Consolidated Financial Results for the Six Months Ended June 30, 2023 [Japanese GAAP]

August 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: Aug 14, 2023
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, 2023 (January 1, 2023, to June 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	
Six months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
June 30, 2023	-	(100.0)	(1,044)	-	(995)	-	(1,033)	-
June 30, 2022	40	-	(868)	-	(780)	-	(775)	-

(Note) Comprehensive income: Six months ended June 30, 2023: ¥ (1,034) million [-%]
Six months ended June 30, 2022: ¥ (746) million [-%]

	Basic earnings per share	Diluted earnings per share
Six months ended	Yen	Yen
June 30, 2023	(34.70)	-
June 30, 2022	(26.70)	-

(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 June 30, 2023	2,855	2,532	88.0
As of December 31, 2022	3,129	2,941	93.4

(Reference) Equity: As of June 30, 2023: ¥2,512million
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	-	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 4 “Explanation of Consolidated Financial Results Forecast and Other Forward-looking Information.”

*** Notes:**

(1) Changes in significant subsidiaries during the six months ended June 30, 2023 (changes in specified subsidiaries resulting in changes in scope of consolidation): No

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

(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):
June 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:
June 30, 2023: 63 shares
December 31, 2022: 63 shares

3) Average number of shares during the period:
Six months ended June 30, 2023: 29,779,233 shares
Six months ended June 30, 2022: 29,055,760 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 4 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 second 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 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 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.

The company just announced the reacquisition of the rights to develop, manufacture, and market MDL-201 and 202, which are targeted for Duchenne muscular dystrophy (DMD) and myotonic dystrophy type 1 (DM1), respectively from Astellas Pharma Inc. Both of these diseases are considered to be among the most common muscle diseases in Japan. We have decided to reacquire MDL-101 because we believe that we can develop two drugs for the same muscle diseases in a better form by applying our experience and know-how of MDL-101, which we have been developing in-house.

With this reacquisition, we have reviewed our pipeline and deleted MDL-102 and 206, and conversely added MDL-103 which is targeted for Facioscapulohumeral Muscular Dystrophy (FSHD). We believe that the development of MDL-101 has further improved our muscle disease program by confirming in mice and monkeys that the combination of a muscle-selective viral vector and a GNDM cassette can efficiently deliver GNDM molecules to muscle and regulate the gene of interest, based on the decision to focus resources on this project.

We received a response from the U.S. Food and Drug Administration (FDA) at the end of June regarding the Pre-IND for MDL-101, and the FDA has confirmed the development pathway and conditions leading up to the start of clinical trials. We believe that our development proposal has been basically accepted and that we will be able to reach clinical trials with some minor modifications. We believe that this is probably the first case in the world where a Pre-IND has been conducted with the authorities among several CRISPR-based epigenetics editing companies, and we consider it very significant that we have taken this new step as a leader in this field.

At the American Society for Gene and Cell Therapy (ASGCT) meeting held in Los Angeles in May, we reported on our MDL-101 development results. This data included data on target engagement in non-human primates, and we believe the data was compelling enough to dispel any skepticism about the direction of the epigenetic editing technology. In fact, we have seen followers of our technology and follow-on presentations from these companies. We believe that this data not only guarantees the efficacy of MDL-101 against its target disease, LAMA2-CMD (aka MDC1A), but also predicts an extrapolatable effect on other muscle disease programs with which it shares the CRISPR-GNDM® muscle platform.

We anticipate that these results will have the effect of expanding partnering possibilities as a financing option and driving ongoing discussions. We also believe that the reacquired MDL-201 and MDL-202 will provide new revenue opportunities for the Company, given the large number of patients and high unmet need in the diseases.

As a result, for the six months ended June 30, 2023, operating loss to ¥1,044,792 thousand, ordinary loss to ¥995,474 thousand, and Loss attributable to owners of parent to ¥1,033,228 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 decreased by ¥278,411 thousand from the end of the previous fiscal year to ¥2,782,816 thousand. This is mainly attributable to a decrease in cash and deposits by ¥341,771 thousand.

(Non-current Assets)

Total non-current assets at the end of the second quarter of the fiscal year under review increased by ¥4,240 thousand from the end of the previous fiscal year to ¥72,845 thousand. This is mainly attributable to an increase in Investments and other assets by ¥4,240 thousand.

(Current Liabilities)

Total current liabilities at the end of the second quarter of the fiscal year under review increased by ¥136,172 thousand from the end of the previous fiscal year to ¥278,012 thousand. This is mainly attributable to an increase in others of ¥112,198 thousand.

(Non-current Liabilities)

Total non-current liabilities at the end of the second quarter of the fiscal year under review decreased by ¥1,612 thousand from the end of the previous fiscal year to ¥45,147 thousand. This is attributable to a decrease in others by ¥2,070 thousand.

(Net Assets)

Total net assets at the end of the second quarter of the fiscal year under review decreased by ¥408,731 thousand from the end of the previous fiscal year to ¥2,532,501 thousand. This is mainly attributable to a decrease in retained earnings by ¥1,033,228 thousand thanks to the posting of loss.

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 ¥2,591,391 thousand, the decrease by ¥341,771 thousand from ¥2,933,162 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 used in operating activities during the six months ended June 30, 2023 amounted to ¥979,332 thousand. This is mainly attributable to the posting of loss before income taxes of ¥1,032,620 thousand.

(Cash Flows from Investing Activities)

Net cash used in investing activities during the six months ended June 30, 2023 amounted to ¥37,830 thousand. This is mainly attributable to the posting of purchase of property, plant and equipment of ¥37,830 thousand.

(Cash Flows from Financing Activities)

Net cash provided by financing activities during the six months ended June 30, 2023 amounted to ¥615,005 thousand. This is mainly attributable to the posting of proceeds from issuance of stock acquisition rights of ¥618,372 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, 2022	As of June 30, 2023
Assets		
Current assets		
Cash and deposits	2,933,162	2,591,391
Supplies	40,307	51,371
Other	87,757	140,052
Total current assets	3,061,228	2,782,816
Non-current assets		
Investments and other assets	68,605	72,845
Total non-current assets	68,605	72,845
Total assets	3,129,833	2,855,661
Liabilities		
Current liabilities		
Income taxes payable	13,112	12,768
Provision for bonuses	—	24,317
Other	128,727	240,925
Total current liabilities	141,840	278,012
Non-current liabilities		
Provision for share-based compensation for director	1,260	1,344
Provision for share-based compensation for employee	6,487	6,860
Other	39,012	36,942
Total non-current liabilities	46,760	45,147
Total liabilities	188,600	323,159
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)	(1,051,680)
Treasury shares	(97)	(97)
Total shareholders' equity	2,905,825	2,497,731
Accumulated other comprehensive income		
Foreign currency translation adjustment	16,483	14,806
Total accumulated other comprehensive income	16,483	14,806
Subscription rights to shares	18,923	19,963
Total net assets	2,941,232	2,532,501
Total liabilities and net assets	3,129,833	2,855,661

(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, 2022	For the six months ended June 30, 2023
Operating revenue	40,500	—
Operating expenses		
Research and development expenses	778,908	906,431
Selling, general and administrative expenses	130,049	138,360
Total operating expenses	908,957	1,044,792
Operating loss	(868,457)	(1,044,792)
Non-operating income		
Interest income	27	14
Foreign exchange income	90,899	54,637
Other	299	8
Total non-operating income	91,227	54,660
Non-operating expenses		
Interest expense	2,311	2,212
Stock issuance cost	654	2,837
Amortization of stock issuance cost	267	293
Total non-operating expenses	3,253	5,343
Ordinary loss	(780,483)	(995,474)
Extraordinary loss		
Impairment loss	—	37,146
Total extraordinary loss	—	37,146
Loss before income taxes	(780,483)	(1,032,620)
Income taxes - current	609	607
Income taxes - deferred	(5,397)	—
Total income taxes	(4,788)	607
Loss	(775,695)	(1,033,228)
Loss attributable to owners of parent	(775,695)	(1,033,228)

Quarterly Consolidated Statements of Comprehensive Income

Six Months Ended June 30

(Thousand yen)

	For the six months ended June 30, 2022	For the six months ended June 30, 2023
Loss	(775,695)	(1,033,228)
Other comprehensive income		
Foreign currency translation adjustment	28,819	(1,676)
Total other comprehensive income	28,819	(1,676)
Comprehensive income	(746,875)	(1,034,904)
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	(746,875)	(1,034,904)

(3) Quarterly Consolidated Statements of Cash Flows

(Thousand yen)

	For the six months ended June 30, 2022	For the six months ended June 30, 2023
Cash flows from operating activities		
Loss before income taxes	(780,483)	(1,032,620)
Depreciation	58,358	683
Impairment loss	—	37,146
Increase (decrease) in provision for share-based compensation for director	371	84
Increase (decrease) in provision for share-based compensation for employee	1,873	373
Increase (decrease) in provision for bonuses	13,839	22,728
Share-based compensation expenses	2,077	4,963
Interest and dividend income	(27)	(14)
Stock issuance cost	654	2,837
Interest expenses	2,331	2,212
Foreign exchange losses (gains)	(64,452)	(37,317)
Increase (decrease) in accounts payable - other	11,807	66,788
Increase (decrease) in accrued expenses	10,434	23,134
Decrease (increase) in consumption taxes refund receivable	26,163	(913)
Other, net	8,401	(66,009)
Subtotal	(708,650)	(975,925)
Interest and dividends received	27	14
Interest expenses paid	(3,551)	(2,212)
Income taxes paid	(1,210)	(1,210)
Net cash provided by (used in) operating activities	(713,384)	(979,332)
Cash flows from investing activities		
Purchase of property, plant and equipment	(129,719)	(37,830)
Payment of lease deposits	(939)	—
Collection of lease deposits	11,694	—
Net cash provided by (used in) investing activities	(118,965)	(37,830)
Cash flows from financing activities		
Proceeds from issuance of stock acquisition rights	7,595	618,372
Repayments of installment payables	(3,674)	(3,073)
Other, net	(267)	(293)
Net cash provided by (used in) financing activities	3,653	615,005
Effect of exchange rate change on cash and cash equivalents	50,993	60,387
Net increase (decrease) in cash and cash equivalents	(777,701)	(341,771)
Cash and cash equivalents at the beginning of period	4,936,193	2,933,162
Cash and cash equivalents at the end of period	4,158,491	2,591,391

(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 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, at the six months ended June 30, 2023, the share capital, capital surplus and retained earnings were ¥1,113,887 thousand, ¥2,435,622 thousand and (¥1,051,680) 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.

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, 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 such as MDL-202.

On the funding side, as of the end of the second quarter of the consolidated fiscal year, the Company had 2,591,391 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.