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October 15, 2024

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

Company name: TMS Co., Ltd.
Listing: Tokyo Stock Exchange
Securities code: 4891
URL: https://www.tms-japan.co.jp/
Representative: Takuro Wakabayashi, Chief Executive Officer
Inquiries: Go Ito, Chief Financial Officer
Telephone: +81-42-307-7480
Scheduled date to file semi-annual securities report: October 15, 2024
Scheduled date to commence dividend payments: –
Preparation of supplementary material on financial results: Yes
Holding of financial results briefing: Yes (for institutional investors and analysts)

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

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

(1) Non-consolidated operating results (cumulative)

(Percentages indicate year-on-year changes.)

	Operating revenue		Operating income		Ordinary income		Net income	
Six months ended	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
August 31, 2024	–	–	(452)	–	(451)	–	(477)	–
August 31, 2023	–	–	(345)	–	(342)	–	(342)	–

	Basic earnings per share	Diluted earnings per share
Six months ended	Yen	Yen
August 31, 2024	(11.85)	–
August 31, 2023	(9.37)	–

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	%
August 31, 2024	3,087	2,988	96.3
February 29, 2024	3,554	3,457	96.9

Reference: Equity
As of August 31, 2024 ¥2,974 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 six months ended August 31, 2024” on page 5 of the attached material.

*** Notes**

(1) Adoption of accounting treatment specific to the preparation of semi-annual financial statements: Yes

Note: For details, please refer to "Adoption of accounting treatment specific to the preparation of semi-annual financial statements" under "(4) Notes to semi-annual financial statements" of "2. Semi-annual financial statements and significant notes thereto" on page 9 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 August 31, 2024	40,328,867 shares
As of February 29, 2024	40,304,367 shares

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

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

(iii) Average number of shares outstanding during the period (six months ended August 31)

Six months ended August 31, 2024	40,307,046 shares
Six months ended August 31, 2023	36,582,487 shares

* Semi-annual financial results reports are exempt from 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 six months ended August 31, 2024" on page 5 of the attached material.

Attached Material

Index

1. Qualitative information regarding financial results for the six months ended August 31, 2024

(1) Explanation of operating results

In the fiscal year 2023, our clinical stage pipeline products increased from one to three. During the six months ended August 31, 2024 (March 1, 2024 - August 31, 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 have now added one new preclinical stage pipeline.

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

(i) TMS-007-related activities

TMS-007 (JX10), under development for the treatment of acute ischemic stroke, is a drug candidate considered to possess two distinct mechanisms of actions. It restores blood flow rapidly through thrombolysis by altering the structure of plasminogen and, at the same time, reduces ischemia-reperfusion injury and hemorrhagic transformation through anti-inflammatory effects driven by soluble epoxide hydrolase (sEH) inhibition. This makes TMS-007 uniquely positioned as a single-agent therapy that addresses both “blood flow restoration” and “ischemia-reperfusion injury reduction,” giving it potential advantages over current treatments like t-PA and other candidates.

TMS-007 has demonstrated 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.

The results showed that TMS-007 demonstrated a statistically significant improvement compared to the placebo treated group 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 efficacy endpoint for acute stroke.

Furthermore, there were no cases with symptomatic intracranial hemorrhage with worsening on the National Institutes of Health Stroke Scale (NIHSS) 4 or higher in the TMS-007 group (0/52) in contrast to 2.6% (1/38) reported in the placebo group, supporting the safety of TMS-007.

The Company holds 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 worldwide, excluding Japan, from JIXING (Ji Xing Pharmaceuticals (Hong Kong) Limited)*.

During the six months ended August 31, 2024, we have cooperated with JIXING in the preparation to start the next phase clinical trial, which is being conducted primarily by JIXING. We expect JIXING to announce the progress by 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 and in the U.S. in December 2023.

* JIXING will change its name to CORXEL 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. Regarding aldosterone synthesis inhibitors for hypertension treatment, it is 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 from JIXING. The Phase 1 clinical trial is currently being conducted by JIXING in Australia. The Company is considering a role in future global trials by conducting 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 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 development and marketing rights have been granted by JIXING for certain TMS-008 indications.

During the six months ended August 31, 2024, the Company initiated first-in-human Phase 1 clinical trial to evaluate the pharmacokinetics, pharmacodynamics, and safety of TMS-008 in healthy adult male subjects. The first dose was administered in June 2024 and the dosing of Cohort 2 was completed in August. To date, there have been no concerns, and the Phase 1 clinical trial has been progressing smoothly.

(iv) TMS-010-related activities

In July 2024, the Company exercised its option from Hokkaido University, which it entered in July 2022 for the exclusive worldwide license to the discovery related to the treatment of spinal cord injury. Subsequently TMS-010 was added to TMS' pipeline.

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

During the six months ended August 31, 2024, the Company started to synthesize the clinical development plan as well as to develop a GMP manufacturing-level formulation for the non-clinical GLP studies and Phase 1 clinical trial.

(v) Pipeline expansion-related activities

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

Regarding the internal initiatives, the Company continued to search for novel sEH inhibitors by leveraging its 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 drug discovery through generation of compounds using AI 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. In addition to TMS-010 mentioned in (iv) above, in depth evaluation of another seed derived from Hokkaido University was conducted under exclusive option agreement.

As a result of these activities, operating expenses for the six months ended August 31, 2024 totaled ¥452,240 thousand, which included ¥314,515 thousand in research and development expenses, mainly for TMS-008, and ¥137,724 thousand in other selling, general and administrative expenses.

Based on these results, operating loss was ¥452,240 thousand (compared to operating loss of ¥345,107 thousand in the same period of the previous fiscal year), ordinary loss was ¥451,834 thousand (compared to ordinary loss of ¥342,149 thousand in the same period of the previous fiscal year), and net loss was

¥477,820 thousand (compared to net loss of ¥342,624 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

(i) Assets, liabilities and net assets

Assets

Total assets as of August 31, 2024 were ¥3,087,337 thousand, a decrease of ¥467,416 thousand from the end of the previous fiscal year.

This was mainly due to a decrease of ¥437,851 thousand in cash and deposits mainly due to payments for operating expenses.

Liabilities

Total liabilities as of August 31, 2024 were ¥99,069 thousand, an increase of ¥1,380 thousand from the end of the previous fiscal year.

This was mainly due to an increase of ¥18,954 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 ¥17,777 thousand due to payments for expenses accrued in the previous fiscal year.

Net assets

Net assets as of August 31, 2024 were ¥2,988,267 thousand, a decrease of ¥468,797 thousand from the end of the previous fiscal year.

This was mainly due to a decrease of retained earnings, resulting from the recording of ¥477,820 thousand in net loss.

(ii) Cash flows

Cash and cash equivalents (“cash”) as of August 31, 2024 were ¥3,008,779 thousand, a decrease of ¥437,851 thousand from the end of the previous fiscal year. The status of cash flows for the six months ended August 31, 2024 is as follows.

Cash flows from operating activities

Net cash used in operating activities for the six months ended August 31, 2024 totaled ¥409,597 thousand (compared to ¥336,694 thousand used in the same period of the previous fiscal year). This was mainly due to the recording of loss before income taxes.

Cash flows from investing activities

Net cash used in investing activities for the six months ended August 31, 2024 totaled ¥29,172 thousand (compared to ¥1,695 thousand used in the same period of the previous fiscal year). This was due to purchase of property, plant and equipment.

Cash flows from financing activities

Net cash provided by financing activities for the six months ended August 31, 2024 totaled ¥918 thousand (compared to ¥1,997 thousand provided in the same period of the previous fiscal year). This was due to proceeds from issuance of shares resulting from exercise of share acquisition rights.

(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. Semi-annual financial statements and significant notes thereto

(1) Semi-annual balance sheet

(Thousands of yen)

	As of February 29, 2024	As of August 31, 2024
Assets		
Current assets		
Cash and deposits	3,446,630	3,008,779
Supplies	–	104
Advance payments to suppliers	32,658	27,289
Prepaid expenses	17,367	20,316
Consumption taxes refund receivable	54,925	27,675
Total current assets	3,551,581	3,084,164
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	3,087,337
Liabilities		
Current liabilities		
Accounts payable - other	32,853	15,076
Accrued expenses	39,206	58,160
Income taxes payable	14,195	11,706
Provision for bonuses	2,956	3,626
Other	8,478	10,500
Total current liabilities	97,689	99,069
Total liabilities	97,689	99,069
Net assets		
Shareholders' equity		
Share capital	1,506,650	1,510,014
Capital surplus	2,682,793	2,686,157
Retained earnings	(744,106)	(1,221,927)
Treasury shares	(2)	(2)
Total shareholders' equity	3,445,335	2,974,242
Share acquisition rights	11,729	14,025
Total net assets	3,457,065	2,988,267
Total liabilities and net assets	3,554,754	3,087,337

(2) Semi-annual statement of income

(Six months ended August 31)

(Thousands of yen)

	Six months ended August 31, 2023	Six months ended August 31, 2024
Operating revenue	–	–
Operating expenses		
Research and development expenses	213,843	314,515
Other selling, general and administrative expenses	131,264	137,724
Total operating expenses	345,107	452,240
Operating loss	(345,107)	(452,240)
Non-operating income		
Subsidy income	3,202	–
Interest on tax refund	42	27
Foreign exchange gains	–	365
Other	29	13
Total non-operating income	3,274	406
Non-operating expenses		
Foreign exchange losses	316	–
Total non-operating expenses	316	–
Ordinary loss	(342,149)	(451,834)
Extraordinary losses		
Impairment losses	–	25,511
Total extraordinary losses	–	25,511
Loss before income taxes	(342,149)	(477,345)
Income taxes	475	475
Net loss	(342,624)	(477,820)

(3) Semi-annual statement of cash flows

(Thousands of yen)

	Six months ended August 31, 2023	Six months ended August 31, 2024
Cash flows from operating activities		
Loss before income taxes	(342,149)	(477,345)
Depreciation	3,158	3,475
Impairment losses	–	25,511
Increase (decrease) in provision for bonuses	154	670
Share-based payment expenses	2,932	8,104
Subsidy income	(3,202)	–
Decrease (increase) in inventories	(125)	(104)
Decrease (increase) in advance payments to suppliers	(8,122)	5,368
Decrease (increase) in consumption taxes refund receivable	28,500	27,250
Increase (decrease) in accrued expenses	8,890	18,954
Increase (decrease) in accounts payable - other	(14,623)	(17,591)
Increase/decrease in other assets/liabilities	(14,357)	(2,940)
Subtotal	(338,946)	(408,647)
Subsidies received	3,202	–
Income taxes paid	(950)	(950)
Net cash provided by (used in) operating activities	(336,694)	(409,597)
Cash flows from investing activities		
Purchase of property, plant and equipment	(1,695)	(29,172)
Net cash provided by (used in) investing activities	(1,695)	(29,172)
Cash flows from financing activities		
Proceeds from issuance of shares resulting from exercise of share acquisition rights	2,000	918
Other, net	(2)	–
Net cash provided by (used in) financing activities	1,997	918
Net increase (decrease) in cash and cash equivalents	(336,391)	(437,851)
Cash and cash equivalents at beginning of period	3,584,667	3,446,630
Cash and cash equivalents at end of period	3,248,275	3,008,779

(4) Notes to semi-annual 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 semi-annual 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 six months ended August 31, 2024, 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 segment information

[Segment information]

I Six months ended August 31, 2023

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

II Six months ended August 31, 2024

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