

Consolidated Financial Results for the Three Months Ended March 31, 2024 [Japanese GAAP]



May 8, 2024

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: May 14, 2024

Scheduled date of commencing dividend payments: -

Availability of supplementary briefing material on quarterly financial results: Available

Schedule of quarterly financial results briefing session: 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, 2024 (January 1, 2024 to March 31, 2024)

(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, 2024	-	-	(490)	-	(457)	-	(457)	-
March 31, 2023	-	(100)	(514)	-	(509)	-	(532)	-

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

Three months ended March 31, 2023: ¥ (531) million [- %]

	Basic earnings per share	Diluted earnings per share
Three months ended	Yen	Yen
March 31, 2024	(13.57)	-
March 31, 2023	(17.86)	-

(Notes)

The amount shown as “business revenue” in the consolidated statements of income has been shown as “Operating revenue” in this document.

Diluted net income per share is not shown in the above table, because net income per share was negative although there are residual shares.

(2) Consolidated Financial Position

	Total assets	Net assets	Capital adequacy ratio
	Million yen	Million yen	%
As of March 31, 2024	1,559	1,011	62.9
As of March 31, 2023	2,025	1,380	66.8

(Reference) Equity: As of March 31, 2024: ¥981 million

As of March 31, 2023: ¥1,353 million

(3) 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, 2023	-	0.00	-	0.00	0.00
Fiscal year ending December 31, 2024	-				
Fiscal year ending December 31, 2024 (Forecast)		0.00	-	0.00	0.00

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

3. Consolidated Financial Forecast for the Fiscal Year Ending December 31, 2024 (January 1, 2024 to December 31, 2024)

The earnings forecasts for fiscal year ending December 2024 are not presented due to the difficulty of formulating reasonably accurate estimates at this time. For further details, please refer to the page on “Explanation of Consolidated Financial Results Forecast and Other Forward-looking Information”

*** Notes:**

- (1) Changes in significant subsidiaries during the three months ended March 31, 2024 (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):
March 31, 2024: 34,193,416 shares
December 31, 2023: 33,355,272 shares
 - 2) Total number of treasury shares at the end of the period:
March 31, 2024: 63 shares
December 31, 2023: 63 shares
 - 3) Average number of shares during the period:
Three month ended March 31, 2024: 33,742,472 shares
Three month ended March 31, 2023: 29,812,326 shares

* These quarterly financial results are outside the scope of quarterly review by certified public accountants or auditing firms.

*** 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 a page on 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 current consolidated fiscal year, the Japanese economy has largely recovered from the outbreak of the new coronavirus, but the outlook remains uncertain due to factors such as instability in Ukraine, the Middle East, and East Asia, including the Taiwan Strait, rising inflation, including sharp rises in raw material prices, and rapid fluctuations in exchange rates. The pharmaceutical and biotech industries also continued to face a difficult business environment. In the pharmaceutical and biotech industries, layoffs and the liquidation and review of pipelines are underway due to the impact of tightening financial and capital markets.

Based on the CRISPR-GNDM[®] platform, which serves as the technological foundation, the Group has continued to lead cutting-edge research as a leading company from its establishment in 2016 to its ninth year as the world's first company to develop gene regulation therapy using CRISPR. To bring these achievements to fruition, we have continued our efforts to initiate clinical trials during the current fiscal year.

We have largely resolved the technical and regulatory challenges in the development of our lead program, MDL-101, and now that the manufacturing process has been established, GLP toxicity testing and GMP manufacturing are the last tasks before the clinical trial application can be submitted. In addition, we have established clinical trial sites, clinical trial protocols, and started to collaborate with patient groups. We believe that MDL-101 has the potential to become the first CRISPR epigenome editing therapeutic candidate to enter the clinic, and we are vigorously pursuing its development.

MDL-202 is currently undergoing animal studies in mice and monkeys, and will be developed using the manufacturing process and development strategy identified in the development of MDL-101, subject to availability of funds.

In addition, we have completed proof-of-concept studies in animal models for our development candidates for Duchenne muscular dystrophy, tauopathy, Dravet syndrome, Angelman syndrome, and others.

On April 12, the company announced the strategic pipeline prioritization and corporate restructuring of our U.S. subsidiary in order to focus more resources on MDL-101 in the current financial environment. The corporate restructuring includes reducing the number of people mainly in the manufacturing-related group whose mission of establishing the manufacturing process of MDL-101 had been completed successfully. Therefore, we are ready to continue our efforts to bring MDL-101 into the clinic, and we plan to move forward with the development of MDL-101 so that it can be used to treat patients as soon as possible.

As a result, for the three months ended March 31, 2024, operating loss to ¥490,087 thousand, ordinary loss to ¥457,445 thousand, and Loss attributable to owners of parent to ¥457,936 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 ¥470,580 thousand from the end of the previous fiscal year to ¥1,485,742 thousand. This is mainly attributable to a decrease in cash and deposits by ¥470,024 thousand.

(Non-current Assets)

Total non-current assets at the end of the first quarter of the fiscal year under review increased by ¥3,779 thousand from the end of the previous fiscal year to ¥73,381 thousand. This is mainly attributable to an increase in investments and other assets by ¥3,779 thousand.

(Current Liabilities)

Total current liabilities at the end of the first quarter of the fiscal year under review decreased by ¥46,413 from the end of the previous fiscal year to ¥151,687 thousand. This is mainly attributable to a decrease in other by ¥74,649 thousand.

(Non-current Liabilities)

Total non-current liabilities at the end of the first quarter of the fiscal year under review decrease by ¥51,629 thousand from the end of the previous fiscal year to ¥395,772 thousand. This is attributable to a decrease in convertible bond by ¥50,000 thousand.

(Net Assets)

Total net assets at the end of the first quarter of the fiscal year under review decreased by ¥368,758 thousand from the end of the previous fiscal year to ¥1,011,664 thousand. This is mainly attributable to a decrease in retained earnings by ¥457,936 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. Regarding 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.

3. Quarterly Consolidated Financial Statements and Primary Notes

(1) Quarterly Consolidated Balance Sheets

(Thousand yen)

	As of December 31, 2023	As of March 31, 2024
Assets		
Current assets		
Cash and deposits	1,883,437	1,413,413
Supplies	6,353	7,476
Other	66,533	64,853
Total current assets	1,956,323	1,485,742
Non-current assets		
Investments and other assets	69,601	73,381
Total non-current assets	69,601	73,381
Total assets	2,025,925	1,559,124
Liabilities		
Current liabilities		
Income taxes payable	5,973	5,233
Provision for bonuses	—	7,104
Provision for business restructuring	—	21,870
Other	192,128	117,479
Total current liabilities	198,101	151,687
Non-current liabilities		
Provision for share-based compensation for director	733	619
Provision for share-based compensation for employee	3,590	2,977
Convertible bond	412,500	362,500
Other	30,577	29,675
Total non-current liabilities	447,401	395,772
Total liabilities	645,502	547,459
Net assets		
Shareholders' equity		
Share capital	1,217,652	1,260,395
Capital surplus	2,539,387	2,582,130
Retained earnings	(2,410,273)	(2,868,210)
Treasury shares	(97)	(97)
Total shareholders' equity	1,346,669	974,217
Accumulated other comprehensive income		
Foreign currency translation adjustment	7,323	6,895
Total accumulated other comprehensive income	7,323	6,895
Subscription rights to shares	26,430	30,551
Total net assets	1,380,422	1,011,664
Total liabilities and net assets	2,025,925	1,559,124

(2) Quarterly Consolidated Statements of Income and Comprehensive Income

Quarterly Consolidated Statements of Income

For the Fiscal Year ended December 31

(Thousand yen)

	For the three months ended March 31, 2023	For the three months ended March 31, 2024
Operating revenue	—	—
Operating expenses		
Research and development expenses	443,308	422,604
Selling, general and administrative expenses	71,137	67,482
Total operating expenses	514,446	490,087
Operating loss	(514,446)	(490,087)
Non-operating income		
Interest income	14	7
Foreign exchange income	7,255	34,618
Other	1	7
Total non-operating income	7,271	34,632
Non-operating expenses		
Interest expenses	1,108	1,032
Bond issuance costs	—	—
Stock issuance cost	1,533	957
Amortization of stock issuance cost	90	—
Miscellaneous losses	—	—
Total non-operating expenses	2,731	1,990
Ordinary loss	(509,905)	(457,445)
Extraordinary loss		
Impairment loss	22,161	188
Total extraordinary loss	22,161	188
Loss before income taxes	(532,067)	(457,633)
Income taxes - current	304	303
Income taxes - deferred	304	303
Loss	(532,371)	(457,936)
Loss attributable to owners of parent	(532,371)	(457,936)

Quarterly Consolidated Statements of Comprehensive Income

For the Fiscal Year ended December 31

(Thousand yen)

	For the three months ended March 31, 2023	For the three months ended March 31, 2024
Loss	(532,371)	(457,936)
Other comprehensive income		
Foreign currency translation adjustment	1,250	△428
Total other comprehensive income	1,250	△428
Comprehensive income	(531,121)	(458,364)
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	(531,121)	(458,364)

(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)

The share capital and the capital surplus both received an addition of ¥42,742 thousand due to the exercise of stock acquisition rights as a stock option. As a result, at the three months ended March 31, 2024, the share capital and capital surplus were ¥1,260,395 thousand, ¥2,582,130 thousand.

(Accounting policies adopted specially for the preparation of quarterly consolidated financial statements)

There is no relevant information.

(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.

3. Other

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

The Modalis group is a drug discovery biotech company engaged in the research and development of gene therapy. We have a plan to stabilize our business by pursuing "hybrid business model" that combines collaboration that bring us short-term earning, and an wholly owned pipelines, that bring us huge upside potential. However, research and development of gene therapy requires a large amount of capital, and the recovery of such investment takes a relatively long time compared to other industries, resulting in continuous operating losses and negative operating cash flow.

In November 2023, the Company issued its first unsecured convertible bond with stock acquisition rights (with a conversion price adjustment clause) through a third-party allotment in order to secure funds for research and development. The said convertible bond with stock acquisition rights has a clause that allows the bondholders to demand redemption of part or all of the remaining bonds at any time under certain conditions, and there is a risk that the bonds will be redeemed before the redemption date of the said convertible bond with stock acquisition rights.

In order to resolve this situation, the Group will focus on the development of MDL-101, which employs an improved AAV based on the CRISPR-GNDM[®] platform, which serves as the technological foundation, and based on the knowledge gained from the development of gene regulatory therapeutics using CRISPR over nine fiscal years. In addition, we will continue negotiations for partnering in parallel with development as in the past. At the same time, we will continue to optimize our R&D structure and reduce costs by improving efficiency, while aiming to obtain partnering for subsequent pipelines as soon as possible.