Consolidated Financial Results for the Nine Months Ended September 30, 2024 [Japanese GAAP]

November 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: -
Scheduled date of commencing dividend payments: -
Preparation of supplementary material on financial results: Yes
Holding of financial results briefing: -

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

1. Consolidated Financial Results for the Nine Months Ended September 30, 2024 (January 1, 2024, to September 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	
Nine months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
September 30, 2024	-	-	(1,062)	-	(1,059)	-	(1,060)	-
September 30, 2023	-	(100.0)	(1,609)	-	(1,542)	-	(1,581)	-

(Note) Comprehensive income: Nine months ended September 30, 2024: ¥ (1,059) million [-%]
Nine months ended September 30, 2023: ¥ (1,586) million [-%]

	Basic earnings per share	Diluted earnings per share
Nine months ended	Yen	Yen
September 30, 2024	(27.21)	-
September 30, 2023	(52.29)	-

(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, 2024	2,811	2,512	88.5
As of December 31, 2023	2,025	1,380	66.8

(Reference) Equity: As of September 30, 2024: ¥2,487million
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 currently. 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 nine months ended September 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):
September 30, 2024: 56,653,746 shares
December 31, 2023: 33,355,272 shares

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

3) Average number of shares during the period:
Nine months ended September 30, 2024: 38,964,683 shares
Nine months ended September 30, 2023: 30,252,107shares

* 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 third quarter of the current consolidated fiscal year unless otherwise stated.

Despite the temporary shockwaves in the market following the increase in Japanese interest rates, the Japanese economy appears to have regained a certain degree of stability during the third quarter of the consolidated cumulative period. Meanwhile, the political landscape remains volatile. Tensions in the Middle East and Ukraine, the rise of right-wing parties in major European countries that are turning their backs on international cooperation, and the trend of policy changes following national elections in Japan and the United States are just a few of the factors contributing to this instability. Furthermore, the market is facing an uncertain future due to persistent and smoldering inflation and rapid fluctuations in exchange rates. Furthermore, the biotech industry is facing a significant decline in funding due to the tightening of financial and capital markets in the United States and other countries. Additionally, there have been layoffs and restructuring, as well as pipeline reviews.

Since our establishment in 2016, our group has continued to spearhead cutting-edge research as a leading company in the development of the world's first gene regulatory therapy using CRISPR, based on our CRISPR-GNDM® platform, which serves as the foundation of our technology. To this end, we are continuing our efforts to initiate clinical trials in the third quarter of the current fiscal year.

MDL-101, our lead program for the treatment of congenital muscular dystrophy type 1A (LAMA2-CMD), is currently preparing for GLP toxicity studies and GMP manufacturing of the investigational drug in advance of clinical trial applications. Furthermore, our preclinical data has been presented in scientific papers and at conferences, as previously mentioned. We have been contacted by patients and their families, as well as medical professionals, suffering from LAMA2-CMD from all over the world. We are working to build a network of patients for future clinical trials. Additionally, we have received inquiries from companies.

Furthermore, during the quarter under review, we received a Rare Pediatric Disease designation (RPDD) from the U.S. Food and Drug Administration (FDA) for MDL-101. The RPDD is a system designed to facilitate the development of new drugs for rare diseases affecting children under the age of 18 in the United States, with fewer than 200,000 individuals currently diagnosed. Upon FDA approval of a product with this designation, it will be eligible for priority review by the FDA for another product. As previously announced in the press release dated October 25th, we have received an Orphan Drug Designation (ODD) from the FDA. This designation will enable us to take advantage of various pharmaceutical and research cost support measures from the FDA, such as exemption from application fees for new drug applications in the US, reduction or exemption of federal taxes related to clinical development, and other development incentives and promotion measures in the US, as well as granting us market exclusivity for the first 7 years after marketing. We believe that this is the result of the RPD designation we received earlier, as well as the recognition of the gene therapy we are developing as a pharmaceutical product with a high level of medical need. We believe that both the RPDD and ODD are the result of our gene therapy being recognized as a pharmaceutical product with high demand in the medical field.

MDL-101 is currently undergoing pre-clinical trials and technology transfer for GMP production. As funding for development has progressed in line with the progress of the fundraising described below, it has become possible to accelerate development. We have concluded a contract with a CDMO and are working to transfer the manufacturing process, which has already been completed. Furthermore, in this quarter, we are preparing to conduct the safety tests on animals that are necessary to realize IND.

The results of this development have been reported at the Cell and Gene Therapy Summit (Jul 8-10 in Boston),

the 5th Next Generation Gene Therapy Immunogenicity Summit (August 20-22), the 16th Bioprocess Summit (August 19-22), and the Nanopore Community Meeting 2024 (September 16-18th) all held in Boston MA, and the company's achievements in maintaining a leading position in epigenome editing have been well received. We also plan to make a presentation on the results and progress of our development at the 5th Genome Editing Therapy Summit (to be held in Boston, USA from December 3rd to 5th).

There has also been progress in terms of patents, and we received notification of an assessment from the Japan Patent Office in September regarding the patent application (patent application 2022-518586) for MDL-202. In addition, in early September, we also received a notice of assessment for a patent (US18/058823) for a modified Cas9 related to the underlying technology of CRISPR-GNDM in the United States. In the development of pharmaceuticals, where the value ultimately accrues to the patent, we believe that progress in the assessment of patents covering products and technology platforms is important.

In order to pursue our business, we raised funds in August through the issuance of the 2nd unsecured convertible bond with stock acquisition rights (with a conversion price revision clause) and the 14th and 15th stock acquisition rights (with an exercise price revision clause), with the EVO Fund as the allottee. The details of this financing are as stated in the press release, but the purpose of this financing is to procure the necessary development funds for the period of the IND enabling and clinical PoC for MDL-101. The convertible bonds were fully converted, and the 14th stock acquisition rights were fully exercised by the end of October. As a result of this financing and the streamlining of our US corporation, which was carried out in July following the April streamlining, we see a light at the end of the tunnel in terms of the immediate funding we need to carry out our development plan for MDL-101, including preclinical trials.

As a result, for the Nine months ended September 30, 2024, operating loss to ¥1,062,397 thousand, ordinary loss to ¥1,059,121 thousand, and Loss attributable to owners of parent to ¥1,060,231 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 ¥786,933 thousand from the end of the previous fiscal year to ¥2,743,257 thousand. This is mainly attributable to an increase in cash and deposits by ¥813,944 thousand.

(Non-current Assets)

Total non-current assets at the end of the third quarter of the fiscal year under review decreased by ¥1,670 thousand from the end of the previous fiscal year to ¥67,931 thousand. This is mainly attributable to a decrease in investments and other assets by ¥1,670 thousand.

(Current Liabilities)

Total current liabilities at the end of the third quarter of the fiscal year under review decreased by ¥135,578 thousand from the end of the previous fiscal year to ¥62,522 thousand. This is mainly attributable to an increase in allowance for bonuses by ¥12,377 thousand and a decrease in others by ¥146,981 thousand.

(Non-current Liabilities)

Total non-current liabilities at the end of the third quarter of the fiscal year under review decreased by ¥211,137 thousand from the end of the previous fiscal year to ¥236,264 thousand. This is mainly attributable to a decrease in warrant bond by ¥202,500 thousand.

(Net Assets)

Total net assets at the end of the third quarter of the fiscal year under review increased by ¥1,131,979 thousand from the end of the previous fiscal year to ¥2,512,401 thousand. This is mainly attributable to an increase in retained earnings by ¥1,139,372 thousand thanks to the posting of loss.

(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.

(4) 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.

Our company will continue to conduct research and development centered on MDL-101, based on the findings of the development of gene regulatory therapeutic drugs using CRISPR over the past nine terms. While we are concentrating on starting clinical trials for the MDL-101 program, we are also working to streamline our management and efficiency of the organization, we are downsizing the research, development and manufacturing departments of our US subsidiary, but we are still in a position to continue our efforts to bring MDL-101 to clinical trials, and we plan to continue development so that we can provide treatment to patients as soon as possible. As before, we will continue to negotiate partnering opportunities in parallel with development. At the same time, we will continue to optimize our R&D structure and work to reduce costs through increased efficiency, while aiming to acquire partnering opportunities for our subsequent pipeline as early as possible.

On the funding side, as of the end of the third quarter of the consolidated fiscal year, the Company had 2,697,381 thousand yen in cash and deposits, which is sufficient to fund our business activities for the next 12 months.

Considering the above, the Company recognizes that there are no significant uncertainties regarding the premise of a going concern.

2. Quarterly Consolidated Financial Statements and Primary Notes

(1) Quarterly Consolidated Balance Sheets

(Thousand yen)

	As of December 31, 2023	As of September 30, 2024
Assets		
Current assets		
Cash and deposits	1,883,437	2,697,381
Supplies	6,353	127
Other	66,533	45,749
Total current assets	1,956,323	2,743,257
Non-current assets		
Investments and other assets	69,601	67,931
Total non-current assets	69,601	67,931
Total assets	2,025,925	2,811,189
Liabilities		
Current liabilities		
Income taxes payable	5,973	5,039
Provision for bonuses	—	12,337
Other	192,128	45,146
Total current liabilities	198,101	62,522
Non-current liabilities		
Provision for share-based compensation for director	733	699
Provision for share-based compensation for employee	3,590	3,185
warrant bond	412,500	210,000
Other	30,577	22,379
Total non-current liabilities	447,401	236,264
Total liabilities	645,502	298,787
Net assets		
Shareholders' equity		
Share capital	1,217,652	1,116,180
Capital surplus	2,539,387	2,437,915
Retained earnings	(2,410,273)	(1,067,956)
Treasury shares	(97)	(97)
Total shareholders' equity	1,346,669	2,486,042
Accumulated other comprehensive income		
Foreign currency translation adjustment	7,323	1,457
Total accumulated other comprehensive income	7,323	1,457
Subscription rights to shares	26,430	24,901
Total net assets	1,380,422	2,512,401
Total liabilities and net assets	2,025,925	2,811,189

(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, 2023	For the nine months ended September 30, 2024
Operating revenue	—	—
Operating expenses		
Research and development expenses	1,401,667	882,155
Selling, general and administrative expenses	207,765	180,241
Total operating expenses	1,609,433	1,062,397
Operating loss	(1,609,433)	(1,062,397)
Non-operating income		
Interest income	25	94
Foreign exchange income	75,924	19,628
Other	400	11
Total non-operating income	76,350	19,734
Non-operating expenses		
Interest expense	3,326	2,978
Bond issuance cost	—	9,133
Stock issuance cost	6,021	4,346
Amortization of stock issuance cost	443	—
Total non-operating expenses	9,791	16,458
Ordinary loss	(1,542,873)	(1,059,121)
Extraordinary loss		
Impairment loss	38,024	188
Total extraordinary loss	38,024	188
Loss before income taxes	(1,580,898)	(1,059,309)
Income taxes - current	911	921
Total income taxes	911	921
Loss	(1,581,809)	(1,060,231)
Loss attributable to owners of parent	(1,581,809)	(1,060,231)

Quarterly Consolidated Statements of Comprehensive Income

Nine Months Ended September 30

(Thousand yen)

	For the nine months ended September 30, 2023	For the nine months ended September 30, 2024
Loss	(1,581,809)	(1,060,231)
Other comprehensive income		
Foreign currency translation adjustment	(4,559)	713
Total other comprehensive income	(4,559)	713
Comprehensive income	(1,586,369)	(1,059,518)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent	(1,586,369)	(1,059,518)

(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 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, during the consolidated cumulative period of the third quarter, the share capital increased by 1,099,802 thousand yen and the capital surplus increased by 1,099,802 thousand yen due to the exercise of convertible bonds and warrants. As a result, at the nine months ended September 30, 2024, the share capital, capital surplus and retained earnings were ¥1,116,180 thousand, ¥2,437,915 thousand and (¥1,067,956) 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.

(Note on the cash flow statements)

We have not prepared the quarterly consolidated cash flow statements for the nine months ended September 30, 2024. The depreciation expense for the nine months ended September 30 (including amortization of intangible assets) is as follows:

(thousand yen)

	For the nine months ended September 30, 2023	For the nine months ended September 30, 2024
Depreciation expense	711	―

(Significant subsequent events)

Capital increase through exercise of stock acquisition rights

After the end of the third quarter, from October 1, 2024, to the end of October 2024, there was an exercise of rights for part of the 2nd convertible bonds and the 14th stock acquisition rights, as detailed below.

(1)Type and number of shares issued common stock 12,750,252 shares.

(2) Increased capital ¥642,806 thousand.

(3) Increased capital reserve ¥642,806 thousand.

As a result, as of October 31, 2024, there were 69,403,998 shares of common stock issued, ¥1,758,987 thousand in capital stock, and ¥2,513,987 thousand in capital reserve. Additionally, the 2nd convertible bonds were fully converted as of October 10, 2024, and the 14th stock acquisition rights were fully exercised as of October 29, 2024.