Consolidated Financial Results for the Nine Months Ended September 30, 2022 [Japanese GAAP]

November 7, 2022

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: November 14, 2022
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, 2022 (January 1, 2022 to September 30, 2022)

(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, 2022	40	-	(1,438)	-	(1,314)	-	(1,309)	-
September 30, 2021	1	(99.7)	(677)	-	(661)	-	(181)	-

(Note) Comprehensive income: Nine months ended September 30, 2022: ¥ (1,280) million [- %]
Nine months ended September 30, 2021: ¥ (174) million [- %]

	Basic earnings per share	Diluted earnings per share
Nine months ended	Yen	Yen
September 30, 2022	(45.04)	-
September 30, 2021	(6.32)	-

(Notes)
For diluted earnings per share for the fiscal year ended September 30, 2022, 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 September 30, 2022	4,886	4,283	87.6
As of December 31, 2021	6,069	5,549	91.4

(Reference) Equity: As of September 30, 2022: ¥4,278 million
As of December 31, 2021: ¥5,549 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, 2021	-	0.00	-	0.00	0.00
Fiscal year ending December 31, 2022	-	0.00	-		
Fiscal year ending December 31, 2022x (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, 2022(January 1, 2022 to December 31, 2022)

The earnings forecasts for fiscal year 2022 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, 2022 (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, 2022

(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: Yes
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, 2022: 29,137,500shares

December 31, 2021: 28,967,500 shares

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

September 30, 2022: 63 shares

December 31, 2021: 63 shares

3) Average number of shares during the period:

Nine months ended September 30, 2022: 29,079,323 shares

Nine months ended September 30, 2021: 28,697,050 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 nine months ended September 30, 2022 was expected to recover due to the improvement of the situation of COVID-19 pandemic and the easing of restrictions on movement. However, uncertainty continues due to concerns over the impact of Russia's ongoing invasion of Ukraine, global inflation, and rapid yen depreciation against US dollar.

Under the corporate philosophy of "*Every life deserves attention*," the Group is committed to research and development with the aim of providing breakthrough precision therapeutics for genetic diseases that overlap substantially with rare diseases. Based on our proprietary CRISPR-GNDM® platform, which serves as the technological foundation, the Company has continued to lead cutting-edge research as a leading company since its inception in 2016 to the current consolidated period, which is the seventh fiscal year since its establishment as the world's third company to develop gene modulation therapy using CRISPR. To bring these results to fruition, we are continuing our efforts toward clinical trials in the current fiscal year.

The Group is developing its pipeline using CRISPR-GNDM® technology both in-house and in collaboration with partners. During the nine months ended December 31, 2012, as announced in a press release on September 15, 2012, the Company decided to redesign the MDL-101 vector and raise the development priority of MDL-104. This change is primarily in the capsid* to improve the efficiency of MDL-101, which is to treat a type of muscular dystrophy, delivery to muscle but the change will be applied to future pipelines as well.

> * Capsid: A protein shell of a virus, enclosing its genetic material. This determines the directionality and efficiency of delivery to the cell.

After the success of local administration in ophthalmology and other areas, the therapeutic target of gene therapies was expanded to include muscle diseases and other conditions, and the search for therapies involving systemic administration of large amount of AAV vectors led to the identification of several safety challenges. As a result, several safety concerns have been identified. The authorities were also concerned about these issues, and the number of items that needed to be closely monitored before clinical trials or market launch increased, raising the hurdles to development. On the other hand, recent technological innovations have led to the development of specialized capsids with enhanced delivery efficiency for each target organ of interest. The advantage of AAV vectors with tailored properties and tropism is that the toxic effect on non-target organs, such as the liver, can be reduced, or the effect can be enhanced by increasing the amount delivered to the target organs without causing toxicity. In addition, the amount of AAV vector to be administered can be reduced to achieve the same efficacy, which is expected to be advantageous in terms of cost.

We have made the decision to apply this change at the point of no return where we are about to lock in the molecule and start GMP manufacturing, and GLP studies for clinical trials. While this will result in a delay in the clinical trial initiation of approximately six months to a year, we believe it will enhance product performance and provide a higher probability of success, which will translate into higher pipeline value in the long term.

On the other hand, in reviewing the timeline associated with this change, we reviewed the other pipelines' potential schedule of IND filing and found that MDL-104, which targets tauopathy, may enter the clinic earlier than we had previously anticipated. We have therefore decided to raise the development priority of MDL-104 in parallel with MDL-101 and to develop both programs in parallel in order to achieve a pre-IND filing for both programs in mid-2023.

On the patent front, a patent application jointly filed by the Company and its partner, Astellas, for the development of a treatment for Duchenne muscular dystrophy targeting the utrophin gene was issued in the U.S. in October.

As a result, for the nine months ended September 30, 2022, operating revenue amounted to ¥40,500 thousand, operating loss to ¥1,438,226 thousand, ordinary loss to ¥1,314,537 thousand, and Loss attributable to owners of parent to ¥1,309,827 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 decreased by ¥1,263,534 thousand from the end of the previous fiscal year to ¥3,803,509 thousand. This is mainly attributable to a decrease in cash and deposits by ¥1,254,894 thousand.

(Non-current Assets)

Total non-current assets at the end of the third quarter of the fiscal year under review increased by ¥80,895 thousand from the end of the previous fiscal year to ¥1,082,988 thousand. This is mainly attributable to an increase in Property, plant and equipment of ¥125,526 thousand.

(Current Liabilities)

Total current liabilities at the end of the third quarter of the fiscal year under review increased by ¥104,296 thousand from the end of the previous fiscal year to ¥285,014 thousand. This is mainly attributable to an increase in Other by ¥80,711 thousand.

(Non-current Liabilities)

Total non-current liabilities at the end of the third quarter of the fiscal year under review decreased by ¥21,658 thousand from the end of the previous fiscal year to ¥317,548 thousand. This is attributable to a decrease in Other by ¥18,315 thousand.

(Net Assets)

Total net assets at the end of the third quarter of the fiscal year under review decreased by ¥1,265,277 thousand from the end of the previous fiscal year to ¥4,283,934 thousand. This is mainly attributable to a decrease in retained earnings by ¥1,309,827 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.

2. Quarterly Consolidated Financial Statements and Primary Notes

(1) Quarterly Consolidated Balance Sheets

(Thousand yen)

	As of December 31, 2021	As of September 30, 2022
Assets		
Current assets		
Cash and deposits	4,936,193	3,681,299
Other	130,850	122,210
Total current assets	5,067,043	3,803,509
Non-current assets		
Property, plant and equipment	223,784	349,311
Intangible assets		
Right to use patent	704,729	657,693
Other	273	209
Total intangible assets	705,003	657,903
Investments and other assets	73,305	75,774
Total non-current assets	1,002,093	1,082,988
Total assets	6,069,137	4,886,498
Liabilities		
Current liabilities		
Income taxes payable	19,282	10,632
Provision for bonuses	—	32,235
Other	161,434	242,146
Total current liabilities	180,717	285,014
Non-current liabilities		
Provision for share-based compensation for director	988	1,235
Provision for share-based compensation for employee	4,775	6,237
Deferred tax liabilities	5,052	—
Other	328,391	310,076
Total non-current liabilities	339,207	317,548
Total liabilities	519,925	602,563
Net assets		
Shareholders' equity		
Share capital	2,744,447	2,067,652
Capital surplus	4,066,182	3,389,387
Retained earnings	(1,266,476)	(1,212,463)
Treasury shares	(97)	(97)
Total shareholders' equity	5,544,055	4,244,478
Accumulated other comprehensive income		
Foreign currency translation adjustment	5,156	34,037
Total accumulated other comprehensive income	5,156	34,037
Subscription rights to shares	—	5,419
Total net assets	5,549,212	4,283,934
Total liabilities and net assets	6,069,137	4,886,498

(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, 2021	For the nine months ended September 30, 2022
Operating revenue	1,100	40,500
Operating expenses		
Research and development expenses	493,784	1,290,857
Selling, general and administrative expenses	184,835	187,868
Total operating expenses	678,619	1,478,726
Operating loss	(677,519)	(1,438,226)
Non-operating income		
Interest income	57	47
Subsidy income	205	—
Foreign exchange income	16,189	128,397
Other	235	303
Total non-operating income	16,688	128,748
Non-operating expenses		
Interest expenses	—	3,584
Stock issuance cost	1,092	817
Amortization of stock issuance cost	—	657
Total non-operating expenses	1,092	5,059
Ordinary loss	(661,924)	(1,314,537)
Extraordinary income		
Income of compensation	485,881	—
Total extraordinary income	485,881	—
Loss before income taxes	(176,042)	(1,314,537)
Income taxes - current	915	914
Income taxes - deferred	4,414	(5,624)
Total income taxes	5,330	(4,709)
Loss	(181,372)	(1,309,827)
Loss attributable to owners of parent	(181,372)	(1,309,827)

Quarterly Consolidated Statements of Comprehensive Income

Nine Months September 30

(Thousand yen)

	For the nine months ended September 30, 2021	For the nine months ended September 30, 2022
Loss	(181,372)	(1,309,827)
Other comprehensive income		
Foreign currency translation adjustment	6,488	28,880
Total other comprehensive income	6,488	28,880
Comprehensive income	(174,883)	(1,280,946)
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	(174,883)	(1,280,946)

(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 ¥681,920 thousand and retained earnings increased by ¥1,363,840 thousand as the result of covering the loss in retained earnings brought forward as of May 16, 2022 based on the resolution of the 6th Ordinary General Meeting of Shareholders held on March 29, 2022. Additionally, the share capital and the capital surplus both received an addition of ¥5,125 thousand due to the exercise of stock acquisition rights as a stock option. As a result, at the nine months ended September 30, 2022, the share capital, capital surplus and retained earnings were ¥2,067,652 thousand, ¥3,389,387 thousand and (¥ 1,212,463) thousand, respectively.

(Change in accounting policy)

(Application of the Accounting Standard for Revenue Recognition, etc.)

The Company has applied the "Accounting Standard for Revenue Recognition" (ASBJ Statement No. 29, March 31, 2020) and relevant ASBJ regulations from the beginning of the first quarter of the fiscal year under review, and recognizes revenue at the amounts expected to be received in exchange for promised goods or services, at the point when the control of such goods or services is transferred to customers. The Company has adopted the "Accounting Standard for Revenue Recognition" (ASBJ Statement No.84) in accordance with the transitional treatment. There is no effect on the beginning balance of retained earnings brought forward and profit and loss for the third quarter of the current fiscal year.

(Application of the Accounting Standard for Fair Value Measurement, etc.)

The Company has applied the "Accounting Standard for Fair Value Measurement" (ASBJ Statement No. 30, July 4, 2019) and relevant ASBJ regulations from the beginning of the first quarter of the fiscal year under review, and it has applied the new accounting policy provided for by the Accounting Standard for Fair Value Measurement, etc. prospectively in accordance with the transitional measures provided for in paragraph 19 of the Accounting Standard for Fair Value Measurement, and paragraph 44-2 of the "Accounting Standard for Financial Instruments" (ASBJ Statement No. 10, July 4, 2019). There is no impact on the quarterly consolidated financial statements from the application of this standard.

(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.