Consolidated Financial Results for the Three Months Ended March 31, 2021 [Japanese GAAP]

May 6, 2021

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, 2021
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, 2021 (January 1, 2021 to March 31, 2021)

(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, 2021	0	(95.4)	(252)	-	(245)	-	201	-
March 31, 2020	13	-	(116)	-	(116)	-	(118)	-

(Note) Comprehensive income: Three months ended March 31, 2021: ¥ 210 million [-%]
Three months ended March 31, 2020: ¥(118)million [-%]

	Basic earnings per share	Diluted earnings per share
Three months ended	Yen	Yen
March 31, 2021	7.07	6.66
March 31, 2020	(4.71)	-

(Notes)
For diluted earnings per share for the fiscal year ended March 31, 2020, 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 March 31, 2021	6,533	6,430	98.4
As of December 31, 2020	6,277	6,206	98.9

(Reference) Equity: As of March 31, 2021: ¥6,430 million
As of December 31, 2020: ¥6,206 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, 2020	-	0.00	-	0.00	0.00
Fiscal year ending December 31, 2021	-				
Fiscal year ending December 31, 2021 (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, 2021(January 1, 2021 to December 31, 2021)

The earnings forecasts for fiscal year 2021 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, 2021 (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, 2021

(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):

March 31, 2021: 28,575,000 shares

December 31, 2020: 28,515,600 shares

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

March 31, 2021: - shares

December 31, 2020: - shares

3) Average number of shares during the period:

Three months ended March 31, 2021: 28,546,560 shares

Three months ended March 31, 2020: 25,100,000 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

The Japanese economy during the three months ended March 31, 2021 was hit by the COVID-19 pandemic, with restrictions on economic activities and social life. It is expected to take a long time for the economy to recover, and it is getting harder and harder to foresee the future.

Against this backdrop, the Group, in the sixth year since establishment in 2016, has promoted its business proactively under the corporate philosophy "Every Life Deserves Attention," aiming to provide epoch-making therapeutic agents for genetic disorders, most of which are rare diseases. Capitalizing on the advantages of the CRISPR-GNDM® platform that is the technology base, the Group has adopted a hybrid business model to create therapeutic agents for genetic disorders for achieving "wide-range development" and "value chain supplement;" combining "collaboration pipelines" where the Group releases the CRISPR-GNDM® technology to partners that develop therapeutic agents for diseases of their choice at their expense; and "internal pipelines" where the Group uses the CRISPR-GNDM® technology, chooses diseases to be targeted, and develops therapeutic agents at the Group's expense. The Group believes that the COVID-19 pandemic has had a limited impact on business results during the three months ended March 31, 2021.

During the three months ended March 31, 2021, five collaboration pipelines and three internal pipelines were in progress. MDL-101 targeting MDC1A completed the 20-week NHP study and found prolonged expression of CRISPR-GNDM® during the period did not cause safety events including severe immune response against transduced molecules. Based on these results, the Group will continue negotiations with partner candidates and continue necessary development efforts leading up to early-stage IND. Steady progress was seen in other internal programs such as MDL-104 targeting tauopathy and MDL-102 for other CNS disease as well as programs in research collaborations MDL-204, MDL-205, and MDL-206. Due to our partner's request, we will not disclose detailed timeline towards IND of licensed programs such as MDL-201.

A shareholder of the Company, Akira Katayama (hereinafter referred to as Mr. Katayama) violated the agreement (lock-up system) of Securities Listing Regulations and Enforcement Rules for Securities Listings Regulations. As a countermeasure, the Group has received an irregular income of 485,881 thousand yen from Mr. Katayama.

As a result, for the three months ended March 31, 2021, operating revenue amounted to ¥600 thousand, operating loss to ¥252,636 thousand, ordinary loss to ¥245,810 thousand, and Profit attributable to owners of parent to ¥201,800 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 increased by ¥217,782 thousand from the end of the previous fiscal year to ¥5,666,329 thousand. This is mainly attributable to an increased in cash and deposits by ¥228,117 thousand.

(Non-current Assets)

Total non-current assets at the end of the first quarter of the fiscal year under review increased by ¥38,674 thousand from the end of the previous fiscal year to ¥867,145 thousand. This is mainly attributable to an increased in investments and other assets of ¥49,791 thousand.

(Current Liabilities)

Total current liabilities at the end of the first quarter of the fiscal year under review increased by ¥30,117 thousand from the end of the previous fiscal year to ¥88,384 thousand. This is mainly attributable to an increase in income taxes payable by ¥20,673 thousand.

(Non-current Liabilities)

Total non-current liabilities at the end of the first quarter of the fiscal year under review increased by ¥3,043 thousand from the end of the previous fiscal year to ¥14,936 thousand. This is attributable to an increase in deferred tax liabilities by ¥3,043 thousand.

(Net Assets)

Total net assets at the end of the first quarter of the fiscal year under review increased by ¥223,296 thousand from the end of the previous fiscal year to ¥6,430,153 thousand. This is mainly attributable to an increase in retained earnings by ¥201,800 thousand thanks to the posting of profit despite an increase in share capital and capital surplus by ¥6,646 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.

2. Quarterly Consolidated Financial Statements and Primary Notes

(1) Quarterly Consolidated Balance Sheets

(Thousand yen)

	As of December 31, 2020	As of March 31, 2021
Assets		
Current assets		
Cash and deposits	5,421,476	5,649,593
Other	27,070	16,735
Total current assets	5,448,546	5,666,329
Non-current assets		
Property, plant and equipment	49,774	54,345
Intangible assets		
Right to use patent	767,445	751,766
Other	374	366
Total intangible assets	767,819	752,132
Investments and other assets	10,876	60,667
Total non-current assets	828,470	867,145
Total assets	6,277,017	6,533,474
Liabilities		
Current liabilities		
Income taxes payable	21,619	42,292
Other	36,647	46,092
Total current liabilities	58,266	88,384
Non-current liabilities		
Deferred tax liabilities	11,893	14,936
Total non-current liabilities	11,893	14,936
Total liabilities	70,160	103,320
Net assets		
Shareholders' equity		
Share capital	2,707,320	2,713,966
Capital surplus	4,029,055	4,035,701
Retained earnings	(527,519)	(325,719)
Total shareholders' equity	6,208,855	6,423,947
Accumulated other comprehensive income		
Foreign currency translation adjustment	(1,998)	6,205
Total accumulated other comprehensive income	(1,998)	6,205
Total net assets	6,206,857	6,430,153
Total liabilities and net assets	6,277,017	6,533,474

(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, 2020	For the three months ended March 31, 2021
Operating revenue	13,000	600
Operating expenses		
Research and development expenses	81,317	184,182
Selling, general and administrative expenses	47,846	69,053
Total operating expenses	129,164	253,236
Operating loss	(116,164)	(252,636)
Non-operating income		
Interest income	19	27
Subsidy income	79	205
Foreign exchange income	—	6,962
Other	—	29
Total non-operating income	98	7,223
Non-operating expenses		
Listing expenses	766	—
Foreign exchange losses	31	—
Stock issuance cost	—	397
Other	60	—
Total non-operating expenses	858	397
Ordinary loss	(116,924)	(245,810)
Extraordinary income		
Income of compensation	—	485,881
Total extraordinary income	—	485,881
Profit before income taxes or Loss before income taxes	(116,924)	240,071
Income taxes - current	240	36,153
Income taxes - deferred	1,121	2,118
Total income taxes	1,362	38,271
Profit or Loss	(118,286)	201,800
Profit attributable to owners of parent or Loss attributable to owners of parent	(118,286)	201,800

Quarterly Consolidated Statements of Comprehensive Income

Three Months Ended March 31

(Thousand yen)

	For the three months ended March 31, 2020	For the three months ended March 31, 2021
Profit or Loss	(118,286)	201,800
Other comprehensive income		
Foreign currency translation adjustment	199	8,203
Total other comprehensive income	199	8,203
Comprehensive income	(118,087)	210,004
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	(118,087)	210,004

(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 ¥6,646 thousand due to the exercise of stock acquisition rights as a stock option. As a result, at the three months ended March 31, 2021, the share capital and capital surplus were ¥2,713,966 thousand, ¥4,035,701 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.