Consolidated Financial Results for the Nine Months Ended September 30, 2023 [Japanese GAAP]

November 7, 2023

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: November 13, 2023
Scheduled date of commencing dividend payments: -
Availability of supplementary briefing material on quarterly financial results: Available
Schedule of quarterly financial results briefing session: -

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

1. Consolidated Financial Results for the Nine Months Ended September 30, 2023 (January 1, 2023 to September 30, 2023)

(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, 2023	-	(100)	(1,609)	-	(1,542)	-	(1,581)	-
September 30, 2022	40	-	(1,438)	-	(1,314)	-	(1,309)	-

(Note) Comprehensive income: Nine months ended September 30, 2023: ¥ (1,586) million [- %]
Nine months ended September 30, 2022: ¥ (1,280) million [- %]

	Basic earnings per share	Diluted earnings per share
Nine months ended	Yen	Yen
September 30, 2023	(52.29)	-
September 30, 2022	(45.04)	-

(Notes)
For diluted earnings per share for the fiscal year ended September 30, 2023, the figure is not presented as the Company's shares were not listed and the average share price was not available, although the Company had dilutive shares.

(2) Consolidated Financial Position

	Total assets	Net assets	Capital adequacy ratio
	Million yen	Million yen	%
As of September 30, 2023	2,179	1,978	90.0
As of December 31, 2022	3,129	2,941	93.4

(Reference) Equity: As of September 30, 2023: ¥1,961 million
As of December 31, 2022: ¥2,922 million

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, 2022	-	0.00	-	0.00	0.00
Fiscal year ending December 31, 2023 (year to date)	-	0.00	-		
Fiscal year ending December 31, 2023 (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, 2023(January 1, 2023 to December 31, 2023)

The earnings forecasts for fiscal year 2023 are not presented due to the difficulty of formulating reasonably accurate estimates at this time. 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, 2023 (changes in specified subsidiaries resulting in changes in scope of consolidation): No
Notes on changes in significant subsidiaries during the nine months ended September 30, 2023

(2) Accounting policies adopted specially for the preparation of quarterly consolidated financial statements: No
Notes on accounting policies adopted specially for the preparation of quarterly consolidated financial statements

(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
Notes on changes in accounting policies

(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, 2023: 31,577,500 shares

December 31, 2022: 29,362,500 shares

2) Total number of treasury shares at the end of the period:

September 30, 2023: 63 shares

December 31, 2022: 63 shares

3) Average number of shares during the period:

Nine months ended September 30, 2023: 30,252,107 shares

Nine months ended September 30, 2022: 29,079,323 shares

Notes on total number of issued shares

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

During the third quarter of the consolidated fiscal year under review, the Japanese economy continued to show a gradual recovery trend as the normalization of new coronavirus infection was completed. On the other hand, amid ongoing global monetary tightening and other factors, the outlook is uncertain due to the risk of a downturn in overseas economies putting downward pressure on the Japanese economy, as well as the effects of Political instability in Eastern Europe and the Middle East, and geopolitical risks in Asia, the weaker yen, rising prices, supply-side constraints, and fluctuations in the financial and capital markets. We also believe that the biotech industries are facing a difficult environment, as the financing environment is stagnant in both Japan and the United States.

Based on the CRISPR-GNDM® platform as the technological foundation, our group has been in business from its inception in 2016 to its eighth fiscal year as the world's first company to develop epigenetic editing therapy using CRISPR. While several similar companies have been established in the past few years, we believe it is noteworthy that we have focused on its potential even before its establishment, continue to take a leading global position in a major and popular field, and have advanced its development to the stage where clinical trials are in sight.

In August 2023, we reacquired the development, manufacturing, and marketing rights for MDL-201 and MDL-202 from Astellas Pharma Inc. and clarified our development strategy focusing on muscle diseases with MDL-101 for LAMA2-CMD and MDL-202 for DM1.

For MDL-202, for which we regained the rights, we have already completed conversion to a muscle-specific capsid version, created candidate compounds, and begun target engagement studies in non-human primate (NHP)s. We were able to respond seamlessly and quickly because the target disease area is the same as MDL-101, a muscle disease, and we were able to directly apply our accumulated know-how in the development of a single platform. We were also able to minimize the lead time because we had carefully studied and made sufficient preparations for the transfer. The target disease, DM1, is a muscle disease with a relatively large number of patients, and there are many development approaches with other modalities, but we hope to establish a competitive advantage with speed.

Since the target patient population for MDL-101 is primarily pediatric, it is necessary to study MDL-101 in age-matched animals. We conducted a study in NHPs and confirmed that MDL-101 induces GNDM expression and LAMA1 at levels comparable to or higher than those observed in adult monkeys, with no signs of toxicity. The Company believes that these results provide strong support for the feasibility of conducting a first-in-human (FIH) study in pediatric patients. Based on the results of these studies, and in light of the response to the PreIND received in June, we are moving forward with preparations for a GLP toxicity study. Regarding manufacturing, another important aspect of clinical trials, we have completed a manufacturing process that achieves reasonable specifications and realistic yields and are preparing for GMP manufacturing.

With the progress of the development described above, on September 11, 2023, the Company resolved to issue bonds with stock acquisition rights ("Former Convertible Bonds") and stock acquisition rights ("Former Stock Warrants") to CS Asia Opportunities Master Fund ("Former Allottee"). However, the Company was informed by the former allottee that, although the former allottee had instructed a financial institution handling the remittance (prime broker) to remit the payment amount to be paid on the payment date, the prime broker had not completed the internal procedures required for remittance and therefore could not complete the remittance of the payment amount by the payment date. As a result, the Company has decided to cancel the issuance of the Former Convertible Bonds and Warrants. On the other hand, since the Company is in a situation where the finance

is currently unfulfilled to achieve our IND by the end of 2024, we sought out fundraising possibilities and, after comparing and examining the offers, and in accordance with the prescribed procedures and timeframes, we have decided to issue new convertible bonds with stock acquisition rights and stock acquisition rights to EVO FUND as the new allottee. More detailed in the separate notes for this matter.

As a result, for the nine months ended September 30, 2023, operating revenue amounted to thousand, operating loss to ¥1,609,433 thousand, ordinary loss to ¥1,542,873 thousand, and Loss attributable to owners of parent to ¥1,581,809 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 third quarter of the fiscal year under review decreased by ¥956,226 thousand from the end of the previous fiscal year to ¥2,105,001 thousand. This is mainly attributable to a decrease in cash and deposits by ¥1,036,086 thousand.

(Non-current Assets)

Total non-current assets at the end of the third quarter of the fiscal year under review increased by ¥5,570 thousand from the end of the previous fiscal year to ¥74,175 thousand. This is mainly attributable to an increase in investments and other assets of ¥5,570 thousand.

(Current Liabilities)

Total current liabilities at the end of the third quarter of the fiscal year under review increased by ¥18,763 thousand from the end of the previous fiscal year to ¥160,603 thousand. This is mainly attributable to a an increase in Provision for bonuses by ¥ 39,110 thousand and a decrease in Income taxes payable by ¥10,847 thousand.

(Non-current Liabilities)

Total non-current liabilities at the end of the third quarter of the fiscal year under review decreased by ¥6,748 thousand from the end of the previous fiscal year to ¥40,011 thousand. This is attributable to a decrease in Provision for share-based compensation for employees by ¥2,462 thousand.

(Net Assets)

Total net assets at the end of the third quarter of the fiscal year under review decreased by ¥962,670 thousand from the end of the previous fiscal year to ¥1,978,562 thousand. This is mainly attributable to a decrease in retained earnings by ¥1,581,809 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.

2. Quarterly Consolidated Financial Statements and Primary Notes

(1) Quarterly Consolidated Balance Sheets

(Thousand yen)

	As of December 31, 2022	As of September 30, 2023
Assets		
Current assets		
Cash and deposits	2,933,162	1,897,075
Supplies	4,037	50,937
Other	87,757	156,989
Total current assets	3,061,228	2,105,001
Non-current assets		
Investments and other assets	68,605	74,175
Total non-current assets	68,605	74,175
Total assets	3,129,833	2,179,177
Liabilities		
Current liabilities		
Income taxes payable	13,112	2,265
Provision for bonuses	—	39,110
Other	128,727	119,227
Total current liabilities	141,840	160,603
Non-current liabilities		
Provision for share-based compensation for director	1,267	806
Provision for share-based compensation for employee	6,487	4,025
Other	39,012	35,180
Total non-current liabilities	46,760	40,011
Total liabilities	188,600	200,615
Net assets		
Shareholders' equity		
Share capital	2,094,767	1,113,887
Capital surplus	3,416,502	2,435,622
Retained earnings	(2,605,346)	(1,600,261)
Treasury shares	(97)	(97)
Total shareholders' equity	2,905,825	1,949,150
Accumulated other comprehensive income		
Foreign currency translation adjustment	16,483	11,923
Total accumulated other comprehensive income	16,483	11,923
Subscription rights to shares	18,923	17,488
Total net assets	2,941,232	1,978,562
Total liabilities and net assets	3,129,833	2,179,177

(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, 2022	For the nine months ended September 30, 2023
Operating revenue	40,500	—
Operating expenses		
Research and development expenses	1,290,857	1,401,667
Selling, general and administrative expenses	187,868	207,765
Total operating expenses	1,478,726	1,609,433
Operating loss	(1,438,226)	(1,609,433)
Non-operating income		
Interest income	47	25
Foreign exchange income	128,397	75,924
Other	303	400
Total non-operating income	128,748	76,350
Non-operating expenses		
Interest expenses	3,584	3,326
Stock issuance cost	817	6,021
Amortization of stock issuance cost	657	443
Total non-operating expenses	5,059	9,791
Ordinary loss	(1,314,537)	(1,542,873)
Extraordinary loss		
Impairment loss	—	38,024
Total extraordinary loss	—	38,024
Loss before income taxes	(1,314,537)	(1,580,898)
Income taxes - current	914	911
Income taxes - deferred	(5,624)	—
Total income taxes	(4,709)	911
Loss	(1,309,827)	(1,581,809)
Loss attributable to owners of parent	(1,309,827)	(1,581,809)

Quarterly Consolidated Statements of Comprehensive Income

Nine Months September 30

(Thousand yen)

	For the nine months ended September 30, 2022	For the nine months ended September 30, 2023
Loss	(1,309,827)	(1,581,809)
Other comprehensive income		
Foreign currency translation adjustment	28,880	(4,559)
Total other comprehensive income	28,880	(4,559)
Comprehensive income	(1,280,946)	(1,586,369)
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	(1,280,946)	(1,586,369)

(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 decreased by ¥1,293,447 thousand and retained earnings increased by ¥2,586,894 thousand as the result of covering the loss in retained earnings brought forward as of May 15, 2023 based on the resolution of the 7th Ordinary General Meeting of Shareholders held on March 28, 2023.

Additionally, the share capital and the capital surplus both received an addition of ¥312,567 thousand due to the exercise of stock acquisition rights as a stock option. As a result, for the nine months ended September 30, 2023, the share capital, capital surplus and retained earnings were ¥1,113,887 thousand, ¥2,435,622 thousand and (¥1,600,261) thousand, respectively..

(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.