However, in cases where the calculation of tax expenses using the estimated effective tax rate yields a result that is considered not to be reasonable to a significant extent, the effective statutory tax rate is used.

Segment information

[Segment information]

I Three months ended May 31, 2023

Segment information is omitted as the Company operates a single segment of drug development business.

II Three months ended May 31, 2024

Segment information is omitted as the Company operates a single segment of drug development business.

Subsequent events

Conclusion of material agreement

On July 3, 2024, the Company entered into an exclusive worldwide license agreement (the "Agreement") with Hokkaido University concerning the intellectual property rights to a drug candidate substance indicated for the treatment of spinal cord injury (the "Drug") owned by the university.

1. Purpose

   Spinal cord injury is a serious condition for which there are still no effective medication, even though it affects approximately 5,000 new patients per year in Japan and 180,000 per year worldwide. Currently, steroid therapy is approved as the standard treatment, but it is difficult to say that sufficient therapeutic effect has been achieved, and the Agreement is concluded to develop a new therapeutic agent.

2. Name of counterparty to the agreement

   Hokkaido University

3. Content of the agreement

   Under the terms of the Agreement, the Company obtains the exclusive right to conduct activities related to the development, production, use, and sale of the Drug in all countries of the world, including Japan.

4. Material impact of the conclusion of the agreement on business activities, etc.

   Under the Agreement, the Company will make an upfront payment and pay annual minimum fees, as well as make milestone payments depending on future development progress and obtainment of approvals, to Hokkaido University. The total amount of such payments can be, at maximum, approximately 30% of the Company's expected research and development expenses for the fiscal year ending February 28, 2025. In addition, if development progresses and the product is launched, the Company may pay royalties to Hokkaido University based on the sales amount.