Consolidated Financial Results for the Three Months Ended March 31, 2023 [Japanese GAAP]

May 9, 2023

Company name: Modalis Therapeutics Corporation
Stock exchange listing: Tokyo Stock Exchange
Code number: 4883
URL: https://www.modalistx.com/en/
Representative: Haruhiko Morita, President and Representative Director
Contact: Naoki Kobayashi, CFO and Executive Officer
Phone: +81-3-6822-4584
Scheduled date of filing quarterly securities report: May 12, 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 Three Months Ended March 31, 2023 (January 1, 2023, to March 31, 2023)

(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, 2023	-	(100.0)	(514)	-	(509)	-	(532)	-
March 31, 2022	40	-	(466)	-	(443)	-	(438)	-

(Note) Comprehensive income: Three months ended March 31, 2023: ¥ (531) million [-%]
Three months ended March 31, 2022: ¥ (427) million [-%]

	Basic earnings per share	Diluted earnings per share
Three months ended	Yen	Yen
March 31, 2023	(17.86)	-
March 31, 2022	(15.13)	-

(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 March 31, 2023	2,899	2,653	90.9
As of December 31, 2022	3,129	2,941	93.4

(Reference) Equity: As of March 31, 2023 : ¥2,634million
As of December 31, 2022: ¥2,922million

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	-				
Fiscal year ending December 31, 2023 (Forecast)		0.00	-	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 three months ended March 31, 2023 (changes in specified subsidiaries resulting in changes in scope of consolidation): No
Notes on changes in significant subsidiaries during the three months ended March 31, 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

(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, 2023: 30,207,500 shares

December 31, 2022: 29,362,500 shares

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

March 31, 2023: 63 shares

December 31, 2022: 63 shares

3) Average number of shares during the period:

Three months ended March 31, 2023: 29,812,326 shares

Three months ended March 31, 2022: 29,015,611 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 first 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 almost complete. 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 rising prices, supply-side constraints, and fluctuations in the financial and capital markets. In the pharmaceutical and biotech industries, layoffs and pipeline liquidations are also becoming more noticeable due to the impact of tightening financial and capital markets.

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 and continue to take a leading global position in a major field and have advanced its development to the stage where clinical trials are in sight.

On the other hand, in light of the economic environment described above, we are also reviewing our resources and plan to revise our portfolio with a focus on MDL-101, for which we have already received favorable data. We believe that promptly bringing one of these programs into clinical trials is the most efficient way to increase corporate value, taking into account the spillover effects to other pipelines, and we will continue to pursue this strategy.

After adopting the improved vector for MDL-101 last September, we constructed and evaluated new development molecules. The results of the evaluation conducted in disease model mice and NHPs were favorable, and we believe that we made right decision as MDL-101 has enhanced the efficacy and safety of MDL-101. The results will be reported at the Annual Meeting of the American Society for Gene and Cell Therapy (ASGCT), Los Angeles, USA, May 16-20, 2023. The abstract was accepted as a late-breaking abstract and will be presented in an oral presentation on May 19. The presentation will focus on the results of NHP studies of MDL-101 as part of preclinical studies, including results of further evaluation of target engagement in NHPs and in the disease model mice, and will include information on dose estimation for a planned clinical trial. The Company believes that these results are positive with respect to LAMA1 elevation, efficacy, and safety in the clinic, and plans to move forward with further clinical trials.

In parallel, we have been in dialogue with the regulatory authorities and have already filed a request for a Pre-IND meeting, which we are awaiting. We believe that this will help clarify issues for clinical trials and allow us to adjust the course of future IND-enabling studies and GMP manufacturing efforts.

In addition, a patent application for "modified Cas9 protein and uses thereof," which was jointly filed between the Company and the University of Tokyo in April after the first quarter of the consolidated fiscal year under review, was granted a patent in Japan. We believe that this is the result of the authorities' recognition of the novelty and inventive step of the patent relating to modified Cas9.

As a result, for the three months ended March 31, 2023, operating loss to ¥514,446 thousand, ordinary loss to ¥509,905 thousand, and Loss attributable to owners of parent to ¥532,371 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 ¥229,900 thousand from the end of the previous fiscal year to ¥2,831,327 thousand. This is mainly attributable to a decrease in cash and deposits by ¥225,109 thousand.

(Non-current Assets)

Total non-current assets at the end of the first quarter of the fiscal year under review decreased by ¥509 thousand from the end of the previous fiscal year to ¥68,096 thousand. This is mainly attributable to a decrease in Investments and other assets by ¥509 thousand.

(Current Liabilities)

Total current liabilities at the end of the first quarter of the fiscal year under review increased by ¥59,515 thousand from the end of the previous fiscal year to ¥201,355 thousand. This is mainly attributable to an increase in others of ¥38,372 thousand.

(Non-current Liabilities)

Total non-current liabilities at the end of the first quarter of the fiscal year under review decreased by ¥2,464 thousand from the end of the previous fiscal year to ¥44,296 thousand. This is attributable to a decrease in others by ¥2,373 thousand.

(Net Assets)

Total net assets at the end of the first quarter of the fiscal year under review decreased by ¥287,460 thousand from the end of the previous fiscal year to ¥2,653,772 thousand. This is mainly attributable to a decrease in retained earnings by ¥532,371 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 March 31, 2023
Assets		
Current assets		
Cash and deposits	2,933,162	2,708,052
Supplies	40,307	42,910
Other	87,757	80,364
Total current assets	3,061,228	2,831,327
Non-current assets		
Investments and other assets	68,605	68,096
Total non-current assets	68,605	68,096
Total assets	3,129,833	2,899,423
Liabilities		
Current liabilities		
Income taxes payable	13,112	21,428
Provision for bonuses	—	12,826
Other	128,727	167,099
Total current liabilities	141,840	201,355
Non-current liabilities		
Provision for share-based compensation for director	1,260	1,234
Provision for share-based compensation for employee	6,487	6,422
Other	39,012	36,639
Total non-current liabilities	46,760	44,296
Total liabilities	188,600	245,651
Net assets		
Shareholders' equity		
Share capital	2,094,767	2,216,593
Capital surplus	3,416,502	3,538,329
Retained earnings	(2,605,346)	(3,137,717)
Treasury shares	(97)	(97)
Total shareholders' equity	2,905,825	2,617,107
Accumulated other comprehensive income		
Foreign currency translation adjustment	16,483	17,734
Total accumulated other comprehensive income	16,483	17,734
Subscription rights to shares	18,923	18,931
Total net assets	2,941,232	2,653,772
Total liabilities and net assets	3,129,833	2,899,423

(2) Quarterly Consolidated Statements of Income and Comprehensive Income

Quarterly Consolidated Statements of Income

Three Months Ended March 31

(Thousand yen)

	For the three months ended March 31, 2022	For the three months ended March 31, 2023
Operating revenue	40,500	—
Operating expenses		
Research and development expenses	442,239	443,308
Selling, general and administrative expenses	64,979	71,137
Total operating expenses	507,218	514,446
Operating loss	(466,718)	(514,446)
Non-operating income		
Interest income	27	14
Foreign exchange income	24,454	7,255
Other	—	1
Total non-operating income	24,481	7,271
Non-operating expenses		
Interest expense	1,119	1,108
Stock issuance cost	346	1,533
Amortization of stock issuance cost	—	90
Total non-operating expenses	1,466	2,731
Ordinary loss	(443,703)	(509,905)
Extraordinary loss		
Impairment loss	—	22,161
Total extraordinary loss	—	22,161
Loss before income taxes	(443,703)	(532,067)
Income taxes - current	306	304
Income taxes - deferred	(5,103)	—
Total income taxes	(4,797)	304
Profit or Loss	(438,906)	(532,371)
Loss attributable to owners of parent	(438,906)	(532,371)

Quarterly Consolidated Statements of Comprehensive Income

Three Months Ended March 31

(Thousand yen)

	For the three months ended March 31, 2022	For the three months ended March 31, 2023
Profit or Loss	(438,906)	(532,371)
Other comprehensive income		
Foreign currency translation adjustment	11,422	1,250
Total other comprehensive income	11,422	1,250
Comprehensive income	(427,484)	(531,121)
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	(427,484)	(531,121)

(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 ¥121,826 thousand due to the exercise of stock acquisition rights as a stock option. As a result, at the three months ended March 31, 2023, the share capital and capital surplus were ¥2,216,593 thousand, ¥3,538,329 thousand.

(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 Company is a drug discovery venture company engaged in the research and development of gene therapeutic drugs. The Company has a plan to stabilize our management base by expanding the range of profit-earning opportunities and optimizing our business options by promoting R&D under a "hybrid model" business model that combines a collaboration pipeline and an in-house pipeline. However, pharmaceutical R&D requires a large initial investment, and the recovery of the invested funds takes a relatively long period of time compared to other industries.

In order to resolve this situation, based on the CRISPR-GNDM® platform, which serves as the technological foundation, and based on the knowledge gained from the development of gene regulation therapeutics using CRISPR over the past seven fiscal years, the Company has decided to launch MDL-101 which employ an improved AAV, in 2023 for Pre We will focus on the development of MDL-101, which employ the improved AAV, with a view to filing a Pre-IND in 2023. Negotiations for partnering will continue in parallel with development as in the past. In addition, we will continue to optimize our R&D structure to reduce costs by improving efficiency, while aiming for early partnering for subsequent pipelines.

On the funding side, as of the end of the first quarter of the consolidated fiscal year, the Company had 2,708,052 thousand yen in cash and deposits, which is sufficient to fund our business activities for the next one year.

Considering the above, the Company recognizes that there are no significant uncertainties regarding the premise of a going concern.