Consolidated Financial Results for the Nine months ended September 30, 2021 [Japanese GAAP]

November 5, 2021

Company name: Modalis Therapeutics Corporation
Stock exchange listing: Tokyo Stock Exchange
Code number: 4883
URL: https://www.modalistx.com/jp/
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: November 15, 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 Nine months ended September 30, 2021 (January 1, 2021 to September 30, 2021)

(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, 2021	1	(99.7)	(677)	-	(661)	-	(181)	-
September 30, 2020	340	-	(168)	-	(209)	-	(214)	-

(Note) Comprehensive income: Nine months ended September 30, 2021: ¥ (174) million [- %]
Nine months ended September 30, 2020: ¥ (215) million [- %]

	Basic earnings per share	Diluted earnings per share
Nine months ended	Yen	Yen
September 30, 2021	(6.32)	-
September 30, 2020	(8.34)	-

(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 September 30, 2021	6,498	6,093	93.8
As of December 31, 2020	6,277	6,206	98.9

(Reference) Equity: As of September 30, 2021: ¥6,093 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	-	0.00	-		
Fiscal year ending December 31, 2021 (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, 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 Nine months ended September 30, 2021 (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, 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):

September 30, 2021: 28,861,700 shares

December 31, 2020: 28,515,600 shares

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

September 30, 2021: 63 shares

December 31, 2020: - shares

3) Average number of shares during the period:

Nine months ended September 30, 2021: 28,697,050 shares

Nine months ended September 30, 2020: 25,665,611 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

In the Japanese economy during the Nine months ended September 30, 2021, economic activity and social life are gradually normalizing due to the spread of vaccination against the COVID-19 pandemic, but the outlook remains uncertain.

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 Nine months ended September 30, 2021.

During the nine months ended September 30, 2021, collaboration pipelines and internal pipelines were in steady progress. The company has initiated manufacturing of the lead internal pipeline, MDL-101, and entered a strategic collaboration with a first tier global CDMO on process development, analytical development, and large-scale manufacturing for preclinical and clinical supply. Both companies have defined requirements, outline the process, and landed at a concrete plan to move forward. With this collaboration, Modalis gains access to the CDMO's proprietary vector system as well as its manufacturing capability for AAV production. Modalis believes that demonstrating a feasible plan of manufacturing is a critical piece potential license partners for the program as well as preclinical data. As a part of our efforts toward the clinic, Modalis was able to achieve further downsize of the CRISPR-GNDM® cassette, which shall contribute higher productivity in manufacturing. On the other hand, our strategy stays with finding a partner for MDL-101 and we believe that moving forward with manufacturing without delay is a way to increase the value of the pipeline for partnering and is also our responsibility to the patients who are waiting for the cure.

To accommodate the in-house manufacturing capacity and to gain rooms for future growth of our research function, we relocated our US research lab to Waltham MA as of Oct 20th. The area is one of the top business growth areas in Massachusetts offering traction to educated, diverse, and growing life science community.

As reported last quarter, Modalis regained the right of MDL-205 targeting Angelman syndrome from Astellas. To pursue the development by ourselves, we have re-obtained necessary licenses or research tools and materials and continues preclinical studies.

A shareholder of the Company 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.

As a result, for the Nine months ended September 30, 2021, operating revenue amounted to ¥1,100 thousand, operating loss to ¥677,519 thousand, ordinary loss to ¥661,924 thousand, and Loss attributable to owners of parent to ¥181,372 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 increased by ¥173,699 thousand from the end of the previous fiscal year to ¥5,622,246 thousand. This is mainly attributable to an increase in other by ¥131,549 thousand.

(Non-current Assets)

Total non-current assets at the end of the third quarter of the fiscal year under review increased by ¥47,646 thousand from the end of the previous fiscal year to ¥876,116 thousand. This is mainly attributable to an increase in investments and other assets of ¥50,446 thousand.

(Current Liabilities)

Total current liabilities at the end of the third quarter of the fiscal year under review increased by ¥28,382 thousand from the end of the previous fiscal year to ¥86,648 thousand. This is mainly attributable to other by ¥36,180 thousand.

(Non-current Liabilities)

Total non-current liabilities at the end of the third quarter of the fiscal year under review increased by ¥306,215 thousand from the end of the previous fiscal year to ¥318,108 thousand. This is attributable to an increase in other by ¥300,693 thousand.

(Net Assets)

Total net assets at the end of the third quarter of the fiscal year under review decreased by ¥113,251 thousand from the end of the previous fiscal year to ¥6,093,605 thousand. This is mainly attributable to a decrease in retained earnings by ¥181,372 thousand thanks to the posting of loss despite an increase in share capital and capital surplus by ¥30,865 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 September 30, 2021
Assets		
Current assets		
Cash and deposits	5,421,476	5,463,626
Other	27,070	158,619
Total current assets	5,448,546	5,622,246
Non-current assets		
Property, plant and equipment	49,774	94,084
Intangible assets		
Right to use patent	767,445	720,408
Other	374	301
Total intangible assets	767,819	720,709
Investments and other assets	10,876	61,322
Total non-current assets	828,470	876,116
Total assets	6,277,017	6,498,362
Liabilities		
Current liabilities		
Income taxes payable	21,619	13,821
Other	36,647	72,827
Total current liabilities	58,266	86,648
Non-current liabilities		
Deferred tax liabilities	11,893	17,414
Other	-	300,693
Total non-current liabilities	11,893	318,108
Total liabilities	70,160	404,757
Net assets		
Shareholders' equity		
Share capital	2,707,320	2,738,185
Capital surplus	4,029,055	4,059,920
Retained earnings	(527,519)	(708,892)
Treasury stock	-	(97)
Total shareholders' equity	6,208,855	6,089,114
Accumulated other comprehensive income		
Foreign currency translation adjustment	(1,998)	4,490
Total accumulated other comprehensive income	(1,998)	4,490
Total net assets	6,206,857	6,093,605
Total liabilities and net assets	6,277,017	6,498,362

(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, 2020	For the Nine months ended September 30, 2021
Operating revenue	340,000	1,100
Operating expenses		
Research and development expenses	348,898	493,784
Selling, general and administrative expenses	159,101	184,835
Total operating expenses	508,000	678,619
Operating loss	(168,000)	(677,519)
Non-operating income		
Interest income	52	57
Subsidy income	79	205
Foreign exchange income	-	16,189
Other	4	235
Total non-operating income	135	16,688
Non-operating expenses		
Listing expenses	20,104	-
Foreign exchange losses	5,038	-
Stock issuance cost	15,915	1,092
Other	89	-
Total non-operating expenses	41,147	1,092
Ordinary loss	(209,012)	(661,924)
Extraordinary income		
Income of compensation	-	485,881
Total extraordinary income	-	485,881
Loss before income taxes or Loss before income taxes	(209,012)	(176,042)
Income taxes - current	850	915
Income taxes - deferred	4,230	4,414
Total income taxes	5,081	5,330
Loss	(214,093)	(181,372)
Loss attributable to owners of parent or	(214,093)	(181,372)

Quarterly Consolidated Statements of Comprehensive Income

Nine months ended September 30

(Thousand yen)

	For the Nine months ended September 30, 2020	For the Nine months ended September 30, 2021
Loss	(214,093)	(181,372)
Other comprehensive income		
Foreign currency translation adjustment	(1,572)	6,488
Total other comprehensive income	(1,572)	6,488
Comprehensive income	(215,665)	(174,883)
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	(215,665)	(174,883)

(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 ¥30,865 thousand due to the exercise of stock acquisition rights as a stock option. As a result, at the Nine months ended September 30, 2021, the share capital and capital surplus were ¥2,738,185 thousand, ¥4,059,920 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.