

Consolidated Financial Results for the Three Months Ended March 31, 2025 [Japanese GAAP]



May 8, 2025

Company name: Modalis Therapeutics Corporation
 Stock exchange listing: Tokyo Stock Exchange
 Code number: 4883
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 Scheduled date of filing quarterly securities report: -
 Scheduled date of commencing dividend payments: -
 Preparation of supplementary material on financial results: Yes
 Holding of financial results briefing: Scheduled (for individual investors)

(Amounts of less than one million yen are rounded down.)

1. Consolidated Financial Results for the three Months Ended March 31, 2025 (January 1, 2025, to March 31, 2025)

(1) Consolidated Operating Results (% indicates changes from the previous corresponding period.)

	Operating revenue		Operating income		Ordinary income		Profit attributable to owners of parent	
Three months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
March 31, 2025	-	-	(632)	-	(651)	-	(652)	-
March 31, 2024	-	-	(490)	-	(457)	-	(457)	-

(Note) Comprehensive income: Three months ended March 31, 2025: ¥ (661) million [-%]

Three months ended March 31, 2024: ¥ (458) million [-%]

	Basic earnings per share	Diluted earnings per share
Three months ended	Yen	Yen
March 31, 2025	(9.02)	-
March 31, 2024	(13.57)	-

(Notes)

For diluted earnings per share, the figure is not presented as the company recorded basic loss per share although the company has dilutive shares.

(2) Consolidated Financial Position

	Total assets	Net assets	Capital adequacy ratio
	Million yen	Million yen	%
As of March 31, 2025	3,676	3,312	89.5
As of December 31, 2024	3,691	3,548	95.5

(Reference) Equity: As of March 31, 2025: ¥3,289million

As of December 31, 2024: ¥3,526million

2. Dividends

	Annual dividends				
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Total
	Yen	Yen	Yen	Yen	Yen
Fiscal year ended December 31, 2024	-	0.00	-	0.00	0.00
Fiscal year ending December 31, 2025	-				
Fiscal year ending December 31, 2025 (Forecast)		0.00	-	0.00	0.00

(Note) Revision to the forecast for dividends announced most recently: No

3. Consolidated Financial Results Forecast for the Fiscal Year Ending December 31, 2025(January 1, 2025, to December 31, 2025)

The earnings forecasts for fiscal year 2025 are not presented due to the difficulty of formulating reasonably accurate estimates currently. For further details, please refer to page 3 “Explanation of Consolidated Financial Results Forecast and Other Forward-looking Information.”

* Notes:

- (1) Changes in significant subsidiaries during the three months ended March 31, 2025 (changes in specified subsidiaries resulting in changes in scope of consolidation): No
- (2) Accounting policies adopted specially for the preparation of quarterly consolidated financial statements: No
- (3) Changes in accounting policies, changes in accounting estimates and retrospective restatement
 - 1) Changes in accounting policies due to the revision of accounting standards: Yes
 - 2) Changes in accounting policies other than 1) above: No
 - 3) Changes in accounting estimates: No
 - 4) Retrospective restatement: No
- (4) Total number of issued shares (common shares)
 - 1) Total number of issued shares at the end of the period (including treasury shares):
March 31, 2025: 73,648,998 shares
December 31, 2024: 69,403,998 shares
 - 2) Total number of treasury shares at the end of the period:
March 31, 2025: 63 shares
December 31, 2024: 63 shares
 - 3) Average number of shares during the period:
Three months ended March 31, 2025: 72,326,490 shares
Nine months ended September 30, 2024: 33,742,472shares

* Explanation of the proper use of financial results forecast and other notes

The earnings forecast and other forward-looking statements herein are based on information available and certain assumptions judged to be reasonable as of the date of publication of this document. They do not represent a commitment from the company that they will be achieved. Actual results may differ significantly from these forecast due to a wide range of factors. Please refer to page 3 of the attachment for matters related to the earnings forecast.

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1. Qualitative Information on Quarterly Financial Results for the Period under Review

(1) Explanation of Business Results

Forward-looking statements in the text are based on our judgment as of the end of the first quarter of the current consolidated fiscal year unless otherwise stated.

During the first quarter of the fiscal year under review, the global economy was shaken up by the U.S. economic policies, including tariffs and other measures. As a result, stocks, credits, and exchange rates have all fluctuated significantly, and concerns of a recession have been raised. Ongoing wars and conflicts in various parts of the world have also worsened the outlook for the geopolitical environment. Shaken markets around the world are becoming more cautious, affecting the pharmaceutical and biotech sectors. In addition, the U.S. government's layoffs and policy changes are also affecting the healthcare administration, and the future impact on the healthcare industry, including the approval application business, is uncertain.

Under such circumstances, our group, now in its 10th year since its establishment in 2016, is the world's first company to develop CRISPR-based gene regulation therapies based on the CRISPR-GNDM[®] platform, which serves as the technological foundation, and to this day continues to lead cutting-edge research as a leading company in epigenome-editing therapeutics. We continue to lead cutting-edge research as a leading company in epigenome-editing therapeutics. In order to bring the results of our cutting-edge technology to fruition, we are continuing our efforts to initiate clinical trials during the current fiscal year.

Our lead program, MDL-101 for congenital muscular dystrophy type 1a (LAMA2-CMD), continues to prepare for GLP toxicity testing and GMP investigational drug manufacturing in preparation for clinical trial submission. Partnered with external CROs and CDMOs, and working with external advisors, we try to obtain the necessary investigational drug and preclinical data.

For MDL-201, which aims to treat Duchenne muscular dystrophy, we have completed pilot manufacturing of a new type of MDL-201 and are conducting studies to evaluate and optimize our product candidate. In addition, the results of the evaluation of an animal model of MDL-202 for the treatment of myotonic dystrophy (DM1) were presented at the 2025 Myotonic Dystrophy Foundation (MDF) conference (May 1-3, 2025) and also will be shared at the annual meeting of the American Society for Gene and Cell Therapy (ASGCT) (May 13-17).

In the area of collaborative research, we have agreed to proceed to the next phase of our collaboration with JCR Pharma in the field of central nervous system (CNS) diseases, having achieved initial validation of the technology concept, and have entered into a new collaboration agreement. Access to new technologies is key to success not only in the area of muscle diseases, which is the leading area of our pipeline, but also in the area of CNS, where we are making progress in therapeutic drug development.

On the financing side, as we announced last year, we allocated the 2nd unsecured convertible bond with stock acquisition rights and the 14th and 15th stock acquisition rights to EVO FUND in August 2024 for the purpose of promoting our future business. All of the convertible bonds and the 14th warrant were converted and exercised in October, and the company raised over 3 billion yen, including the 15th warrant, which was initiated in January of this year. This has enabled us to raise the necessary funds for development and business operations, mainly for pre-clinical trials and clinical PoC of MDL-101.

As a result, for the three months ended March 31, 2025, operating loss to ¥632,884 thousand, ordinary loss to ¥651,776 thousand, and loss attributable to owners of parent to ¥652,212 thousand.

The group consists of a single business segment of developing therapeutic agents for genetic disorders. Accordingly, the company omits statements of segment information.

(2) Explanation of Financial Position

Status of Assets, Liabilities and Net Assets

(Current Assets)

Total current assets at the end of the first quarter of the fiscal year under review decreased by ¥10,176 thousand from the end of the previous fiscal year to ¥3,606,903 thousand. This is mainly attributable to a decrease in cash and deposits by ¥15,285 thousand.

(Non-current Assets)

Total non-current assets at the end of the third quarter of the fiscal year under review decreased by ¥4,514 thousand from the end of the previous fiscal year to ¥69,955 thousand. This is mainly attributable to a decrease in investments and other assets by ¥4,514 thousand.

(Current Liabilities)

Total current liabilities at the end of the first quarter of the fiscal year under review increased by ¥225,492 thousand from the end of the previous fiscal year to ¥342,815 thousand. This is mainly attributable to an increase in accounts payable-other by ¥238,346 thousand.

(Non-current Liabilities)

Total non-current liabilities at the end of the first quarter of the fiscal year under review decreased by ¥4,660 thousand from the end of the previous fiscal year to ¥21,487 thousand. This is mainly attributable to a decrease in others by ¥4,118 thousand.

(Net Assets)

Total net assets at the end of the first quarter of the fiscal year under review decreased by ¥235,522 thousand from the end of the previous fiscal year to ¥3,312,555 thousand. This is mainly attributable to a decrease in retained earnings by ¥651,073 thousand thanks to the posting of loss.

(3) Explanation of Consolidated Financial Results Forecast and Other Forward-looking Information

At present, there are many uncertain factors affecting our business performance, including the progress of negotiations with our partners, significant fluctuations in performance due to upfront payments for licensing, the possibility of concluding agreements with new partners, and the acquisition of new pipelines. In regard to the future outlook, the company believes it is difficult to calculate an appropriate and rational figure, so the company has decided not to disclose the full-year earnings forecast. When it becomes possible to make a forecast, the company will promptly make an announcement.

(4) Important Events Related to the Premise of a Going Concern etc.

MODALIS group is a biotech company that conducts research and development of gene therapy drugs. We plan to expand our revenue opportunities and stabilize our business foundation by optimizing our business options by advancing research and development through a “hybrid business model” that combines collaborative model pipelines and in-house model pipelines, but because pharmaceutical/biotech research and development requires a large amount of funding and the recovery of investment funds also takes a relatively long time compared to other industries, we are currently experiencing continuous operating losses and negative operating cash flow, and there are circumstances that raise significant doubt about the company's ability to continue as a going concern.

We will continue to conduct research and development centered on MDL-101 in the 10th fiscal year and beyond, based on the knowledge we have gained from developing gene therapies using CRISPR over the past nine fiscal years. While we are concentrating on starting clinical trials for the MDL-101 program, as part of our efforts to improve the efficiency of our management and organization, we are downsizing the research, development and manufacturing departments of our US subsidiary during 2024, but we have a system in place that will allow us to continue our efforts to bring MDL-101 to clinical trials, and we plan to continue development so that we can provide treatment to patients as soon as possible. In addition, as before,

we will continue partnering negotiations in parallel with development. At the same time, we will continue to optimize our R&D structure and work to reduce costs through increased efficiency, while aiming to acquire partnerships for our subsequent pipeline as early as possible.

In terms of funding, at the end of the first quarter of this fiscal year we had cash and deposits of ¥3,559,992 thousand, and we believe that we have secured sufficient funds to develop our business for the next twelve months through the above initiatives.

Based on the above, we believe that there is no material uncertainty about the going concern assumption.

2. Quarterly Consolidated Financial Statements and Primary Notes

(1) Quarterly Consolidated Balance Sheets

(Thousand yen)

	As of December 31, 2024	As of March 31, 2025
Assets		
Current assets		
Cash and deposits	3,575,277	3,559,992
Supplies	141	133
Other	41,661	46,777
Total current assets	3,617,079	3,606,903
Non-current assets		
Investments and other assets	74,469	69,955
Total non-current assets	74,469	69,955
Total assets	3,691,549	3,676,858
Liabilities		
Current liabilities		
Accounts payable- other	79,338	317,685
Accrued expenses	20,308	18,184
Income taxes payable	16,496	5,253
Other	1,179	1,692
Total current liabilities	117,322	342,815
Non-current liabilities		
Provision for share-based compensation for director	822	739
Provision for share-based compensation for employee	3,624	3,165
Other	21,701	17,583
Total non-current liabilities	26,148	21,487
Total liabilities	143,471	364,303
Net assets		
Shareholders' equity		
Share capital	1,758,987	1,970,588
Capital surplus	3,080,722	3,292,323
Retained earnings	(1,325,620)	(1,976,694)
Treasury shares	(97)	(97)
Total shareholders' equity	3,513,992	3,286,120
Accumulated other comprehensive income		
Foreign currency translation adjustment	12,337	3,539
Total accumulated other comprehensive income	12,337	3,539
Subscription rights to shares	21,748	22,895
Total net assets	3,548,078	3,312,555
Total liabilities and net assets	3,691,549	3,676,858

(2) Quarterly Consolidated Statements of Income and Comprehensive Income

Quarterly Consolidated Statements of Income

Three Months Ended March 31

(Thousand yen)

	For the three months ended March 31, 2024	For the three months ended March 31, 2025
Operating revenue	—	—
Operating expenses		
Research and development expenses	422,604	571,613
Selling, general and administrative expenses	67,482	61,271
Total operating expenses	490,087	632,884
Operating loss	(490,087)	(632,884)
Non-operating income		
Interest income	7	1,295
Foreign exchange income	34,618	—
Other	7	3
Total non-operating income	34,632	1,298
Non-operating expenses		
Interest expense	1,032	815
Foreign exchange loss	—	19,275
Stock issuance cost	957	100
Total non-operating expenses	1,990	20,191
Ordinary loss	(457,445)	(651,776)
Extraordinary loss		
Impairment loss	188	—
Total extraordinary loss	188	—
Loss before income taxes	(457,633)	(651,776)
Income taxes - current	303	435
Total income taxes	303	435
Loss	(457,936)	(652,212)
Loss attributable to owners of parent	(457,936)	(652,212)

Quarterly Consolidated Statements of Comprehensive Income

Three Months Ended March 31

(Thousand yen)

	For the three months ended March 31, 2024	For the three months ended March 31, 2025
Loss	(457,936)	(652,212)
Other comprehensive income		
Foreign currency translation adjustment	(428)	(8,797)
Total other comprehensive income	(428)	(8,797)
Comprehensive income	(458,364)	(661,009)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent	(458,364)	(661,009)

(3) Notes to Quarterly Consolidated Financial Statements

(Notes on going concern assumption)

There is no relevant information.

(Notes in the case of significant changes in shareholders' equity)

During the consolidated cumulative period of the first quarter, the share capital increased by ¥211,600 thousand and the capital surplus increased by ¥211,600 thousand due to the exercise of warrants. As a result, at the three months ended March 31, 2025, the share capital, capital surplus and retained earnings were ¥1,970,588 thousand and ¥3,292,323 thousand.

(Changes in accounting policies)

(Application of "Accounting Standards for Corporate, Resident and Business Taxes", etc.)

We have applied "Accounting Standards for Corporate, Resident and Business Taxes" (Corporate Accounting Standards No. 27, October 28, 2022) etc. from the beginning of this first quarter consolidated accounting period. This has no impact on the quarterly consolidated financial statements.

(Segment information)

The group consists of a single business segment of developing therapeutic agents for genetic disorders. Accordingly, the company omits statements of segment information.

(Notes on the cash flow statements)

We have not prepared a quarterly consolidated cash flow statement for the current first quarter consolidated cumulative period. In addition, depreciation expenses (including amortization expenses for intangible fixed assets) for the first quarter consolidated cumulative period are omitted because they are not applicable.

(Significant subsequent events)

Capital increase through exercise of stock acquisition rights

After the end of the first quarter, from April 1, 2025, to the end of April 2025, there was an exercise of rights for part of the stock acquisition rights, as detailed below.

(1) Type and number of shares issued common stock 1,295,000 shares.

(2) Increased capital ¥48,704 thousand.

(3) Increased capital reserve ¥48,704 thousand.

As a result, as of April 31, 2025, there were 74,943,998 shares of common stock issued, ¥2,019,293 thousand in capital stock, and ¥2,774,293 thousand in capital reserve.