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Key Influences at Different Stages of Development for Medical Device Start-Ups

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Abstract: Experiencing the effects of the global epidemic era the medical device industry is standing on the threshold of a new era full of challenges and opportunities. As a highly knowledge-intensive industry, the medical device industry cannot develop without continuous product innovation and technological improvement, which provides start-ups with a power source for sustained growth. This research starts from the R&D product stage of start-ups and takes a closer look at the growth of start-ups along the key development stage of the prototype, type examination, clinical, licensing, and promotion. Through this process, the research can identify the characteristics and challenges that the company exhibits at different growth stages, as well as the main goals of each stage. After analysis and summarization, this research aims to reveal the most important innovation capabilities that start-ups need to develop in the early stages and how this capability affects a company's ability to access financing resources. Innovation capability is seen as a long-term investment, and the financing resources that match it should be correspondingly long-term. For traditional debt financing methods that rely on stable cash flows, highly innovative firms may find that they do not have easy access to these financing resources. Therefore, while pursuing innovation, start-ups need to explore financing modes that are compatible with their innovative capacity to ensure that they have access to sustained financial support in their pursuit of long-term development.

Keywords: Financing resources, Innovation, Start-ups

1. Introduction

Innovation is the core competitiveness of medical device companies. Product innovation is the basis for the continuous development of companies, and the core power that can help to open up new markets and create new products. In the innovation process of medical device companies, they need a lot of money. How to obtain resources efficiently and allocate resources effectively? It has become the top priority of medical device companies' development. According to the theory of the company life cycle, the development stages of companies can be divided into start-up, growth, maturity, and decline. Because of the heterogeneity of financing activities' impact on business operations, different stages of financing activities have different marginal effects and different impacts on companies. With high investment and high return in the start-up period and low investment and low return in the maturity period, companies' needs for financing are constantly changing. Therefore, exploring the

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impact of financing activities on the growth path of medical device companies can help the company allocate its resources rationally, which is meaningful for the future development of the company.

Sheng provided an overview of the general development environment of medical device companies in China, his research summarizes the development opportunities for companies and the intensity of competition in the market. Based on this analysis of the general environment, an EVA valuation model is used to value the enterprise. Therefore, companies can use this valuation model to standardize their research and development [1]. Price et al. found that a healthcare organization with adequate funding is the only one that can provide efficient medical treatment to patients. This is not only the best approach for the health of the individual patient, but it also improves the per capita treatment level in society and improves the overall quality of healthcare [2].

Guo and Chen found a large financing gap faced by lots of start-ups, which is a common predicament of start-ups, these start-ups only have a scarce number of financing and also the amount is corresponding small. All because start-ups lack credibility in the social market which undermines external funding capability and also start-ups don't have insufficient financial support in internal funding [3]. Petra et al. evaluated new product development in the medical device market in terms of economics, health, technology regulations, and current market knowledge. The MedDee model is summarized and designed for the economic evaluation of medical device development, which involves initiation, concept, design, production, final verification, and market disposition in six parts. Ultimately, integrated the entire process with an economic method providing a standard for economic spending in product development and supporting the financing of companies [4].

Benam et al. analyzed the possibilities of commercialization of biomedical, with Academic Medical Centers as the main research body throughout the study. The authors have analyzed two operation models proposed by the University of Colorado, which are CCTSI and CU Innovations. In both operation models, the I-Corps and SPARK|REACH programs contribute to both innovation capacity and commercialization [5]. Pogue et al. pointed out that continuous innovation of a company can bring more financial budget support for research programs, especially for technology and innovation-oriented companies. Innovation and profitability are interdependent, there's an internal transformational relationship between the two of them, and both of them can boost each other to reach a higher value [6]. In their study, Pirogova et al. took into account the characteristics of different stages in the life cycle of the company and indicated the implication of intellectual capital in different development stages of companies. In addition, the research clarifies how companies can use intellectual capital to generate profit income for themself, and also highlights the importance of intellectual capital in business development [7]. Nigam et al. collected data from various databases about 204 start-ups from 2014 to 2017. The authors found that for knowledge-intensive companies such as medical devices, there is a significant relationship between financing and intellectual capital. The research indicates that intellectual capital is an important capital for companies to finance at the start-up stage, and it becomes an indication of a company's credibility in the market [8].

Liao's study analyzed the share of internal and external financing among Chinese oncology drug companies and pointed out how different types of financing vary among sub-industry classifications. Finally, based on the regression model, it indicated the innovation's impact on the company and analyzed that the impact has positive and negative influences on the different types of financing resources [9]. Ryu et al. indicated the crowdfunding method which is a new funding resource because of the Internet. After using a bivariate probit model and propensity score matching, the author compared how the receipt of crowdfunding and angel investment at the start-up stage affects the subsequent venture capital aspect of the company, and found that crowdfunding is only positively correlated with investment by corporate venture capitalists, but not with independent venture capitalists [10].

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Observing and analyzing start-ups in the medical device industry reveals that the medical device industry is in an era where business models are in dire need of change. The primary issue faced by a start-up is the way of financing resources. By looking at the financing perspective, the key demand points of today's changing market are analyzed to find out the changing factors affecting the financing resources for the companies. Therefore, it is the purpose to identify the important factors that start-ups in the medical device industry need to focus on to adapt to the environment.

2. Medical Device Start-up Development

2.1. Motivation

Since the 20th century, the continuous increase in life expectancy has led to an exacerbation of the global aging problem, which has caused a huge burden on the medical service systems of various countries. However, this is not only a pressure on the industry but also an opportunity for medical device company’s development. According to statistics, Sheng pointed out that the number of people who die from chronic diseases in the world is as high as 41 million every year, which leads to an increasing demand for medical equipment in society. The market requires a more complete medical system and more advanced medical equipment [1].

2.2 Innovation and Competition

At the same time, the competition in the medical device market is also very fierce, innovation and R&D capabilities of companies have become the decisive competitive ability of companies. One of the major development characteristics of medical device companies is having a strong R&D driving force. The strong innovation awareness of companies can not only bring a more high-end market position to the company's products but also reduce the production cost of medical devices. In summary, the driving force of innovation within a company can play a role in increasing revenue and reducing expenses. However, expanding R&D investment by companies means that companies need to obtain a large amount of financial support. However, Guo and Chen indicated that society generally lacks an objective view of start-ups and a unified evaluation method for internal management models and financial data. During the start-up stage, companies may not be able to publicly disclose their financial and non-financial information to the public like IPO listed companies. Therefore, due to the lack of social credibility, companies may find it difficult to obtain large amounts of financing, resulting in a shortage of funds [3].

2.3 Financing Problems

However, it is worth noting that the innovation capability of a company can become an indication for a company's financing in the start-up stage, Pogue et al. concluded that there is a mutually reinforcing relationship between the two of them. Having a high awareness of innovative R&D will bring more financing possibilities to companies, and obtaining more financing will encourage companies to engage in more technological innovation, forming a mutually reinforcing closed loop [6].

Therefore, for companies, quantifying their R&D process reasonably will have a huge impact on their subsequent financing process. When evaluating the R&D process, the MedDee model proposed by Petra et al. can be used to connect the R&D process with economic methods from six aspects, providing investors with more detailed and authentic data in order to increase the credibility of the enterprise in the market [4].

However, the innovation consciousness of companies does not have the same effect on various financing sources of companies. Innovation consciousness is certainly a good signal for the development of companies, but its long return cycle is an unavoidable problem. Therefore, for the

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commercial credit financing and long-term bond financing of companies, the short-term funding shortage of actively innovative companies is not conducive to these financing methods. However, for long-term financing such as internal funding and IPO financing, having a good consciousness of innovation is a good signal for investors. In addition, innovation is a good signal of financing by the financial subsidies, the government also focuses on the R&D capabilities of companies. The state also provides a large number of subsidies for high-tech R&D companies, therefore is also advantageous [9].

Medical device companies, as knowledge-intensive companies, have innovation consciousness as a form of knowledge capital that exists within the company. Its impact is not only on the start-up stage of the company. Based on the life cycle theory of the company, innovation affects every development stage of the enterprise. Having innovation capability means that the company is still willing to continuously reform and develop, but as the company enters a mature and declining period, its innovation capability will naturally weaken. Investors also hope that the company's cash flow can be more stable, rather than continuing to conduct large-scale R&D. So, the marginal utility of innovation capability in the initial stage of a company is the highest, and as the company continues to develop into a mature stage, the overall business model will become more stable, and innovation's impact to the company's financing capability will continue to reduce.

3. Impact of Different Financing Stages

During COVID-19, the worldwide epidemic infection had many impacts on many manufacturing industries, including the medical device industry. The market demand for medical devices increased greatly during the epidemic, but the actual supply in the market was much lower than the demand. The shortage of devices caused an increase in the price of medical devices, so many start-ups wanted to grab this opportunity so that their company could have a market share in the market [11].

According to the development characteristics of the medical device industry, medical device start-ups go through the prototype, type examination, clinical, licensing, and promotion stages in the development process. Considering the different marginal effects that financing activities possess at each stage of a company's development, the different financing activities at these stages are analyzed [12].

In the prototype stage, the medical device company is in the process of bringing an ideal design to reality. Many medical device companies cannot develop initially without innovative ideas. Therefore, companies need capital to design and build initial prototypes to realize their ideal design and these prototypes are also ultimately used to demonstrate the basic functionality of the product [13]. Financing is mainly used in this phase for R&D activities including design, prototyping and initial testing. This is also a very costly stage and there is uncertainty about future developments. The funding resources for medical device start-up companies at this stage can come from angel investors, government grants, crowdfunding, or venture capital. All of these resources have a salient indication which is high risk awareness. It’s a counterpart of the high uncertainty of this stage. At this stage, financing is critical to assess the product's innovation ability which is the intellectual capital, as using a financing resource. It helps the company evaluate the product's technical feasibility and market potential.

The type examination stage refers to the testing and validation of the product, all these aspects need to be considered before the prototype is put into mass production. This is an essential stage in the development of medical devices, and the amount of financing for this stage is basically used to pay for the testing costs of third-party organizations, to ensure that the medical device products produced comply with the relevant standards and regulations of the government. Only when the type examination meets the requirements of various technical specifications, the product can be officially put into mass production. Because in recent years there has been a more innovative integration of

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medical devices with a number of industries, including digital, intelligent, and minimally invasive, the combination of medical devices and digitalization has opened up a new way, which also means that the regulatory process is more complex, and the demand for capital is also more enormous compared to the previous [14]. Financing at this stage is more to help companies meet market regulatory requirements and provide financial support for the subsequent development phase.

The clinical phase is one of the most expensive financing phases of the medical device development process. The purpose of clinical trials is also to ensure that the medical device can work safely and effectively on the patients. The types of medical devices can be categorized into three classes; the first is low risk, the second is medium risk and the third is high risk. An increase in risk also means an increase in the cost of the clinical phase, therefore there is a positive relationship between the two. Obviously, the overview of this medical device development is becoming more exact, and the investors outside the company are becoming more confident in the company. In addition, they prefer to invest bigger amounts of funding, therefore funding can come from venture capital, private equity, or debt financing, the financing resources are more stable and the required interest is lower. Successful clinical trials mean that the end result of the medical device meets the expectations of the developer and investors. Success in the clinical phase also has a significant impact on subsequent qualification and marketing.

During the validation phase, the regulatory approval process has a variety of costs that require the company to pay sufficient funds, including document preparation, submission costs, and possibly consulting and legal fees. Financing is critical to ensure that companies can successfully complete the approval process and quickly enter the market [11].

Once the product has been reviewed and approved, it is ready to be marketed, and in the promotion phase, the firm needs more funds for marketing and sales than for innovation research and development. Financing in this phase is mainly used for marketing activities, advertising, participation in industry trade shows, building customer relationships, and providing customer support. The fund which invests in the market has a positive relation with the market effect. An effective promotion strategy can increase the market awareness and acceptance of the product, thereby increasing sales and market share.

4. Conclusion

In the current business environment, start-ups in the medical device industry are facing unprecedented financing challenges. This study provides an in-depth look at the funding challenges that these firms encounter in the early stages of their existence, and also analyzes the specific issues they face at different stages of development. Through careful observation and analysis, investors are particularly interested in a company's ability to innovate and its potential for growth in the early stages of financing. In the knowledge-intensive industry like medical devices, financing is not only an injection of capital but also an important part of intellectual capital, which plays a key role in the various stages of the development of start-ups.

With the rapid development of the medical device industry in the 21st century, the competition in the market has become more and more intense. Driven by innovative concepts such as brain-computer interfaces, artificial organs, and medical robots, corporate competition is no longer limited to the competition of a single product but has shifted to the competition of innovation capability. In this environment, medical device companies must increase R&D investment and promote technological innovation if they want to stand out in the market. Such innovation should not only stay at the application level but also affect the basic logic and research of medical devices.

When evaluating start-ups, investors often consider various factors such as the company's technological advantages and team background. In the medical device industry, especially those fields involving cutting-edge and high-precision technologies, the ability to innovate is even more crucial

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to whether a company can obtain investment. In such a context, the innovation capability of the start-up team becomes crucial. They not only need to have professional skills and business intelligence but also need to continuously maintain a strong motivation to innovate. This high level of innovation will be the investors' attention in the future, and become an important asset for companies in the capital market, as well as an important indicator for investors to assess the potential of a company.

In order to gain an advantage in the fierce market competition, medical device start-ups must continuously improve their innovation ability and technological strength. Only in this way, the company can gain the attention of investors in the capital market, so as to obtain the necessary financial support and promote the continuous development and innovation of the company.

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