Consolidated Financial Results for the Nine Months Ended September 30, 2026 [Japanese GAAP]

November 12, 2026

Company name: Modalis Therapeutics Corporation
Stock exchange listing: Tokyo Stock Exchange
Code number: 4883
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Scheduled date of commencing dividend payments: -
Preparation of supplementary material on financial results: Yes
Holding of financial results briefing: No (Financial results briefing video to be released)

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

1. Consolidated Financial Results for the Nine Months Ended September 30, 2026 (January 1, 2026, to September 30, 2026)

(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, 2026	-	-	(1,686)	-	(1,650)	-	(1,608)	-
September 30, 2025	-	-	(1,815)	-	(1,798)	-	(1,801)	-

(Note) Comprehensive income: Nine months ended September 30, 2026: ¥ (1,608) million [-%]
Nine months ended September 30, 2025: ¥ (1,810) million [-%]

	Basic earnings per share	Diluted earnings per share
Nine months ended	Yen	Yen
September 30, 2026	(16.59)	-
September 30, 2025	(23.91)	-

(Notes)
In this summary information, the Company presents the amount recorded as operating revenue in the quarterly consolidated statement of income as net sales.
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, 2026	2,459	2,317	91.9
As of December 31, 2025	2,964	2,793	93.0

(Reference) Equity: As of September 30, 2026: ¥2,260million
As of December 31, 2025: ¥2,755million

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, 2025	-	0.00	-	0.00	0.00
Fiscal year ending December 31, 2026	-	0.00	-		
Fiscal year ending December 31, 2026 (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, 2026 (January 1, 2026, to December 31, 2026)

The earnings forecasts for fiscal year 2026 are not presented due to the difficulty of formulating reasonably accurate estimates currently. For further details, please refer to page 4 of the attached materials, "1. Qualitative Information on Quarterly Financial Results for the Period under Review, (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, 2026 (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: No
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, 2026: 113,634,098 shares
December 31, 2025: 86,674,098 shares

2) Total number of treasury shares at the end of the period:
September 30, 2026: 64 shares
December 31, 2025: 63 shares

3) Average number of shares during the period:
Nine months ended September 30, 2026: 96,927,257 shares
Nine months ended September 30, 2025: 75,344,139 shares

* Review by a certified public accountant or an audit firm of the attached quarterly consolidated financial statements: No

* 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 forecasts due to a wide range of factors. Please refer to page 4 of the attachment for matters related to the earnings forecast.

Table of Contents

1. Qualitative Information on Quarterly Financial Results for the Period under Review 2
(1) Explanation of Business Results 2
(2) Explanation of Financial Position 3
(3) Explanation of Consolidated Financial Results Forecast and Other Forward-looking Information 4
(4) Important Events Related to the Premise of a Going Concern etc. 4
2. Quarterly Consolidated Financial Statements and Primary Notes 5
(1) Quarterly Consolidated Balance Sheets 5
(2) Quarterly Consolidated Statements of Income and Comprehensive Income 6
Quarterly Consolidated Statements of Income 6
Nine Months Ended September 30 6
Quarterly Consolidated Statements of Comprehensive Income 7
Nine Months Ended September 30 7
(3) Notes to Quarterly Consolidated Financial Statements 8
(Notes on going concern assumption) 8
(Notes in the case of significant changes in shareholders' equity) 8
(Notes to Quarterly Consolidated Statements of Income) 8
(Segment information) 8
(Notes on the cash flow statements) 8
(Significant subsequent events) 8

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 three quarters of the fiscal year, the Japanese economy continued to face an uncertain outlook, influenced not only by rising prices and ongoing geopolitical risks but also by the monetary policies and interest rate trends of various countries.

In the biotechnology and pharmaceutical sectors, against the backdrop of rising interest rates—particularly in the United States—the fundraising environment and stock market conditions remained challenging, especially for emerging biotech companies. Meanwhile, in the gene therapy sector, the practical application of innovative treatment modalities is making steady progress—as evidenced by the recent approval of several new gene therapy drugs in the U.S.—and expectations for research, development, and commercialization in this field are once again on the rise. Against this backdrop, the business environment—including healthcare policies and drug pricing systems—continues to evolve, and while growth opportunities are expanding, the business environment for drug discovery companies remains highly uncertain. In this environment, the Company advanced the research and development of gene-regulating therapeutics utilizing its proprietary CRISPR-GNDM® technology and made steady progress in the development of its key development programs and platform technologies.

For MDL-101, key development activities leading up to the IND application have transitioned from the validation and preparation phase to the execution phase.

On the nonclinical front, based on the results of pilot studies using non-human primates conducted through the previous quarter, we have initiated additional GLP toxicity studies. These studies are being conducted with the intention of submitting an IND application using the evaluation results scheduled for December 2026, three months after dosing; the various observational items and test parameters obtained to date are generally progressing as expected. At this time, no events have been identified that would affect the continuation of the study or the IND filing plan, and the study is proceeding according to plan.

In terms of manufacturing and quality (CMC), we began GMP manufacturing of the investigational drug to be used in clinical trials during this quarter, and as of November, actual production has already been completed. As a result, we have secured the yield required for clinical trials and quality testing. We are currently conducting quality verification tests in preparation for the product release in December, and as of now, no significant issues have been identified that would affect the manufacturing schedule or product release plan.

Furthermore, to ensure a smooth start to clinical development following the IND submission, we have identified the medical institution where the clinical trials will be conducted and the principal investigator and are proceeding with detailed preparations for the trials in collaboration with the institution. In addition to the contents of the clinical trial protocol, we have begun coordinating with the medical institution and other relevant parties regarding operations necessary for conducting the trials, such as subject enrollment, the supply and storage of the investigational drug, and the collection and transport of specimens. We are working to establish a system that will allow us to begin clinical trials as soon as possible after obtaining IND clearance.

In light of this progress, we are currently maintaining our goal of submitting an IND application between late 2026 and early 2027, and we are proceeding in parallel with preparations for GLP toxicity studies, GMP manufacturing, and the initiation of clinical trials.

Additionally, in late October 2026, the U.S. AI company Anthropic announced that it had acquired Mithril Medicine, a company working on the development of treatments for LAMA2-related congenital muscular dystrophy, and that it is now advancing drug discovery research for this disease in-house. We welcome the fact that a global technology company has taken a new interest in LAMA2-related muscular dystrophy—a condition for which effective treatment options have been extremely limited—and has entered the field of research and development. We hope that these developments will lead to increased awareness of the disease and stimulate research and development, so that new treatment options can be delivered to patients as soon as possible. We, too, will continue our efforts toward the clinical development of MDL-101 using our proprietary CRISPR-GNDM® technology.

Regarding other next-generation programs, for MDL-201 (Duchenne muscular dystrophy [DMD]), we decided to adopt Exegenesis Bio's capsid as a next-generation muscle-targeted capsid suitable for systemic administration, and in September 2026, we entered into a license agreement and a joint research agreement with the company. As a result, the key components required for the product composition—including the capsid, promoter, and gRNA—have been finalized. With the vector design for MDL-201 now established, we are making progress in preparing the framework for future preclinical development. We are currently preparing for the next phase of preclinical studies, which will include evaluations in non-human primates using this vector.

Regarding MDL-202 (Dystonia Myotonic Type 1 (DM1)), we received a patent grant in September 2026 for a U.S. patent related to this program, which uses CRISPR-GNDM® technology to suppress the expression of the target gene, DMPK. We believe this patent grant further strengthens the intellectual property foundation supporting the research and development of MDL-202.

We will continue to explore the next phase of development based on the nonclinical data obtained to date.

For MDL-103 (facioscapulohumeral muscular dystrophy (FSHD)), we are continuing efficacy evaluations using disease model mice as part of a collaborative research project with the University of Massachusetts (UMass), funded by SOLVE FSHD.

As a result, for the nine months ended September 30, 2026, the Company recorded operating revenue of ¥- thousand, compared with operating revenue of ¥- thousand for the same period of the previous year; operating loss of ¥1,686,340 thousand, compared with operating loss of ¥1,815,034 thousand; ordinary loss of ¥1,650,924 thousand, compared with ordinary loss of ¥1,798,231 thousand; and loss attributable to owners of parent of ¥1,608,271 thousand, compared with loss attributable to owners of parent of ¥1,801,774 thousand.

The Group consists of a single business segment, which is gene therapy drug development. Accordingly, the Company omits segment information by business segment.

(2) Explanation of Financial Position

Status of Assets, Liabilities and Net Assets

(Current Assets)

Total current assets at the end of the third quarter consolidated fiscal period under review decreased by ¥483,777 thousand from the end of the previous fiscal year to ¥2,408,495 thousand. This was mainly attributable to a decrease of ¥444,033 thousand in cash and deposits.

(Non-current Assets)

Total non-current assets at the end of the third quarter of the current consolidated fiscal year under review decreased by ¥21,227 thousand from the end of the previous fiscal year to ¥50,749 thousand. This was attributable to a decrease of ¥21,227 thousand in investments and other assets.

(Current Liabilities)

Total current liabilities at the end of the third quarter of the current consolidated fiscal year under review increased by ¥6,322 thousand from the end of the previous fiscal year to ¥141,125 thousand. This was mainly attributable to an increase of ¥12,367 thousand in accrued expenses.

(Non-current Liabilities)

Total non-current liabilities at the end of the third quarter of the current consolidated fiscal year under review decreased by ¥35,060 thousand from the end of the previous fiscal year to ¥1,082 thousand. This was mainly attributable to a decrease of ¥34,914 thousand in other non-current liabilities.

(Net Assets)

Total net assets at the end of the third quarter of the current consolidated fiscal year decreased by ¥476,266 thousand from the end of the previous fiscal year to ¥2,317,037 thousand. This was mainly attributable to decreases of ¥568,239 thousand each in capital stock and capital surplus, and an increase of ¥640,953 thousand in retained earnings.

(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 addition, research and development expenses, which are a major expense item for the Group, are also subject to significant uncertainty, as whether such expenses are borne by the Group or its partners depends on the terms of out-licensing agreements, collaborative research and development agreements, and other arrangements. Regarding the 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.

The Group is a drug discovery venture company engaged in the research and development of gene control therapeutics utilizing its CRISPR-GNDM® technology. The Group pursues a “hybrid model” that combines collaboration-based pipeline programs with proprietary pipeline programs, with the aim of broadening revenue opportunities, optimizing strategic options, and strengthening its business foundation.

On the other hand, the research and development of pharmaceutical products requires substantial upfront investment, and the recovery of such investment generally takes a longer period than in many other industries. Accordingly, the Group has continued to incur operating losses and negative operating cash flows. As a result, events and conditions exist that may cast significant doubt on the Group’s ability to continue as a going concern.

The Group is advancing research and development centered on MDL-101, its lead development program, by leveraging the expertise it has accumulated in the development of CRISPR-based gene control therapeutics. For MDL-101, the Group is optimizing its development and manufacturing plans, prioritizing the allocation of research and development resources, and advancing preparations for IND submission and the initiation of clinical trials.

In addition, the Group continues to evaluate opportunities for business partnerships, co-development arrangements, and license agreements with respect to its proprietary pipeline programs, including MDL-101, while seeking to secure early partnering opportunities for follow-on pipeline programs. The Group is also working to improve capital efficiency and control expenditures through the prioritization of research and development activities, optimization of development expenses including outsourced costs, and company-wide cost management.

With respect to its financial position, at the end of the third quarter of this fiscal year, the Group held cash and deposits of ¥2,368,333 thousand. Based on its available funds and the measures described above, the Group believes that it has secured sufficient funds to continue its business operations for the next 12 months.

Based on the foregoing, the Group has concluded that no material uncertainty related to going concern exists.

2. Quarterly Consolidated Financial Statements and Primary Notes

(1) Quarterly Consolidated Balance Sheets

(Thousand yen)

	As of December 31, 2025	As of September 30, 2026
Assets		
Current assets		
Cash and deposits	2,812,367	2,368,333
Others	79,904	40,161
Total current assets	2,892,272	2,408,495
Non-current assets		
Investments and other assets	71,976	50,749
Total non-current assets	71,976	50,749
Total assets	2,964,248	2,459,244
Liabilities		
Current liabilities		
Accounts payable-other	94,403	95,300
Accrued expenses	25,745	38,113
Income taxes payable	13,330	5,806
Other	1,324	1,904
Total current liabilities	134,802	141,125
Non-current liabilities		
Provision for share-based compensation for employees	145	—
Other	35,996	1,082
Total non-current liabilities	36,142	1,082
Total liabilities	170,945	142,207
Net assets		
Shareholders' equity		
Share capital	1,728,097	1,159,857
Capital surplus	3,049,832	2,481,592
Retained earnings	(2,037,247)	(1,396,293)
Treasury shares	(97)	(97)
Total shareholders' equity	2,740,583	2,245,059
Accumulated other comprehensive income		
Foreign currency translation adjustment	15,331	15,505
Total accumulated other comprehensive income	15,331	15,505
Share acquisition rights	37,388	56,471
Total net assets	2,793,303	2,317,037
Total liabilities and net assets	2,964,248	2,459,244

(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, 2025	For the nine months ended September 30, 2026
Operating revenue	—	—
Operating expenses		
Research and development expenses	1,632,592	1,536,525
Selling, general and administrative expenses	182,441	149,814
Total operating expenses	1,815,034	1,686,340
Operating loss	(1,815,034)	(1,686,340)
Non-operating income		
Interest income	3,839	4,791
Foreign exchange income	—	5,597
Donation income	—	9,840
Other	49,651	28,379
Total non-operating income	53,491	48,609
Non-operating expenses		
Interest expense	2,182	1,448
Bond issuance costs	7,257	5,652
Foreign exchange loss	23,979	—
Stock issuance cost	3,269	6,093
Total non-operating expenses	36,688	13,193
Ordinary loss	(1,798,231)	(1,650,924)
Extraordinary gain		
Gain on sale of fixed assets	—	17,439
Recovery of written-off receivables	—	36,373
Total extraordinary gains	—	53,812
Extraordinary loss		
Impairment loss	2,241	2,695
Total extraordinary loss	2,241	2,695
Loss before income taxes	(1,800,473)	(1,599,807)
Income taxes -current	1,300	8,464
Total income taxes	1,300	8,464
Loss for the third quarter	(1,801,774)	(1,608,271)
Loss attributable to owners of parent for the third quarter	(1,801,774)	(1,608,271)

Quarterly Consolidated Statements of Comprehensive Income

Nine Months Ended September 30

(Thousand yen)

	For the nine months ended September 30, 2025	For the nine months ended September 30, 2026
Loss for third quarter	(1,801,774)	(1,608,271)
Other comprehensive income		
Foreign currency translation adjustment	(8,897)	174
Total other comprehensive income	(8,897)	174
Comprehensive income for third quarter	(1,810,671)	(1,608,096)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent for third quarter	(1,810,671)	(1,608,096)

(3) Notes to Quarterly Consolidated Financial Statements

(Notes on going concern assumption)

There is no applicable information.

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

Based on the resolution approved at the 10th Annual General Meeting of Shareholders held on March 26, 2026, the Company compensated for the deficit in retained earnings carried forward on May 15, 2026. As a result, the share capital and capital surplus decreased by ¥1,124,612 thousand each and retained earnings increased by ¥2,249,224 thousand. In addition, during the nine months ended September 30, 2026, the share capital and capital surplus increased by ¥553,873 thousand each due to the exercise of stock acquisition rights with exercise price adjustment provisions. As a result, as of September 30, 2026, the share capital, capital surplus and retained earnings were ¥1,159,857 thousand, ¥2,481,592 thousand and negative ¥1,396,293 thousand, respectively.

(Notes to Quarterly Consolidated Statements of Income)

(Non-operating income)

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

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 "Modalis has been selected as a finalist in the XPRIZE Healthspan FSHD Bonus Prize Competition and awarded research funds".

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 "SOLVE FSHD and Modalis Announce Strategic Collaboration to Develop an Innovative CRISPR-Based Epigenome Editing Treatment for Facioscapulohumeral Muscular Dystrophy" dated June 9, 2025.

Nine Months Ended September 30, 2026 (January 1, 2026, to September 30, 2026)

The Company recorded ¥26,178 thousand as other non-operating income for research and development support funds received under a strategic collaboration agreement with SOLVE FSHD for the development of an innovative treatment for facioscapulohumeral muscular dystrophy. For details, please refer to the "SOLVE FSHD and Modalis Announce Strategic Collaboration to Develop an Innovative CRISPR-Based Epigenome Editing Treatment for Facioscapulohumeral Muscular Dystrophy" dated June 9, 2025.

(Segment information)

The Group consists of a single business segment of developing gene therapy drugs. Accordingly, the Company omits segment information by business segment.

(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)

After the end of the nine months ended September 30, 2026, some of the stock acquisition rights with exercise price adjustment provisions were exercised during the period from October 1, 2026, to October 31, 2026, as follows.

(1) Type and number of shares issued	Common stock	2,320,000 shares.
(2) Increase in capital stock		¥33,217 thousand.
(3) Increase in capital reserve		¥33,217 thousand.

As a result, the total number of common shares issued and outstanding as of October 31, 2026, was 115,954,098 shares, capital stock was ¥1,193,075 thousand, and capital surplus was ¥2,514,810 thousand.