

Consolidated Financial Results for the Six Months Ended June 30, 2025 [Japanese GAAP]



August 7, 2025

Company name: Modalis Therapeutics Corporation

Stock exchange listing: Tokyo Stock Exchange

Code number: 4883

URL: <https://www.modalistx.com/en/>

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Scheduled date of filing quarterly securities report: Aug 14, 2025

Scheduled date of commencing dividend payments: -

Preparation of supplementary material on financial results: Yes

Holding of financial results briefing: Scheduled (for securities analysts and institutional investors)

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

1. Consolidated Financial Results for the Six Months Ended June 30, 2025 (January 1, 2025, to June 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	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%
Six months ended								
June 30, 2025	-	-	(1,031)	-	(1,019)	-	(1,020)	-
June 30, 2024	-	-	(838)	-	(780)	-	(780)	-

(Note) Comprehensive income: Six months ended June 30, 2025: ¥ (1,031) million [-%]

Six months ended June 30, 2024: ¥ (772) million [-%]

	Basic earnings per share	Diluted earnings per share
	Yen	Yen
Six months ended		
June 30, 2025	(13.78)	-
June 30, 2024	(21.98)	-

(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 June 30, 2025	3,416	3,187	92.5
As of December 31, 2024	3,691	3,548	95.5

(Reference) Equity: As of June 30, 2025: ¥3,160million

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 4“Explanation of Consolidated Financial Results Forecast and Other Forward-looking Information.”

* Notes:

- (1) Changes in significant subsidiaries during the six months ended June 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):
June 30, 2025: 76,928,198 shares
December 31, 2024: 69,403,998 shares
 - 2) Total number of treasury shares at the end of the period:
June 30, 2025: 63 shares
December 31, 2024: 63 shares
 - 3) Average number of shares during the period:
Six months ended June 30, 2025: 74,042,423 shares
Six months ended June 30, 2024: 35,524,843shares

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

During the period under review, the Japanese economy experienced significant disruption due to U.S. policies, including tariffs. Consequently, all markets, including stocks, bonds, and foreign exchange, experienced significant volatility, and concerns about an economic downturn have emerged. Ongoing wars and conflicts in various regions around the world, such as Eastern Europe and the Middle East, are also contributing to a deteriorating geopolitical environment. Major markets affected by these fluctuations have become more cautious, which has also impacted the pharmaceutical and biotechnology sectors that require significant upfront investment. Additionally, changes in the U.S. government's healthcare policies are expected to have a significant impact on the research, development, and manufacturing of pharmaceuticals, including approval application processes, creating uncertainty in the pharmaceutical and biotechnology industries.

Amid such circumstances, our group has successfully completed its 9th fiscal year since its establishment in 2016 and entered 10th. Our company is at the forefront of epigenome editing therapeutics thanks to our CRISPR-GNDM® platform, which serves as our technological foundation. We are proud to have developed the world's first CRISPR-based gene control therapy and to be a leading company in this field. We are committed to the initiation of clinical trials in the current fiscal year to demonstrate the potential of our advanced technology.

MDL-101, our lead program targeting congenital muscular dystrophy type 1a (LAMA2-CMD), has started GLP toxicity study and GMP manufacturing in preparation for a clinical trial application. We have announced our outlook for submitting an IND application at the end of June this year. To that end, we are collaborating with external CROs and CDMOs, as well as external advisors, to obtain the necessary investigational drugs and preclinical data. Additionally, in July, we entered into an agreement to license MYOAAV, a muscle-selective capsid developed by the Broad Institute for this program. We are also advancing efforts to establish the technological and intellectual property foundations necessary for future manufacturing and sales.

MDL-201, a treatment for Duchenne muscular dystrophy (DMD), has shown promising results in a mouse disease model and demonstrated significant functional improvement at doses approximately one-tenth of those of a benchmark gene therapy that is currently on the market. These results support the rationality of MDL-201 as a treatment for DMD. Furthermore, since MDL-201 is based on the same platform as MDL-101, we believe that we can efficiently develop MDL-201 for the large DMD market by leveraging our existing know-how.

Furthermore, MDL-103, which targets facioscapulohumeral muscular dystrophy (FSHD), received research grants from the XPrize Foundation and Solve FSHD Foundation in May and June, respectively. These grants are intended to support research and development of viable FSHD treatments, and we believe that our approach has been thoroughly evaluated by these foundations and the expert groups responsible for their selection.

In addition to MDL-101, which has been steadily developed to date, we believe that the results of MDL-201 and MDL-103, which share the same platform and have the potential to address a larger patient population, represent an opportunity to further enhance our corporate value. Therefore, we have decided to raise additional funds through the issuance of the third unsecured straight bonds and the 17th stock acquisition rights (with an exercise price adjustment clause) to cover development costs for MDL-101 preclinical trials and clinical proof-of-concept (PoC) studies, development costs for MDL-201 and MDL-103, and general corporate expenses.

As a result, for the six months ended June 30, 2025, operating loss to ¥1,031,954, thousand, ordinary loss to

¥1,019,197 thousand, and loss attributable to owners of parent to ¥1,020,456, 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 second quarter of the fiscal year under review decreased by ¥268,119 thousand from the end of the previous fiscal year to ¥3,348,960 thousand. This is mainly attributable to a decrease in cash and deposits by ¥313,604 thousand.

(Non-current Assets)

Total non-current assets at the end of the second quarter of the fiscal year under review decreased by ¥7,107 thousand from the end of the previous fiscal year to ¥67,362 thousand. This is mainly attributable to a decrease in investments and other assets by ¥7,107 thousand.

(Current Liabilities)

Total current liabilities at the end of the second quarter of the fiscal year under review increased by ¥54,564 thousand from the end of the previous fiscal year to ¥171,886 thousand. This is mainly attributable to an increase in accounts payable-other by ¥56,826 thousand.

(Non-current Liabilities)

Total non-current liabilities at the end of the second quarter of the fiscal year under review increased by ¥30,783 thousand from the end of the previous fiscal year to ¥56,932 thousand. This is mainly attributable to an increase in others by ¥34,047 thousand.

(Net Assets)

Total net assets at the end of the second quarter of the fiscal year under review decreased by ¥360,574 thousand from the end of the previous fiscal year to ¥3,187,504 thousand. This is mainly attributable to increased by retained earnings by ¥420,626 thousand.

b. Status of Cash Flow

Cash and cash equivalents (hereinafter referred to as “cash”) at the end of the second quarter of the fiscal year under review amounted to ¥3,261,672 thousand, the decrease by ¥313,604 thousand at the previous fiscal year end. The status of respective cash flows and key factors are as follows.

(Cash Flows from Operating Activities)

Net cash used in operating activities during the six months ended June 30, 2025 amounted to ¥910,281 thousand. This is mainly attributable to the posting of loss before income taxes of ¥1,019,780 thousand.

(Cash Flows from Investing Activities)

Net cash used in investing activities during the six months ended June 30, 2025 amounted to ¥583 thousand. This is mainly attributable to the posting of purchase of property, plant and equipment of ¥583 thousand.

(Cash Flows from Financing Activities)

Net cash provided by financing activities during the six months ended June 30, 2025 amounted to ¥658,323 thousand. This is mainly attributable to the posting of proceeds from issuance of stock acquisition rights of ¥662,623 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 second quarter of this fiscal year we had cash and deposits of ¥3,261,672 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 June 30, 2025
Assets		
Current assets		
Cash and deposits	3,575,277	3,261,672
Supplies	141	—
Accounts receivable- other	—	37,189
Other	41,661	50,098
Total current assets	3,617,079	3,348,960
Non-current assets		
Investments and other assets	74,469	67,362
Total non-current assets	74,469	67,362
Total assets	3,691,549	3,416,323
Liabilities		
Current liabilities		
Accounts payable- other	79,338	72,160
Accrued expenses	20,308	77,134
Income taxes payable	16,496	11,148
Provision for bonuses	—	9,624
Other	1,179	1,819
Total current liabilities	117,322	171,886
Non-current liabilities		
Provision for share-based compensation for director	822	—
Provision for share-based compensation for employee	3,624	1,183
Other	21,701	55,749
Total non-current liabilities	26,148	56,932
Total liabilities	143,471	228,819
Net assets		
Shareholders' equity		
Share capital	1,758,987	1,372,205
Capital surplus	3,080,722	2,693,940
Retained earnings	(1,325,620)	(904,993)
Treasury shares	(97)	(97)
Total shareholders' equity	3,513,992	3,161,054
Accumulated other comprehensive income		
Foreign currency translation adjustment	12,337	(390)
Total accumulated other comprehensive income	12,337	(390)
Subscription rights to shares	21,748	26,840
Total net assets	3,548,078	3,187,504
Total liabilities and net assets	3,691,549	3,416,323

(2) Quarterly Consolidated Statements of Income and Comprehensive Income

Quarterly Consolidated Statements of Income

Six Months Ended June 30

	(Thousand yen)	
	For the six months ended June 30, 2024	For the six months ended June 30, 2025
Operating revenue	—	—
Operating expenses		
Research and development expenses	716,518	906,324
Selling, general and administrative expenses	122,437	125,629
Total operating expenses	838,956	1,031,954
Operating loss	(838,956)	(1,031,954)
Non-operating income		
Interest income	8	1,311
Foreign exchange income	63,032	—
Other	11	49,606
Total non-operating income	63,052	50,917
Non-operating expenses		
Interest expense	2,057	1,524
Foreign exchange loss	—	35,934
Stock issuance cost	2,190	702
Total non-operating expenses	4,248	38,160
Ordinary loss	(780,152)	(1,019,197)
Extraordinary loss		
Impairment loss	188	583
Total extraordinary loss	188	583
Loss before income taxes	(780,340)	(1,019,780)
Income taxes - current	606	675
Total income taxes	606	675
Loss	(780,946)	(1,020,456)
Loss attributable to owners of parent	(780,946)	(1,020,456)

Quarterly Consolidated Statements of Comprehensive Income

Six Months Ended June 30

(Thousand yen)

	For the six months ended June 30, 2024	For the six months ended June 30, 2025
Loss	(780, 946)	(1, 020, 456)
Other comprehensive income		
Foreign currency translation adjustment	8, 801	(12, 728)
Total other comprehensive income	8, 801	(12, 728)
Comprehensive income	(772, 145)	(1, 033, 184)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent	(772, 145)	(1, 033, 184)

(3) Quarterly Consolidated Statements of Cash Flows

(Thousand yen)

	For the six months ended June 30, 2024	For the six months ended June 30, 2025
Cash flows from operating activities		
Loss before income taxes	(780,340)	(1,019,780)
Depreciation	188	583
Impairment loss	(244)	(82)
Increase (decrease) in provision for share-based compensation for director	(1,283)	(520)
Increase (decrease) in provision for bonuses	8,561	9,852
Share-based compensation expenses	(7,795)	7,460
Increase (decrease) in provision for Allowance for business structure improvement	(8)	(1,311)
Interest and dividend income	2,190	702
Stock issuance cost	2,057	1,524
Interest expenses	(56,613)	41,390
Foreign exchange losses (gains)	—	(37,840)
Increase (decrease) in accounts payable - other	(47,435)	(3,568)
Increase (decrease) in accrued expenses	(67,081)	60,355
Decrease (increase) in consumption taxes refund receivable	7,442	5,733
Other, net	12,209	26,383
Subtotal	(928,151)	(909,119)
Interest and dividends received	8	1,311
Interest expenses paid	(2,057)	(1,524)
Income taxes paid	(1,210)	(950)
Net cash provided by (used in) operating activities	(931,410)	(910,281)
Cash flows from investing activities		
Purchase of property, plant and equipment	(188)	(583)
Net cash provided by (used in) investing activities	(188)	(583)
Cash flows from financing activities		
Proceeds from issuance of stock acquisition rights	260,054	662,623
Repayments of installment payables	(3,910)	(4,300)
Net cash provided by (used in) financing activities	256,143	653,323
Effect of exchange rate change on cash and cash equivalents	70,299	(61,062)
Net increase (decrease) in cash and cash equivalents	(605,155)	(313,604)
Cash and cash equivalents at the beginning of period	1,883,437	3,575,277
Cash and cash equivalents at the end of period	1,278,281	3,261,672

(4) 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 yen and retained earnings increased by ¥1,441,083 thousand, respectively. Additionally, during the current interim consolidated accounting period, capital stock and capital surplus increased by ¥332,830 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 ¥929 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 and 14 May 2025. As a result, at the six months ended June 30, 2025, the share capital, capital surplus and retained earnings were ¥1,372,205 thousand and ¥2,693,940 thousand and (¥904,993) thousand, respectively.

(Change in accounting policy)

(Application of "Accounting Standard for Income Taxes, Inhabitant Taxes and Enterprise Taxes", etc.)

The "Accounting Standard for Corporate, Inhabitant and Enterprise Taxes" (ASBJ Statement No. 27, October 28, 2022. Hereinafter referred to as the "Revised 2022 Accounting Standard") The "Accounting Standard for Income Taxes" (ASBJ Statement No. 27, October 28, 2022) and others are applied from the beginning of the current interim consolidated accounting period.

With respect to the revision regarding the classification of income taxes (taxation on other comprehensive income), the transitional treatment stipulated in the proviso of paragraph 20-3 of the Revised Accounting Standard for 2022 and the "Guidance on Accounting Standard for Tax Effect Accounting" (ASBJ Guidance No. 28, October 28, 2022; hereinafter referred to as the "Guidance on the Revised 2022 Accounting Standard") have been applied. The "Guidance on Accounting Standard for Tax Effect Accounting" (ASBJ Guidance No. 28, October 28, 2022; hereinafter referred to as the "2022 Revised Guidance") The transitional treatment prescribed in the proviso of Paragraph 65-2 (2) of the "Guidance on Accounting Standard for Tax Effect Accounting" (ASBJ Guidance No. 28, October 28, 2022) is followed. There is no effect on the interim consolidated financial statements.

With respect to the revision related to the revised treatment in the consolidated financial statements of the deferral for tax purposes of gains or losses arising from the sale of shares of subsidiaries and other securities among consolidated companies, the Company has applied the Revised 2022 Implementation Guidance from the beginning of the interim period under review. The change in accounting policy has been applied retrospectively, and the interim consolidated and consolidated financial statements for the previous interim period and the previous fiscal year have been prepared on a retrospective basis. There is no effect on the consolidated interim financial statements for the previous interim period and consolidated financial statements for the previous fiscal year.

(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 FSHDBonusPrize 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.

(Significant subsequent events)

There is no relevant information.