

Case Study



Strategic Spin-Out and Expansion of Immunomodulatory Portfolio

Challenge

An investment bank was considering spinning out a portfolio of oral and inhaled immunomodulatory approaches from a larger pharmaceutical company affiliate.

The portfolio included a bacterial lysate, which was already approved in other regions for the prevention of respiratory tract infections (RTI) in both adults and children.

The key challenge was to conduct due diligence on the affiliate's portfolio, with a particular focus on evaluating the opportunities for expansion into the U.S. market.

This evaluation needed to consider the regulatory landscape, potential market size, and the strategic fit with the new company's goals.

Solution

The solution involved a comprehensive due diligence process, which included the following steps:

Portfolio Analysis and Prioritisation:

- **Technical and Clinical Evaluation:** Each project within the portfolio was assessed based on the stage of development, clinical trial data, and the strength of preclinical evidence. Special attention was given to the bacterial lysate for RTI, evaluating its mechanism of action, safety profile, and efficacy data from existing markets.
- **Market Potential Analysis:** Market research was conducted to estimate the potential market size in the U.S. for the RTI product, including the prevalence of respiratory infections and the unmet needs in this therapeutic area. The competitive landscape was also analysed to understand the positioning and potential differentiation of the product.
- **Regulatory Pathway Assessment:** The regulatory requirements for approval in the U.S. were outlined, including necessary clinical trials, timelines, and potential challenges. The focus was on identifying the fastest and most efficient pathway to approval, leveraging existing data where possible.

Outcome

The outcome of this due diligence and strategic planning process led to:

Successful Spin-Out:

- The immunomodulatory portfolio was successfully spun out into a new independent company, providing it with the focus and resources needed to drive the development of its products.

Focused Development Strategy:

- The company decided to prioritise the development of the RTI bacterial lysate for the U.S. market. This decision was based on the product's strong clinical data, significant unmet medical need, and relatively clear regulatory pathway.

Accelerated Development Timeline:

- By rationalising the approach and focusing resources on the RTI product, the company was able to streamline its development processes and set an accelerated timeline for FDA approval and market entry.

Conclusion

This case study highlights the importance of thorough due diligence and strategic planning in pharmaceutical portfolio management.

By carefully evaluating the potential of each project and focusing on the most promising opportunities, the new company was positioned to achieve its geographical and commercial goals effectively.

The spin-out not only allowed for dedicated focus on the portfolio but also maximised the chances of success for the RTI product in the U.S. market, potentially benefiting both patients and investors.