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January 14, 2025

Non-consolidated Financial Results for the Nine Months Ended November 30, 2024 [Japanese GAAP]

Company name: TMS Co., Ltd.
Listing: Tokyo Stock Exchange
Securities code: 4891
URL: https://www.tms-japan.co.jp/
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Scheduled date to commence dividend payments: –
Preparation of supplementary material on financial results: None
Holding of financial results briefing: None

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

1. Non-consolidated financial results for the nine months ended November 30, 2024 (from March 1, 2024 to November 30, 2024)

(1) Non-consolidated operating results (cumulative)

(Percentages indicate year-on-year changes.)

	Operating revenue		Operating income		Ordinary income		Net income	
Nine months ended	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
November 30, 2024	–	–	(656)	–	(655)	–	(682)	–
November 30, 2023	–	–	(566)	–	(563)	–	(564)	–

	Basic earnings per share	Diluted earnings per share
Nine months ended	Yen	Yen
November 30, 2024	(16.93)	–
November 30, 2023	(15.42)	–

Note: 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	%
November 30,2024	2,916	2,788	95.0
February 29, 2024	3,554	3,457	96.9

Reference: Equity
As of November 30, 2024 ¥2,769 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	–	0.00	–		
Fiscal year ending February 28, 2025 (Forecast)				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 nine months ended November 30, 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 8 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 November 30, 2024	40,330,067 shares
As of February 29, 2024	40,304,367 shares

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

As of November 30, 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)

Nine months ended November 30, 2024	40,314,547 shares
Nine months ended November 30, 2023	36,587,203 shares

* Review of the Japanese-language originals of the attached quarterly financial statements by certified public accountants or an audit corporation: None

* 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 nine months ended November 30, 2024" on page 4 of the attached material.

Attached Material

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1. Qualitative information regarding financial results for the nine months ended November 30, 2024

(1) Explanation of operating results

In fiscal year 2023, our clinical stage pipeline products increased from one to three. During the first nine months of this fiscal year (March 1, 2024 - November 30, 2024), we made steady progress advancing our pipeline products. As a result of our efforts to further expand the pipeline through both internal and external sources, we successfully added one new preclinical stage asset. Additionally, we are making progress in the TMS-008 program and have completed administration to all participants in the Phase 1 clinical trial in December 2024.

The following is a summary of each pipeline product:

(i) TMS-007 (JX10)-related activities

TMS-007, a small-molecule compound targeting acute ischemic stroke, was solely developed by the Company up to the Phase 2a clinical trial. It was subsequently out-licensed along with other SMTP compound families. Currently, preparations for the next phase of clinical trials are being led primarily by Corxel Pharmaceuticals Hong Kong Limited (hereinafter "CORXEL," formerly Ji Xing Pharmaceuticals Hong Kong Limited*). The Company retains the exclusive rights to develop and commercialize TMS-007 in Japan, along with the rights to receive upfront milestone payments and royalties associated with the development and commercialization of TMS-007 in all regions outside Japan through our agreement with CORXEL.

TMS-007 combines two mechanisms of action: thrombolysis-mediated blood flow restoration through structural modification of plasminogen, and suppression of ischemia-reperfusion injury via anti-inflammatory effects driven by soluble epoxide hydrolase inhibition. This dual mechanism makes TMS-007 a promising drug candidate capable of addressing both therapeutic strategies of blood flow restoration and ischemia-reperfusion injury suppression as a single-agent therapy. As a result, it is considered to have potential advantages over existing drugs such as t-PA and candidate compounds.

TMS-007 has demonstrated a positive outcome in the Phase 2a clinical trial conducted by the Company in Japan in May 2021. The only existing thrombolytic agent currently approved for the treatment of acute stroke, t-PA, is known to increase the risk of bleeding, including intracranial bleeding. Due to the increased risk of bleeding, the use of t-PA is limited (in principle) to 4.5 hours after the onset of symptoms. In contrast, the risk of bleeding associated to TMS-007 is considered to be low, therefore, patients whose symptoms occurred within up to 12 hours were included (average 9.5 hours for the TMS-007 group) in the Phase 2a clinical trial. As a result, the incidence of symptomatic intracranial hemorrhage (sICH) with a worsening of 4 or more points on the National Institutes of Health Stroke Scale (NIHSS) was 2.6% (1/38) in the placebo group, compared to 0% (0/52) in the TMS-007 group, demonstrating the safety profile of TMS-007. Moreover, in terms of the outcome rate, TMS-007 demonstrated a statistically significant improvement in the rate of patients achieving a score of zero (no symptoms at all) or one (symptoms but no obvious disability) on the modified Rankin Scale (mRS), a scale used to assess the degree of independence in everyday life, thus achieving the gold standard endpoint for acute stroke.

During the first nine months of this fiscal year, we have been supporting CORXEL in preparations for the initiation of the next phase of clinical trials. For the upcoming global clinical trial, CORXEL submitted a clinical trial application in China in November 2024. Meanwhile, we are making preparations for clinical trials in Japan. CORXEL is expected to announce progress updates in March 2025.

As for intellectual properties related to SMTP compounds, the Company was granted a patent covering "an agent for treating or preventing cerebral hemorrhage and a method for treating or preventing cerebral hemorrhage using said agent" in Japan in May 2024. In the United States, the patent was granted earlier, in December 2023.

In connection with this, a research paper on the Phase 2a clinical trial of TMS-007 was published in November 2024 in Stroke, a peer-reviewed scientific journal published by the American Heart Association (AHA) and the American Stroke Association (ASA).

* Ji Xing Pharmaceuticals Hong Kong Limited changed its name to Corxel Pharmaceuticals Hong Kong Limited in November 2024.

(ii) JX09-related activities

JX09 is an oral, small-molecule aldosterone synthesis inhibitor intended 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 a best-in-class compound.

The Company has been granted the exclusive rights to develop and market JX09 in Japan from CORXEL. The Phase 1 clinical trial is currently being conducted by CORXEL in Australia. The Company is considering a role in future global trials by conducting clinical studies in Japan.

(iii) TMS-008-related activities

TMS-008, currently under development for the potential treatment of acute kidney injury (AKI) and cancer cachexia, is a compound that belongs to the SMTP family that exhibits anti-inflammatory effects by inhibiting sEH with little pro-thrombolytic activity. TMS-008 has the potential to treat a wide range of inflammatory diseases.

The exclusive worldwide rights for development, manufacturing, and commercialization have been granted by CORXEL for certain TMS-008 indications.

During the first nine months of this fiscal year, we initiated a first-in-human Phase 1 clinical trial, with the first dose administered on June 19, 2024, and completed dosing for all participants in December 2024. Currently, we are conducting analysis and evaluation of pharmacokinetics, pharmacodynamics and safety, and expect to report Phase 1 topline results by the end of May 2025. This trial involved incremental dosing in healthy adult males. Regarding patents for TMS-008, a use patent was granted in the United States in November 2024, following earlier grants in Japan (October 2023) and China (December 2023).

(iv) TMS-010-related activities

TMS-010, targeting spinal cord injury, was added to our pipeline through a license agreement with Hokkaido University on July 3, 2024. This compound had been under evaluation since we entered into an option agreement with the university in July 2022. Under this license agreement, we have obtained exclusive worldwide rights for the development, manufacturing, and commercialization of TMS-010.

Spinal cord injury is a serious disease that can lead to motor paralysis, sensory paralysis, and urinary and defecation disorders, and more importantly there are no effective drugs available to treat this condition. The candidate therapeutic compound discovered by Hokkaido University is expected to have neuroprotective effects by preventing the breakdown of the blood-brain spinal cord barrier (BBSCB), thereby inhibiting secondary damage to the spinal cord.

During the first nine months of this fiscal year, the Company has been working toward initiating clinical trials. This includes conducting necessary non-clinical studies such as GLP tests, developing GMP-grade formulations for Phase 1 trials, and formulating clinical trial plans.

(v) Pipeline expansion-related activities

During the first nine months of this fiscal year, the Company 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 have been 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 identified and is being evaluated. Regarding external initiatives, the Company continued to search and evaluate early-stage programs being developed in academic research institutions and biopharma companies. In addition to TMS-010 mentioned in (iv) above, in depth evaluation of another seed derived from Hokkaido University is being conducted under an exclusive option agreement.

As a result of these activities, operating expenses for the nine months ended November 30, 2024 totaled ¥656,331 thousand, which included ¥447,289 thousand in research and development expenses, mainly development expenses for TMS-008, and ¥209,041 thousand in other selling, general and administrative expenses.

Based on these results, operating loss was ¥656,331 thousand (compared to operating loss of ¥566,505 thousand in the same period of the previous fiscal year), ordinary loss was ¥655,929 thousand (compared to ordinary loss of ¥563,602 thousand in the same period of the previous fiscal year), and net loss was ¥682,646 thousand (compared to net loss of ¥564,315 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 third quarter were ¥2,916,038 thousand, a decrease of ¥638,715 thousand from the end of the previous fiscal year.

This was mainly due to a decrease of ¥643,231 thousand in cash and deposits due to payments for operating expenses.

Liabilities

Total liabilities as of the end of the third quarter were ¥127,622 thousand, an increase of ¥29,932 thousand from the end of the previous fiscal year.

This was mainly due to an increase of ¥41,591 thousand in accrued expenses for contractors and others in line with an increase in clinical trial expenses for TMS-008, etc., while accounts payable - other decreased by ¥12,485 thousand due to payments for expenses accrued in the previous fiscal year.

Net assets

Net assets as of the end of the third quarter were ¥2,788,416 thousand, a decrease of ¥668,648 thousand from the end of the previous fiscal year.

This was mainly due to a decrease of retained earnings, resulting from the recording of ¥682,646 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 November 30, 2024
Assets		
Current assets		
Cash and deposits	3,446,630	2,803,398
Supplies	–	285
Advance payments to suppliers	32,658	60,919
Prepaid expenses	17,367	11,636
Consumption taxes refund receivable	54,925	36,625
Total current assets	3,551,581	2,912,866
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	2,916,038
Liabilities		
Current liabilities		
Accounts payable - other	32,853	20,368
Accrued expenses	39,206	80,797
Income taxes payable	14,195	6,347
Provision for bonuses	2,956	15,080
Other	8,478	5,028
Total current liabilities	97,689	127,622
Total liabilities	97,689	127,622
Net assets		
Shareholders' equity		
Share capital	1,506,650	1,510,203
Capital surplus	2,682,793	2,686,346
Retained earnings	(744,106)	(1,426,753)
Treasury shares	(2)	(2)
Total shareholders' equity	3,445,335	2,769,794
Share acquisition rights	11,729	18,622
Total net assets	3,457,065	2,788,416
Total liabilities and net assets	3,554,754	2,916,038

(2) Quarterly statement of income

(Cumulative)

(Thousands of yen)

	Nine months ended November 30, 2023	Nine months ended November 30, 2024
Operating revenue	–	–
Operating expenses		
Research and development expenses	364,393	447,289
Other selling, general and administrative expenses	202,112	209,041
Total operating expenses	566,505	656,331
Operating loss	(566,505)	(656,331)
Non-operating income		
Subsidy income	3,202	–
Interest on tax refund	42	27
Foreign exchange gains	–	360
Other	83	14
Total non-operating income	3,328	401
Non-operating expenses		
Foreign exchange losses	425	–
Total non-operating expenses	425	–
Ordinary loss	(563,602)	(655,929)
Extraordinary losses		
Impairment losses	–	26,004
Total extraordinary losses	–	26,004
Loss before income taxes	(563,602)	(681,933)
Income taxes	712	712
Net loss	(564,315)	(682,646)

(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.

Notes on 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 third 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.

Notes on quarterly statement of cash flows

The Company has not prepared quarterly statement of cash flows for the nine months ended November 30, 2024. The amounts of depreciation (including amortization of intangible assets) for the nine months ended November 30, 2023 and 2024, are as follows:

(Thousands of yen)

	Nine months ended November 30, 2023	Nine months ended November 30, 2024
Depreciation	4,935	3,564

Notes on segment information

[Segment information]

I Nine months ended November 30, 2023

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

II Nine months ended November 30, 2024

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