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Implications of China's Innovative Drug Investment Bubble

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Abstract:

As an industry closely related to the physical and mental health of the people, the pharmaceutical industry has a pivotal position. In recent years, with the development of life science, China has vigorously promoted the development of innovative drugs. However, with the outbreak of the epidemic and the downward trend of the domestic economy, the innovative drug industry has been greatly affected, and the bubble crisis in the entire industry has occurred. This paper starts from two aspects. First, by collecting relevant materials at home and abroad and referring to relevant literature, it starts with the status quo and characteristics of the development of innovative drugs in China, compares the market of innovative drugs in foreign countries, finds out the reasons for the investment bubble, and gives solutions to the reasons for the emergence of the innovative drugs industry. Then, it briefly explains the investment mode under the current situation of China's innovative drug bubble by using Davis's double-click theoretical valuation method, and finally summarizes the enlightenment of China's innovative drug investment bubble.

Keywords: Innovative drugs; investment bubble; Davis Double click.

1. Introduction

With the progress of life science, people are using drugs more and more widely, and solving difficult diseases in medicine has become a new focus of attention, in which drug innovation is inevitable.

The innovative drug this paper mentioned, also known as the original drug, refers to the drug developed from the mechanism and has independent intellectual property rights [1]. It fights disease through pharmacological or molecular mechanisms, alleviating symptoms and preventing disease. In addition, New Molecular Entity (NME) and Biologic License Application (BLA) are both innovative drugs in the evaluation standards of the US Food and Drug Administration (FDA) [1]. Over the past two decades, the introduction rate of new drugs for CDER has been stable. Drug approvals for neurological diseases (depression, psychosis, multiple sclerosis, etc.) and lifestyle diseases such as obesity and diabetes progress slowly, while accelerated approvals for anticancer and biologics are seen as the latest trend in drug development [2]. To a certain extent, this reflects the increased attention paid to the research of anticancer drugs and biologics [2]. With the rapid development of innovative drugs in Europe and the United States, China's innovative drugs are also developing rapidly. China has repeatedly put forward the phase plan of "major Special projects for innovative drugs" to highlight the support for the development of the innovative drug industry. The R&D investment of China's pharmaceutical manufacturing industry increased from 53.42 billion yuan in 2017 to 94.24 billion yuan in 2021, and the R&D investment intensity of the pharmaceutical manufacturing industry increased from 2% to 3.2%, realizing exceeding the national R&D investment intensity [3]. Simultaneously, the Chinese government actively implements measures to promote research and development as well as investment in innovative pharmaceuticals, such as streamlining the approval process for innovative drugs and expediting their registration and listing, in order to enhance the market competitiveness of innovative drugs and attract investment from both domestic and foreign enterprises [4]. With the unprecedented growth in the industry, significant capital has been invested in the innovative pharmaceutical market, particularly in response to the COVID-19 outbreak, resulting in substantial financial gains for many investors. However, the fast-growing innovative drug industry soon ushered in the winter of 2022. With the high investment and long cycle situation causing corporate debt, the improvement of China's COVID-19 situation, and the year-on-year decline in new drug approval causing many companies to be depressed, compared with the mature innovative drug investment environment in the United States and other Western countries, the investment bubble in China's innovative drug industry appeared. Since the third quarter of 2021, China's secondary market biomedicine index has also fallen by about 51% from its

peak, and problems such as overvaluation and repeated innovation have caused the overall decline of the industry [5].

2. Current Situation and Characteristics of Innovative Drug Development in China

2.1 Current Situation of Innovative Drug Development

With the improvement of China's pharmaceutical industry and the increase of the aging population, China has gradually become the second-largest pharmaceutical market in the world, and the international status of China's pharmaceutical industry has been continuously improved. Under such rigid demand, China began to develop innovative drugs and become a pharmaceutical power as the next stage of the goal.

2.1.1 The size of the market

The global innovative drug market grew from $738.4 billion in 2014 to $848.7 billion in 2018, with a CAGR of 3.5% [6]. The market size of China's innovative drugs will increase from 547.5 billion yuan in 19 years to 700 billion yuan in 2023, accounting for about 10% of the global innovative drugs market. It is expected that the market size of China's innovative drugs will reach 753.4 billion yuan in 2024, as shown in Fig.1 [6].

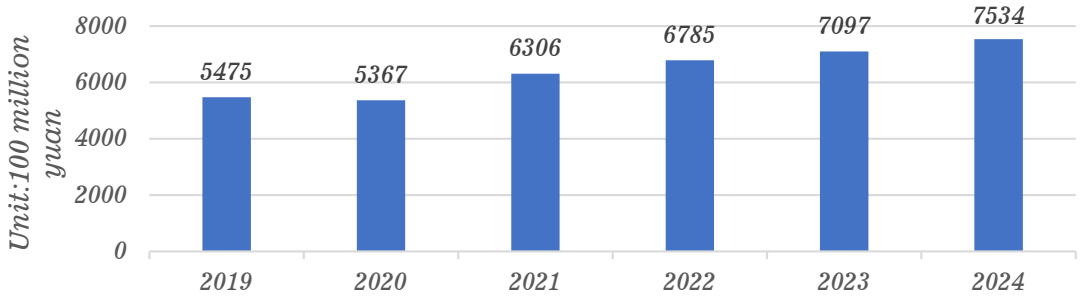

Fig. 1 Trend chart for predicting the size of China's innovative drug market from 2019 to 2024

In 2021, the United States will account for more than half of the global sales of innovative drugs, while in other developed countries, the five European countries will account for 16%, Japan and South Korea will account for 8%, and China will only account for 3%, which is far lower than the level of developed countries [6]. At present, the development of China's innovation in medicine is still in its infancy, or a piece of the blue ocean market, as shown in Fig.2.

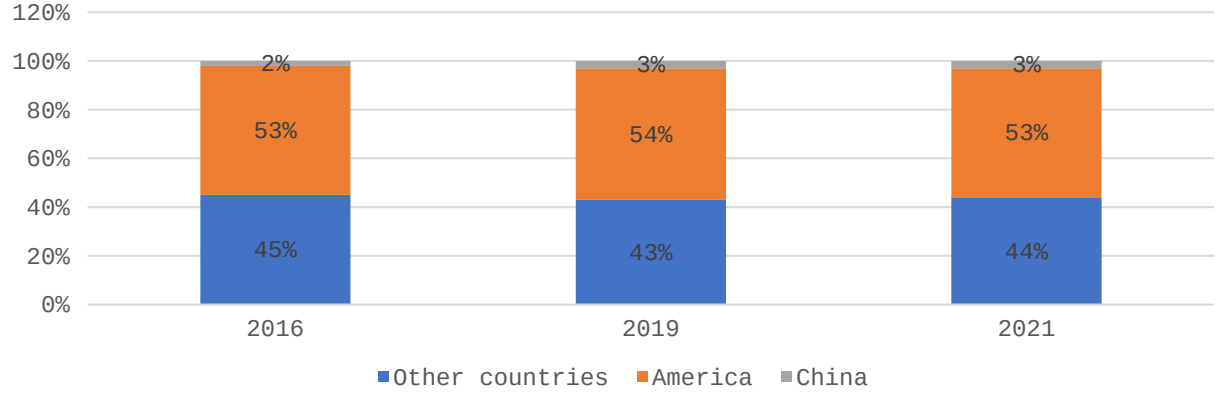

Fig. 2 The proportion of innovative drug sales in major global countries from 2016 to 2021

2.1.2 Invest in research and development

For innovative drug companies, the most important way to make profits is to obtain patent production rights through a large amount of capital investment in the early stage, to enjoy a high rate of return in a certain patent period in the future. Therefore, the proportion of R&D investment can be used as an important indicator to measure the R&D strength and future achievements of innovative pharmaceutical enterprises.

As shown in Fig. 3, according to statistics from the annual reports of 366 listed pharmaceutical companies, the total investment in research and development of the pharmaceutical industry in 2022 exceeded 100 billion for the first time, doubling compared with 50 billion in 2018. It can be seen that with the support and promotion of a series

of pharmaceutical reform policies in our country, pharmaceutical enterprises in our country pay more and more attention to the research and development of innovative drugs [6].

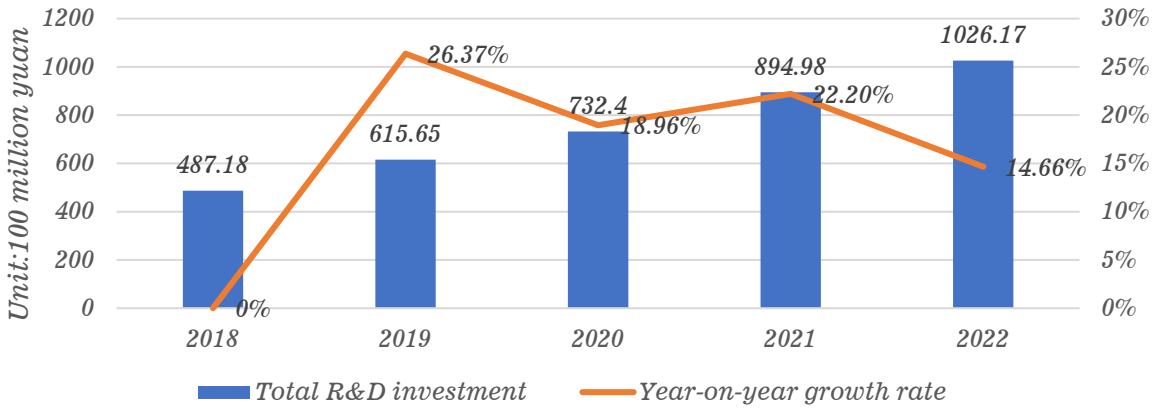

Fig. 3 Total R&D investment in the pharmaceutical industry from 2018 to 2022

When it comes to investing in research and development, then it has to mention its success rate and periodicity. Any innovative thing is inseparable from a large number of failure cases, and the research and development of innovative drugs also has the characteristics of high risk, high investment, and long cycle. According to statistics, the average cost of global innovative drug research and development in 2021 was 2.06 billion US dollars, and the average period of research and development was 6.9 years. In such cases, the average success rate from Phase I to FDA approval was only 7.9%, as shown in Fig. 4 [6].

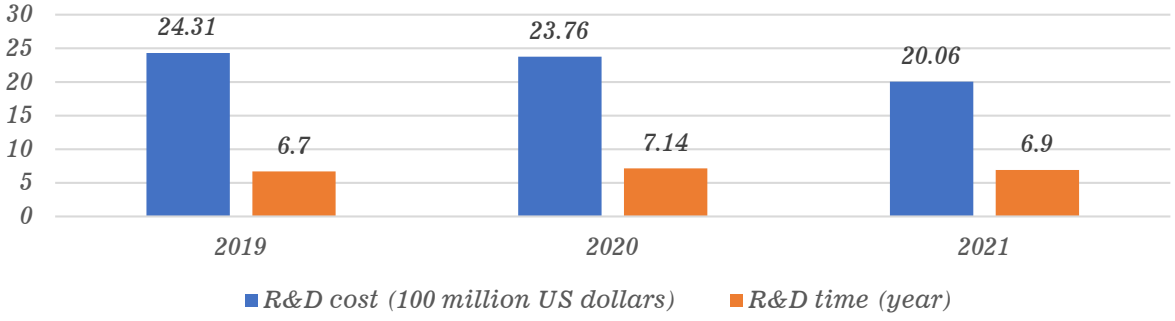

Fig. 4 Global innovative drug research and development costs and timeline from 2019 to 2021

2.2 Highlights of the Development of Innovative Drugs in China

(1) Stable output of innovative drug types. In recent years, the types of innovative drugs have been increasing, and the number of Class 1 new drugs approved by NMPA in 2023 has reached a new high compared with previous years, 33 new drugs have been launched, and 8 new biological drugs (class 3.1 *) and 34 new chemical drugs (class 5.1 *) have been approved by NMPA in 2023 [7]. In addition, from the perspective of treatment, the emergence of these innovative drugs covers many existing areas with unmet clinical needs, such as cancer, providing patients with more treatment options, as shown in Fig. 5.

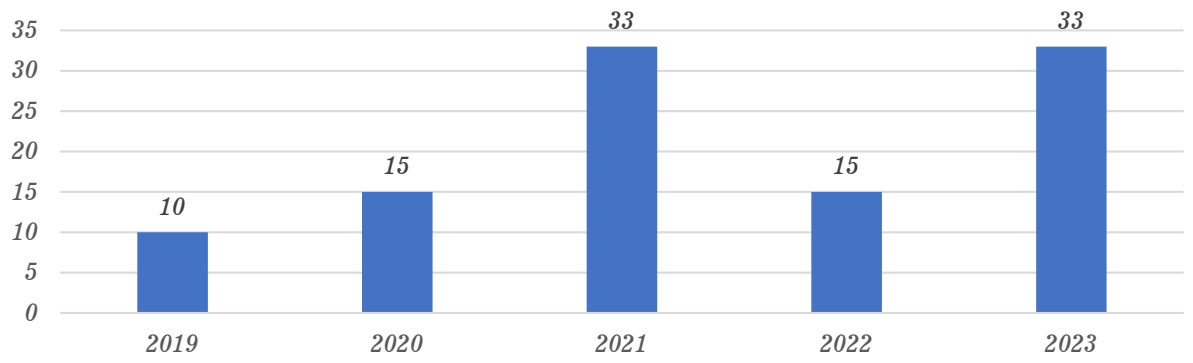

Fig. 5 The number of Class 1 new drugs approved by China's NMPA in recent years

(2) CAR T-cell therapy has been a huge success. CAR - T T Cell Immunotherapy therapy is Chimeric Antigen receptors (Chimeric Antigen Receptor T - Cell Immunotherapy). This is a new type of precision-targeted therapy with broad prospects, which can be rapid, efficient and precise, and may cure cancer tumors. In the future, it may overcome the treatment of solid tumors through delivery technology [7]. This has attracted much attention in China, and four CAR-T cell therapies have been approved in China.

(3) Several new Chinese drugs have been approved by the US FDA. In 2023, more than 40 new drugs under research, including small molecule drugs, antibody drugs, and cell and gene therapies, were born and qualified by the US FDA, and the total amount reached a new high in the past four years (Fig. 6) [7].

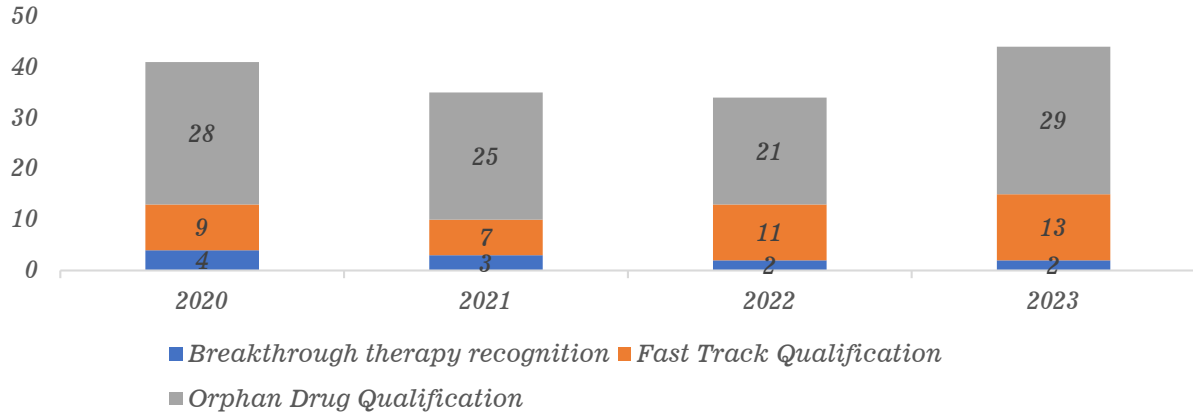

Fig. 6 The number of Chinese new drugs qualified by the US FDA from 2020 to 2023

(4) The number and amount of international license-out products reached a new high. According to the statistics, as of December 19, as many as 50 innovative drug products and at least 40 international licensing cooperation have been reached by Chinese companies and international companies, at least 13 partnerships have exceeded $1 billion in total value, setting a new high in both volume and value in recent years [7]. In addition, the new drugs agreed upon in 2023 cover various categories such as novel small molecules, monoclonal antibodies, double antibodies, antibody-coupled drugs (ADCs), and CAR T cell therapy products [7]. Among them, the total number of small molecule drugs and ADC products accounted for nearly 60%. This reflects the market's high degree of attention and preference for small-molecule drugs and ADC products.

3. Problems in China's Innovative Drug Industry

3.1 Capital Constraint Problem

As the early-stage R&D investment of innovative drugs requires a large amount of financial support, and the R&D cycle of innovative drugs is long and the risks involved are large, it is difficult for enterprises to obtain financial support and the problem of financial constraints is prone to occur [8].

(1) High research and development costs. According to statistics, the average cost of an innovative drug is billions of dollars. The stage of clinical research requires a huge investment. Taking the research and development of innovative drugs in the field of oncology as an example, the cost of research and development from phase I to

phase III is as high as 2.6 billion US dollars [8]. As can be seen from the data in Table 1, the R&D expenditure of enterprises is increasing year by year, and affected by the epidemic, the main R&D investment in 2020 and 2021 is used for the treatment of novel coronavirus-related projects, and the proportion of R&D expenditure of enterprises in the total funds is also increasing. This situation not only occurred during COVID-19 but also increased in the following years, which became a major problem for enterprises.

Table 1. Research and development expenses of major biopharmaceutical enterprises in China from 2017 to 2021

The Enterprise	Time of establishment	2017-12-31	2018-12-31	2019-12-31	2020-12-31	2021-12-31
Kangtai Biology	1992-9-8	84.74 million	177.8 million	198.3 million	267.71 million	354.3 million
Zhifei Biology	1995-7-20	78.38 million	142.9 million	169.6 million	299.7 million	552.6 million
Watson Biology	2001-1-16	99.01 million	142.22 million	64.81 million	176.65 million	621.5 million
Concino	2009-1-13	68.10 million	113.4 million	151.7 million	428.5 million	878.7 million
Beigene	2010-10-28	2.017 billion	4.597 billion	6.588 billion	8.943 billion	9.538 billion
Junshi Biology	2012-12-27	275.3 million	538.2 million	946.1 million	1.778 billion	2.069 billion

(2) The research and development cycle is long. Innovative drugs need to go through the long process of "discovery - preclinical research - clinical research (phase I - Phase II - phase III) - new drug application - marketing approval - Phase IV clinical trial" from research and development to the final listing, which usually takes 10-15 years [8].

(3) Research and development risk is high. The final success rate of innovative drug development is less than 7.9%, so enterprises need to face great risks, that is, the possibility of continuous failure of research, or the situation of core technology being "stuck" by other enterprises, and the regulation of certain materials due to policy changes [8]. Therefore, it is easy for enterprises to encounter many obstacles from the production of innovative drugs to the promotion, which also increases the risk factor of research and development.

3.2 The Overall Research and Development Strength

(1) Insufficient key technologies in clinical research and development, especially the ability to create new drugs combined with clinical research [9]. More than 90% of domestic innovative drugs rely on imports, and in the key machinery and equipment is also heavily dependent on imports, the proportion also reached more than 90%.

(2) The total amount of R&D investment is insufficient. Pharmaceutical Research and Development Committee of China Association of Enterprises with Foreign Investment Kang Wei, CEO of RDPAC, and others believe that at present, nearly 90% of the total drug sales in China are used for drug expenditures such as generic drugs and Chinese patent drugs, and only about 10% is used for new drugs, which is far lower than that in European and American countries [9].In addition, Chinese pharmaceutical enterprises cluster on hot targets while ignoring innovative drugs, and generally show the intention of avoiding high risks in the research and development of new drugs, and lack patience for results with a long transformation cycle, but have high requirements for technology landing and liquidity [9].

3.3 The Influx of Hot Money Leads to the Bubble Problem of Innovative Drugs

In recent years, under the change of the new drug application policy, a large number of funds have flowed into the field of innovative drugs in China, but with the repeated innovation, excessive concentration of targets and other problems have gradually exposed and then caused the innovative drug bubble.

Starting from the index of innovative drugs, it is not difficult to find that its value continues to rise, showing a steep slope in early 2020, reaching the peak in September of the same year, and then fluctuating down, and then the heat index of innovative drugs sector plummeting [5].

At the same time, in 2020, the innovative drug sector raised 376 financing deals, totaling 85.8 billion yuan; Although the 519 financing deals in 2021 increased by 38%

simultaneously, the total amount was only 68.1 billion yuan, down 21% year-on-year [5].In 2022, there is also a downward trend, and the bubble of innovative drugs is squeezed out, and the winter is coming.

4. Solutions

4.1 Aiming at the Problem of Capital Constraint

(1) High research and development costs. Return through capital market financing, or take strategic cooperative financing to give full play to the advantages of multiple parties, help enterprises reduce the huge financial pressure of part of R&D, and provide a good foundation for cooperation for later commercialization [8].

(2) Long research and development cycle. By utilizing the characteristics of big data, deep learning models are tried to build corresponding pharmaceutical research models for data analysis and optimization strategies of innovative drugs, and the cycle of drug development is shortened digitally [9].

(3) The risk of competing for research and development is high. Take the country as the leading, form the agglomeration effect of related enterprises, share resources and successful experience, form complementary advantages, avoid enterprises fighting alone repeatedly hit the wall; Establish strict legal policies to strongly protect the relevant core technologies of enterprises [10].

4.2 Aiming at the Lack of Overall Research and Development Strength

Formulate relevant policies to support enterprises, constantly improve the innovation vitality of enterprises, and drive enterprises to carry out innovative drug research and development; The state integrates resources, strengthens the introduction of emerging technologies, and appropriately gives enterprises the equipment needed for research and development; Form industrial agglomeration effect, promote resource sharing and complementary advantages among enterprises, enhance cooperation ability among enterprises, and build enterprise clusters with international influence and competitiveness [10].

4.3 Aiming at the bubble problem of innovative drugs caused by hot money influx

Investors should choose enterprises with potential and development prospects, and should not blindly choose to follow the trend; Relevant investment institutions shall provide financial support to innovative pharmaceutical enterprises with good qualifications and potential; The state should raise the threshold of the innovative drug industry, strengthen the supervision of the relevant capital flow of innovative drug enterprises, and prevent the bubble of capital using innovative drugs from affecting the development of the industry.

5. Use Davis Double-Click Theory to Conduct Investment Analysis on Innovative Drugs

In the analysis of investment in finance, people often use a theory called Davis's Double-click theory. Davis Double-click theory and Buffett's "eternal value" theory are classic theories of value investment [11]. The formula is as follows.

Market capitalization = Net profit * P/E ratio (1)

Formula (1) can be divided into Formula (2) according to the financial calculation formula.

Stock price * Number of shares = (Earnings per share * Number of shares) * P/E Ratio (2)

In this formula, Davis expressed the key factors affecting the company's market value in two aspects: net profit and price-earnings ratio. Net profit reflects the performance side of a stock, while the price-earnings ratio reflects the valuation side of a stock, and these two factors affect the company's market value [11]. It is not difficult to find that Davis's Double-click strategy is to buy an enterprise when it is at a low price-earnings ratio and hold it until it grows up so that it can enjoy the multiplier effect brought about by the simultaneous growth of enterprise performance and valuation and benefit from it [11].

According to the formula, both sides of this equation should be equal. But that only happens when markets are rational when everyone is rational. People know that investment markets are not as rational as investors think they are, and that investors are not all rational people. On the contrary, irrationality is the hallmark of investment markets, resulting in a mismatch between the two sides of the equation. And if investors want to profit from this, they can analyze it from the formula. It divides both sides of the formula (2) by the number of stocks, and we get the formula (3).

Stock price = Earnings per share * P/E ratio (3)

If earnings per share are certain and we know that the price of a stock should rise and fall with its value, it is not difficult to find that when the two sides are not equal, we can buy a low P/E or low-price stock and gain on the correction. In the same way, we bring it into the current innovative drug market. Due to the existence of bubbles, a large number of excellent innovative drug enterprises in China have low valuations, while the net profit of enterprises is still getting better. This makes the innovative drug industry now have greater investment opportunities and more investment space compared with the innovative drug industry in the previous two years.

But this does not mean that you can completely avoid the innovative drug bubble, investors need to be aware of several points: First, if the innovative drug company itself has only a very low net profit and the prospects are gloomy, even if the price is low, it should not blindly invest. Second, the bubble in the innovative drug industry is still present, the market is still in the screening stage, and the industry competition is fierce, and the enterprises in the forefront may be eliminated in the future, so it is necessary to find companies with definite profit growth as investment targets [11].

6. Conclusion

Through analysis, this paper studies the investment bubble of China's innovative drug industry from the comparison between the current situation of China's innovative drug market and foreign countries, and the existing problems in China's innovative drug market. Through the analysis, it is found that many excellent enterprises have emerged in the field of innovative drugs in our country, and the research of many drugs has filled the gap in China. However, due to the rapid development, there are still many problems: less research and development equipment, improper allocation of funds, cutthroat competition and so on. This makes the domestic innovative drug enterprises weak competitiveness, and development is less than expected. And as a result of a lot of hot money influx leading to a serious bubble in the whole industry, to a certain extent, hindered the development of our country's innovative drug industry.

What investors learn from the investment bubble after it emerged: First, the government needs to formulate relevant policies for the innovative drug market to create a stable environment and achieve a balance between stimulating the market and regulating the market. Second, investors should not blindly follow investment institutions but should have the ability to make independent judgments and choose enterprises with potential and profitability for investment. Third, companies should choose the direction of research and development according to their own ability, and make the best use of it, and not misuse investors' money for other aspects unrelated to drug innovation. Fourth, investment institutions should also give full play to their advantages, reduce investment risks by strengthening reasonable valuation analysis of enterprise investment and financing projects, and should not interfere with the investment market at will, but let the market regulate itself to make it operate smoothly. From a long-term perspective, the bubble in the innovative drug industry may become a new opportunity for investment layout.

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