

Q & A regarding Notice of Revision of Full- Year Consolidated Financial Results Forecast

The switch is the Key



(TSE4883) Modalis Therapeutics Corporation

December 15, 2020

MODALIS

In case of any discrepancy,
the Japanese version shall prevail

Disclaimer

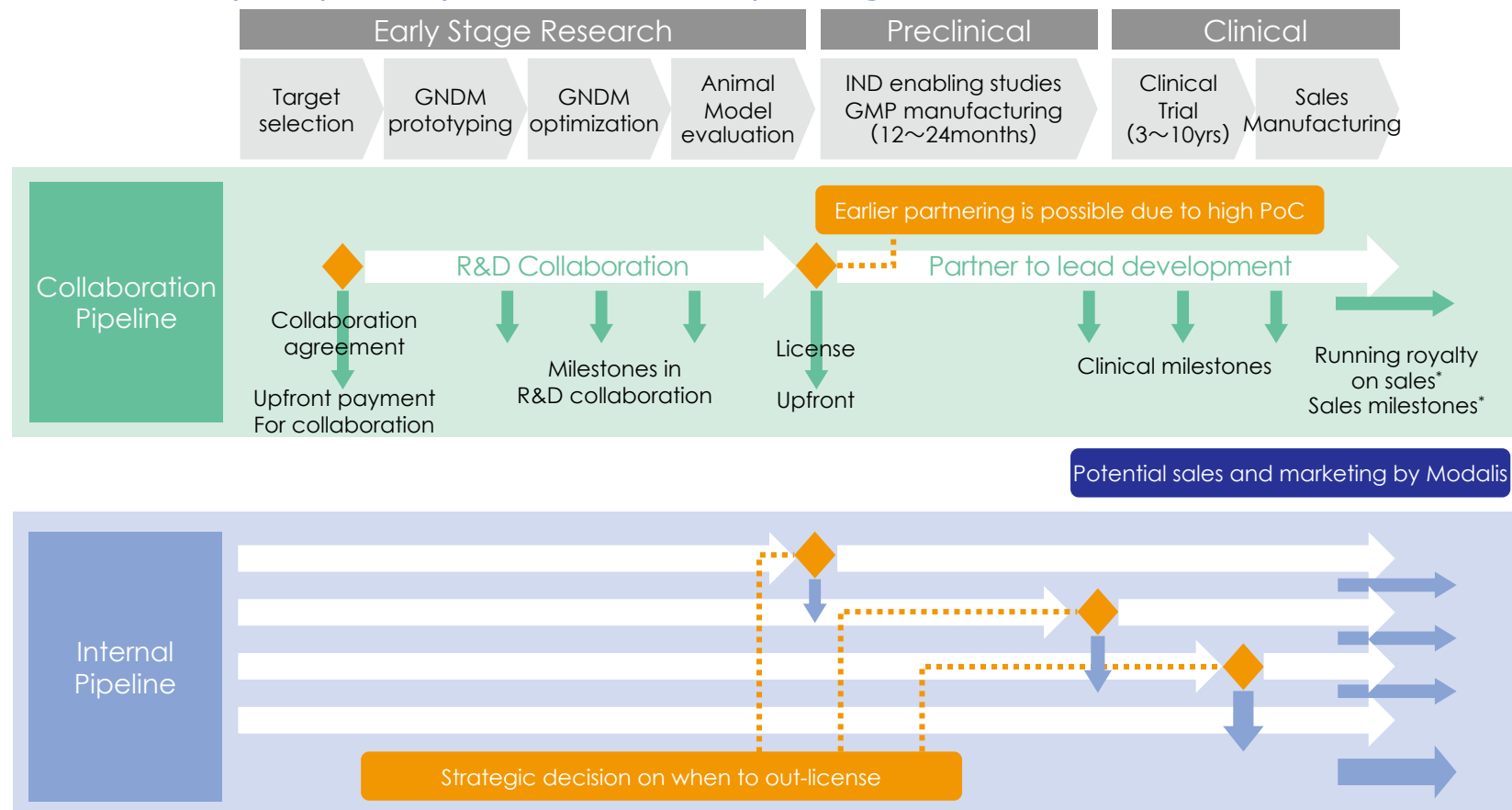
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When will the operating revenue be recognized ? (1/3)

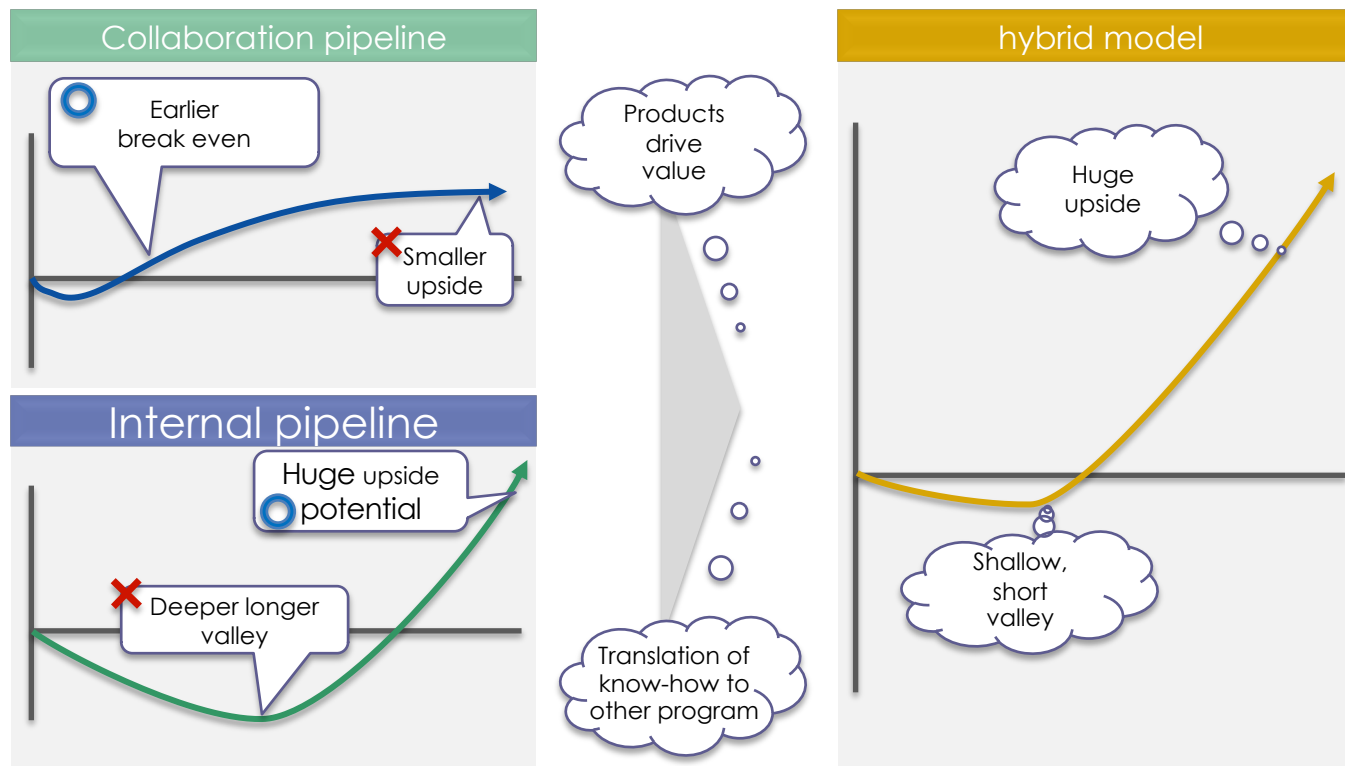
A) As shown in the figure below, our major operating revenues consist of upfront and milestone payments in R&D collaborations, as well as revenue from clinical/sales milestones and royalty from license agreements. Each revenue is recorded as operating revenue when the contract is signed or when the conditions 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.



When will the operating revenue be recognized ? (2/3)

- A) 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.

In the "hybrid model," we take the advantage of maintaining both the stability of the management base and opportunities to invest in growth areas by optimizing the number of options in the business plan through the effective use of funds supported by a wide range of revenue sources.



When will the operating revenue be recognized ? (3/3)

- A) Currently, Modalis' operating revenue is significantly dependent on upfront and milestone payments in R&D collaboration as well as those derived from license agreements. As a result, operating revenue and net income (or net loss) may fluctuate depending on the timing and amount of such payment.

【Please note】

For general risk information on drug discovery bioventures, please refer to

<https://www.jpx.co.jp/listing/others/risk-info/>.

In addition, Modalis is engaged in the gene therapy drug development business. For risk information specific to this business, please refer to the "Business Description," "Management Policy, Management Environment and Issues to be Addressed," "Business Risks," "Important Management Contracts," and other sections of the "Prospectus for Issuance and Sale of New Shares" (and amendments thereto).

Why was the license agreement of MDL-101 not achieved within FY2020 ?
What is the current status of MDL-101 ?

- A) We've been in discussion with domestic and overseas pharmaceutical companies, including major pharmaceutical companies, for the partnership of MDL-101, but have not yet executed a contract. As a result, the Board of Directors decided to revise the full-year consolidated financial results forecast effective today (December 15, 2020).

The Company believes that we may expect better conditions by adding more data and exploring more opportunities that will be beneficial to the Company and lead to an increase in corporate value over the mid to long term. The company anticipates to enter into a partnership in 2021. Data from non-human primate studies, which are currently undergoing analysis and expected to be finalized in early 2021, will support the negotiations.

Please tell me about MDL-104. (1/2)

A) MDL-104, which was newly reported today (December 15, 2020), is a new pipeline whose target indication belongs to neurodegenerative diseases.

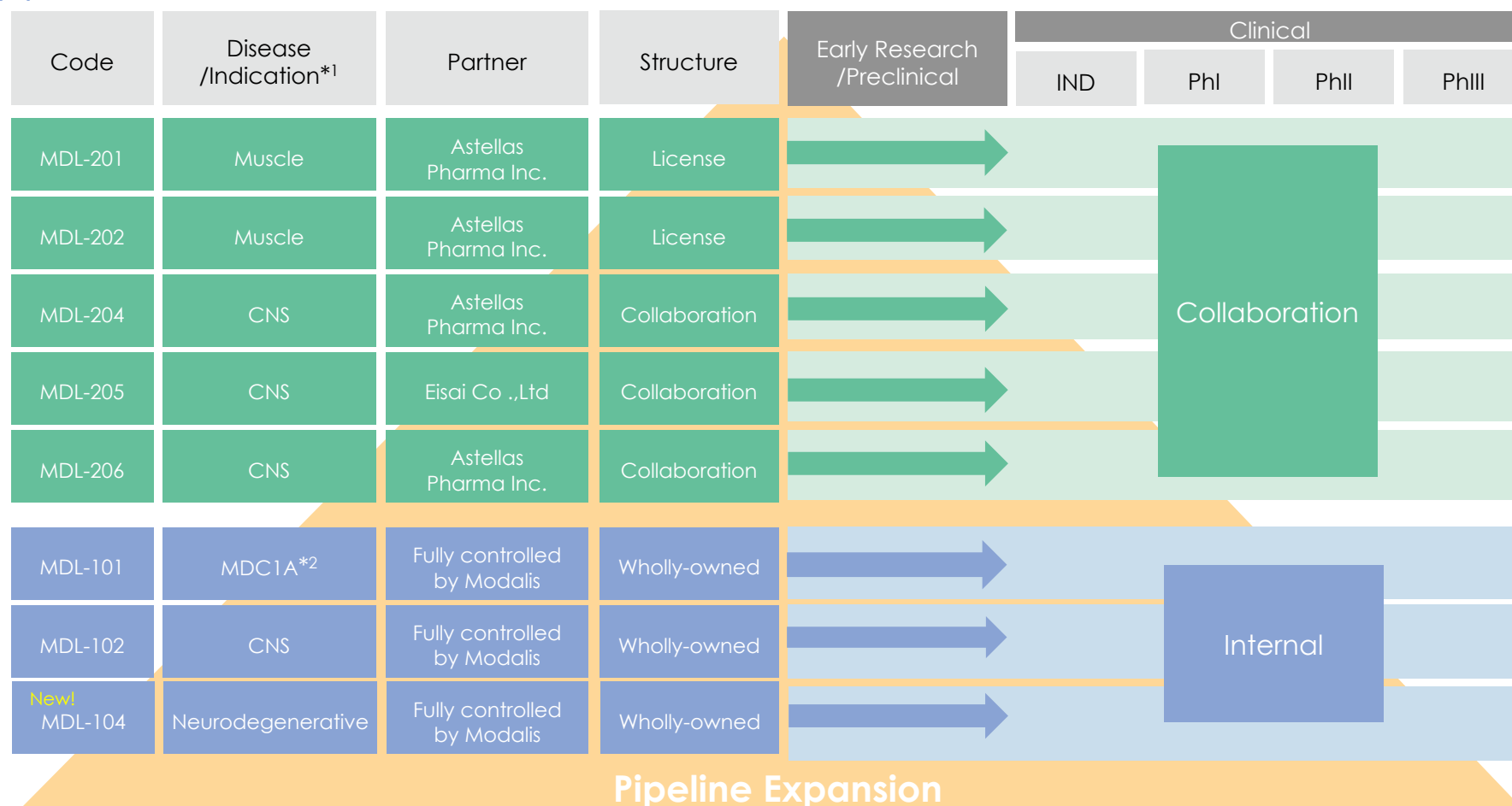
Our strategy is to keep the names of the specific indications undisclosed for competitive reasons until the patents we have applied for are published.

While MDL-104, which Modalis has committed to develop as an internal pipeline, is in the early stages of development, we have received multiple requests for licensing from several major domestic and overseas pharmaceutical companies. As we are still in the process of intensive negotiations, the timing of the license agreement is yet to be determined but is expected to be in 2021. There will be no impact on our business results for the current fiscal year.

In addition to the filing of a patent application, an evaluation of feasibility, which is required before the company decides to introduce new products to the internal pipeline, was approved by the Board of Directors today.

Please tell me about MDL-104. (2/2)

A) With the addition of MDL-104, our internal pipeline now consists of three products, and together with the five products in our Collaboration Pipeline, we now have a total of eight products in our pipeline.



*1: We have adopted a strategy of withholding specific indications until the patent application is published for competitive reasons.

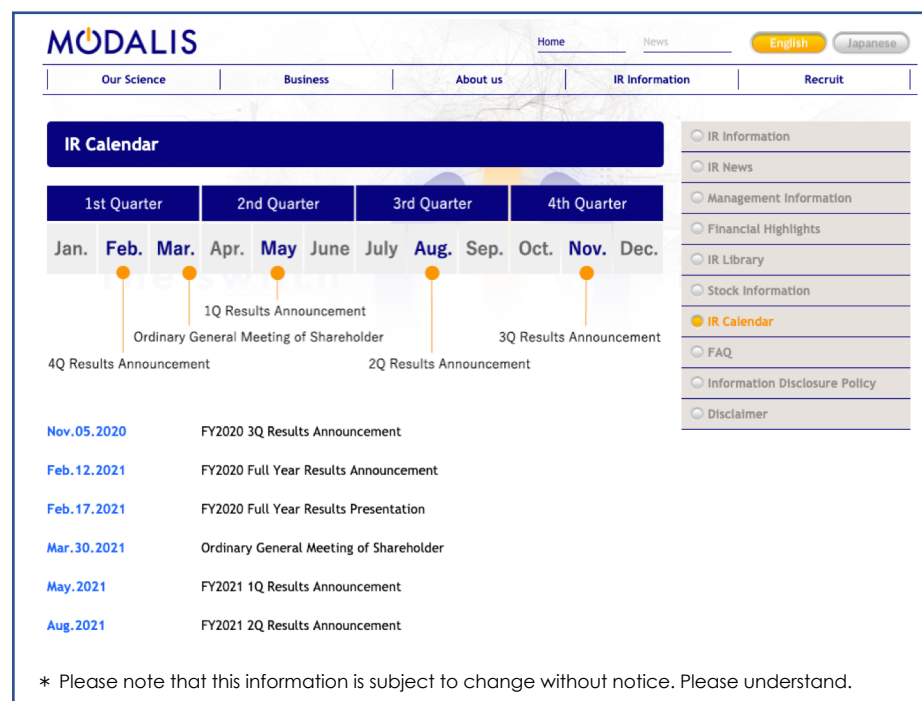
*2: MDC1A=Merosin-deficient congenital muscular dystrophy type 1A

What is the earnings forecast for the fiscal year ending December 31, 2021 and beyond ?

- A) The business forecast for the fiscal year ending December 31, 2021 is currently in the process of being formulated.
At this point, we are aiming not only to receive upfront payment from the execution of the licensing agreement for MDL-101 and MDL-104, which are currently under negotiation, but also to receive business income from the progress of other pipelines.
The financial forecast for the fiscal year ending December 31, 2021 will be announced concurrently with the announcement of the financial results for the fiscal year ending December 31, 2020.

The date of the earnings announcement will be announced on the IR page of our website below as soon as it is determined.

<https://www.modalistx.com/en/ir/calendar/>



What is the status of important contracts (licensing agreements, completion of milestone achievements, etc.) and the progress of R&D in the pipeline ?

- A) In accordance with the disclosure rules of the Tokyo Stock Exchange, we will disclose necessary information in a timely manner.

In this context, we will proactively disclose information in a timely and appropriate manner if it has a significant impact on Modalis' business performance and business strategy, or if we consider it to be important information that will contribute to investors' investment decisions. In addition, there is some information that we do not disclose for competitive reasons to enhance our corporate value, and some information that we cannot disclose due to contracts with partners. We disclose information based on these factors.

Is there any effect of COVID-19 on Modalis ?

A) In response to COVID-19, Modalis has implemented safety measures such as telecommuting whenever possible, minimizing necessary work at research facilities, prohibiting unnecessary trips and face-to-face meetings, promoting the use of web conferencing and other tools, and preventing infection by early detection of infection through temperature checks when employees arrive at work. In addition, although the trends of our business partners are not under our control, we have not confirmed any events that would have a significant impact on our business to date. Based on the above, COVID-19 has not had a significant impact on the execution of our business.

We will continue to carry out our business by taking thorough measures against COVID-19, but if any impact beyond our expectation becomes apparent in the future and an event that should be disclosed occurs, we will promptly announce it.