

Consolidated Financial Results for the Six Months Ended June 30, 2022 [Japanese GAAP]



August 5, 2022

Company name: Modalis Therapeutics Corporation

Stock exchange listing: Tokyo Stock Exchange

Code number: 4883

URL: <https://www.modalistx.com/jp/>

Representative: Haruhiko Morita, President and Representative Director

Contact: Naoki Kobayashi, CFO and Executive Officer

Phone: +81-3-6822-4584

Scheduled date of filing quarterly securities report: August 12, 2022

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, 2022 (January 1, 2022 to June 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	
Six months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
June 30, 2022	40	-	(868)	-	(780)	-	(775)	-
June 30, 2021	1	(99.7)	(477)	-	(464)	-	17	(34.1)

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

Six months ended June 30, 2021: ¥ 22 million [(15.6) %]

	Basic earnings per share	Diluted earnings per share
Six months ended	Yen	Yen
June 30, 2022	(26.70)	-
June 30, 2021	0.62	0.59

(Notes)

For diluted earnings per share for the fiscal year ended June 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 June 30, 2022	5,343	4,812	90.0
As of December 31, 2021	6,069	5,549	91.4

(Reference) Equity: As of June 30, 2022: ¥4,810 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
Fiscal year ended December 31, 2021	Yen -	Yen 0.00	Yen -	Yen 0.00	Yen 0.00
Fiscal year ending December 31, 2022	-	0.00			
Fiscal year ending December 31, 2022 (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 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, 2022 (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, 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):

June 30, 2022: 29,117,500 shares

December 31, 2021: 28,967,500 shares

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

June 30, 2022: 63 shares

December 31, 2021: 63 shares

3) Average number of shares during the period:

Six months ended June 30, 2022: 29,055,760 shares

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

Table of Contents

1. Qualitative Information on Quarterly Financial Results for the Period under Review	2
(1) Explanation of Business Results	2
(2) Explanation of Financial Position	3
(3) Explanation of Consolidated Financial Results Forecast and Other Forward-looking Information	4
2. Quarterly Consolidated Financial Statements and Primary Notes	5
(1) Quarterly Consolidated Balance Sheets	5
(2) Quarterly Consolidated Statements of Income and Comprehensive Income	6
(3) Quarterly Consolidated Statements of Cash Flows	8
(4) Notes to Quarterly Consolidated Financial Statements	9
(Notes on going concern assumption)	9
(Notes in the case of significant changes in shareholders' equity)	9
(Change in accounting policy)	9
(Segment information)	9

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, 2022 was hit by the 7th wave of 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.

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 second company to develop gene modulation therapy using CRISPR. To bring these results to fruition, the Company is now moving full steam ahead with clinical trials in the current fiscal year.

The Group has been developing programs using CRISPR-GNDM[®] technology in-house and in collaboration with partners, and is now moving more fully into clinical entry, which is now in view as a reality, including the assignment of preclinical experts.

In the second quarter of the current fiscal year, research and development of each cooperative pipeline and in-house pipeline, centered on MDL-101, is progressing steadily. In mid-July, we held an INTERACT meeting with the FDA to confirm challenges that need to be resolved before the IND can be submitted. Since the development of gene-regulated therapeutics that we are pursuing is a new approach that has not yet entered the clinic using CRISPR or any other platform, and it is also a new approach for the FDA, there were some uncertainties regarding the applicable guidelines and the trials required for clinical entry. However, the dialogue with the authorities has been very fruitful. However, we believe that our recent dialogue with the authorities has made it clear that we can generally follow our hypothesis.

During the quarter, the Company made steady progress in research and development of its co-development pipeline, centered on MDL-101, as well as its in-house development pipeline. Development of MDL-101 is continuing with the aim of filing an IND by the end of 2023. The focus of our work is toxicology studies and process development. On the regulatory front, the U.S. Food and Drug Administration (FDA) issued a draft guidance on genome editing in March. We believe that this is reflection of the fact that genome editing is becoming more widely recognized as a major field in gene therapy as clinical trials of genome editing pipelines are underway at various companies. In February, the company submitted an INTERACT meeting application to the FDA for MDL-101, which was accepted in March, and we have received notification that the meeting will be held in mid-July. We are also preparing to file for a Pre-IND meeting by the end of 2022. We believe that this will clarify the hurdles to the start of the clinical trial and allow us to tune up the trial plan.

Other programs are also showing solid progress. MDL-104, which targets tauopathies including Alzheimer's disease, has been shown to inhibit tau protein by GNDM in humanized tau model mice. This allows us to directly observe the effects of the human version of MDL-104, rather than the mouse surrogate version of MDL-104. The MDL-105 program also included discussions with clinical and genetic experts to better understand future clinical trials and the patient population that will be targeted once the drug is launched. The results suggest that a significant number of patients have dilated cardiomyopathy caused by mutations in the Titin gene, and that there is some rationale for our approach to drug development.

In parallel to the development effort, we are creating engagements with CureCMD, the CMD1a patient organization, and clinical experts in the disease to accelerate our clinical efforts. We believe this pre-clinical facilitation is critical to the smooth execution of future clinical trials, as the rare disease we are targeting will require a networked, individualized approach to patient recruitment for clinical trials, rather than a mass approach.

At the American Society for Gene and Cell Therapy (ASGCT) meeting held in Washington, DC in May, we presented six abstracts. These included reports on our lead programs MDL-101, MDL-104 for tauopathy, MDL-105 targeting dilated cardiomyopathy, and MDL-205 for Angelman syndrome. This was our first presentation at a scientific conference, and we believe it has helped to draw attention to our CRISPR-GNDM[®] platform.

On the IP side, a patent for "a method of treating muscular dystrophy by targeting the Utrophin gene," which was jointly filed by the Company and its partner Astellas for the development of a treatment for Duchenne muscular dystrophy, was granted in April, and registered in May in Japan. The patent was also granted in the U.S. in June. We consider it a great achievement as the U.S. is the largest market for therapeutic drugs.

As a result, for the six months ended June 30, 2022, operating revenue amounted to ¥40,500 thousand, operating loss to ¥868,457 thousand, ordinary loss to ¥780,483 thousand, and Profit attributable to owners of parent to ¥775,695 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 ¥811,942 thousand from the end of the previous fiscal year to ¥4,255,101 thousand. This is mainly attributable to a decrease in cash and deposits by ¥777,701 thousand.

(Non-current Assets)

Total non-current assets at the end of the second quarter of the fiscal year under review increased by ¥85,947 thousand from the end of the previous fiscal year to ¥1,088,041 thousand. This is mainly attributable to an increase in Property, plant and equipment of ¥117,980 thousand.

(Current Liabilities)

Total current liabilities at the end of the second quarter of the fiscal year under review increased by ¥24,582 thousand from the end of the previous fiscal year to ¥205,300 thousand. This is mainly attributable to an increase in provision for bonuses by ¥18,634 thousand.

(Non-current Liabilities)

Total non-current liabilities at the end of the second quarter of the fiscal year under review decreased by ¥14,028 thousand from the end of the previous fiscal year to ¥325,178 thousand. This is attributable to a decrease in deferred tax liabilities by ¥11,221 thousand.

(Net Assets)

Total net assets at the end of the second quarter of the fiscal year under review decreased by ¥736,548 thousand from the end of the previous fiscal year to ¥4,812,663 thousand. This is mainly attributable to a decrease in retained earnings by ¥775,695 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 ¥4,158,491 thousand, the decrease by ¥777,701 thousand from ¥4,936,193 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, 2022 amounted to ¥713,384 thousand. This is mainly attributable to the posting of loss before income taxes of ¥780,483 thousand.

(Cash Flows from Investing Activities)

Net cash used in investing activities during the six months ended June 30, 2022 amounted to ¥118,965 thousand. This is mainly attributable to the posting of purchase of property, plant and equipment of ¥129,719 thousand.

(Cash Flows from Financing Activities)

Net cash used in financing activities during the six months ended June 30, 2022 amounted to ¥3,653 thousand. This is mainly attributable to the posting of proceeds from issuance of stock acquisition rights of ¥7,595 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, 2021	As of June 30, 2022
Assets		
Current assets		
Cash and deposits	4,936,193	4,158,491
Other	130,850	96,610
Total current assets	5,067,043	4,255,101
Non-current assets		
Property, plant and equipment	223,784	341,764
Intangible assets		
Right to use patent	704,729	673,372
Other	273	240
Total intangible assets	705,003	673,612
Investments and other assets	73,305	72,663
Total non-current assets	1,002,093	1,088,041
Total assets	6,069,137	5,343,143
Liabilities		
Current liabilities		
Income taxes payable	19,282	19,475
Provision for bonuses	—	18,634
Other	161,434	167,189
Total current liabilities	180,717	205,300
Non-current liabilities		
Provision for share-based compensation for director	988	1,359
Provision for share-based compensation for employee	4,775	6,648
Deferred tax liabilities	5,052	—
Other	328,391	317,170
Total non-current liabilities	339,207	325,178
Total liabilities	519,925	530,479
Net assets		
Shareholders' equity		
Share capital	2,744,447	2,066,652
Capital surplus	4,066,182	3,388,387
Retained earnings	(1,266,476)	(678,331)
Treasury shares	(97)	(97)
Total shareholders' equity	5,544,055	4,776,610
Accumulated other comprehensive income		
Foreign currency translation adjustment	5,156	33,975
Total accumulated other comprehensive income	5,156	33,975
Subscription rights to shares	—	2,077
Total net assets	5,549,212	4,812,663
Total liabilities and net assets	6,069,137	5,343,143

(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, 2021	For the six months ended June 30, 2022
Operating revenue	1,100	40,500
Operating expenses		
Research and development expenses	349,005	778,908
Selling, general and administrative expenses	129,412	130,049
Total operating expenses	478,418	908,957
Operating loss	(477,318)	(868,457)
Non-operating income		
Interest income	27	27
Subsidy income	205	—
Foreign exchange income	12,834	90,899
Other	63	299
Total non-operating income	13,129	91,227
Non-operating expenses		
Interest expenses	—	2,331
Stock issuance cost	793	654
Amortization of stock issuance cost	—	267
Total non-operating expenses	793	3,253
Ordinary loss	(464,982)	(780,483)
Extraordinary income		
Income of compensation	485,881	—
Total extraordinary income	485,881	—
Profit before income taxes or Loss before income taxes	20,899	(780,483)
Income taxes - current	1,269	609
Income taxes - deferred	1,927	(5,397)
Total income taxes	3,196	(4,788)
Profit or Loss	17,702	(775,695)
Profit attributable to owners of parent or Loss attributable to owners of parent	17,702	(775,695)

Quarterly Consolidated Statements of Comprehensive Income

Six Months Ended June 30

(Thousand yen)

	For the six months ended June 30, 2021	For the six months ended June 30, 2022
Profit or Loss	17,702	(775,695)
Other comprehensive income		
Foreign currency translation adjustment	4,618	28,819
Total other comprehensive income	4,618	28,819
Comprehensive income	22,321	(746,875)
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	22,321	(746,875)

(3) Quarterly Consolidated Statements of Cash Flows

(Thousand yen)

	For the six months ended June 30, 2021	For the six months ended June 30, 2022
Cash flows from operating activities		
Profit before income taxes or Loss before income taxes	20,899	(780,483)
Depreciation	36,622	58,358
Increase (decrease) in provision for share-based compensation for director	932	371
Increase (decrease) in provision for share-based compensation for employee	4,229	1,873
Increase (decrease) in provision for bonuses	—	13,839
Share-based compensation expenses	—	2,077
Interest and dividend income	(27)	(27)
Subsidy income	(205)	—
Stock issuance cost	793	654
Interest expenses	—	2,331
Foreign exchange losses (gains)	(6,128)	(64,452)
Compensation received	(485,881)	—
Increase (decrease) in accounts payable - other	(3,013)	11,807
Increase (decrease) in accrued expenses	5,528	10,434
Decrease (increase) in consumption taxes refund receivable	(1,725)	26,163
Other, net	(38,551)	8,401
Subtotal	(466,527)	(708,650)
Interest and dividends received	27	27
Interest expenses paid	—	(3,551)
Subsidies received	205	—
Income taxes paid	(1,210)	(1,210)
Compensation received	485,881	—
Net cash provided by (used in) operating activities	18,377	(713,384)
Cash flows from investing activities		
Purchase of property, plant and equipment	(5,620)	(129,719)
Proceeds from contribution received for right to use patent	329,670	—
Payment of lease deposits	(49,346)	(939)
Collection of lease deposits	—	11,694
Other, net	319	—
Net cash provided by (used in) investing activities	275,022	(118,965)
Cash flows from financing activities		
Proceeds from issuance of stock acquisition rights	56,436	7,595
Repayments of installment payables	—	(3,674)
Other, net	—	(267)
Net cash provided by (used in) financing activities	56,436	3,653
Effect of exchange rate change on cash and cash equivalents	13,267	50,993
Net increase (decrease) in cash and cash equivalents	363,103	(777,701)
Cash and cash equivalents at the beginning of period	5,421,476	4,936,193
Cash and cash equivalents at the end of period	5,784,579	4,158,491

(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 ¥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 ¥4,125 thousand due to the exercise of stock acquisition rights as a stock option. As a result, at the six months ended June 30, 2022, the share capital, capital surplus and retained earnings were ¥2,066,652 thousand, ¥3,388,387 thousand and (¥ 678,331) 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 second 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 second 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 second 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.