On Corporate Intellectual Property & Technological Competencies in Co-Financing Innovative Biomedical Enterprises

From the perspective of small and medium-sized enterprises (SMEs) innovative biomedical enterprises, this paper conducts a comprehensive analysis of technological core competence challenges encountered during the equity financing process, aiming to provide significant reference value for the successful implementation of venture financing. In light of the problems surrounding technological core competence in equity financing, such as the absence of novelty in innovative product approval processes and the lack of emphasis on intellectual property, this study proposes several countermeasures. These include enhancing enterprises' innovation capabilities and awareness, focusing on promising research and development (R&D) fields, strengthening the protection of project intellectual property, and reasonably designing R&D model of enterprises. Venture capital can effectively address the bottleneck issue of equity financing for SMEs innovative biomedical enterprises and play a pivotal role in the field of innovative drug R&D. By promoting the development of more efficient novel drugs, it significantly contributes to the robust growth of China's biomedical industry.

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key words

small and medium-sized enterprises, biomedical enterprise, equity financing, technological core competence, intellectual property rights

As a critical component of the biotechnology sector, the biomedical industry holds strategic importance pertaining to national economic vitality, public health, and national security. The burgeoning biomedical market in China, propelled by technological advancements, industrial restructuring, and the augmentation of consumer purchasing power, has demonstrated a consistent upward trend. The government actively promotes the profound integration of biomedical enterprises' R&D, production, and sales with cutting-edge information technologies, such as internet big data and cloud computing, to inject fresh momentum into the biomedical industry and facilitate leapfrog growth.

Reflecting on the annals of history, the pharmaceutical industry in China has undergone a trio of stages: a dearth of healthcare and medications, a decade of robust growth in the development of generic drugs, and a transition from imitation to innovation and the emergence of innovative drugs. The capability for innovative biomedical R&D serves as a crucial hallmark of nation's pharmaceutical industry [1]. The pursuit of biomedical novel drug research and development is characterized by high investment, high risk, and long cycle, and SMEs innovative biomedical enterprises in China have long been grappling with the challenges posed by financing constraints. This study delves into the current status of equity financing for SMEs innovative biomedical enterprises (referred to as financing enterprises) and one of their prevailing predicaments, namely, the enterprise's technological core competence, and offers corresponding countermeasures and recommendations to facilitate the successful equity financing of SMEs innovative biomedical enterprises.

Financing channels for SMEs innovative biomedical enterprises

The primary financing avenues for Chinese biomedical companies currently include self-funding, government research grants, commercial bank loans, and IPO financing [2]. Start-ups primarily rely on personal savings or founder's investments. However, compared to the total cost of innovative drug R&D, these sums can only marginally demonstrate the potential efficiency of candidate drugs, inadequately satisfying the enterprise's phase-specific needs. The annual allocations from Chinese provincial governments for supporting innovative drug R&D represent a relatively minor portion of the total national science and technology expenditure, making it challenging to finance the expensive preclinical pharmaceutical research and clinical phase trials. Commercial bank loans impose stringent lending criteria and evaluation standards, necessitating that the borrowing company possesses a certain market share, order volume, business volume, and profit margin,

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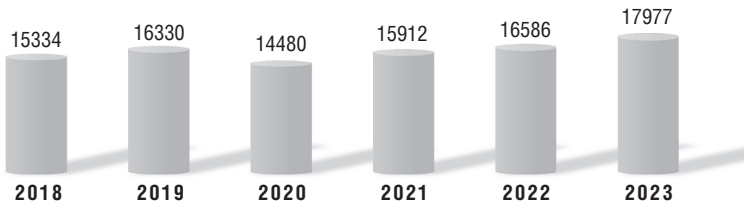


Fig. 1. Dynamics of China's biomedical market size from 2018 to 2023 (according to BioDiscovery data)
[Динамика объема биомедицинского рынка Китая с 2018 по 2023 год (по данным BioDiscovery)]

along with collateral and guarantees. The SMEs innovative biomedical enterprises confront the possibility of R&D failure for their future innovative drug projects, which could hinder the fulfillment of preconditions for commercial bank loans. The Chinese stock market and securities regulatory system impose stringent requirements on the assets, profit model, company prospect, and growth of enterprises seeking listing. As such, these SMEs innovative drug R&D enterprises have a long journey ahead and currently cannot meet their capital needs.

The findings indicate that for SMEs innovative biomedical enterprises, the aforementioned financing avenues are not optimal choices. Nonetheless, venture capital serves as a crucial equity financing channel and method. It is a vital instrument for fostering the industrialization of scientific and technological achievements within the framework of a market economy [3].

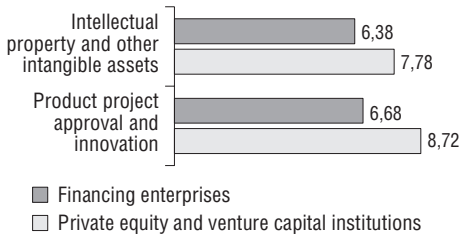


Fig. 2. Results of investigation and research in the field of intellectual property and product innovation
[Результаты исследований в области интеллектуальной собственности и инновационных продуктов]

Methodology and results

Based on a comprehensive review of the existing literature concerning innovative biomedical R&D, as well as equity financing within this field, the questionnaire was designed to include a set of candidate questions. Subsequently, the study and analysis were conducted through a survey of private equity and venture capital institutions and SMEs innovative biomedical enterprises. The aim is to identify the financing bottlenecks and key problems that arise in the equity financing practice of these SMEs innovative biomedical enterprises.

Based on the outcomes of the survey and statistical analysis, it can be deduced that the primary factors influencing the equity financing of SMEs innovative biomedical enterprises are related to the enterprise's technological core competence (Fig. 2), including but not limited to the following aspects: First, the approval process for innovative products is not innovative, indicating a lack of vision in the project approval process for innovative drugs due to the limitations of the past experience and background of researchers and technical experts. Second, insufficient attention is paid to intellectual property rights.

Technological core competence problems and analysis of financing enterprises

Innovation serves as the foundation for the execution of projects and the growth and expansion of SMEs innovative biomedical enterprises. However, this innovation must be

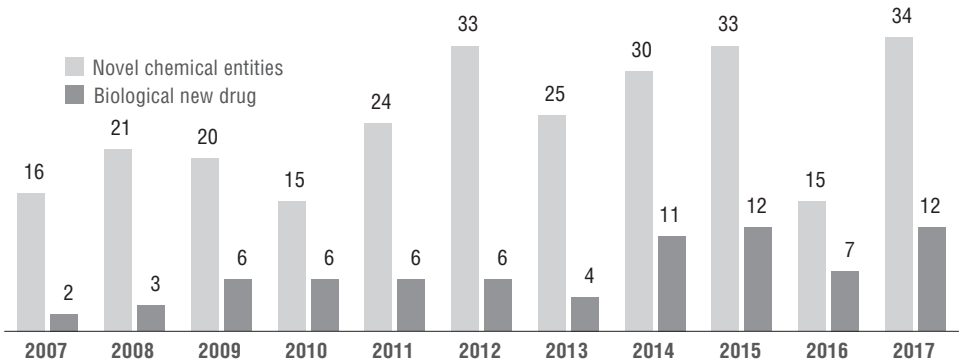


Fig. 3. Innovative drugs approved by FDA from 2007 to 2017 (according to FDA and Pharmacodia® data)
[Инновационные препараты, одобренные FDA с 2007 по 2017 год (по данным FDA и Pharmacodia ®)]

acknowledged by the market and society, particularly by capital investors, rather than being self-perceived or recognized by the financiers themselves.

As illustrated in Fig. 2, venture capital institutions assigned a high importance rating of 8.72 to the product project approval and innovation of SMEs innovative biomedical enterprises. However, the corresponding score from SMEs innovative biomedical enterprises in a questionnaire survey was only 6.68. These data indicate that while venture capital institutions recognize the significance of product project approval innovation, financing enterprises do not seem to prioritize it enough, potentially affecting the equity financing process. The primary reasons for this discrepancy are as follows: (1) The constraints imposed by the limited professional experience and background of researchers and technical experts. The majority of entrepreneurs in China's innovative biomedical enterprises possess a professional knowledge base in medicine, pharmacy, or life sciences. Although many have studied abroad for extended periods and are proficient in advanced innovative drug R&D techniques, there are also domestic experts and scholars in higher education institutions or national-level scientific institutes who have been involved in major innovative pharmaceutical projects. However, the development of innovative drugs requires a systematic approach that involves multidisciplinary collaboration. (2) Financing enterprises exhibit a lack of insight during the approval process for innovative drug projects. Entrepreneurs and technical experts often fail to conduct adequate preliminary research on the innovative drug projects established within their own enterprises. This research should encompass the international frontier R&D directions (see Fig. 3), the distribution field of new drug R&D and treatment in China (Fig. 4), and their competitors. These aspects are frequently overlooked by entrepreneurs and technical experts, resulting in a lack of favor from private equity and venture capital institutions during the financing process.

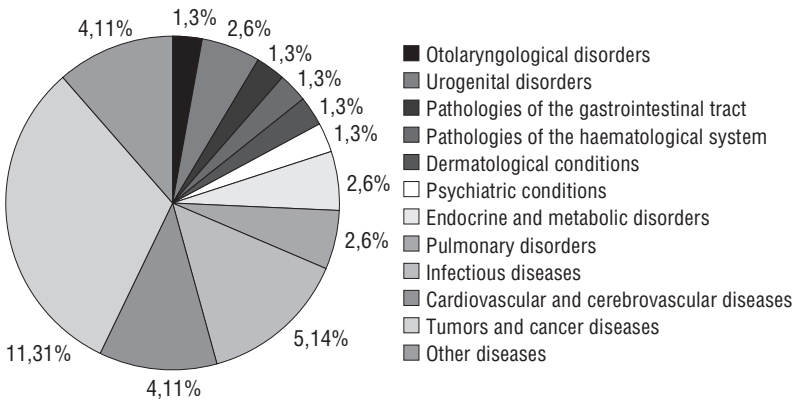
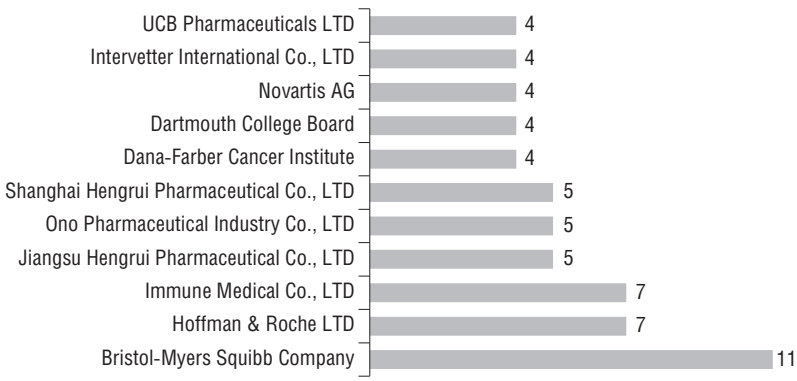


Fig. 4. Distribution of new drug R&D by treatment directions in China in 2016, % (according to Pharmacodia® data) [Распределение исследований и разработок новых лекарственных средств по направлениям лечения в Китае в 2016 году, % (по данным Pharmacodia ®)]

Insufficient attention to the implications of intellectual property rights. The findings from an investigation into the pilot regions of China's intellectual property strategy for SMEs enterprises in the new era reveal that the average annual growth rate of invention patent applications in areas with a high concentration of SMEs enterprises stands at 53 %. Concurrently, the number of granted invention patents has surged by over 30 %. Despite these promising statistics, SMEs innovative biomedical enterprises continue to overlook and underutilize the intellectual property rights of their technological innovations, particularly in relation to patents for innovative pharmaceutical technology inventions.

This finding signifies a significant disparity in patent protection for innovative drug R&D institutions and enterprises in our country when compared to their foreign counterparts. It further suggests that such domestic institutions

Fig. 5. Top 10 patent applicants for PD-1/PD-L1 monoclonal antibodies in China [Топ-10 заявителей на получение патента на моноклональные антитела к PD-1/PD-L1 в Китае]



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information

Over the past decade, the scale of China's biotechnology industry has undergone a steady expansion, growing from 2.3 trillion yuan in 2012 to 6.1 trillion yuan in 2021, with a compound annual growth rate of approximately 11.45 %. It is projected that by 2022, the market size of China's biomedical sector will approximate 1,658.6 billion yuan, and by 2023, the market size is anticipated to escalate to 1,797.7 billion yuan (see Fig. 1)

and enterprises are not devoting adequate attention to intellectual property, as illustrated in Fig. 5.

Venture capital institutions assigned a mean importance score of 7.78 to intangible assets such as intellectual property rights for SMEs innovative biomedical enterprises (see Fig. 2). However, R&D enterprises only allocated 6.38 points in the questionnaire survey. The data reveal that while venture capital institutions significantly prioritize the intellectual property of equity financing enterprises, and financing enterprises seem to insufficiently emphasize this aspect, thereby influencing the equity financing process. The primary reasons for this problem are: a lack of profound respect for intellectual property rights, inadequate protection for innovative intellectual achievements, and the failure of high-tech intensive innovative biomedical enterprises to reasonably determine the value of intangible assets during equity financing. This, in turn, affects the negotiation of pricing and collaboration outcomes between financing enterprises and venture capital investors.

Measures and recommendations

Propose measures and recommendations for addressing the challenges related to the technological core competence of financing enterprises.

1. Enhance the technological innovative capacity and consciousness of enterprises. The spirit of innovation serves as the linchpin of high-tech enterprises. Only through persistent innovation and development of novel therapeutics with diverse indication pipelines can R&D-driven biomedical enterprises effectively mitigate the unpredictable risks stemming from the market, thus fostering the sustainable growth of R&D enterprises [4]. As illustrated in Fig. 6, the proportion of investments allocated to SMEs enterprises, high-tech enterprises, and SMEs high-tech enterprises in China from 2006 to 2016 demonstrates the predilection of venture capital institutions towards high-tech enterprises.

It is proposed that SMEs innovative biomedical enterprises should prioritize fostering innovation in the following five aspects: (1) continuously enhancing and refining innovative pharmaceutical technology; (2) promptly transforming novel drug innovation into productivity, that is, commercializing innovative medications; (3) innovating sales approaches and after-sales service consciousness for end-user drugs; (4) advancing management systems within new drug enterprises; (5) standing at a higher vantage point to construct and establish new pharmaceutical enterprise culture platforms.

Moreover, the existence of a genuine market demand for the novel drug product, the competitive landscape of agents with the same mechanism of action as the target, and the potential risks posed by substitutes sharing the same indication, among other factors, should be meticulously assessed by the project team in devising the corporate development strategy and planning. Consequently, it is proposed that enterprises in the equity financing stage provide timely and explicit explanations of the project's innovative aspects, enabling capital investors to comprehend the project's novelty and creativity. This should be communicated via clear language or designs, supplemented when possible by relevant technological invention patent authorization documents.

2. Focus on the field of R&D technology. Premium and proficient capital investors assess the market growth potential from a technical standpoint to determine

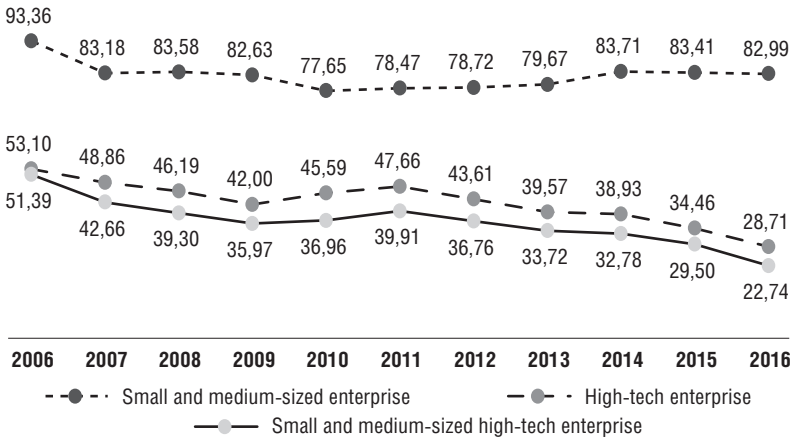

Fig. 6. Proportion of projects invested in small and medium-sized enterprises, high-tech enterprises and small and medium-sized high-tech enterprises from 2006 to 2016 (according to Equity and Venture Capital Committee of Investment Association of China)
[Доля проектов, инвестированных в малые и средние предприятия, высокотехнологичные предприятия и малые и средние высокотехнологичные предприятия в период с 2006 по 2016 год (по данным Комитета по акционерному и венчурному капиталу Инвестиционной ассоциации Китая)]

whether significant returns can be realized from innovative pharmaceutical projects in the future, as well as the magnitude of investment risks. The R&D of innovative biomedical projects encompass a multidisciplinary field with significant technical barriers, spanning diverse technical domains such as biology, chemistry, formulation, pharmacology, clinical, quality control, and regulations. It becomes imperative for innovative drug research teams to possess adequate complementary expertise and distinctive drug development concepts to identify opportunities for novel medications in the future. Furthermore, reinforcing the equity incentive mechanism is crucial to secure the scientific research team, thereby enabling swift progression of the project.

It is proposed that R&D teams within SMEs innovative biomedical enterprises should establish multiple product pipelines within their specific indications, concurrently monitoring the most recent international and domestic novel drug registration information and field distribution data of newly approved medications **(**as depicted in Fig. 7**)**. The R&D strategies for innovative drugs with varying indications differ significantly. Consequently, R&D teams must concentrate on their areas of expertise, conducting robust and in-depth research, while refraining from blindly following trends. Otherwise, they risk relinquishing their position at the forefront of their respective R&D fields.

3. Strengthen intellectual property protection for biomedical projects. The biomedical industry is characterized by a high technical threshold, stringent market access, a protracted drug R&D cycle, and substantial drug R&D costs. Consequently, to safeguard the innovations in medicinal therapies, biomedical enterprises worldwide pursue patent protection to secure market exclusivity, enabling them to reap substantial profit margins and reinvest in continuous innovation.

Perfection of intellectual property protection, including the safeguarding of technical invention patents, constitutes the fundamental prerequisite for innovative drugs to achieve substantial market returns. According to the report published by the department of social development and science and technology of the Ministry of Science and Technology of the People's Republic of China in 2023, an analysis of the annual trends in the proportion of patent applications from China globally, as visualized in Fig. 8 and 9, indicates an escalating contribution and influence of China in the field of biomedicine. The proportion of China's patent applications in the global landscape has incrementally escalated from 19.34 % in 2013 to 33.82 % in 2022, mirroring a consistent rise in the proportion of worldwide patent applications. In terms of patent applications under the Patent Cooperation Treaty (PCT), the number of China's applications has been growing continuously since 2013, rising rapidly from 2016 to 2021, and tends to slow down in 2022. The number of PCT patent applications in China escalated to 2,645 in 2022, marking a 9.98 percent increase from the previous year.

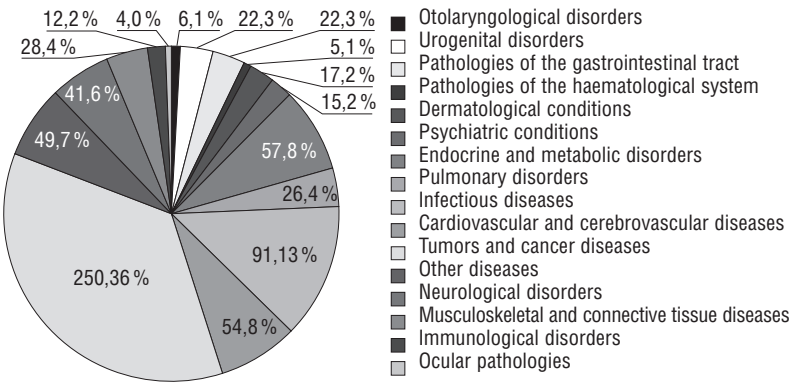

Fig. 7. Distribution of class I chemical new drugs developed by enterprises of China (according to Pharmacodia ® data) [Распределение новых химических препаратов класса I, разработанных предприятиями Китая (по данным Pharmacodia ®)]

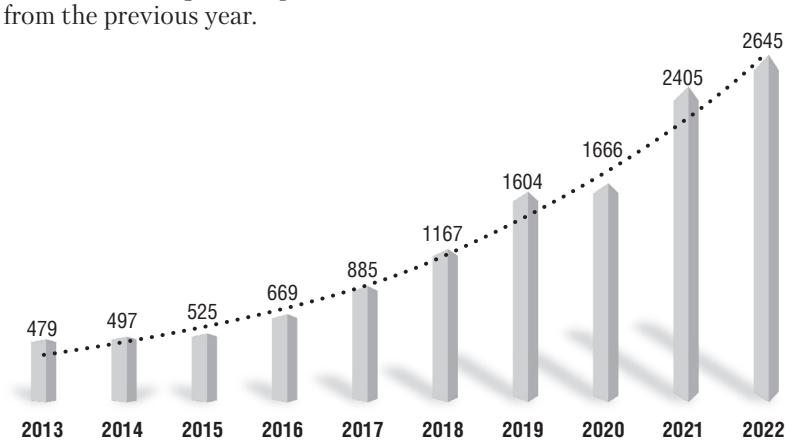

Fig. 8. Annual trend of PCT patent applications in the field of biotechnology in China from 2013 to 2022 (according to China Ministry of Science and Technology) [Ежегодная динамика заявок на патенты PCT в области биотехнологий в Китае с 2013 по 2022 год (по данным Министерства науки и технологий Китая)]

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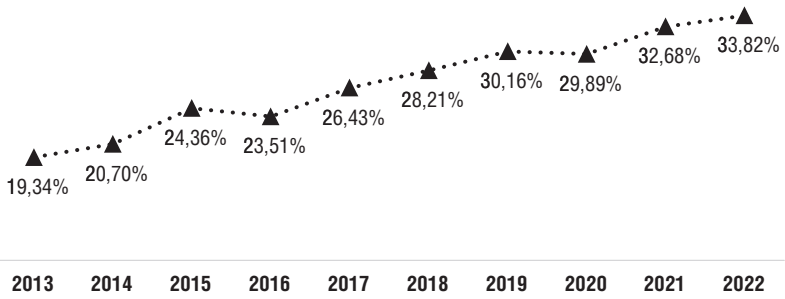
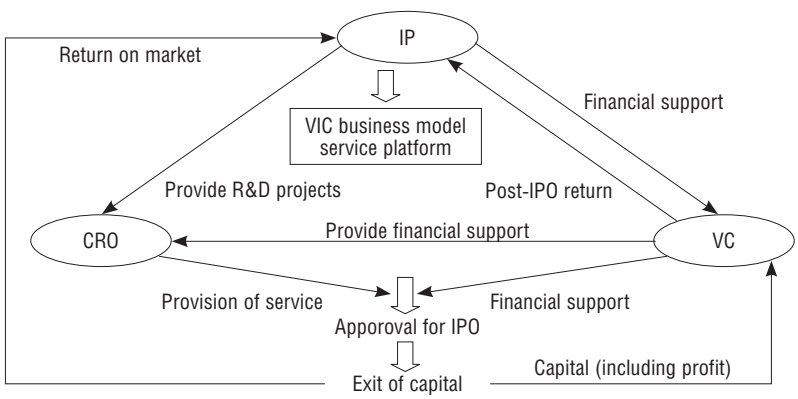


Fig. 9. Global proportion of patent applications in the field of biotechnology in China from 2008 to 2017 (according to China Ministry of Science and Technology) [Общемировая доля патентных заявок в области биотехнологий в Китае с 2008 по 2017 год (по данным Министерства науки и технологий Китая)]

Only via robust patent protection can the benefits of innovative drug R&D be maximized in the market. The competition in the drug market is, at its core, a contest of invention patents, a tangible manifestation of corporate patent strategy. It is proposed that SMEs innovative biomedical enterprises initially establish a firm grasp of the importance of intellectual property protection for innovative drugs, enabling them to meet the fundamental criteria of novelty, creativity and practicality for patent application submission. Subsequently, a planned and incremental approach should be taken to establish or enhance the protection of patents related to novel drugs, constructing a stringent peripheral patent network surrounding the foundational patents of enterprise projects. Furthermore, the establishment of a comprehensive intellectual property protection system, encompassing both domestic and international realms, should be prioritized to grant innovative drugs an extended period of protection post-market launch, ultimately accomplishing the objective of maximizing exclusive market access.

Fig. 10. Operational mechanism of VC+IP+CRO business model for innovative drug R&D [5] [Операционный механизм бизнес-модели VC+IP+CRO для исследований и разработок инновационных лекарственных средств]



4. Rational design of an enterprise's R&D model to enhance its innovative capabilities and competitiveness. The R&D strategies of SMEs innovative biomedical enterprises exhibit considerable diversity, encompassing independent R&D, mergers and acquisitions, independent clinical promotion, cooperative development, and pursuit of commercial transfers, among others. Among them, the independent innovation mode typically relies on the scale effect generated by the commercialization of generic drugs to provide a robust guarantee for autonomous innovation, thereby facilitating increased investment in R&D and enhancing pipeline layout. The licensing cooperation mode is generally adopted by biomedical enterprises possessing distinctive technological competitive advantages. Owing to the constraints of early-stage operations, such as limited resources and the need to minimize costs, these enterprises generally do not invest heavily in establishing independent research laboratories or hiring large R&D teams.

It is proposed that SMEs innovative biomedical enterprises establish a distinct corporate positioning and business strategy, as failure to do so may result in obstacles at every stage of innovative drug R&D. This not only impedes the advancement of the project but also affects its ultimate commercial value. Asset-intensive SMEs enterprises may not always receive favor from venture capital funds. Consequently, it is suggested that SMEs innovative biomedical companies consider adopting a VC+IP+CRO (VIC, venture capital/fund + intellectual property including invention patent and trademark + biomedical technology contract research organization service) model [6], see Fig. 10. The VIC mode aims to conduct new drug R&D through asset-light R&D outsourcing, leveraging the advantages of venture capital, intellectual property, and R&D outsourcing. This approach not only establishes a novel model for new drug R&D but also fundamentally supports the progress of biomedical enterprises in this field. Simultaneously, it attracts additional capital investment while expediting the

process of innovative new drug R&D, thereby synergizing with the growth of the R&D outsourcing industry. Collaborating with biomedical technology contract research organization service providers not only expedites the R&D time cycle and process of the project parties but also enhances the capital utilization efficiency of the financing enterprises.

It is proposed that financing enterprises should explore appropriate targets globally, directly import foreign projects in the clinical or relatively advanced pre-clinical stage into China, rapidly tap into the domestic unexplored market, expedite the approval process of domestic novel drugs, abbreviate the marketing cycle, and mitigate the costs and risks associated with pre-clinical drug R&D. Concurrently, the VIC model enables small and medium-sized innovative biomedical enterprises to aggregate capital, intellectual property, professional expertise, and other elements through a specific collaboration mechanism, aiming to attract increased venture capital funds. This fosters the incubation of high-quality, high-efficacy innovative drug candidates from the pre-clinical research and clinical trial stages, abbreviating the development cycle and establishing a comprehensive chain of innovative drug R&D.

Conclusion

SMEs innovative biomedical enterprises should adhere to patient-centered, research-based, market-oriented strategic planning management and strategic implementation management that constantly strive for improvement. They should determine the direction of R&D, focus on advantageous areas, establish and expand a differentiated product line suitable for their own enterprise, and develop low-cost, high-quality new medical products with clinical and commercial value under an appropriate R&D model. By doing so, they can enhance Chinese influence and competitiveness in the field of new drugs.

Additionally, SMEs innovative biomedical enterprises should strengthen the dynamic adjustment of R&D strategic planning. They should formulate a mechanism for supervision and tracking achievements while analyzing potential barriers to implementation. Moreover, it is crucial to implement necessary resource conditions along with establishing a mechanism for prioritizing implementation.

Such problems as corporate governance of financing enterprises, project evaluation of biotechnology innovative drugs, allocation of interests during the financing process, post-investment management and exit of investment funds, and valuation of financing projects necessitate further exploration and research.

Being the world's second largest unilateral drug consumption market, the Chinese market for biomedical innovative drugs is set to embrace significant growth prospects [7]. Venture capital plays a crucial role in the field of biomedical innovative drug R&D, aiding biomedical enterprises in creating more efficient innovative drugs, thereby accelerating the swift development of innovative drugs in China and further propelling the entire pharmaceutical industry's upgrading.

Venture capital can address the financing constraints faced by SMEs innovative biomedical enterprises, thus serving as the optimal equity financing channel for them. As a SMEs innovative biomedical enterprise, in the process of collaboration with venture capital institutions, the biomedical science and technology industry, the financial industry, the pharmaceutical industry, and government departments are confronted with a lasting research topic [8]. ■

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The primary methodologies of this study encompassed various approaches, such as email distribution, WeChat group dissemination, telephonic interviews, and on-site visits. A total of 400 questionnaires were distributed to private equity and venture capital institutions (Paper A) and SMEs innovative new drug R&D companies (Paper B) associated with the project. A total of 187 valid questionnaires were collected from Paper A, yielding a calculated response rate of 93.5 %. Similarly, 196 valid questionnaires were gathered for Paper B, corresponding to a calculated response rate of 98 %. The data derived from the questionnaires were primarily analyzed utilizing Microsoft Excel, a widely recognized application software

In the China life science and biotechnology development report of 2018, issued by the China biotechnology development center of the department of social development and science and technology of the Ministry of Science and Technology, it was revealed that among the top 10 patentees for monoclonal antibody drugs targeting PD-1/PD-L1 in the field of innovative biopharmaceuticals, excluding Hengrui, all other patent applicants were foreign institutions and enterprises

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О корпоративной интеллектуальной собственности и технологических компетенциях при софинансировании инновационных биомедицинских предприятий

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ключевые слова

малые и средние предприятия, биомедицинское предприятие, акционерное финансирование, основная технологическая компетенция, права интеллектуальной собственности

Растущий биомедицинский рынок Китая, стимулируемый технологическими достижениями, промышленной реструктуризацией и увеличением покупательной способности населения, продемонстрировал устойчивую тенденцию к расширению. Правительство активно способствует глубокой интеграции исследований, разработок, производства и продаж биомедицинских предприятий с передовыми информационными технологиями, такими как большие данные в интернете и облачные вычисления, чтобы придать новый импульс биомедицинской отрасли и способствовать прорывному продвижению вперед.

Автор проводит всесторонний анализ основных проблем, возникающих в процессе акционерного финансирования малых и средних инновационных биомедицинских предприятий, определяет стратегические направления для успешной реализации венчурного финансирования. В исследовании предлагаются меры по решению вопросов, связанных с отсутствием новых подходов в процессах продвижения инновационных продуктов и недостаточным вниманием к интеллектуальной собственности. Среди них: повышение инновационного потенциала и осведомленности предприятий, сосредоточение усилий на перспективных областях исследований и разработок (НИОКР), защите интеллектуальной собственности проектов и оптимальном, хорошо продуманном проектировании модели НИОКР предприятий.

Малые и средние инновационные биомедицинские предприятия должны ориентироваться прежде всего на потребности пациента и требования рынка, основанные на глубоких исследованиях и анализе, для совершенствования управления стратегическим планированием и стратегической реализацией. Важно определить направления НИОКР, сосредоточиться на наиболее полезных и экономически выгодных областях, создать и расширить дифференцированную линейку производства, подходящую для предприятия, разработать недорогие, высококачественные новые медицинские продукты, имеющие клиническую и коммерческую ценность. Кроме того, следует сформулировать механизм надзора и отслеживания достижений, проанализировать потенциальные препятствия на пути реализации, обеспечить необходимые ресурсы и создать механизм определения приоритетности реализации.

Будучи вторым по величине в мире рынком потребления лекарственных препаратов, китайский рынок биомедицинских инновационных средств имеет значительные перспективы роста. Содействуя разработке новых, более совершенных продуктов, венчурный капитал может эффективно решать проблему долевого финансирования малых и средних инновационных биомедицинских предприятий, занимая ключевые положения в области исследований и разработок инновационных лекарств и внося значительный вклад в устойчивый рост биомедицинской промышленности Китая.