

Life Sciences Case Studies

Our clients include emerging and established pharmaceutical and biotechnology companies. As a result of our work, many of these clients return to us when they face new business challenges. Some of our recent assignments are reflected in the following case examples:

Developing Disease Area Strategy

A medium-sized biotech company had just completed a Phase III study that showed a positive trend, but failed to meet its primary efficacy endpoint. The company needed to determine the next-best clinical study that would maximize its ability to show efficacy. In addition, the company had in-licensed another distinct molecule with a different mechanism of action that had the potential to treat the same disease. Given these multiple opportunities to treat the same patient population, the company needed help developing the best disease area strategy

Applied Strategies helped the client develop several clinical development options for each molecule. We worked closely with the project teams and senior management to define the risk and return of each option. Because both molecules had the potential to be developed for the same indication, each option was carefully evaluated to determine the optimal timing of launch, mitigate cannibalization of the first product by the second, address pricing issues for each, and to develop an appropriate pricing and market positioning strategy for the two products.

Applied Strategies was asked to present the results of this disease strategy development project to the Board of Directors, who agreed with the final recommendations to fund both programs, despite significant pressure to reduce R&D spending.

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Prioritizing Molecule Strategy Opportunities

A mid-sized biotech company had more development opportunities than available funding. The company's most pressing issue was centered on a molecule that had six ongoing clinical programs and three in draft protocol stage. The company needed help with prioritizing opportunities and determining which indications should be developed internally vs. preparing for an out-licensing strategy. The molecule's potential covered a broad range of diseases including oncology, infectious diseases, and fibrotic diseases.

Applied Strategies helped the client establish a consistent and transparent methodology for valuing the risk and return of all the potential indications. Working with client project teams, as well as middle and senior management groups across all functions, we helped the client define development plan options, develop detailed timelines, and evaluate the risk and potential return of each indication. These analyses generated insights about the current and future competitive environment, competitor dynamics, and the potential for off-label use. These analyses enabled the client to maximize the value of this versatile molecule and better prioritize its projects going forward.

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Determining Asset Strategy

A start-up biotech company was within a year of submitting an IND and needed to identify their lead indication among various potential oncology and autoimmune indications. In addition to identifying the lead indication, the client needed insight into when to partner and under what potential deal terms. Applied Strategies worked with client teams and outside oncology and autoimmune experts to design development programs for each potential indication. Through facilitated workshops the teams identified the program risks and developed contingency plans based on the results of future clinical trials. We also provided insight into the risk and return of each program over the development timeframe for use by the business development group in partnering discussions.

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Setting Direction in Corporate Strategy

A top-ten biopharmaceutical company with three products in the market and seven products in development appointed a new CEO who immediately launched a Corporate Strategy initiative to determine the company's time to profitability and to develop its five-year plan. As part of this initiative, Applied Strategies was asked to work with project and management teams to analyze the company's two therapeutic area portfolios, including alternative development plans that might speed products to market or otherwise increase revenues in the target profitability window. Using our powerful valuation methodology, we were able to:

- Assess the value of the current development plans
- Generate and assess the value of alternative development plans
- Define success criteria and assess probabilities for each alternative
- Estimate development cost for following year, to next decision milestone, and to completion
- Assess market size, share and price; competitor dynamics; commercial costs
- Identify key commercial value drivers
- Calculate value measures for each alternative and recommend a path forward

As a result of these analyses, most project teams were re-directed to pursue development plans that differed from their existing plan in order to maximize value, accelerate revenue, or minimize spend. In addition, the subsequent portfolio analysis of the selected development plans identified a significant earnings gap during the targeted profitability window and less than acceptable earnings growth over the long-range planning period. The company asked Applied Strategies to assist the company in its work to identify options for addressing the earnings gap and significantly increasing earnings growth over the next five years.

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Strategic Planning

An antibody technology and product development company appointed a new CEO who immediately launched a Five-Year Strategic Planning initiative to determine the company's time to profitability and to develop its five-year strategic plan. As part of this initiative, Applied Strategies was asked to work with the executive team and a newly chartered Strategic Planning Group to identify the company's core competencies, map and analyze the company's pipeline from target identification stage through late stage development, determine the company's time to profitability, and develop options for accelerating time to profitability and mitigating risk.

As a result of this effort, the company shifted its focus from technology out-licensing and co-development partnerships to internally focused R&D, reorganized to improve productivity and streamline costs, and chartered an Implementation Planning and Execution Team to manage the formation and progress of over a dozen special initiative teams. Applied Strategies was asked to provide transitional support and guidance to the implementation team.

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Guiding Corporate Reorganization

The new leadership team of a biopharmaceutical company with several in-market products and many development products found the company with low morale, high turnover, and an unaligned and underperforming organization that threatened the company's long-term viability. The company engaged Applied Strategies to help develop the company's optimal organizational design. Working closely with the Executive Committee and employees at every level of the company, we helped to:

- Reorganize by therapeutic area to enable synergy, consistency, and improved alignment in product planning
- Clearly define roles and responsibilities throughout the organization to improve decision-making, efficiency, and productivity
- Strengthen the team through internal promotion and recruitment
- Improve morale and motivation through employee participation, improved communications, better understanding of vision and strategy, and the pushing of decision-making lower in the organization

As a result of the reorganization, the company is now aligned in its strategy, people, products, and processes and it is well positioned for long-term success.

As part of the post-reorganization implementation, Applied Strategies helped the company establish a Strategic Planning and Analysis Group, led and staffed its Project Management Department until full-time staff could be hired, and facilitated a decimated Medical Affairs Department through a department strategy and planning process to determine how best to rebuild under the new organizational structure and corporate strategy. In addition, Applied Strategies periodically facilitates Executive Committee off-sites to assess progress against goals and organizational and management team behavior and performance.