Consolidated Financial Results for the Six Months Ended June 30, 2024 [Japanese GAAP]

August 7, 2024

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 13, 2024
Scheduled date of commencing dividend payments: -
Preparation of supplementary material on financial results: Yes
Holding of financial results briefing: Yes (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, 2024 (January 1, 2024, to June 30, 2024)

(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, 2024	-	-	(838)	-	(780)	-	(780)	-
June 30, 2023	-	(100.0)	(1,044)	-	(995)	-	(1,033)	-

(Note) Comprehensive income: Six months ended June 30, 2024: ¥ (772) million [-%]
Six months ended June 30, 2023: ¥ (1,034) million [-%]

	Basic earnings per share	Diluted earnings per share
Six months ended	Yen	Yen
June 30, 2024	(21.98)	-
June 30, 2023	(34.24)	-

(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, 2024	1,409	1,112	77.8
As of December 31, 2023	2,025	1.380	66.8

(Reference) Equity: As of June 30, 2024: ¥1,096million
As of December 31, 2023: ¥1.353million

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, 2023	-	0.00	-	0.00	0.00
Fiscal year ending December 31, 2024	-	0.00			
Fiscal year ending December 31, 2024 (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, 2024(January 1, 2024, to December 31, 2024)

The earnings forecasts for fiscal year 2024 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, 2024 (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, 2024: 39,438,762 shares
December 31, 2023: 33,355,272 shares

2) Total number of treasury shares at the end of the period:
June 30, 2024: 63 shares
December 31, 2023: 63 shares

3) Average number of shares during the period:
Six months ended June 30, 2024: 35,524,843 shares
Six months ended June 30, 2023: 30,966,143 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

Forward-looking statements in the text are based on our judgment as of the end of the second quarter of the current consolidated fiscal year unless otherwise stated.

During the first half of the current fiscal year, the Japanese economy continued to face a number of challenges, including continued instability in Ukraine, the Middle East, and East Asia, including the Taiwan Strait, while the Nikkei Index reached new highs; unstable political conditions in major countries in this year of national elections; rising inflation, including soaring raw material prices; and exchange rate The outlook remains uncertain due to such factors as sharp fluctuations in exchange rates. In the pharmaceutical and biotech industries, the tightening of financial and capital markets in the U.S. has also led to layoffs and the liquidation and review of pipelines.

Based on the CRISPR-GNDM® platform, which serves as the technological foundation, the Modalis Group has continued to lead cutting-edge research as a leading company from its establishment in 2016 to its ninth year as the world's first company to develop gene modulation therapy using CRISPR. In order to achieve this goal, we have continued to work toward the start of clinical trials. .

Our lead program, MDL-101, established manufacturing process and analytical methods to achieve stable production and quality control of muscle tropic engineered AAV vectors, is preparing for GLP toxicity testing and GMP investigational drug manufacturing in preparation for submission for clinical trials. The preclinical data was published in a paper in May and has also been reported at conferences. The results of this paper have been well received, and we have received multiple inquiries from patients suffering from LAMA2-CMD, their families, and physicians from all over the world to participate in the potential clinical trial. We have also received several inquiries from pharma and biotech companies for strategic partnering. Although we had been aiming to reach the IND for this program by the end of 2024, this will be delayed to the first half of 2025 as a result of the budget review and reallocation of development resources following the business restructuring implemented in April and at the end of June. On the other hand, we have submitted orphan drug designation (ODD) and applications for rare pediatric disease designation (RPDD) to the U.S. FDA after the second quarter, and the rationale and medical relevance of the development are expected to be reviewed. If these applications are accepted, the company will benefit from a number of economic advantages, including a tax credit for clinical trial costs and a seven-year market exclusivity after launch.

Other programs, as reported earlier, have made marginal progress in development due to the decision to focus development resources on MDL-101, but we have, for example, been working in the area of the central nervous system to try to expand access to technology that can cross the blood-brain barrier, and we are working with JCR Pharma's capsid technology, JBC-AAV, and our payload, which is based on our CRISPR-GNDM® technology and has obtained excellent preclinical PoC in various target diseases. While we continue to conduct the ongoing research, partnering activities are ongoing by leveraging the partnership with Ginkgo Bioworks, which has a diverse network in a wide range of bio-space globally and we are preparing to resume full-speed development as soon as resources become available.

As we reported in July, we have also entered a memorandum of understanding for research collaboration to develop next-generation therapeutics for Alzheimer’s disease with Genixcure, a South Korean emerging company, using their engineered capsid technology based on its AI-powered system. Thus, we are actively exploring innovative capsid technology , which is a common bottleneck for gene therapy.

In early July, we also announced additional layoff of our U.S. subsidiary, as a follow up of what was announced in April, in order to focus business resources on MDL-101 and to create a leaner business structure. As we complete the development of manufacturing processes, we are reducing our workforce, particularly some

remaining manufacturing-related personnel. The Company remains well-positioned to continue development efforts to bring MDL-101 into the clinic, and plans to move forward with development so that patients can be treated as soon as possible.

As a result, for the six months ended June 30, 2023, operating loss to ¥838,956 thousand, ordinary loss to ¥780,152 thousand, and Loss attributable to owners of parent to ¥780,946 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 ¥623,813 thousand from the end of the previous fiscal year to ¥1,332,510 thousand. This is mainly attributable to a decrease in cash and deposits by ¥605,155 thousand.

(Non-current Assets)

Total non-current assets at the end of the second quarter of the fiscal year under review increased by ¥7,563 thousand from the end of the previous fiscal year to ¥77,165 thousand. This is mainly attributable to an increase in Investments and other assets by ¥7,563 thousand.

(Current Liabilities)

Total current liabilities at the end of the second quarter of the fiscal year under review decreased by ¥94,861 thousand from the end of the previous fiscal year to ¥103,239 thousand. This is mainly attributable to a decrease in others by ¥103,426 thousand.

(Non-current Liabilities)

Total non-current liabilities at the end of the second quarter of the fiscal year under review decreased by ¥253,693 thousand from the end of the previous fiscal year to ¥193,708 thousand. This is attributable to a decrease in warrant bond by ¥250,000 thousand.

(Net Assets)

Total net assets at the end of the second quarter of the fiscal year under review decreased by ¥267,695 thousand from the end of the previous fiscal year to ¥1,112,727 thousand. This is mainly attributable to a decrease in retained earnings by ¥780,946 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 ¥1,278,281 thousand, the decrease by ¥605,155 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, 2024 amounted to ¥931,410 thousand. This is mainly attributable to the posting of loss before income taxes of ¥780,340 thousand.

(Cash Flows from Investing Activities)

Net cash used in investing activities during the six months ended June 30, 2024 amounted to ¥188 thousand. This is mainly attributable to the posting of purchase of property, plant and equipment of ¥188 thousand.

(Cash Flows from Financing Activities)

Net cash provided by financing activities during the six months ended June 30, 2024 amounted to ¥256,143 thousand. This is mainly attributable to the posting of proceeds from issuance of stock acquisition rights of ¥260,054 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, 2023	As of June 30, 2024
Assets		
Current assets		
Cash and deposits	1,883,437	1,278,281
Supplies	6,353	3,486
Other	66,533	50,741
Total current assets	1,956,323	1,332,510
Non-current assets		
Investments and other assets	69,601	77,165
Total non-current assets	69,601	77,165
Total assets	2,025,925	1,409,675
Liabilities		
Current liabilities		
Income taxes payable	5,973	5,510
Provision for bonuses	—	9,026
Other	192,128	88,701
Total current liabilities	198,101	103,239
Non-current liabilities		
Provision for share-based compensation for director	733	489
Provision for share-based compensation for employee	3,590	2,307
warrant bond	412,500	162,500
Other	30,577	28,412
Total non-current liabilities	447,401	193,708
Total liabilities	645,502	296,948
Net assets		
Shareholders' equity		
Share capital	1,217,652	273,583
Capital surplus	2,539,387	1,595,318
Retained earnings	(2,410,273)	(788,671)
Treasury shares	(97)	(97)
Total shareholders' equity	1,346,669	1,080,132
Accumulated other comprehensive income		
Foreign currency translation adjustment	7,323	16,124
Total accumulated other comprehensive income	7,323	16,124
Subscription rights to shares	26,430	16,470
Total net assets	1,380,422	1,112,727
Total liabilities and net assets	2,025,925	1,409,675

(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, 2023	For the six months ended June 30, 2024
Operating revenue	—	—
Operating expenses		
Research and development expenses	※1 906,431	716,518
Selling, general and administrative expenses	※2 138,360	122,437
Total operating expenses	1,044,792	838,956
Operating loss	(1,044,792)	(838,956)
Non-operating income		
Interest income	14	8
Foreign exchange income	54,637	63,032
Other	8	11
Total non-operating income	54,660	63,052
Non-operating expenses		
Interest expense	2,212	2,057
Stock issuance cost	2,837	2,190
Amortization of stock issuance cost	293	—
Total non-operating expenses	5,343	4,248
Ordinary loss	(995,474)	(780,152)
Extraordinary loss		
Impairment loss	37,146	188
Total extraordinary loss	37,146	188
Loss before income taxes	(1,032,620)	(780,340)
Income taxes - current	607	606
Total income taxes	607	606
Loss	(1,033,228)	(780,946)
Loss attributable to owners of parent	(1,033,228)	(780,946)

Quarterly Consolidated Statements of Comprehensive Income

Six Months Ended June 30

(Thousand yen)

	For the six months ended June 30, 2023	For the six months ended June 30, 2024
Loss	(1,033,228)	(780,946)
Other comprehensive income		
Foreign currency translation adjustment	(1,676)	8,801
Total other comprehensive income	(1,676)	8,801
Comprehensive income	(1,034,904)	(772,145)
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	(1,034,904)	(772,145)

(3) Quarterly Consolidated Statements of Cash Flows

(Thousand yen)

	For the six months ended June 30, 2023	For the six months ended June 30, 2024
Cash flows from operating activities		
Loss before income taxes	(1,032,620)	(780,340)
Depreciation	683	—
Impairment loss	37,146	188
Increase (decrease) in provision for share-based compensation for director	84	(244)
Increase (decrease) in provision for share-based compensation for employee	373	(1,283)
Increase (decrease) in provision for bonuses	22,728	—
Share-based compensation expenses	4,963	(7,795)
Increase (decrease) in provision for Allowance for business structure improvement	—	—
Interest and dividend income	(14)	(8)
Stock issuance cost	2,837	2,190
Interest expenses	2,212	2,057
Foreign exchange losses (gains)	(37,317)	(56,613)
Increase (decrease) in accounts payable - other	66,788	(47,435)
Increase (decrease) in accrued expenses	23,134	(67,081)
Decrease (increase) in consumption taxes refund receivable	(913)	7,442
Other, net	(66,009)	12,209
Subtotal	(975,925)	(928,151)
Interest and dividends received	14	8
Interest expenses paid	(2,212)	(2,057)
Income taxes paid	(1,210)	(1,210)
Net cash provided by (used in) operating activities	(979,332)	(933,696)
Cash flows from investing activities		
Purchase of property, plant and equipment	(37,830)	(188)
Net cash provided by (used in) investing activities	(37,83)	(188)
Cash flows from financing activities		
Proceeds from issuance of stock acquisition rights	618,372	260,054
Repayments of installment payables	(3,073)	(3,910)
Other, net	(293)	—
Net cash provided by (used in) financing activities	615,005	256,143
Effect of exchange rate change on cash and cash equivalents	60,387	70,299
Net increase (decrease) in cash and cash equivalents	(341,771)	(605,155)
Cash and cash equivalents at the beginning of period	2,933,162	1,883,437
Cash and cash equivalents at the end of period	2,591,391	1,278,281

(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 ¥1,201,273 thousand and retained earnings increased by ¥2,402,547 thousand as the result of covering the loss in retained earnings brought forward as of May 15, 2024 based on the resolution of the 8th Ordinary General Meeting of Shareholders held on March 26, 2024. Additionally, As a result, at the six months ended June 30, 2024, the share capital, capital surplus and retained earnings were ¥273,583 thousand, ¥1,595,318 thousand and (¥788,671) 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.

(Significant subsequent events)

Capital increase through exercise of stock acquisition rights

After the end of the current interim consolidated accounting period, during the period from July 1, 2024 to the end of July 2024, unsecured convertible bonds with stock acquisition rights (with conversion price amendment clause) and a portion of stock acquisition rights with exercise price amendment clause were exercised as follows.

(1)Type and number of shares issued common stock 3,157,695 shares.

(2) Increased capital ¥111,237 thousand.

(3) Increased capital reserve ¥111,237 thousand.

As a result, as of July 31, 2024, there were 42,596,457 shares of common stock issued, ¥384,820 thousand in capital stock, and ¥1,139,820 thousand in capital reserve.

3. Other

Important Events Related to the Premise of a Going Concern etc.

The Modalis group is a drug discovery venture company engaged in the research and development of gene therapeutic drugs. We have a plan to stabilize our business foundation by expanding the range of profit-earning opportunities and optimizing our business options by promoting R&D strategy under a “hybrid model” business model that combines 1) a collaborative model pipeline, which partner with the other pharma/biotech company to share risk and return and 2) an in-house model pipeline which we fully fund the R&D. However, pharmaceutical research and development requires a large amount of capital, and the recovery of such investment takes a relatively long period of time compared to other industries, resulting in continuous operating losses and negative operating cash flows.

In the previous consolidated fiscal year, the Company issued the 1st unsecured convertible bond with stock acquisition rights (with a clause to revise the conversion price) and the 12th warrant (with a clause to revise the exercise price) by third-party allotment in November 2023 in order to secure funds for research and development. The said convertible bonds with stock acquisition rights have a clause that allows the bondholders to request redemption of a part or all of the remaining bonds at any time under certain conditions, one of which is triggered when our share price at any closing price reached minimum exercise price. As it hit on a day during the period, The redemption right has been activated and the risk of redemption of the convertible bonds before the redemption date exists.

The Company will continue to focus its research and development efforts on MDL-101, based on the knowledge gained from the development of CRISPR-based gene regulation therapeutics over the past nine fiscal years. As part of our efforts to streamline our management and organization, we downsized the research, development, and manufacturing departments of our U.S. subsidiary in July and reduced the number of employees by an additional five FTEs. We plan to continue the development of MDL-101 so that we can make it available for patients as soon as possible. At the same time, we will continue to optimize our R&D structure to reduce costs by improving efficiency, while aiming to obtain partnering for subsequent pipeline products as soon as possible.

On the funding side, as of the end of the second quarter of the consolidated fiscal year, the Company had 1,278,281 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.