

Consolidated Financial Results for the Nine Months Ended September 30, 2025 [Japanese GAAP]



November 7, 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 Nine Months Ended September 30, 2025 (January 1, 2025, to September 30, 2025)

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

	Operating revenue		Operating income		Ordinary income		Profit attributable to owners of parent	
Nine months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
September 30, 2025	-	-	(1,815)	-	(1,798)	-	(1,801)	-
September 30, 2024	-	-	(1,062)	-	(1,059)	-	(1,060)	-

(Note) Comprehensive income: Nine months ended September 30, 2025: ¥ (1,810) million [-%]

Nine months ended September 30, 2024: ¥ (1,059) million [-%]

	Basic earnings per share	Diluted earnings per share
Nine months ended	Yen	Yen
September 30, 2025	(23.91)	-
September 30, 2024	(27.21)	-

(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 September 30, 2025	3,423	2,693	77.7
As of December 31, 2024	3,691	3,548	95.5

(Reference) Equity: As of September 30, 2025: ¥2,659million

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	-	0.00	-		
Fiscal year ending December 31, 2025 (Forecast)				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 nine months ended September 30, 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):
September 30, 2025: 80,073,798 shares
December 31, 2024: 69,403,998 shares
 - 2) Total number of treasury shares at the end of the period:
September 30, 2025: 63 shares
December 31, 2024: 63 shares
 - 3) Average number of shares during the period:
Nine months ended September 30, 2025: 75,344,139 shares
Nine months ended September 30, 2024: 38,964,683shares

* 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 third quarter of the current consolidated fiscal year unless otherwise stated.

During the first nine months of the current fiscal year, Japan's economy experienced significant volatility, influenced by shifts in U.S. economic policies, including tariff measures, as well as domestic political transitions. While the overall market maintained resilience, capital concentration in the AI and semiconductor sectors became pronounced, forcing other sectors, including biotechnology, into relatively weaker performance. Furthermore, prolonged wars and conflicts in various regions, including Eastern Europe and the Middle East, have heightened geopolitical risks, further increasing uncertainty about the global economic outlook. This environment is also impacting the pharmaceutical and biotech industry, primarily in Japan and the United States, where our company operates. Furthermore, changes in U.S. healthcare policy and temporary government shutdowns stemming from budget issues have impacted pharmaceutical R&D, manufacturing, and sales activities, including regulatory submissions. Consequently, the overall business environment for the industry remains unpredictable.

Amidst this environment, MODALIS entered its 10th fiscal year since its establishment in 2016. Since our founding, leveraging our foundational CRISPR-GNDM® platform technology, we have pursued the development of the world's first CRISPR-based gene control therapeutics. As a leading company in epigenome editing therapeutics, we have spearheaded cutting-edge research. During this fiscal year, we continued our efforts to initiate clinical trials, aiming to translate these advanced technological achievements into clinical applications.

Our lead program, MDL-101, targeting LAMA2-CMD (Congenital Muscular Dystrophy Type 1A), is currently undergoing GLP-tox in non-human primates and GMP manufacturing of the investigational drug product, both critical steps toward submitting a clinical trial application. Our current outlook targets a clinical trial application in mid-2026. To date, no significant events or data affecting the application plan have been identified. Furthermore, we are progressing with the selection and coordination of clinical trial sites, building a framework to initiate trials promptly upon application acceptance.

Furthermore, for MDL-201, a therapeutic candidate for Duchenne muscular dystrophy (DMD), comparative evaluations were conducted against a benchmark drug mimicking an existing approved gene therapy using a disease model mouse. The results confirmed equivalent disease improvement effects in both treadmill tests and EDL (extensor digitorum longus) muscle strength measurements, even at a dose one order of magnitude lower. These results demonstrate that the therapeutic concept of MDL-201 for DMD has been validated in animal models. We also believe they suggest that our technology platform, which has advanced through the development of MDL-101, holds potential efficacy for DMD.

Furthermore, regarding MDL-103 for facioscapulohumeral muscular dystrophy (FSHD), we previously reported receiving grants from both the XPRIZE and the Solve FSHD Foundation in the previous quarter. Subsequently, under a collaborative research agreement, we conducted animal studies and obtained initial promising data. These results demonstrate that our CRISPR-GNDM molecule acts on the Dux4 gene and significantly suppresses the expression of its downstream genes. We believe this represents important foundational data for future development.

Thus, pipelines such as MDL-201 and MDL-103, which share the same technology platform as MDL-101 and target similar muscular dystrophy areas, are progressing in a synergistic manner. This is establishing a foundation where development pipelines beyond the lead program can continuously create value and steadily advance toward clinical development. Furthermore, through multiple external collaborations, including joint

research with JCR Pharma, we are expanding access to new elemental technologies and strengthening our capabilities to consistently deliver optimal therapeutic options to patients using cutting-edge technologies.

As a result, for the Nine months ended September 30, 2025, operating loss to ¥1,815,034, thousand, ordinary loss to ¥1,798,231 thousand, and loss attributable to owners of parent to ¥1,801,774, 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

a. Status of Assets, Liabilities and Net Assets

(Current Assets)

Total current assets at the end of the third quarter of the fiscal year under review decreased by ¥262,853 thousand from the end of the previous fiscal year to ¥3,354,226 thousand. This is mainly attributable to a decrease in cash and deposits by ¥267,365 thousand.

(Non-current Assets)

Total non-current assets at the end of the third quarter of the fiscal year under review decreased by ¥5,640 thousand from the end of the previous fiscal year to ¥68,829 thousand. This is attributable to a decrease in investments and other assets by ¥5,640 thousand.

(Current Liabilities)

Total current liabilities at the end of the third quarter of the fiscal year under review increased by ¥558,456 thousand from the end of the previous fiscal year to ¥675,778 thousand. This is mainly attributable to an increase in current portion of bonds by ¥262,500 thousand and an increase in accounts payable-other by ¥296,974 thousand.

(Non-current Liabilities)

Total non-current liabilities at the end of the third quarter of the fiscal year under review increased by ¥27,501 thousand from the end of the previous fiscal year to ¥53,650 thousand. This is mainly attributable to an increase in others by ¥31,528 thousand.

(Net Assets)

Total net assets at the end of the third quarter of the fiscal year under review decreased by ¥854,451 thousand from the end of the previous fiscal year to ¥2,693,627 thousand. This is mainly attributable to a decrease in retained earnings by ¥360,690 thousand.

(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 pipelines and in-house 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.

Based on the knowledge gained from nine years of developing CRISPR-based gene control therapeutics, we will continue research and development of MDL-101 as well as the other programs such as MDL-201 and MDL-103 in the tenth year and beyond. We have the human resources and partnerships with external organizations necessary to continue our efforts to bring MDL-101 to clinical use, and we plan to advance development with the goal of making it available to patients as soon as possible. We will also continue to pursue partnerships in parallel with development, as we have done in the past. Furthermore, regarding our pipeline, we will aim to secure partnerships at an early stage while continuing to optimize our research and development structure and work to reduce costs through efficiency improvements.

In terms of funding, at the end of the third quarter of this fiscal year we had cash and deposits of ¥3,307,911 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 September 30, 2025
Assets		
Current assets		
Cash and deposits	3,575,277	3,307,911
Supplies	141	—
Other	41,661	46,314
Total current assets	3,617,079	3,354,226
Non-current assets		
Investments and other assets	74,469	68,829
Total non-current assets	74,469	68,829
Total assets	3,691,549	3,423,055
Liabilities		
Current liabilities		
Current portion of bonds	—	262,500
Accounts payable- other	79,338	376,313
Accrued expenses	20,308	28,974
Income taxes payable	16,496	5,102
Other	1,179	2,888
Total current liabilities	117,322	675,778
Non-current liabilities		
Provision for share-based compensation for director	822	—
Provision for share-based compensation for employee	3,624	420
Other	21,701	53,230
Total non-current liabilities	26,148	53,650
Total liabilities	143,471	729,428
Net assets		
Shareholders' equity		
Share capital	1,758,987	1,510,133
Capital surplus	3,080,722	2,831,868
Retained earnings	(1,325,620)	(1,686,311)
Treasury shares	(97)	(97)
Total shareholders' equity	3,513,992	2,655,592
Accumulated other comprehensive income		
Foreign currency translation adjustment	12,337	(3,523)
Total accumulated other comprehensive income	12,337	(3,523)
Subscription rights to shares	21,748	34,511
Total net assets	3,548,078	2,693,627
Total liabilities and net assets	3,691,549	3,423,055

(2) Quarterly Consolidated Statements of Income and Comprehensive Income

Quarterly Consolidated Statements of Income

Nine Months Ended September 30

	(Thousand yen)	
	For the nine months ended September 30, 2024	For the nine months ended September 30, 2025
Operating revenue	—	—
Operating expenses		
Research and development expenses	882,155	1,632,592
Selling, general and administrative expenses	180,241	182,441
Total operating expenses	1,062,397	1,815,034
Operating loss	(1,062,397)	(1,815,034)
Non-operating income		
Interest income	94	3,839
Foreign exchange income	19,628	—
Other	11	49,651
Total non-operating income	19,734	53,491
Non-operating expenses		
Interest expense	2,978	2,182
Bond issuance cost	5,304	7,257
Foreign exchange loss	—	23,979
Stock issuance cost	8,175	3,269
Total non-operating expenses	16,458	36,688
Ordinary loss	(1,059,121)	(1,798,231)
Extraordinary loss		
Impairment loss	188	2,241
Total extraordinary loss	188	2,241
Loss before income taxes	(1,059,309)	(1,800,473)
Income taxes - current	921	1,300
Total income taxes	921	1,300
Loss	(1,060,231)	(1,801,774)
Loss attributable to owners of parent	(1,060,231)	(1,801,774)

Quarterly Consolidated Statements of Comprehensive Income

Nine Months Ended September 30

(Thousand yen)

	For the nine months ended September 30, 2024	For the nine months ended September 30, 2025
Loss	(1,060,231)	(1,801,774)
Other comprehensive income		
Foreign currency translation adjustment	713	(8,897)
Total other comprehensive income	713	(8,897)
Comprehensive income	(1,059,518)	(1,810,671)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent	(1,059,518)	(1,810,671)

(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)

Due to the appropriation of the deficit in retained earnings brought forward as of 15 May 2025, in accordance with the resolution of the 9th Annual General Meeting of Shareholders held on 27 March 2025, capital stock and capital surplus decreased by ¥720,541 thousand and retained earnings increased by ¥1,441,083 thousand, respectively. Additionally, during the current third consolidated accounting period, capital stock and capital surplus increased by ¥470,495 thousand each due to the exercise of stock acquisition rights with a clause to revise the exercise price. Furthermore, the capital stock and capital surplus increased by ¥1,191 thousand each due to the issuance of new shares as post-delivery type stock compensation, in accordance with resolutions passed at respective board meetings on 14 April, 14 May, 13 June and 14 July 2025. As a result, at the nine months ended September 30, 2025, the share capital, capital surplus and retained earnings were ¥1,510,133 thousand and ¥2,831,868 thousand and (¥1,686,311) thousand, respectively.

(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.

(Quarterly consolidated statements of income.)

(Non-operating income)

The Company recorded ¥37,150 thousand as other non-operating income from the prize money won in the FSHD Bonus Prize, which is part of XPRIZE Healthspan, one of the world's largest technology competitions. For details, please refer to the May 13, 2025 press release titled "Notice Regarding Selection as Finalist for FSHD Bonus Prize of XPRIZE Healthspan, the World's Largest Technology Competition, and Winning \$250,000 Prize.

Research and development support payments based on the strategic alliance with SOLVE FSHD for the development of an innovative facioscapulohumeral muscular dystrophy treatment were recorded as other non-operating income in the amount of ¥12,327 thousand. For details, please refer to the "Announcement of Strategic Alliance between SOLVE FSHD and Modaris Inc. for the Development of Innovative Facioscapulohumeral Muscular Dystrophy Therapeutics" dated June 9, 2025.

(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 third quarter consolidated cumulative period. In addition, depreciation expenses (including amortization expenses for intangible fixed assets) for the third 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 third quarter, from October 1, 2025, to the end of October 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 1,740,000 shares.

(2) Increased capital ¥65,389 thousand.

(3) Increased capital reserve ¥65,389 thousand.

As a result, as of October 31, 2025, there were 81,813,798 shares of common stock issued, ¥1,575,522 thousand in capital stock, and ¥2,330,522 thousand in capital reserve.