Modalis Therapeutics Reports Operational Highlights and Second Quarter 2025 Financial Results

07-August-2025 TOKYO & WALTHAM, Mass.- Modalis Therapeutics Corporation ("Modalis" 4883.T TSE), a pioneer in developing innovative solutions for rare genetic diseases through its proprietary CRISPR-GNDM® epigenetic gene editing technology, today announced its financial results for the second quarter ended June 30, 2025, alongside recent operational milestones.

" We are pleased to share with you the significant progress we have made in the first half of 2025. The lead program, MDL-101, is steadily progressing toward GMP manufacturing through the process development and scale-up, and GLP toxicity testing has also begun. In addition, MDL-201, a drug for the treatment of Duchenne muscular dystrophy (DMD), has shown promising efficacy even in initial analyses, " CEO Morita added, " Furthermore, we must also mention that we have received grants from both the xPrize Foundation and the Slove FSHD Foundation for the development of MDL-103 for the treatment of facioscapulohumeral muscular dystrophy (FSHD). We believe that all of these achievements are proof that our research and development efforts are beginning to bear fruit."

In addition, in early July, we entered into a license agreement with Broad Institute for MYOAAV, a muscle-tropic capsid for development of MDL-101. This is an excellent delivery technology that further enhances the effectiveness of our superior payload technology and is part of our efforts to combine the best elemental technologies we are working on to deliver the best therapeutic drugs to patients.

Concurrent to this quarterly report, we are reporting on new financing. This is intended to provide additional funding for MDL-101 and to fund the new growth opportunities for MDL-201 and MDL-103 reported above, with the aim of enhancing value.

Recent R&D and Business Highlights

- **MDL-101 is advancing to IND**
  - Transferred technology to a CDMO and preparing for GMP manufacturing after the successful scale-up.
  - Started animal studies in two species, including GLP toxicity testing, in collaboration with a CRO for IND filing.
  - The current main scenario is clinical trials in the US but exploring the possibility of conducting trials in other countries concurrently or instead.
- **Other programs**
  - MDL-201 (DMD): Confirmed efficacies, including functional improvement, exceeding benchmark drugs in a study using disease models
  - MDL-103(FSHD): Initiated studies with the funding from xPrize and Solve FSHD foundations.
- **License and collaboration**
  - Entered into a license agreement with Broad Institute for MYOAAV, a muscle-tropic capsid for development of MDL-101
- **Conference and presentation**
  - 2025 Scientific & Family Conference, Congenital Muscular Dystrophy/Nemaline Myopathy/Titinopathy (2025 SciFam: Aug 1-5 in Philadelphia)
  - 6th Annual Genome Editing Therapeutics Summit (Sept 29th-Oct 1st, 2025, Boston)

Fiscal Year 2025 Financial Results:

- **Cash Position**: Cash and deposits as of June 30, 2025, was ¥3,261 million, compared to ¥3,575 million as of December 31, 2024, a decrease of ¥313 million. The decrease in Cash and deposits was primarily due to payments for research and development expenses.
- **Revenues**: No revenues in the six months ended June 30, 2025.
- **Research & Development (R&D) Expenses:** R&D expenses were ¥906 million in the six months ended June 30, 2025, compared to ¥716 million in the six months ended June 30, 2024, an increase of ¥189 million.
- **General & Administrative (G&A) Expenses**: G&A expenses were ¥125 million in the six months ended June 30, 2025, compared to ¥122 million in the six months ended June 30, 2024, a decrease of ¥3 million.
- **Net Loss**: Net Loss was ¥1,020 million in the six months ended June 30, 2025, compared to ¥780 million in the six months ended June 30, 2024, a decrease of ¥239 million.
- 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 the use of epigenome editing. Modalis is developing treatments for rare genetic disorders using its proprietary CRISPR-GNDM technology, which allows for the specific modulation of gene expression or histone modification without the necessity for double-stranded DNA cleavage, gene editing, or base editing. Modalis' primary focus is on genetic disorders caused by loss of gene regulation, resulting in excess or insufficient protein production. This includes multiple neuromuscular disorders. The company is headquartered in Tokyo with laboratories and facilities in Waltham, Massachusetts. For additional information, visit www.modalistx.com.

Forward-Looking Statements:

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Consolidated Financial Results for the Six Months Ended June 30, 2025 [Japanese GAAP]

August 7, 2025

Company name: Modalis Therapeutics Corporation
Stock exchange listing: Tokyo Stock Exchange
Code number: 4883
URL: https://www.modalistx.com/en/
Representative: Haruhiko Morita, CEO and Representative Director
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Scheduled date of filing quarterly securities report: Aug 14, 2025
Scheduled date of commencing dividend payments: -
Preparation of supplementary material on financial results: Yes
Holding of financial results briefing: 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, 2025 (January 1, 2025, to June 30, 2025)

(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	-	-	(1,031)	-	(1,019)	-	(1,020)	-
June 30, 2025	-	-	(838)	-	(780)	-	(780)	-

(Note)Comprehensive income: Six months ended June 30, 2025: ¥ (1.031) million [-%]
Six months ended June 30, 2024: ¥ (772) million [-%]

	Basic earnings per share	Diluted earnings per share
Six months ended	Yen	Yen
June 30, 2024	(13.78)	-
June 30, 2025	(21.98)	-

(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, 2025	3,416	3,187	92.5
As of December 31, 2024	3,691	3,548	95.5

(Reference) Equity: As of June 30, 2025: ¥3,160million
As of December 31, 2024: ¥3,526million