

Corporate governance and operational management optimization in private biotechnology enterprises

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Abstract. As a vital force within China's strategic emerging industries, private biotechnology enterprises play a crucial role in advancing technological innovation and economic development. At the same time, they face dual challenges arising from the industry's inherent characteristics—namely high investment, high risk, and long development cycles—and from deficiencies in internal governance mechanisms. From the perspective of corporate governance, this paper systematically examines the current conditions and core issues faced by private biotechnology enterprises in areas such as internal control, digital transformation, financing efficiency, cost management, capital control, and diversification strategies. The study finds that these enterprises commonly exhibit problems including imperfect governance structures, weak internal control environments, limited financing channels, significant talent attrition, lagging brand development, and the phenomenon of diversification discount. In response, this paper proposes a set of integrated optimization pathways, including improving ownership structure and corporate governance frameworks, strengthening internal control systems, advancing digital transformation, establishing lean cost management systems, broadening financing channels, and implementing moderate diversification strategies. The aim is to provide both theoretical reference and practical guidance for enhancing governance efficiency and operational management in private biotechnology enterprises.

Keywords: biotechnology enterprises, private enterprises, corporate governance, internal control, operational management optimization

1. Introduction

The biotechnology industry, as a strategic emerging sector, plays an essential role in promoting high-quality economic development and safeguarding public health. In recent years, private biotechnology enterprises in China have experienced rapid growth and have become a major source of technological innovation and market dynamism. However, compared with well-established biotechnology firms in developed countries, China's private biotechnology enterprises still face multiple bottlenecks in corporate governance and operational management. Biotechnology enterprises are characterized by "high investment, high risk, high return, and long development cycles". Their research and development processes are complex, capital-intensive, and subject to stringent regulatory requirements, making internal management significantly more challenging than in most other industries [1]. At the same time, private enterprises often exhibit concentrated ownership structures,

family-oriented management practices, and incomplete governance mechanisms, which further exacerbate operational risks.

Existing studies indicate that the soundness of corporate governance structures and the effectiveness of internal controls are directly linked to a firm's ability to mitigate risks and create value [2]. For private biotechnology enterprises, the construction of a scientific governance system and the optimization of operational management models have thus become critical to achieving sustainable development. From a corporate governance perspective, this paper integrates the specific characteristics of the biotechnology sector to systematically analyze existing issues in internal control, digital transformation, financing efficiency, cost management, capital control, and diversification strategies. On this basis, it proposes targeted optimization pathways, with the aim of providing theoretical support and practical insights for relevant enterprises.

2. Characteristics and governance dilemmas of private biotechnology enterprises

2.1. Industry characteristics of biotechnology enterprises

Biotechnology enterprises differ significantly from traditional manufacturing firms. First, they are characterized by long research and development cycles and substantial capital investment. The process from early-stage discovery to product commercialization typically involves extended periods of R&D, clinical trials, and regulatory approval, resulting in continuous and high-risk capital demands [3]. Second, the core assets of biotechnology enterprises are predominantly intangible, such as patented technologies and research outcomes. The lack of tangible assets suitable for collateral significantly constrains their financing capacity [4]. Third, the industry is subject to stringent regulatory oversight. Policy changes—including adjustments to drug registration procedures and the implementation of the "two-invoice system"—have far-reaching implications for corporate strategies and operational decision-making [5].

2.2. Governance characteristics of private enterprises

Compared with state-owned enterprises, private enterprises benefit from greater flexibility in decision-making and faster market responsiveness. However, they commonly suffer from deficiencies in governance structures. Most private enterprises adopt family-based management models in which ownership and managerial control are highly concentrated. As a result, the functions of boards of directors and supervisory boards are often weakened, making it difficult to establish effective checks and balances [6]. In terms of internal control, private enterprises tend to prioritize business expansion over managerial standardization, often lacking systematic internal control frameworks. This leads to insufficient risk prevention capabilities. In addition, private enterprises face multiple constraints in areas such as talent acquisition, brand development, and access to financing channels [7].

2.3. Dual challenges facing private biotechnology enterprises

Private biotechnology enterprises are confronted with the dual pressures of high industry entry barriers and imperfect corporate governance. On the one hand, the high uncertainty inherent in technological innovation requires strong financial capacity and robust risk tolerance. On the other hand, deficiencies in governance mechanisms limit the efficiency of resource allocation and the effectiveness of strategic execution. This structural tension makes such enterprises particularly vulnerable to challenges including capital chain strain, talent attrition, and weakened innovation capacity during their development process. Therefore, adopting a

corporate governance perspective to systematically optimize internal control systems and operational management has become an inevitable pathway for overcoming developmental bottlenecks in private biotechnology enterprises.

3. Analysis of internal control issues in private biotechnology enterprises

As a critical instrument of enterprise risk management, internal control holds particular significance for private biotechnology enterprises. Drawing on existing research, this paper analyzes the issue across five dimensions: control environment, risk assessment, control activities, information and communication, and internal supervision.

3.1. Weak control environment

The control environment constitutes the foundation of internal control, encompassing governance structures, corporate culture, and human resource policies. At present, private biotechnology enterprises exhibit notable deficiencies in this regard. First, management often lacks a comprehensive understanding of internal control, frequently regarding it as merely the responsibility of the finance department rather than elevating it to a strategic level [8]. Second, corporate governance structures are underdeveloped: the decision-making mechanisms of shareholders' meetings, boards of directors, and supervisory boards fail to function effectively. In some cases, independent technical committees are not established, undermining the scientific rigor of decision-making. Third, corporate culture development lags behind. Employees demonstrate low levels of participation in internal control processes, and the absence of systematic internal control training further weakens the effectiveness of implementation.

3.2. Inadequate risk assessment system

Risk assessment is a key process for identifying and analyzing risks associated with achieving organizational objectives. Biotechnology enterprises face highly complex and dynamic risks; however, most private firms have yet to establish comprehensive risk assessment systems. On the one hand, enterprises show limited capacity to identify market and policy risks. They often fail to track regulatory changes in a timely manner, particularly those issued by drug regulatory authorities, resulting in misalignment between strategic planning and the policy environment. On the other hand, internal risk identification mechanisms are insufficient. Critical risks—such as R&D failure, liquidity constraints, and production safety issues—lack systematic early-warning and response mechanisms. Moreover, risk assessment tends to remain confined to senior management and does not penetrate operational levels, leaving frontline employees with generally weak risk awareness and identification capabilities.

3.3. Ineffective execution of control activities

Control activities include specific measures such as authorization and approval procedures, segregation of duties, and performance evaluation systems. In private biotechnology enterprises, several prominent issues can be identified. In the R&D process, budget management is often superficial, and accounting for R&D expenditures lacks standardization. Key stages—including project initiation, feasibility analysis, and commercialization of outcomes—lack end-to-end control, resulting in low efficiency of R&D investment. In procurement, supplier management mechanisms are underdeveloped. The absence of scientific supplier evaluation and classification systems makes it difficult to ensure the quality of raw material procurement. In production and inventory management, stocktaking systems are incomplete, and pharmaceutical safety control

measures are insufficient. This leads to risks such as material backlog and potential quality hazards. In sales and receivables management, accounts receivable controls are weak. Customer credit evaluation lacks a scientific basis, and overdue payments are not collected in a timely manner, adversely affecting cash flow and capital turnover.

3.4. Inefficient information and communication mechanisms

Information and communication constitute a core element of internal control. Currently, private biotechnology enterprises commonly suffer from "information silos." Financial systems, operational systems, and capital management systems are poorly integrated, resulting in inconsistent data standards and low efficiency in interdepartmental information sharing. Furthermore, communication mechanisms with external stakeholders—such as suppliers and customers—are underdeveloped. The lack of coordination across the supply chain hinders enterprises' ability to respond swiftly to market changes. In terms of digital infrastructure, some enterprises underinvest in information systems or remain at a basic application level, failing to leverage advanced technologies such as big data and cloud computing to upgrade management practices.

3.5. Weak internal supervision

Internal supervision involves the continuous evaluation of internal control effectiveness. In private biotechnology enterprises, this function is often undermined by formalistic systems and insufficiently quantified performance metrics. Supervisory methods are limited, relying primarily on manual inspections and whistleblowing mechanisms, with a lack of digital monitoring tools. Internal audit departments often lack independence, reducing their ability to effectively oversee key business processes. In addition, performance evaluation systems are incomplete, as the implementation of internal control is not adequately incorporated into performance appraisal frameworks. As a result, internal control requirements are difficult to enforce in practice.

4. Key challenges in the operational management of private biotechnology enterprises

4.1. Misalignment between technological innovation and market demand

Technological innovation constitutes the core competitiveness of biotechnology enterprises. However, approximately 70% of R&D projects are misaligned with market demand, and fewer than 30% of enterprises have established systematic mechanisms for market demand analysis. Information barriers persist between R&D teams and marketing departments, preventing firms from adjusting research directions in a timely manner in response to market changes. This results in low efficiency in the conversion of R&D inputs into outputs. Furthermore, the mechanisms for commercializing research outcomes remain underdeveloped, leaving a substantial number of patented technologies unindustrialized and leading to significant waste of innovation resources.

4.2. Narrow financing channels and low efficiency

Biotechnology enterprises are characterized by long R&D cycles and substantial capital requirements, yet private firms commonly face difficulties in accessing financing and bear relatively high financing costs. Due to information asymmetry, insufficient collateral, and underdeveloped credit guarantee systems, private enterprises often struggle to obtain bank loans. Although capital markets such as the Hong Kong Stock

Exchange have introduced "green channel" policies for pre-profit biotechnology firms, most private enterprises still fail to meet listing requirements. While private equity and venture capital have become important supplementary financing sources, their efficiency remains limited, partly due to investors' insufficient understanding of the technical complexities of biotechnology.

4.3. Severe talent attrition

The biotechnology sector is highly dependent on high-level human capital. However, talent attrition rates in private enterprises exceed 30% and are projected to surpass 40% within the next two years. Key contributing factors include uncompetitive compensation and benefits, unclear career development pathways, and lagging corporate culture development. In addition, inadequate human resource management—manifested in the absence of systematic talent development programs and effective performance evaluation mechanisms—further exacerbates the risk of losing core technical personnel.

4.4. Lagging brand development

Compared with multinational biotechnology firms, domestic private enterprises invest insufficiently in brand development and generally exhibit low levels of market recognition. Brand communication channels are limited, and firms have not fully leveraged new media platforms to conduct multi-dimensional brand promotion. Membership service systems are underdeveloped, making it difficult to cultivate stable customer bases and strong brand loyalty. Moreover, the lack of distinctive brand identity and vague market positioning hinders the formation of differentiated competitive advantages in an increasingly competitive marketplace.

4.5. Fragmented capital management and risk accumulation

Biotechnology enterprise groups often exhibit fragmented capital management, inadequate monitoring, and outdated management methods [9]. Subsidiaries tend to exercise discretionary control over funds, making it difficult for parent companies to achieve centralized allocation and unified management of capital. Insufficient digital infrastructure prevents real-time monitoring of financial data, and the absence of effective early-warning mechanisms increases financial risk exposure. Resource allocation also lacks strategic focus, with insufficient prioritization of core R&D projects, thereby constraining long-term development.

4.6. Diversification strategy and value discount

Diversification is an important pathway for biotechnology enterprises seeking growth. However, empirical evidence indicates a negative relationship between the degree of diversification and firm value, with higher levels of diversification leading to greater value discount [10]. In China's biopharmaceutical sector, diversification exhibits a clear stage-dependent pattern: moderate diversification may enhance firm value, whereas medium to high levels of diversification tend to result in significant valuation discounts. The underlying causes include the absence of strong core competencies, increased agency costs, and inefficiencies in internal capital markets, all of which contribute to the diversification discount effect.

5. Optimization pathways for corporate governance and operational management

5.1. Optimizing governance structure and improving decision-making mechanisms

To address the deficiencies in governance structures of private biotechnology enterprises, optimization should proceed along several dimensions. First, the corporate governance framework should be restructured to establish a more scientific governance system. Shareholders' meetings, boards of directors, and supervisory boards should be fully integrated into formal decision-making processes. At the same time, a specialized biopharmaceutical technical committee should be established to participate in major corporate decisions, thereby enhancing the scientific rigor and authority of decision-making. Second, a hierarchical authorization mechanism should be implemented. Approval authority should be reasonably delegated based on business type and risk level, shortening decision-making chains and improving efficiency. Third, the independent director system should be strengthened. The introduction of external experts into board-level decision-making can enhance both transparency and professional competence in corporate governance.

5.2. Improving the internal control system and strengthening risk management

The construction of an internal control system should encompass the entire operational process of the enterprise. At the level of the control environment, management must shift its mindset and fully recognize the strategic importance of internal control. Regular training programs should be conducted to enhance employees' theoretical understanding and execution capabilities related to internal control. In terms of risk assessment, enterprises should establish comprehensive risk databases and define key risk indicators. Leveraging big data technologies, firms can achieve dynamic risk identification and early warning, with particular attention to critical areas such as policy changes, capital turnover, and production safety. Regarding control activities, internal control measures should be strengthened across all operational stages, including R&D, procurement, production, and sales. In the R&D phase, budget management and accounting practices should be standardized, and a full-process traceability mechanism should be established, with clear distinctions between research and development stages. In procurement, a supplier evaluation and classification system should be developed, adopting a selection strategy based on quality, cost-effectiveness, and proximity. In production and inventory management, stocktaking systems should be improved and pharmaceutical safety controls reinforced to ensure product quality. In sales and receivables management, stricter accounts receivable controls should be implemented, including dynamic monitoring of customer operating conditions and timely collection of overdue payments.

5.3. Promoting digital transformation and enhancing operational efficiency

Digital transformation has a significant positive impact on the performance of biotechnology enterprises, particularly in state-owned enterprises and firms located in eastern regions [11]. Private enterprises should therefore increase investment in digital infrastructure. This includes integrating financial, operational, and capital management systems to establish unified data standards and enable seamless interconnection across platforms. By adopting integrated management systems such as SAP, enterprises can build end-to-end platforms linking production, procurement, and sales, thereby enhancing standardization and operational efficiency. At the same time, firms should establish effective communication mechanisms with external stakeholders, including suppliers and customers, and develop biopharmaceutical supply chain information platforms to facilitate extensive information sharing. This will strengthen the enterprise's ability to respond to

external market dynamics. At the institutional level, digital transformation can improve firm performance by alleviating financing constraints. Enterprises should therefore recognize this transmission mechanism and treat digitalization as an important tool for improving their financing environment.

5.4. Establishing a lean cost management system

From a supply chain perspective, biotechnology enterprises should implement lean cost management, with a focus on eliminating waste and improving efficiency, thereby optimizing costs and enhancing the efficiency of resource allocation [12]. Procurement strategies should be refined by establishing long-term partnerships with suppliers, implementing supplier evaluation and performance assessment systems, and leveraging digital technologies to improve transparency and efficiency in procurement processes. Production efficiency should be enhanced through the adoption of automated production systems, optimization of production workflows, and the promotion of lean manufacturing principles to minimize various forms of waste. Inventory management should be strengthened by adopting inventory-sharing strategies, applying advanced inventory management technologies, and establishing comprehensive inventory control systems to reduce inventory costs and operational risks. In addition, enterprises should promote technological innovation by increasing R&D investment, deepening industry–university–research collaboration, and fostering a culture of innovation, thereby achieving an organic integration of cost reduction, efficiency enhancement, and value creation.

5.5. Expanding financing channels and optimizing capital structure

To address financing constraints, private biotechnology enterprises should adopt a multi-pronged approach to broaden financing channels. First, enterprises should strengthen internal management, improve revenue generation and profitability, and expand endogenous financing capacity. Second, firms should select financing methods appropriate to their stage of development. For enterprises that have not achieved profitability in the past three years, listing on the Hong Kong Stock Exchange may be considered, taking advantage of its "green channel" policy for pre-profit biotechnology companies. Third, enterprises should introduce professional talent to enhance financial management and listing preparation, thereby reducing information asymmetry and operational barriers during the financing process. At the governmental level, it is essential to improve the legal framework for SME financing and establish a sound credit guarantee system to create a favorable financing environment for biotechnology enterprises. Meanwhile, firms may draw on off-balance-sheet financing instruments such as SWORDS to raise funds for specific R&D projects, thereby reducing information asymmetry and financing costs.

5.6. Strengthening centralized capital management and preventing financial risks

Biotechnology enterprise groups should establish centralized capital management models by setting up dedicated treasury management departments responsible for unified allocation and supervision of subsidiary funds. Information technology should be leveraged to enhance capital control capabilities. For example, ERP systems can be used to achieve real-time monitoring of cash flows, while deep cooperation with banks can ensure transparency and controllability of fund movements. A comprehensive budgeting system for monetary funds should be established, with budgets prepared on quarterly and annual bases. For departments with frequent capital usage, daily and weekly budgeting mechanisms should be introduced to improve the scientific and rational use of funds. In addition, incentive mechanisms for capital management should be refined by incorporating capital utilization efficiency into performance evaluation systems, thereby motivating employees and fostering organization-wide participation in financial control.

5.7. Implementing moderate diversification strategies with a focus on core business

Based on empirical evidence regarding the relationship between diversification and firm value, biotechnology enterprises should maintain a low level of diversification and avoid the value discount associated with medium to high levels of diversification. Firms should recognize the stage-dependent nature of diversification strategies. At the stage of limited diversification, surplus resources can be utilized to create additional value. However, once diversification exceeds a critical threshold, strategic adjustments should be made to concentrate limited resources on core business segments and cultivate core competencies. For enterprises that have already adopted high levels of diversification, measures such as asset divestiture and business restructuring should be undertaken to reduce diversification and enhance firm value. When implementing diversification strategies, enterprises should prioritize related diversification, extending along the industrial chain based on core technologies, and avoid blind expansion into unrelated fields.

5.8. Strengthening talent management and brand development

Talent is the cornerstone of innovation-driven development in biotechnology enterprises. Private firms should establish comprehensive systems for talent recruitment and development, design market-competitive compensation schemes, and adopt diversified incentive mechanisms—such as equity incentives—to attract and retain high-level innovative talent. A multi-tiered talent development framework should be constructed, including initiatives such as postdoctoral research stations and joint laboratories with universities, to provide robust development platforms for scientific researchers. In terms of brand development, enterprises should formulate well-defined brand strategies, clarify brand positioning and value propositions, and deeply explore brand connotations to highlight their distinctive strengths in biotechnology innovation, product quality, and service delivery. By leveraging new media platforms for multi-dimensional brand promotion and establishing comprehensive membership service systems, enterprises can enhance brand visibility and strengthen market recognition.

6. Conclusion and recommendation

Private biotechnology enterprises play an irreplaceable role in advancing China's biopharmaceutical industry. However, significant challenges remain in improving their corporate governance and operational management. From a corporate governance perspective and in light of the specific characteristics of the biotechnology sector, this paper has systematically analyzed key issues faced by private enterprises in areas such as internal control, digital transformation, financing efficiency, cost management, capital control, and diversification strategy. It has further proposed integrated optimization pathways, including improving governance structures, strengthening internal control systems, promoting digital transformation, establishing lean cost management systems, expanding financing channels, enhancing centralized capital management, implementing moderate diversification strategies, and reinforcing talent management and brand development. The findings indicate that private biotechnology enterprises should attach great importance to the foundational role of corporate governance. By improving corporate governance structures and strengthening internal control systems, firms can establish robust institutional safeguards for sustainable development. At the operational level, enterprises should align with the trend of digital transformation and leverage information technology to enhance both operational efficiency and financing capacity. At the same time, greater emphasis should be placed on capital control and cost management to mitigate financial risks and ensure the continuity and stability of R&D investment. From a strategic perspective, enterprises should maintain a low level of diversification, focus on core business areas, and avoid value erosion caused by blind expansion. In addition, talent acquisition and

brand development should be advanced as long-term strategies to strengthen core competitiveness. In conclusion, optimizing corporate governance and operational management in private biotechnology enterprises is a systematic undertaking that requires coordinated efforts from enterprises, government, and society. Enterprises should strengthen governance awareness and refine internal mechanisms; governments should improve the policy environment and enhance financing support systems; and industry participants should promote self-regulation and information sharing. Only through such coordinated efforts can private biotechnology enterprises achieve high-quality development and make substantive contributions to the growth of China's biopharmaceutical industry.

1References

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