

# Modalis Therapeutics Reports Operational Highlights and Second Quarter 2021 Financial Results

05-Aug-2021 TOKYO & CAMBRIDGE, Mass.- Modalis Therapeutics Corporation (Modalis), a leading company developing innovative products for the treatment of rare genetic diseases utilizing its proprietary CRISPR-GNDM epigenetic gene modulation technology, today reported financial results for the second quarter ended June 30, 2021, as well as recent operational highlights.

"We made substantial progress in the last quarter, where we advanced our MDC1A program to establish NHP safety data as well as mice disease model data. In addition to the muscle disorders, which we have worked on for MDL-101 as well as 2 licensed programs, Modalis has established in vivo proof-of-concept through our transformational neuroscience collaborations. This convinces us that our technology is real in the field," said Haru Morita, Chief Executive Officer of Modalis. "For the rest of 2021, we will continue to push our science forward and bring our diversified pipelines into clinic."

#### **Operational Highlights:**

- Collaboration Programs: The Company continued to make progress in its existing collaborations with Astellas Pharma Inc. and Eisai Co., Ltd. which are focused on the use of the GNDM technology for the treatment of genetic diseases. As announce separately today, Modalis and our partner, Astellas, have confirmed completion of research collaboration on MDL-206, a program targeting Angelman Syndrome, and Modalis regains right to further develop the molecule. On the other hand, Modalis and Astellas entered into an agreement on 11-Jun-2021, pursuant to which Astellas obtained a sublicense to certain fundamental CRISPR patents for two product candidates being developed in collaboration with Modalis. Modalis received an upfront payment and may receive future milestone payments in conjunction with the agreement.
- Internal Programs:
  - **MDL-101**: With convincing safety data in NHP and efficacy data in mice disease models as previously reported, Modalis further advances preclinical studies toward clinic as well as initiating process development for GMP manufacturing.

#### **Second Quarter 2021 Financial Results:**

- Cash Position: Cash and deposits as of June 30, 2021 was ¥5,784 million, compared to ¥5,421 million as of December 31, 2020, an increase of ¥363 million. Increases in Cash and deposits were primarily due to an irregular income.
- **Revenues**: Revenues were ¥1.1 million for the six months ended June 30, 2021 respectively. Increases in Operating Revenue were primarily due to ongoing collaborations.
- Research & Development (R&D) Expenses: R&D expenses were ¥349 million for the six months ended June 30, 2021, compared to ¥204 million for June 30, 2020, an increase of ¥145 million. Increases in R&D expenses were primarily due to increases in development costs associated with the advancement of the Company's proprietary GNDM platform and product candidates.
- General &Administrative (G&A) Expenses: G&A expenses were ¥129 million for the six months ended June 30, 2021, compared to ¥94 million for June 30, 2020, an increase of ¥35 million. Increases in G&A expenses were primarily due to increases in payroll and personnel costs as well as increases in legal and professional costs.
- Extraordinary income: Extraordinary income was 485 million for the six months ended June 30, 2021. Because a shareholder of the Company, Akira Katayama (hereinafter referred to as Mr. Katayama) violated the agreement (lock-up system) of Securities Listing Regulations and Enforcement Rules for Securities Listings Regulations. As a countermeasure, the Group has received an irregular income of ¥485 million from Mr. Katayama.
- **Net Profit**: Net Profit was ¥17 million for the six months ended June 30, 2021, compared to ¥26 million for June 30, 2020.
- Please refer to 2Q Consolidated Financial Results disclosed according to Japanese accounting rules in the English version below.

#### **About Modalis:**

Modalis Therapeutics is developing precision genetic medicines through epigenetic gene modulation. Modalis is pursuing therapies for orphan genetic diseases using its proprietary CRISPR-GNDM technology which enables the locus specific modulation of gene expression or histone modification without the need for double-stranded DNA cleavage, gene editing or base editing. Modalis is focusing initially on genetic disorders caused by loss of gene regulation – resulting in excess or insufficient protein production – which includes more than 660 genes that are currently estimated to cause human disease due to haploinsufficiency. Headquartered in Tokyo with laboratories and facilities in Cambridge, Massachusetts. For additional information, visit www.modalistx.com.

#### **Forward-Looking Statements:**

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#### Contacts

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### Consolidated Financial Results for the Six Months Ended June 30, 2021 [Japanese GAAP]



August 5, 2021

Company name: Modalis Therapeutics Corporation Stock exchange listing: Tokyo Stock Exchange

Code number: 4883

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

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Scheduled date of filing quarterly securities report: August 13, 2021

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, 2021 (January 1, 2021 to June 30, 2021)

(1) Consolidated Operating Results (% indicates changes from the previous corresponding period.)

	Operating re	venue	Operating income		Ordinary income		Profit attributable to owners of parent	
Six months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
June 30, 2021	1	(99.7)	(477)	-	(464)	-	17	(34.1)
June 30, 2020	337	-	38	-	29	-	26	-

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

Six months ended June 30, 2020: \(\frac{1}{2}\) 26 million [-\%]

	Basic earnings per share	Diluted earnings per share
Six months ended	Yen	Yen
June 30, 2021	0.62	0.59
June 30, 2020	1.07	-

(Notes)

For diluted earnings per share for the fiscal year ended June 30, 2020, 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, 2021	6,697	6,286	93.9
As of December 31, 2020	6,277	6,206	98.9

(Reference) Equity: As of June 30, 2021: ¥6,286 million
As of December 31, 2020: ¥6,206 million