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October 13, 2023

Non-consolidated Financial Results for the Six Months Ended August 31, 2023 [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

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Scheduled date to file quarterly securities report: October 13, 2023

Scheduled date to commence dividend payments:

Preparation of supplementary material on quarterly financial results: Yes

Holding of quarterly 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, 2023 (from March 1, 2023 to August 31, 2023)

(1) Non-consolidated operating results (cumulative)

(Percentages indicate year-on-year changes.)

	Operating rev	enue/	Operating in	come	Ordinary inc	come	Net incon	ne
Six months ended	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
August 31, 2023	_	_	(345)	_	(342)	-	(342)	-
August 31, 2022	_	_	(268)	_	(469)	-	(468)	-

	Basic earnings per share	Diluted earnings per share
Six months ended	Yen	Yen
August 31, 2023	(9.37)	_
August 31, 2022	(14.14)	=

- Notes: 1. The Company began disclosing the non-consolidated financial results for the first six months of the fiscal year starting from the fiscal year ended February 28, 2023. Therefore, the year-on-year changes for the six months ended August 31, 2023 are not shown.
 - Diluted earnings per share is not stated because, although potential shares existed for the six months ended August 31, 2022, the Company's shares are unlisted and it is therefore not possible to ascertain an average share price during the period, and also because, although potential shares existed for the six months ended August 31, 2023, 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, 2023	3,437	3,376	98.1
February 28, 2023	3,790	3,714	98.0

Reference: Equity

As of August 31, 2023 ¥3,373 million As of February 28, 2023 ¥3,714 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 28, 2023	_	0.00	_	0.00	0.00
Fiscal year ending February 29, 2024	_	0.00			
Fiscal year ending February 29, 2024 (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 29, 2024 (from March 1, 2023 to February 29, 2024)

The forecast of non-consolidated financial results for the fiscal year ending February 29, 2024 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 29, 2024, 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, 2023" 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 "(4) 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 August 31, 2023	36,594,880 shares
As of February 28, 2023	36,574,880 shares

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

As of August 31, 2023	10 shares
As of February 28, 2023	- shares

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

Six months ended August 31, 2023	36,582,487 shares
Six months ended August 31, 2022	33,102,080 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 six months ended August 31, 2023" on page 4 of the attached material.

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1. Qualitative information regarding financial results for the six months ended August 31, 2023

(1) Explanation of operating results

In the first six months of this fiscal year (March 1, 2023 - August 31, 2023), while normalization of economic activities continued and improvement in private consumption were noted in the Japanese economy, the economic outlook remains unclear due to foreign currency fluctuations due to the prolonged geopolitical instabilities and rising prices of goods accompanying soaring resource and raw materials prices.

Under these circumstances, the Company vigorously conducted the business activities, aiming at developing unique drugs based on unconventional mechanisms and bringing them to the market.

(i) TMS-007-related activities

TMS-007/BIIB131 is a drug candidate for the treatment of acute ischemic stroke which was acquired by Biogen MA Inc. ("Biogen") in May 2021. A Phase 2b clinical trial was planned to be initiated in the first half of 2023. Details of the study were published in the U.S. clinical trial database, ClinicalTrials.gov, on March 10, 2023, in which the estimated study start date was stated as April 17, 2023. On April 25, 2023, Biogen announced in its first quarter 2023 earnings call that it would pause the initiation of the Phase 2b clinical trial of TMS-007/BIIB131 and reassess whether it should initiate the study. In Biogen's second quarter 2023 earnings call on July 25, 2023, the status of TMS-007/BIIB131 remained unchanged, and that is the current status to date. The information in the ClinicalTrials.gov was updated twice, and presently the estimated study start date is indicated to be December 1, 2023. The key information of the study is summarized in the table below. The Company continues to maintain close communication with Biogen and is requesting prompt decision making.

(https://clinicaltrials.gov/ct2/show/NCT05764122)

Official Title	A Multicenter, Operationally Seamless, Double-Blind, Dose-Ranging, Placebo-Controlled, Randomized, Parallel-Group, Phase 2b Study to Evaluate the Efficacy and Safety of Intravenous BIIB131 for Participants With Ischemic Stroke Between 4.5 and 24 Hours After Last Known Well
Estimated Enrollment	760 participants
Estimated Start Date	December 1, 2023 ¹
Estimated Completion Date	July 7, 2025

[Note] 1. The registered information was updated again on July 25, 2023, from April 17, 2023, to December 1, 2023.

(ii) TMS-008-related activities

TMS-008 is a drug candidate for the treatment of acute kidney injury and cancer cachexia. Progress was made in CMC (Chemistry, Manufacturing, and Control) and non-clinical GLP toxicology studies, preparing for a Phase 1 clinical trial. Manufacturing of the drug substance for a clinical trial was completed in the second quarter of this fiscal year. In addition, a consultation meeting with the PMDA (Pharmaceuticals and Medical Devices Agency) was held in June 2023, and selection of the CRO (Contract Research Organization) has started.

With regard to TMS-009, a backup compound of TMS-008, the Company is currently investigating methods for its manufacturing.

(iii) Pipeline expansion

The Company has made substantial efforts to expand its pipeline through internal and external initiatives. With regard to internal initiatives, the Company continued to search for novel soluble Epoxide Hydrolase (sEH) inhibitors, leveraging the Company's knowledge and experience on the enzyme accumulated through development of SMTP compounds (TMS-007 and TMS-008). To achieve this goal, the Company has been taking multiple approaches including optimization of AI-generated compounds and screening of

a natural compound library. With regard to external initiatives, the Company continued to search for and evaluate early-stage programs being developed in academic research institutions and biopharma companies. The Company entered into an option agreement with Hokkaido University on May 8, 2023, to exclusively evaluate and license certain compounds, and evaluation of those compounds has started. With regard to another program pertaining to an option agreement with Hokkaido University in July 2022, the Company completed evaluation and has now entered into a next step discussion with the university.

(iv) Reorganization of research and development structure to enhance activities

Effective on April 1, 2023, Keiji Hasumi, Ph.D., a co-founder of the Company, was assigned as a full-time Chief Scientific Officer, following the retirement from the professor position at Tokyo University of Agriculture and Technology on March 31, 2023. Dr. Hasumi leads the research activities in the Company. He continues to be the Board Member of the Company. Accordingly, the research and development activities of the Company are led by Dr. Hasumi, Chief Scientific Officer and Noriaki Inamura, Ph.D., Executive Vice President, Development, as summarized below.

In addition, in April 2023, a research alliance laboratory with Tokyo University of Agriculture and Technology sponsored by the Company was established in order to strengthen its research and development functions.

Name	Title	New field in charge	Old field in charge	
Keiji Hasumi	Chief Scientific Officer	Research		
Ph.D.	Cinei Scientific Officei	Research	-	
Noriaki Inamura	Executive Vice	Davidonment	Research and	
Ph.D.	President, Development	Development	development	

Based on these results, operating loss was \(\frac{\pmathbb{3}45,107}{\pmathbb{4}}\) thousand (compared to operating loss of \(\frac{\pmathbb{2}268,513}{\pmathbb{4}}\) thousand in the same period of the previous fiscal year), ordinary loss was \(\frac{\pmathbb{3}342,149}{\pmathbb{4}}\) thousand (compared to ordinary loss of \(\frac{\pmathbb{4}469,091}{\pmathbb{4}}\) thousand in the same period of the previous fiscal year), and net loss was \(\frac{\pmathbb{3}342,624}{\pmathbb{4}}\) thousand (compared to net loss of \(\frac{\pmathbb{4}468,070}{\pmathbb{4}}\) 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

<u>Assets</u>

Total assets as of the end of the second quarter were \(\frac{1}{3}\),437,597 thousand, a decrease of \(\frac{1}{3}\)52,617 thousand from the end of the previous fiscal year.

This was mainly due to a decrease of \(\frac{\pmax}{336,391}\) thousand in cash and deposits mainly due to payments for operating expenses.

Liabilities

Total liabilities as of the end of the second quarter were $\$61,\!238$ thousand, a decrease of $\$14,\!922$ thousand from the end of the previous fiscal year.

This was mainly due to a decrease of \(\xi\)14,435 thousand in accounts payable - other due to payments for outsourcing.

Net assets

Net assets as of the end of the second quarter were \(\frac{\pma}{3}\),376,358 thousand, a decrease of \(\frac{\pma}{3}\)37,694 thousand from the end of the previous fiscal year.

This was mainly due to a decrease of retained earnings, resulting from the recording of \(\frac{\pma}{3}\) 42,624 thousand in net loss.

(ii) Cash flows

Cash and cash equivalents ("cash") as of the end of the second quarter were \(\frac{\pma}{3}\),248,275 thousand, a decrease of \(\frac{\pma}{3}\)36,391 thousand from the end of the previous fiscal year. The status of cash flows for the six months ended August 31, 2023 is as follows.

Cash flows from operating activities

Net cash used in operating activities for the six months ended August 31, 2023 totaled \(\frac{2}{3}36,694\) thousand (compared to \(\frac{2}{3}64,367\) 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, 2023 totaled \(\xi_1,695\) thousand (compared to \(\xi_6,835\) 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, 2023 totaled \(\xi\)1,997 thousand (compared to \(\xi\)233,314 thousand used 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 29, 2024, the Company will continue to develop TMS-008. 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 29, 2024 are expected to be as follows.

- Research and development expenses are expected to be in the range of ¥500 million to ¥800 million.
- Other selling, general and administrative expenses are expected to be in the range of ¥350 million to ¥450 million.

2. Quarterly financial statements and significant notes thereto

(1) Quarterly balance sheet

		(Thousands of ye
	As of February 28, 2023	As of August 31, 2023
Assets		
Current assets		
Cash and deposits	3,584,667	3,248,275
Supplies	223	349
Advance payments to suppliers	121,715	129,837
Prepaid expenses	12,970	18,813
Consumption taxes refund receivable	47,033	18,532
Other	36	24
Total current assets	3,766,646	3,415,832
Non-current assets		
Property, plant and equipment	12,142	11,432
Intangible assets	4,112	3,546
Investments and other assets	7,314	6,785
Total non-current assets	23,568	21,764
Total assets	3,790,215	3,437,597
Liabilities		
Current liabilities		
Accounts payable - other	28,690	14,254
Accrued expenses	19,557	28,447
Income taxes payable	19,315	9,662
Provision for bonuses	2,447	2,601
Other	6,151	6,273
Total current liabilities	76,161	61,238
Total liabilities	76,161	61,238
Net assets		
Shareholders' equity		
Share capital	1,160,988	1,161,988
Capital surplus	2,337,131	2,338,131
Retained earnings	215,933	(126,691)
Treasury shares	_	(2)
Total shareholders' equity	3,714,053	3,373,426
Share acquisition rights		2,932
Total net assets	3,714,053	3,376,358
Fotal liabilities and net assets	3,790,215	3,437,597

(2) Quarterly statement of income (Cumulative)

		(Thousands of yen)
	Six months ended August 31, 2022	Six months ended August 31, 2023
Operating revenue	-	-
Operating expenses		
Research and development expenses	151,548	213,843
Other selling, general and administrative expenses	116,964	131,264
Total operating expenses	268,513	345,107
Operating loss	(268,513)	(345,107)
Non-operating income		
Subsidy income	_	3,202
Interest on tax refund	89	42
Other	_	29
Total non-operating income	89	3,274
Non-operating expenses		
Going public expenses	199,943	_
Foreign exchange losses	724	316
Total non-operating expenses	200,667	316
Ordinary loss	(469,091)	(342,149)
Loss before income taxes	(469,091)	(342,149)
Income taxes	(1,020)	475
Net loss	(468,070)	(342,624)

	Six months ended August 31, 2022	Six months ended August 31, 2023
Cash flows from operating activities		
Loss before income taxes	(469,091)	(342,149)
Depreciation	2,401	3,158
Increase (decrease) in provision for bonuses	565	154
Share-based payment expenses	_	2,932
Subsidy income	_	(3,202)
Going public expenses	199,943	=
Decrease (increase) in inventories	(136)	(125)
Decrease (increase) in advance payments to suppliers	(11,995)	(8,122)
Decrease (increase) in consumption taxes refund receivable	68,587	28,500
Increase (decrease) in accrued expenses	1,531	8,890
Increase (decrease) in accounts payable - other	(163,220)	(14,623)
Increase/decrease in other assets/liabilities	7,996	(14,357)
Subtotal	(363,417)	(338,946)
Subsidies received	-	3,202
Income taxes paid	(950)	(950)
Net cash provided by (used in) operating activities	(364,367)	(336,694)
Cash flows from investing activities		
Purchase of property, plant and equipment	(6,835)	(1,695)
Net cash provided by (used in) investing activities	(6,835)	(1,695)
Cash flows from financing activities		· · · · · · · · · · · · · · · · · · ·
Proceeds from issuance of shares resulting from exercise of share acquisition rights	-	2,000
Payment for going public expenses	(233,314)	=
Other, net	_	(2)
Net cash provided by (used in) financing activities	(233,314)	1,997
Net increase (decrease) in cash and cash equivalents	(604,517)	(336,391)
Cash and cash equivalents at beginning of period	2,598,002	3,584,667
Cash and cash equivalents at end of period	1,993,484	3,248,275

(4) 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 second quarter of the year ending February 29, 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.

Segment information

[Segment information]

I Six months ended August 31, 2022

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

II Six months ended August 31, 2023

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