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Revisions to Q&A on Upfront Investment Type Biotech Startups

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Japan Exchange Regulation, Listing Examination Department

March 10, 2025

Revisions to Q&A on Upfront Investment Type Biotech Startups（Nov. 2024）

- Due to the diversification of biotech startup business models, Tokyo Stock Exchange, Inc. (TSE) revised the Q&A entries in the New Listing Guidebook last November. The revisions changed the entries that treated “platform-type business models” and business models that form post-listing alliances as exceptions and added new Q&A entries on drug discovery biotech startups to the Listing Examination FAQ.

Q48: What exactly do you mean by “situation where the efficacy of a developed product is reasonably evaluated based on objective data, etc.”?

A48: As it depends on the business model, there is no one-size-fits-all answer. However, some examples would be a situation in which the pharmacological effects have been confirmed in the “Phase II a” clinical trial stage of the typical pharmaceutical development process, or cases where the pharmacological effects are suggested based on data from early-phase clinical trials (administration to patients) for regenerative medicine products, products for rare diseases, and so on. In a business model that aims to generate revenue by licensing out many pipelines based on core technologies at an early stage, the usefulness of the core technology may be confirmed through the status of licensing, including preclinical pipelines. In addition, even if the effectiveness of the product under development is not adequately evaluated, it may be possible to confirm the rationality of the business plan based on investor evaluations, etc., as described in A47 (*Deep tech)

Q50: What sort of information must companies disclose if they plan on performing all processes from R&D to manufacturing/sales in-house versus if they plan to outsource these processes by forming an alliance after going public?

A50: The business of developing new pharmaceutical products involves many processes, from R&D to manufacturing, sales and post-launch follow-up. Since the process of commercialization is a long-term one, even if a company has a policy of carrying out the processes leading up to commercialization of its main pipeline in-house, it is possible that at the time of listing, the company will not have a system in place to handle future processes such as manufacturing and sales. In such cases, it is necessary to disclose information that investors need to evaluate corporate value, including plans for developing a system to handle each step of commercializing the relevant main pipeline in-house, specific milestones up to the time of market launch, and the marketability of the product under development, both before and after listing. In addition, if a company plans to outsource some or all of these processes by entering into an alliance after listing, the company will need to disclose this policy at the time of listing, then disclose the details appropriately when they make the decision to enter into an alliance after listing, considering the details described in A51.

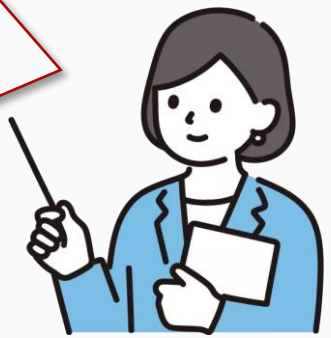
FAQ (5) Listing of Upfront Investment Type Biotech Startups

Updated Nov. 2024

For listing, do upfront investment type biotech startups require confirmation of pharmacological effects from clinical trials for drugs in their pipeline or an alliance with a pharmaceutical company?

These are not requirements.

The business models of upfront investment type biotech startups are diverse, and the listing examination takes into account the characteristics of the business model. TSE has published “Approaches and Examination Points for Listing of Upfront Investment Type Biotech Startups“ to help such businesses to prepare for listing based on their respective business models.



Ref: Approaches and Examination Points for Listing of Upfront Investment Type Biotech Startups

Updated Nov. 2024

Basic Approaches: To ensure fair and smooth price formation in the market and investor protection, it is necessary that "the **information necessary for investors to evaluate corporate value is available for disclosure,** and that this information is **accurately disclosed** even after listing."

Rationality of Business Plan		Appropriate Disclosure
Efficacy of Products Under Development	**Development/Commercialization Prospects**	
Examination Points		
• **Efficacy is reasonably evaluated based on objective data, etc.**	• **Company-wide development plans** are reasonably formulated (development priorities, securing resources including human resources, intellectual property, and funds, and policies for handling development discontinuation) • **Plans for commercialization** for each pipeline are reasonably formulated. ➢ Its policy on whether to perform research and development, manufacturing, and sales **in-house or outsourced** to an alliance partner is reasonably formulated.	• The following items are **appropriately disclosed.** ➢ Details of products under development (disease, treatment, clinical trial design, competing drugs, sales area, etc.) ➢ Evaluation of product safety and efficacy ➢ Patent details (duration, etc.) ➢ Business plan (development plan, plan for commercialization, etc.) ➢ Details of alliances, if any ➢ Risks for discontinuation of development and policies for its handling **Note: The disclosure policy for information necessary for evaluating corporate value after listing** will be checked.
Possible Cases*		
○ In the typical pharmaceutical development process, "pharmacological effects in Phase IIa clinical trials" have been confirmed. ○ For regenerative medical products and products for rare diseases, "pharmacological effects based on data from clinical trials, among others in the early phase (administration to patients) have been indicated. ○ The utility of the core technology has been confirmed through out-licensing, including the preclinical pipeline, in businesses based on the core technology.	○ When multiple compounds are developed, the development priorities are clear, and resources are secured. ○ It is also assumed that development will be carried out on the premise that the same compound or technology will be applied to multiple diseases. ○ When a pharmaceutical for a large number of patients is developed, an alliance has already been formed or is scheduled to be formed for the main pipeline to secure commercialization. ○ When regenerative medical products and products for rare diseases are developed, sales channels are secured in-house through collaboration with specialist doctors and patient groups, etc. ○ When a product is manufactured in-house, the manufacturing method has been established and there is a prospect for mass production.	○ The current development status and future development schedule have been indicated for each pipeline. ○ When an alliance has been formed, in addition to details of the consignment, information important for investment decisions such as milestones and royalties has also been indicated. (When an alliance is scheduled to be formed after listing, the policy of disclosing such information at the time of decision has been indicated.) ○ A policy has been indicated for when risks for the discontinuation of development arise.

*These cases are generally assumed based on past examination cases. However, actual listing examinations are conducted based on the situation of each company, so listing may be approved even if the situation is different from the one in the aforementioned cases, whereas, even if the situation is the same as that in the aforementioned cases, it does not necessarily mean that listing will be approved.

Provision of Information for Investors in Upfront Investment Type Biotech Startups

Updated Nov. 2024

For upfront investment type biotech startups, their businesses are highly specific compared to those of other sectors listed on the Growth Market because they are still in the process of research and development at the time of listing and require a long time for investment payback. In addition, they are highly specialized and require approval from the relevant authorities.

It is particularly important for such businesses to actively disclose information about their business models, business plans, and risks, so that investors can make an appropriate evaluation.
In addition, it is expected that they will actively provide information to investors (IR) not only at the time of listing, but also after listing.