Consolidated Financial Results for the Six Months Ended June 30, 2021 [Japanese GAAP]

August 5, 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: August 13, 2021
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 securities analysts and institutional investors)

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

1. Consolidated Financial Results for the Six Months Ended June 30, 2021 (January 1, 2021 to June 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	
Six months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
June 30, 2021	1	(99.7)	(477)	-	(464)	-	17	(34.1)
June 30, 2020	337	-	38	-	29	-	26	-

(Note) Comprehensive income: Six months ended June 30, 2021: ¥ 22 million [(15.6) %]
Six months ended June 30, 2020: ¥ 26 million [-%]

	Basic earnings per share	Diluted earnings per share
Six months ended	Yen	Yen
June 30, 2021	0.62	0.59
June 30, 2020	1.07	-

(Notes)
For diluted earnings per share for the fiscal year ended June 30, 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 June 30, 2021	6,697	6,286	93.9
As of December 31, 2020	6,277	6,206	98.9

(Reference) Equity: As of June 30, 2021: ¥6,286 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 six months ended June 30, 2021 (changes in specified subsidiaries resulting in changes in scope of consolidation): No
Notes on changes in significant subsidiaries during the six months ended June 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):

June 30, 2021: 28,805,200shares

December 31, 2020: 28,515,600 shares

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

June 30, 2021: - shares

December 31, 2020: - shares

3) Average number of shares during the period:

Six months ended June 30, 2021: 28,625,482 shares

Six months ended June 30, 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 six months ended June 30, 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 six months ended June 30, 2021.

During the six months ended June 30, 2021, collaboration pipelines and internal pipelines were in progress. The lead internal pipeline, MDL-101, has added mouse disease model data in addition to the non-human primate studies which has been reported. They revealed systemic injection of mMDL-101 (MDL-101 with mice version gRNA) shows a dose-dependent improvement in muscle function. To advance further development of the program, we have hired an expert to initiate full-scale preparations for GMP material to initiate clinical trial as well as GLP studies. Concurrently, we are in discussion with multiple pharma and biotech companies for potential patnering.

MDL-206 had been jointly researched with a partner Astellas Pharma Inc. ("Astellas") for Angelman Syndrome, but Astellas notified us today of its decision not to extend the joint research program for MDL-206. All rights to MDL-206 will be returned to Modalis, and the Company will continue to advance the program internally as we believe the program, of which we established animal proof-of-concept in the collaboration, is highly differentiated and competitive. Additional research programs with Astellas and with other partner will continue as currently planned.

In this second quarter, Modalis and Astellas entered into sublicense agreements of certain CRISPR/Cas9 foundational patents for use in connection with exploiting MDL-201 and 202.

This outcome was already contemplated under the terms of our existing license agreements for the two programs entered into in 2019 as well as under our business plan. Therefore, this will not have impact on our business while this allows our partner, Astellas, and licensed products to pursue further development.

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 six months ended June 30, 2021, operating revenue amounted to ¥1,100 thousand, operating loss to ¥477,318 thousand, ordinary loss to ¥464,982 thousand, and Profit attributable to owners of parent to ¥17,702 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

a. Status of Assets, Liabilities and Net Assets

(Current Assets)

Total current assets at the end of the second quarter of the fiscal year under review increased by ¥398,336 thousand from the end of the previous fiscal year to ¥5,846,883 thousand. This is mainly attributable to an increased in cash and deposits by ¥363,103 thousand.

(Non-current Assets)

Total non-current assets at the end of the second quarter of the fiscal year under review increased by ¥22,008 thousand from the end of the previous fiscal year to ¥850,479 thousand. This is mainly attributable to an increased in investments and other assets of ¥49,720 thousand.

(Current Liabilities)

Total current liabilities at the end of the second quarter of the fiscal year under review increased by ¥33,351 thousand from the end of the previous fiscal year to ¥91,618 thousand. This is mainly attributable to other by ¥33,341 thousand.

(Non-current Liabilities)

Total non-current liabilities at the end of the second quarter of the fiscal year under review increased by ¥307,443 thousand from the end of the previous fiscal year to ¥319,336 thousand. This is attributable to an increase in other by ¥304,650 thousand.

(Net Assets)

Total net assets at the end of the second quarter of the fiscal year under review increased by ¥79,551 thousand from the end of the previous fiscal year to ¥6,286,408 thousand. This is mainly attributable to an increase in retained earnings by ¥17,702 thousand thanks to the posting of profit despite an increase in share capital and capital surplus by ¥28,615 thousand.

b. Status of Cash Flows

Cash and cash equivalents (hereinafter referred to as “cash”) at the end of the second quarter of the fiscal year under review amounted to ¥5,784,579 thousand, up by ¥363,103 thousand from ¥5,421,476 thousand at the previous fiscal year end. The status of respective cash flows and key factors are as follows.

(Cash Flows from Operating Activities)

Net cash provided by operating activities during the six months ended June 30, 2021 amounted to ¥18,377 thousand. This is mainly attributable to the posting of profit before income taxes of ¥20,899 thousand.

(Cash Flows from Investing Activities)

Net cash provided by investing activities during the six months ended June 30, 2021 amounted to ¥275,022 thousand. This is mainly attributable to the posting of proceeds from contribution received for right to use patent of ¥329,670 thousand.

(Cash Flows from Financing Activities)

Net cash provided by financing activities during the six months ended June 30, 2021 amounted to ¥56,436 thousand. This is mainly attributable to the posting of proceeds from issuance of stock acquisition rights of ¥56,436 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 June 30, 2021
Assets		
Current assets		
Cash and deposits	5,421,476	5,784,579
Other	27,070	62,304
Total current assets	5,448,546	5,846,883
Non-current assets		
Property, plant and equipment	49,774	53,462
Intangible assets		
Right to use patent	767,445	736,087
Other	374	331
Total intangible assets	767,819	736,419
Investments and other assets	10,876	60,597
Total non-current assets	828,470	850,479
Total assets	6,277,017	6,697,362
Liabilities		
Current liabilities		
Income taxes payable	21,619	21,628
Other	36,647	69,989
Total current liabilities	58,266	91,618
Non-current liabilities		
Deferred tax liabilities	11,893	14,685
Other	-	304,650
Total non-current liabilities	11,893	319,336
Total liabilities	70,160	410,954
Net assets		
Shareholders' equity		
Share capital	2,707,320	2,735,935
Capital surplus	4,029,055	4,057,670
Retained earnings	(527,519)	(509,816)
Total shareholders' equity	6,208,855	6,283,788
Accumulated other comprehensive income		
Foreign currency translation adjustment	(1,998)	2,620
Total accumulated other comprehensive income	(1,998)	2,620
Total net assets	6,206,857	6,286,408
Total liabilities and net assets	6,277,017	6,697,362

(2) Quarterly Consolidated Statements of Income and Comprehensive Income

Quarterly Consolidated Statements of Income

Six Months Ended June 30

(Thousand yen)

	For the six months ended June 30, 2020	For the six months ended June 30, 2021
Operating revenue	337,000	1,100
Operating expenses		
Research and development expenses	204,083	349,005
Selling, general and administrative expenses	94,093	129,412
Total operating expenses	298,176	478,418
Operating loss	38,823	(477,318)
Non-operating income		
Interest income	19	27
Subsidy income	79	205
Foreign exchange income	-	12,834
Other	3	63
Total non-operating income	101	13,129
Non-operating expenses		
Listing expenses	5,414	-
Foreign exchange losses	3,580	-
Stock issuance cost	-	793
Other	60	-
Total non-operating expenses	9,055	793
Ordinary loss	29,869	(464,982)
Extraordinary income		
Income of compensation	-	485,881
Total extraordinary income	-	485,881
Profit before income taxes or Loss before income taxes	29,869	20,899
Income taxes - current	477	1,269
Income taxes - deferred	2,525	1,927
Total income taxes	3,003	3,196
Profit or Loss	26,865	17,702
Profit attributable to owners of parent or	26,865	17,702

Quarterly Consolidated Statements of Comprehensive Income

Six Months Ended June 30

(Thousand yen)

	For the six months ended June 30, 2020	For the six months ended June 30, 2021
Profit or Loss	26,865	17,702
Other comprehensive income		
Foreign currency translation adjustment	(412)	4,618
Total other comprehensive income	(412)	4,618
Comprehensive income	26,453	22,321
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	26,453	22,321

(3) Quarterly Consolidated Statements of Cash Flows

(Thousand yen)

	For the six months ended June 30, 2020	For the six months ended June 30, 2021
Cash flows from operating activities		
Profit before income taxes	29,869	20,899
Depreciation	19,814	36,622
Interest and dividend income	(19)	(27)
Subsidy income	-	(6,128)
Stock issuance cost	(79)	(205)
Listing expenses	-	793
Foreign exchange losses (gains)	5,414	-
Compensation received	-	(485,881)
Decrease (increase) in trade receivables	(338,800)	-
Increase (decrease) in accounts payable - other	24,925	(3,013)
Increase (decrease) in accrued expenses	55	5,528
Decrease (increase) in consumption taxes refund receivable	-	(1,725)
Increase (decrease) in accrued consumption taxes	(25,130)	-
Other, net	(19,481)	(33,389)
Subtotal	(303,431)	(466,527)
Interest and dividends received	19	27
Subsidies received	79	205
Income taxes paid	(977)	(1,210)
Compensation received	-	485,881
Net cash provided by (used in) operating activities	(304,310)	18,377
Cash flows from investing activities		
Purchase of property, plant and equipment	(242)	(5,620)
Purchase of intangible assets	(814,481)	
Proceeds from contribution received for right to use patent	-	329,670
Payment of lease deposits	-	(49,346)
Other, net	(5)	319
Net cash provided by (used in) investing activities	(814,728)	275,022
Cash flows from financing activities		
Proceeds from issuance of stock acquisition rights	-	56,436
Payments of listing expenses	(1,766)	-
Other, net	(60)	-
Net cash provided by (used in) financing activities	(1,827)	56,436
Effect of exchange rate change on cash and cash equivalents	(766)	13,267
Net increase (decrease) in cash and cash equivalents	(1,121,633)	363,103
Cash and cash equivalents at the beginning of period	3,857,235	5,421,476
Cash and cash equivalents at the end of period	2,736,601	5,784,579

(4) 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 ¥28,615 thousand due to the exercise of stock acquisition rights as a stock option. As a result, at the six months ended June 30, 2021, the share capital and capital surplus were ¥2,735,935 thousand, ¥4,057,670 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.