

# FY2021 1 Q Financial Results Q&A

**The switch is the Key**



(TSE4883) Modalis therapeutics Corporation

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In case of any discrepancy,  
the Japanese version shall prevail

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## Q & A ①

Q) As 20-week non-human primate (NHP) study has completed, what is the status of partnering discussion on MDL-101 licensing out?

A) The 20-week NHP study has been completed as well as its analysis. We continue to work on partnering discussion of MDL-101 with multiple potential partners utilizing the data and detailed analysis from the NHP study data.

The timing of the license-out is expected to be the latter half of 2021.

## Q & A ②

Q) Other than during the announcement of financial results, do you release information/IR regarding the status of R&D activities (such as the NHP trial)?

A) The company is currently in R&D phase, so the release of IR regarding the status of individual pre-clinical R&D activities is restricted. Depending on the progress and expansion of future pipelines, we believe there may be increased opportunity for IR.

Moreover, regarding the status of individual R&D activities, we have decided that publicly disclosing this information is not favorable from a competition standpoint, as it could be advantageous for our competitors and could have a harmful impact on stock value in the long-term. Furthermore, when a license is being negotiated, details of the research status can be communicated only to the negotiating party, so restrictions on public disclosure are standard.

Disclosures regarding individual R&D activities occasionally give stockholders expectations which may have an excessive influence on the stock price. The company has decided to proactively disclose information that will have serious impacts for stockholders.

## Q & A ③

Q) Does the change in the disclosure policy of the licensing programs, MDL-201 and 202, indicate a setback in the development?

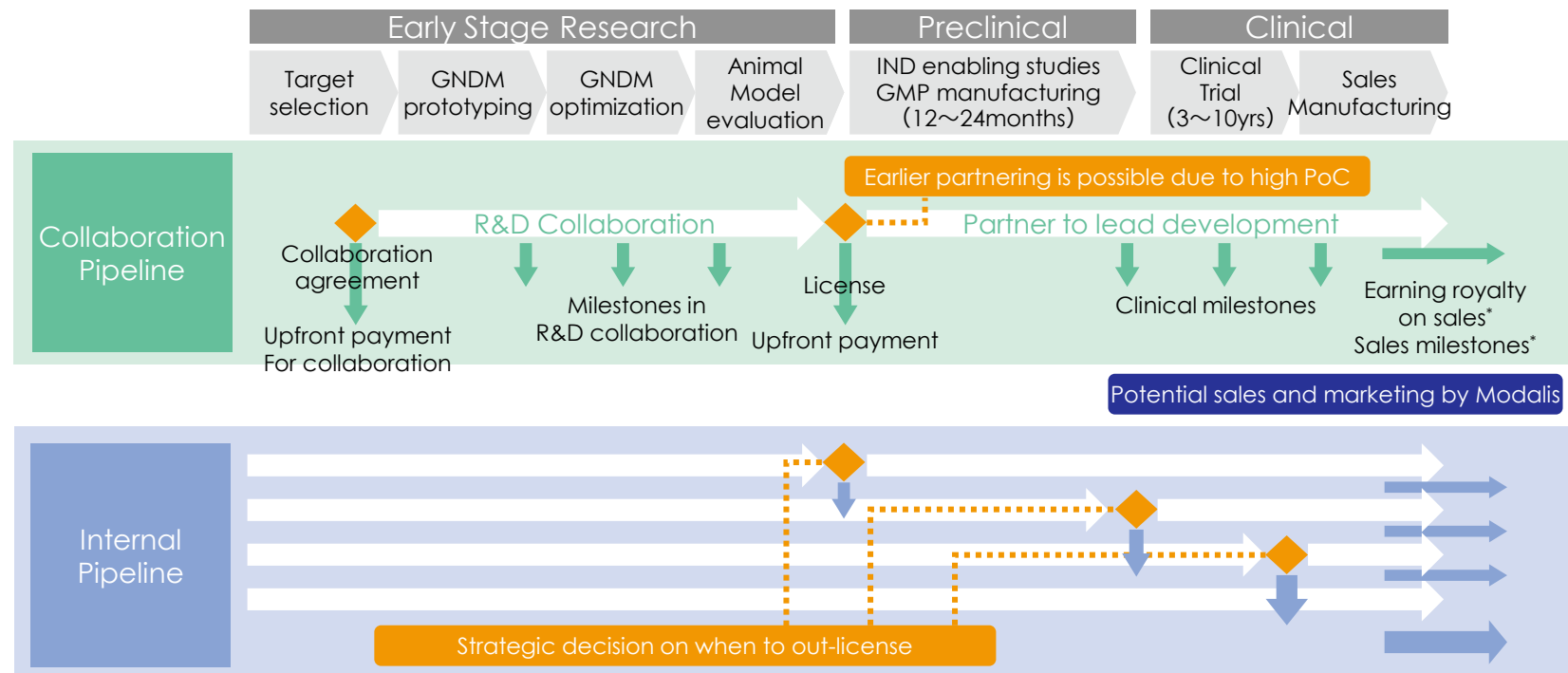
A) No. Our partner, Astellas, diligently continues to work on the development of MDL-201 and 202.

Current IND filing is anticipated to be after 2022 due to preparations of large-scale IND enabling studies.

## Q & A ④

Q) When will the operating revenue be recognized ?

A) As shown in the figure below, our major operating revenues consist of upfront and milestone payments in R&D collaborations, as well as revenue from clinical/sales milestones and royalties from license agreements. Each revenue is recorded as operating revenue when the contract is signed or when the conditions stipulated in the contract are met. As a result, our operating revenue is not reported monthly or quarterly but fluctuates depending on achievement of results.



## Q & A ⑤

Q) Have there been any delays in your business recently as a result of the COVID-19 pandemic?

A) There have been no major impacts resulting from the COVID-19 pandemic on the company group's business. Aside from matters that have been previously disclosed, there are no other factors that could cause delays or changes to our business plan.

As preventative measures in response to the spread of COVID-19, the Company has implemented measures such as work from home, minimizing time spent in the research facility to perform only necessary work, prohibiting unnecessary and non-urgent outings and face-to-face meetings, promoting the use of teleconferencing tools, and offering PCR testing. We have been able to maintain this condition and carry out all work without issue.

Furthermore, we have no control over any contractor's actions, but we are not currently aware of any matters that would have an impact on our group business.

We will disclose any relevant matters or changes to our business plan in a timely manner.

## Q & A ⑥

Q) I understand that this is an industry where if you spend money in the business, the deficit may increase by that much, but what about using funds aggressively to advance development?

A) As one of our options, the company believes that the Company can reap more fruits by making a larger investment in R&D. On the other hand, the Company also believes that financial discipline is important.

To achieve financial discipline, by combining collaboration pipelines and the internal pipelines, Modalis aims to establish a "hybrid model" that benefits from early revenues from the collaboration pipeline and huge potential future profits from the internal pipeline.

The Company will aggressively invest more in our R&D within this framework of discipline.



## Q & A ⑦

Q) Regarding the violation of the lock-up system, do you believe the matter to be completely resolved after receiving a payment of 484 million yen from Mr. Akira Katayama?

A) As reported in a press release on March 29, 2021, the proposed payment of 484 million yen from Mr. Akira Katayama for the the serious impacts incurred by the company was received, but we do not believe that this matter has been fully resolved with the receipt of 484 million yen.

After the incident, the company contacted our underwriter, the Tokyo Stock Exchange, and a lawyer to investigate any appropriate measures that could be taken and examined the matter in detail. We will continue to consider all possibilities and take appropriate measures in the future.

## Q & A ⑧

Q) Will the 484 million yen received from Mr. Akira Katayama be allotted to shareholders as used to implement measures such as dividends or a share buy-back scheme?

A) The Company is investigating the most effective way to utilize the money received for the shareholders who were impacted by this problem.

Of these, dividends and share-buy back were considered but given the current financial affairs of the Company and because there is no fiscal resources stipulated in Article 461 of the Companies Act, we are unable to implement dividends or a share-buy back scheme.

For this reason, after considering the above matter and the current allotment policy of the Company, the Company concluded that investing the money as a business resource for R&D activities would be the most effective means for maximizing corporate value and the benefit to shareholders.

We will continue to investigate effective ways to return profit to our shareholders.