

---

## RISK FACTORS

---

*This prospectus contain forward-looking statements that include, among other things, statements of business objectives concerning the Group's business, expectations as to funding its capital requirements, statements as to the revenue and profitability of the Company and other statements of expectation, belief, future plans and strategies, anticipated developments and other matters that are not historical facts. The Directors caution potential investors that there are risks and uncertainties associated with the Company and actual events or results may differ materially from those expressed or implied by the statements.*

*Potential investors should carefully consider all the information set out in this prospectus and, in particular, should evaluate the following risks and special considerations associated with an investment in the Company before deciding to invest in the Company.*

### RISKS RELATING TO THE GROUP

#### I. Trust arrangements in respect of Tianao and Vitapharm Research

Yugofoil, a wholly-owned subsidiary of the Company, has a 95% attributable interest in Tianao. In October 1998, Yugofoil acquired from Bright Future a 70% interest in Tianao for a consideration of HK\$500,000, which was paid by Mr. Tao in cash to Mr. Chan Chak Yeung, a shareholder of Bright Future until 1995 and director of Bright Future since 1994. The 70% interest was held by Bright Future on trust for Yugofoil pursuant to a trust agreement between Yugofoil and Bright Future dated 10th November, 1998 (the "Trust Agreement"). Subsequently in July and October 1999, Yugofoil, through Bright Future, further acquired in aggregate a 20% interest in Tianao from the PRC joint venture partners for a total consideration of RMB2,050,000. Since the 20% interest was acquired by Bright Future as its nominee, the consideration of RMB2,050,000 was therefore paid by Yugofoil direct to the respective PRC joint venture partners. As at 1st December, 1999, 90% of the interests in Tianao was held by Bright Future under the Trust Agreement, which was not stamped. Pursuant to the Trust Agreement and an agreement between Yugofoil and Bright Future dated 15th September, 2000, Bright Future transferred the 90% interest back to Yugofoil as the beneficial owner and no consideration was paid to Bright Future for the transfer, thereby terminating the Trust Agreement. The transfer was approved by the relevant PRC authorities. Yugofoil further acquired a 5% interest in Tianao from the PRC joint venture party in January, 2001.

Mr. Shen Song Qing and Mr. Huang Jian Ming were appointed as directors of Tianao representing Bright Future's interests in the board of Tianao in October 1996 and January 1997, respectively. After Yugofoil's acquisition of the 70% interest in Tianao, they continued to act as directors of Tianao representing the interests of Yugofoil. Further details of the directorship of Tianao are set out in the paragraph headed "Tianao" in the section headed "Business" of this prospectus.

Bright Future is a company incorporated in Hong Kong in which none of the Directors, their respective associates or, so far as the Directors are aware, shareholders who own more than 5% of the issued share capital of the Company (immediately following completion of the Placing and Capitalisation Issue and taking no account of any Shares which may be taken up under the Placing or allotted and issued pursuant to the exercise of the Over-allotment Option) has any interest during the Track Record Period. As shown in the public records of Bright Future filed with the Companies Registry of Hong Kong, as at 2nd September, 2001, the entire issued share capital of Bright Future was held as to 9,999 shares by Bright Future Pharmaceutical Holdings Limited and as to the remaining one share by Mr. Wong Cheong Moon, and Mr. Chan Chak Yeung and Mr. Wong Cheong Moon were directors of Bright Future. Bright Future is engaged in the sub-contracting and manufacture of pharmaceutical products. It owns and operates a GMP compliant manufacturing plant in Yuen Long, New Territories, Hong Kong which consists of either "a dedicated" or "one" building designed and constructed in accordance with the GMP standards.

---

## RISK FACTORS

---

The PRC legal advisers to the Company have confirmed that (a) although the Trust Agreement was not entered into under the laws of the PRC, which require that any changes in the shareholding of a foreign investment company should be approved by and registered with the relevant PRC authorities, the trust arrangement would normally be respected by the PRC authorities in the absence of disputes between the parties thereto, as it did not contravene any jus cogens of the laws of the PRC; (b) even if Bright Future now claims any entitlement to the interests in Tianao against Yugofoil, it would be time-barred under the laws of the PRC; and (c) therefore, under the laws of the PRC, there would not be any substantial legal risks in Yugofoil's interests obtained under such trust arrangement. The Group has also obtained a legal opinion from a leading counsel in Hong Kong that, on the basis of the facts set out in the prospectus and on the assumptions that Yugofoil's beneficial ownership in the shares of Tianao is recognised as valid and enforceable under the law of the PRC and that the various transfers of shares set out in this prospectus are valid and enforceable under the law of the PRC, the declaration of trust and the various transfers of interests in Tianao are, as a matter of Hong Kong law, valid and enforceable and that the declaration of trust is not chargeable to stamp duty. Each of the Directors has made a statutory declaration to confirm the following matters:

1. he was a director or proposed executive director of the Company incorporated in the Cayman Islands and having its head office and principal place of business at Units 1001 and 1002, 10th Floor, Kwai Hung Holdings Centre, No. 89 King's Road, Hong Kong.
2. he was duly authorised by the board of directors of the Company to make the statutory declaration for and on its behalf.
3. Tianao is an equity joint venture established in the PRC and is currently owned as to 95% by Yugofoil and as to 5% by Wuhan Tianao Pharmaceutical Factory (武漢天奧製藥廠).

The Company was undergoing certain corporate reorganisation pursuant to which Yugofoil would become a wholly-owned subsidiary of the Company.

On 30th October, 1998, Yugofoil acquired 70% equity interest in Tianao from Bright Future and pursuant to a declaration of trust dated 10th November, 1998 between Yugofoil and Bright Future, such interest was held by Bright Future on trust for Yugofoil until Bright Future transferred such interest back to Yugofoil in December 2000.

In July 1999 and November 1999, Yugofoil, through Bright Future acting as its trustee, acquired a further 10% and 10% interest in Tianao, respectively.

On 15th September, 2000, Bright Future, upon instructions from Yugofoil, transferred back to Yugofoil the 20% interest in Tianao which was acquired by it on behalf of Yugofoil. On 8th December, 2000, the original PRC approving authority approved the change of the registered holder of the 90% interest in Tianao from Bright Future to Yugofoil.

Yugofoil has at all times since October 1998 been the beneficial owner of the interest held by Bright Future in Tianao.

In turn, Yugofoil has, since April 1997, been beneficially owned by Mr. Ko, Mr. Au Yeung, Mr. Liu, Mr. Tao, Goldfield and Pernanga as to 33%, 6%, 12%, 42%, 4% and 3%, respectively.

---

## RISK FACTORS

---

4. Vitapharm Research is a company incorporated in Australia. The Company was undergoing certain corporate reorganisation pursuant to which Vitapharm Research would become a wholly-owned subsidiary of the Company.

Since its incorporation on 1st April, 1998, the entire issued share capital of Vitapharm Research has been held by King Laboratories Pty. Ltd. and WB Nominees Pty. Ltd. on trust for Mr. Ko who in turn held such shares on trust for Farthinghoe. Accordingly, the entire issued share capital of Vitapharm Research has at all times since its incorporation been held by Farthinghoe beneficially.

The entire issued share capital of Farthinghoe has since its incorporation been held by each of Mr. Ko, Mr. Au Yeung and Mr. Liu as to one share of US\$1 each in Farthinghoe.

5. The business of Vitapharm Research has since its incorporation been managed by Mr. Ko, Mr. Au Yeung and Mr. Liu with the assistance of other management and supporting staff.
6. After the acquisition of equity interest in Tianao in 1998, Yugofoil has appointed its representatives including Mr. Huang Jian Ming and Mr. Shen Song Qing, directors of Yugofoil to the board of Tianao. Since 7th February, 1999, Mr. Shen Song Qing was relieved from his duties as a representative of Yugofoil on the board of Tianao but Mr. Huang Jian Ming remained as the representative of Yugofoil in Tianao. Subsequently, Yugofoil nominated another two of its directors, Mr. Au Yeung and Mr. Liu to be appointed as directors of Tianao respectively on 28th December, 2000.
7. Yugofoil, principally through Mr. Huang Jian Ming, Mr. Au Yeung and Mr. Liu, has been actively involved in the management of Tianao since the acquisition by Yugofoil of the equity interest in Tianao.

Notwithstanding the foregoing, in the event that the Trust Agreement is not recognised or is invalid or unenforceable under the PRC laws or any other applicable laws, the combined results of the Group would have to be adjusted to take into account the 90% interest held by Bright Future during the Track Record Period. The adjusted loss attributable to shareholders for the year ended 31st December, 1999 would have amounted to approximately HK\$676,000 and the adjusted profit attributable to shareholders for the year ended 31st December, 2000 would have amounted to approximately HK\$7,707,000. This would lead to a change in the results of the Group for the same period as reported in the accountants' report.

In April 1998, Vitapharm Research was incorporated in the State of Victoria, Australia with its entire issued share capital beneficially held by Mr. Ko, Mr. Liu and Mr. Au Yeung as to 33.33%, 33.34% and 33.33% respectively. Such beneficial interests were held through trust arrangements which involved, first, declarations of trust dated 1st April, 1998 by King Laboratories Pty. Ltd. ("King Laboratories") and WB Nominees Pty. Ltd. ("WB Nominees") in favour of Mr. Ko in respect of the 20 issued shares of AUD1 (approximately HK\$4) each in Vitapharm Research (representing the entire issued share capital of Vitapharm Research) and second, declarations of trust dated 1st April, 1998 by Mr. Ko in respect of those 20 issued shares in favour of Farthinghoe. Accordingly, the 20 issued shares in Vitapharm Research have at all times been held by the trustees, King Laboratories, WB Nominees and Mr. Ko upon trust for Farthinghoe, the ultimate beneficial owner. In this connection, the Group has obtained Australian legal advice confirming that under Victorian law, the declarations of trust are valid and binding in accordance with their terms and entitle Farthinghoe to require transfers of shares to it, and also that the declarations of trust are not chargeable with stamp duty under Victorian law. The transfers of shares pursuant to the declarations of trust have also been properly denoted by the State Revenue Office of the State of Victoria, Australia as not stampable. In August 2001, the shares of Vitapharm Research held

---

## RISK FACTORS

---

by King Laboratories and WB Nominees were transferred back to Farthinghoe, whose name was thereafter entered into the register of members of Vitapharm Research.

Notwithstanding the foregoing, if the trust arrangement in respect of Vitapharm Research is not recognised or is invalid or unenforceable under any applicable laws, the results of Vitapharm Research could not be combined with the results of the Group during the Track Record Period. The adjusted profit attributable to shareholders for the years ended 31st December, 1999 and 2000 and the six months ended 30th June, 2001 would have amounted to approximately HK\$1,278,000, HK\$15,286,000 and HK\$13,822,000 respectively. This would lead to a change in the results of the Group for the same period as reported in the accountants' report.

The Directors have entered into a deed of indemnity with and in favour of the Company to provide indemnities on a joint and several basis, among other matters, against any depletion in value of assets, costs, fees, expenses, claims, losses, liabilities and proceedings which might be incurred or suffered by any member of the Group as a result of the Trust Agreement in respect of the Group's interests in Tianao or the trust arrangement in respect of Vitapharm Research being declared or determined by any court or relevant government authority to be illegal, invalid or unenforceable. Details of the deed of indemnity are set out in the paragraph headed "Estate duty, tax and other indemnities" in Appendix IV to this prospectus.

### **2. The Group may not succeed in its patent applications for its platform technologies**

To protect its platform technologies, the Group filed an Australian Provisional Patent Application No. PR2729 and the International Patent Application No. PCT/AU 00/01419. The Group has not yet obtained the patents for its platform technologies. To complete the application procedures, the Group will need to file formal applications in countries of interest and to go through searching and examination processes. The status of the applications is set out in the section headed "Business" of this prospectus. Patent application is a lengthy and complicated process, and there can be no guarantee as to success of the application. If the Group is not successful in its patent applications, other pharmaceutical manufacturers, if they get hold of the technologies, may use the technologies on their products and the Group will be subject to more intense market competition, which will materially affect its business performance.

### **3. Reliance on contract with Pharmco**

A substantial proportion of the Group's revenue is derived from the distribution of Osteoform. For the two years ended 31st December, 2000 and the six months ended 30th June, 2001, the turnover generated from the sales of Osteoform was approximately nil, HK\$32.2 million and HK\$33.4 million respectively, representing approximately 0%, 50.5% and 63.3% respectively, of the Group's turnover. Currently, the Group has the exclusive distribution right of Osteoform in the PRC and East Asia for a term of 20 years under a marketing and distribution agreement entered into in December 2000 with Pharmco. Pursuant to the marketing and distribution agreement, the Group agreed to purchase Osteoform powder exclusively from Pharmco. Under the terms of the marketing and distribution, if the Group fails to purchase the minimum quantities as agreed, or

---

## RISK FACTORS

---

is otherwise in breach of the agreement, Pharmco may have a right to terminate the agreement. The minimum quantities of Osteoform material which Beshabar (HK) shall purchase from Pharmco each calendar year are as follows:

<b>Calendar Year</b>	<b>Quota</b>
2001	143,590 kilogrammes
2002	164,102 kilogrammes
2003	194,872 kilogrammes
2004	225,641 kilogrammes
2005	256,410 kilogrammes
2006 and each calendar year thereafter	287,180 kilogrammes

Hence, there is no assurance that the distribution agreement with Pharmco will not be terminated or will be renewed upon expiry. Furthermore, Pharmco has a unilateral discretion under the agreement to amend the schedule of territories within which the Group is entitled to the exclusive distribution right of Osteoform. The scheduled territories are currently Australia, Cambodia, Hong Kong, Indonesia, Japan, Laos, Macau, Malaysia, New Zealand, North Korea, the PRC, Philippines, Russia, Singapore, South Korea, Taiwan, Thailand and Vietnam. In the event that the Group is unable to continue to secure the exclusive distribution right of Osteoform, or loses its exclusive distributorship right for the PRC, its business performance and profitability will be seriously affected.

#### **4. Reliance on major suppliers**

During the two years ended 31st December, 2000 and the six months ended 30th June, 2001, the largest supplier of the Group accounted for approximately 81%, 43% and 48% respectively of the Group's purchase. As the Group only produced and distributed Opin in 1999 and obtained its supply of interferon, which is the most important and most expensive material for the production of Opin, from one supplier for the year ended 31st December, 1999, the percentage of purchase from that particular supplier to the total purchase of the Group for the year ended 31st December, 1999 was relatively high. For the year ended 31st December, 2000 and the six months ended 30th June, 2001, the Group purchased Osteoform powder from Pharmco, and Pharmco became the largest supplier to the Group for these periods. Pursuant to the marketing and distribution agreement entered into between Beshabar (HK) and Pharmco on 26th December, 2000, the Group agreed to purchase Osteoform powder exclusively from Pharmco. The Group has not entered into any other exclusive purchase agreement with any of its suppliers, and has not entered into any long term contracts with its suppliers. In the past, the Group has not encountered any production disruption due to the shortage of supply of raw materials. The Directors believe that all the principal raw materials used by the Group can be purchased from a number of other suppliers at prices comparable to those paid to the Group's current suppliers. Nevertheless, if the Group encounters any production disruption due to a shortage of supply of major raw materials, the production and business performance of the Group will be seriously affected.

#### **5. Reliance on sub-contractor**

The Group currently sub-contracts the packaging process of Osteoform to an independent third party. For the year ended 31st December, 2000 and the six months ended 30th June, 2001, the Group paid sub-contracting charge amounting to HK\$4.4 million and HK\$4.3 million respectively, which accounted for approximately 11.7% and 14.8% of its total cost of sales. The Directors consider that the services provided by

---

## RISK FACTORS

---

the sub-contractor are material to the production process. However, there is no assurance that the relationship with the sub-contractor will not be terminated. Should this happen, the production and the business performance of the Group may be affected.

### 6. Reliance on major customers

During the two years ended 31st December, 2000 and the six months ended 30th June, 2001, the Group's largest customer accounted for approximately 95%, 45% and 23%, respectively of the Group's turnover; whilst the Group's five largest customers accounted for approximately 99%, 86% and 70% respectively of the aggregate turnover. The reason for such a high concentration of customers, especially in the year ended 31st December, 1999, is the reliance on sales to distributors. For the year ended 31st December, 1999, Wuhan Gao Zhuo Pharmaceutical Sales Limited (武漢高卓醫藥銷售有限公司) (formerly known as Wuhan Tianao Pharmaceutical Sales Limited (武漢天奧醫藥銷售有限公司)) was appointed as the sole distributor of Opin and it was, therefore, the Group's largest customer accounted for 95% of the Group's turnover. Since November 2000, the Group has been distributing Opin through independent distributors. In January 2001, the Group established its own distribution network in the PRC for Opin and since then, the Group has been distributing Opin to end-users through its own sales and marketing team and independent distributors. As regards Osteoform, the Group distributes this product in the PRC through two distributors located in Shenzhen and Shanghai. The Group has entered into a non-exclusive distribution agreement with each of the distributors for a term of 3 years from November 2000. However, there is no assurance that these distributors will achieve the required sales volume or that the distribution agreements will not be terminated or will be renewed upon expiry. In the event that these distribution agents fail to purchase products in sufficient volume or at all from the Group, the Group's business and profitability may be adversely affected.

### 7. Compliance with the GMP standards

Since 1988, the Ministry of Health, the PRC (中國國家衛生部) has started to require the pharmaceutical manufacturing enterprises in the PRC to satisfy the GMP standards. In 1999, the SDA issued the Notice on the Guidelines on Good Manufacturing Practice (the "Notice") (關於重申實施(藥品生產質量管理規範)有關規定的通知), which requires, among other matters, the manufacturers of certain kinds of pharmaceutical products to comply with the GMP standards within the time limit stipulated by the SDA. If these manufacturers do not obtain GMP certification within the stipulated time limit, their Pharmaceutical Manufacturing Enterprise Permit will not be renewed and the production of such pharmaceutical products will have to cease. Details of the GMP standards are set out in the paragraph headed "GMP" under the section headed "Industry overview" of this prospectus.

In October 2001, the SDA announced various deadlines for different categories of pharmaceutical manufacturers to comply with the GMP standards. The Group's products fall into the general category of "pharmaceutical products and raw materials" for which the deadline with respect to the compliance with the GMP standards is 30th June, 2004. The Group has a production plant in Chengdu City, Sichuan Province, the PRC, which has obtained GMP certification. This production plant is expected to commence production in early 2002. However, the existing production plant in Wuhan, the PRC, is not fully in compliance with the GMP standards. The Group plans to gradually shift the current production of Opin in the Wuhan plant to the GMP compliant plant in Chengdu City, Sichuan Province, the PRC, which is owned by Weiao, before 30th June, 2004, and in this process, the Group will be faced with such tasks as locating a suitable site, renovating the premises, removing the production facilities and recruiting and training new staff. If the Group encounters any major problems in this process, the Group's production operations and business performance will be seriously affected.

---

## RISK FACTORS

---

### **8. The business licence of a member of the Group may be revoked for not fulfilling the obligation of making full capital investment contribution within the prescribed time**

Vital (Sichuan), established in the PRC on 25th July, 2001, is a wholly-owned subsidiary of Vital BioTech (Hong Kong) principally engaged in the research and development projects of the pharmaceutical products. According to the business licence and the articles of association of Vital (Sichuan), Vital BioTech (Hong Kong) shall make full capital investment contribution in the amount of US\$1,400,000 on or before 24th July, 2003. According to the Foreign Owned Enterprise Law of the PRC, an enterprise with foreign capital shall make investments in the PRC within the period approved by the authorities in charge of examination and approval. If it fails to do so, the industry and commerce administration authorities may cancel its business licence. The industry and commerce administration authorities shall inspect and supervise the investment situation of an enterprise with foreign capital. Under the PRC law, Vital BioTech (Hong Kong), being the holding company of Vital (Sichuan) shall also be responsible for the outstanding amount of the investment. Out of the requisite total capital investment of US\$1,400,000, the Group has so far invested US\$210,000 into Vital (Sichuan) as capital contribution and the Group intends to fund the balance of the requisite investment by revenue generated from the ordinary course of business of the Group. Should Vital (Sichuan) fail to contribute full investment within the prescribed time and that its business licence be cancelled or Vital BioTech (Hong Kong) will be held responsible for the outstanding amount of the capital investment contribution, the profitability of the Group may be adversely affected.

### **9. Expiry of protection period**

One of the products of the Group, Opin, was registered as a new pharmaceutical product on 2nd June, 1998 and was protected from competition under the Regulations on the Protection of New Pharmaceutical Products and Technology Transfer (關於新藥保護及技術轉讓的規定) during the protection period from 2nd June, 1998 to 1st June, 2001. The protection period has already expired and currently, the Group is not entitled to any such protection. In May 2000, the Group applied for a new indication for Opin as a Class 5 new drug in relation to a project which involves the use of Opin for the treatment of herpes. The project is at the stage of clinical trial currently and the application is still being processed. The Directors believe that upon the application being approved, Opin will enjoy 6 years of regulatory protection for the new indication; however, there is no assurance that the application will be successful. If the application is approved, then, during the protection period, no pharmaceutical manufacturing enterprises other than the original manufacturer of the new pharmaceutical products approved by the SDA (i.e. Tianao), may engage in the manufacture of Opin unless it enters into a technology transfer agreement with the original manufacturer. The transferee must hold a Pharmaceutical Manufacturing Enterprise Permit (藥品企業生產許可證) and a Pharmaceutical GMP Certificate (藥品GMP證書) before such a technology transfer can become effective. Upon the expiry of the protection period, other manufacturers will be entitled to produce the same product as Opin but they will have to do so under a different brand name. This may adversely affect the profitability of this product for the Group.

### **10. There is no assurance that the plans of the Group will be achieved within the proposed time frame as set out in the section headed “Statement of business objectives” of this prospectus**

The future plans as set forth in this prospectus are based on the existing plans and intentions of the Group which are either at a conceptual or a preliminary stage. These intentions and plans are based on assumptions, which by their nature are uncertain, subject to changes, and may turn out to be inaccurate. The Group's actual course of action may therefore vary from the intentions and plans set forth herein.

---

## RISK FACTORS

---

Although the Directors will endeavour to execute such plans within the proposed time frame as set out in the section headed “Statement of business objectives”, there is no assurance that the plans of the Group will be materialised resulting in the implementation of the plans within the time frame set out herein. Accordingly, there is no assurance that the objectives of the Group will be fully accomplished or can be accomplished at all. If the Group is not able to implement its business objectives effectively, the Group’s business operations and financial performance may be adversely affected.

The Directors will continue to review and closely monitor the feasibility of the proposed plans for fulfilment of the Group’s objectives and may, where necessary, adjust the future plans/business objectives accordingly in order to adapt to the changing circumstances.

### **11. Some statistics relating to the biotechnology and pharmaceutical industry in the PRC after 1997 are not available**

Part of the statistics stated in this prospectus refer to the year 1997, which the Directors believe to be the latest available information relating to the biotechnology and pharmaceutical industry in the PRC. The trend of the biotechnology and pharmaceutical industry in the PRC after 1997 may be substantially different from the trend indicated by such available statistics. As a result, future plans of the Group which are formulated on the basis of such statistics may not produce the desired results and the future profitability of the Group may be adversely affected as a result.

### **12. Limited track record**

The Group was established in 1998. Owing to the Group’s limited track record, it is difficult to assess the Group’s future prospects by reference to its historical record, as compared with those companies with longer track records. Whilst the Group has achieved growing profits during the Track Record Period, there is no guarantee that the Group’s operations will continue to be profitable in the future or that such profit growth can be sustained. The Group’s ability to make a profit or to achieve profit growth in the future will be dependent on a variety of factors, including the intensity of competition, the ability to respond to rapid changes in technology and the Group’s success in implementing its business strategies and objectives.

### **13. May not be able to successfully manage its expanding operations**

In the past, the Group has undergone significant transformation, including setting up production facilities, expanding production lines and relocating production facilities to increase production capacity. The Group intends to continue the expansion of its operation and the geographic coverage of its customer base. The Group’s ability to continue to compete effectively and to manage future expansion of its operations will require continuous improvement of the management and financial control system, reporting procedures, and training and management of its employees. If the Group fails to address such issues adequately and in a timely manner, the Group’s business operation and profitability may be adversely affected.

### **14. Future success will depend on its ability to keep pace with the production methodology of the biotechnology and pharmaceutical industry in the PRC**

The future success of the Group will depend on its ability to continuously develop and enhance its existing products as well as production capability for the production of drugs in a cost effective and timely manner.



---

## RISK FACTORS

---

If the Group is unable to respond to the continuous improvement in production methodology in manufacturing drugs in the PRC effectively, its business, financial condition and results of operations may be adversely affected.

### **15. Defective products or harmful effects from the consumption or use of the Group's products and lack of product liability insurance coverage may result in material liability and loss of market share**

Under the current PRC laws, manufacturers and vendors of defective products in the PRC may incur liability for loss and injury caused by such products. Pursuant to the General Principles of the Civil Law of PRC (中華人民共和國民法通則), which took effect in 1987, a defective product which causes property damage or physical injury to any person may subject the manufacturer or vendor of such product to civil liability for such damage or injury.

In 1993, the PRC Civil Law was supplemented by the Product Quality Law of the PRC (中華人民共和國產品質量法), which was enacted to protect the legitimate rights and interests of the end-users and consumers and to strengthen the supervision and control of the quality of products. Under the Product Quality Law of the PRC, manufacturers who produce defective products may be subject to criminal liability and having their business licences revoked.

In 1994, the Law of the PRC on Protection of the Rights and Interests of Consumers (中華人民共和國消費者權益保護法) (the "Consumers' Rights Law") was promulgated to further protect the legal rights and interests of customers in connection with the purchase or use of goods and services. All business operations, including the Group, must observe and comply with the Consumers' Rights Law.

Accordingly, product liability claims may arise out of the Group's operations if counterfeit or harmful products are sold to the public. If there is any allegation that there are harmful effects from the consumption or use of the Group's products, product liability claims may arise.

The Directors believe that it is the industry practice in the PRC that biotechnology/pharmaceutical manufacturers do not have product liability insurance cover for the biotechnology/pharmaceutical products they manufacture. Presently, the Group does not carry product liability insurance in the PRC. If any product liability claim is brought against the Group, the Group's financial position or even operations may be adversely affected.

### **16. There is no assurance that new products will be successfully developed and/or approved by the relevant authority**

One of the principal factors for the Group's success is its senior management's experience in research and development in the pharmaceutical industry in the PRC. For the two years ended 31st December, 2000 and the six months ended 30th June, 2001 the research and development costs incurred by the Group were approximately HK\$21,000, HK\$216,000 and HK\$534,000 respectively. The Group will continue to invest in the research and development of new products.

However, there is no assurance that any research project undertaken by the Group will lead to any result or can be completed within the anticipated time frame or that the costs of such project can be recovered, there is also no assurance that the findings of such research project will lead to commercial production of any products or that the newly developed products will be approved by the relevant authority.

---

## RISK FACTORS

---

Moreover, in the event that the Group is unable to register its new biotechnology and pharmaceutical products as required by the Regulations on the Protection of New Pharmaceutical Products and Technology Transfer (關於新藥保護及技術轉讓的規定), the Group will not be able to recover the costs incurred in the development of such products. In addition, in the event other manufacturers are able to register earlier than the Group new pharmaceutical products similar to the products being developed by the Group, the Group might not be able to obtain the relevant registration under the same regulation. Accordingly, the Group's profitability may be adversely affected.

### **17. Unsuccessful launch of new products may result in the inability to recover expenses incurred in developing new products**

If the Group is unable to attract sufficient demand for any new biotechnology or pharmaceutical products that have been successfully developed by the Group and are approved by the relevant authorities, the costs of development or the costs incurred for the completion of clinical testing or promotion of the new drugs may not be recoverable and it may affect the Group's profitability.

### **18. Reliance on the PRC market**

For the two years ended 31st December, 2000 and the six months ended 30th June, 2001, most of the sales of the Group took place in the PRC. Currently, all of the Group's products are sold in the PRC. The Directors expect that the PRC will continue to be the Group's major market. Changes in the monetary policy or any state policy of the PRC or any significant decline in the condition of the PRC economy may have an adverse impact on the Group's sales and hence, its profitability.

### **19. Failure to protect and defend its intellectual property rights may adversely affect the Group's business**

Most of the Group's products are distributed under registered trademarks in the PRC. The Group has developed two platform technologies, namely the PSD and the SDDS technologies and that the two platform technologies are in the process of applying for the patent registration. New drugs registered with the SDA may be protected by statutory legislation for various periods depending on the classification. However, third parties might produce counterfeit, copy or otherwise infringe the Group's intellectual property rights without obtaining authorisation from the Group. The Group's inability to protect its intellectual property may materially and adversely affect on the Group's reputation, business, financial condition and results of operations.

### **20. Renewal of certificates, permits and business licences**

As a pre-requisite to carrying on pharmaceutical manufacturing business in the PRC, all pharmaceutical enterprises are required to obtain from various governmental authorities certain certificates, permits and business licences. Details of these certificates, permits and business licences are set out in the paragraph headed "Manufacture of pharmaceutical products" under the section headed "Industry overview" of this prospectus.

Since the commencement of its operation, the Group has successfully obtained all requisite certificates, permits and business licences for the manufacture of its pharmaceutical products. The Pharmaceutical Manufacturing Enterprise Permit (藥品生產企業許可證) of the Group have been renewed to 31st December, 2005. However, these certificates, permits and business licences held by the Group are subject to periodic

---

## RISK FACTORS

---

renewal, reassessment by the relevant government authorities and the standards of compliance required in relation thereto may from time to time be changed. In addition, it may be costly for the Group to comply with any subsequent modification of, additions or new restrictions to, these compliance standards.

It should be noted that the requirements under these permits and business licences may change from time to time, which may give rise to compliance problems. Furthermore, if it becomes too costly for the Group to comply with any subsequent modification of, additions or new restrictions mandatorily imposed by the PRC laws, rules and regulations, the Group's profitability may be affected.

### **21. May not be able to attract and retain key management and technical personnel whom it needs for its success**

The Directors believe that one of the key factors for the Group's success is its ability to recruit and retain key management and technical personnel. Their expertise and experience in the business is instrumental to the Group developing and upgrading the Group's products. If the Group is unable to retain its key management and technical personnel and further recruits high calibre employees, the Group's operation and profitability may be adversely affected.

## **RISKS RELATING TO THE INDUSTRY**

### **1. Slow down of the growth of the pharmaceutical industry in the PRC**

The growth of the pharmaceutical industry in the PRC may slow down for the short term due to the release of "Opinion on medical and hygiene system reform in cities and towns" (關於城鎮醫藥衛生體制改革的指導意見) by various PRC government authorities in February 2000, which contains proposals on reforming the medicare system and on separating management of the drug dispensing and medical practice. The Directors believe that the social medicare reforms contemplated in the above document may lead to a separation of the medicine dispensing and the doctoring functions and the removal of hospitals' incentive to sell medicine. The Directors believe that these social medicare reforms may result in a change in the structure of the distribution channel for medicine whereby hospitals will reduce their purchases for pharmaceutical products which may in turn affect the profitability of the Group.

### **2. Competition as a result of the PRC's admission as a member of the WTO**

The PRC signed an accord on its accession to the WTO on 12th November, 2001 and became a member of the WTO on 11th December, 2001. The Directors anticipate that upon China's entry to the WTO, competition in the pharmaceutical industry will intensify in two aspects. With lower import tariffs, the Directors anticipate that imported pharmaceutical products manufactured overseas will become more competitive in terms of pricing to domestic products. The Directors also believe that foreign pharmaceutical manufacturers with more experience are likely to set up their production facilities in the PRC and compete with domestic manufacturers directly. Accordingly, the Group may face increasing competition from foreign pharmaceutical manufacturers and other manufacturers who have obtained or shall have obtained GMP accreditation certificates after the PRC becomes a member of the WTO. Although the Group has an established customer base in the PRC, the Group's profitability may be adversely affected by the PRC's admission to the WTO.

---

## RISK FACTORS

---

### **3. Change in price control policy in the PRC may adversely affect the Group's profitability**

The prices of certain pharmaceutical products in the PRC are subject to the control by the price administration authorities at the national or provincial level. The prices of Opin and Osteoform are currently subject to such price control. As a matter of practice, there is a price ceiling set on the ex-factory price, wholesale price and retail price of the subject pharmaceutical products. Details of the price control regime are set out in the section headed "Price control" under the heading "Industry overview" in this prospectus. In the event that the manufacturing costs of the Group's products increase and that application for upward adjustment of price ceilings of the relevant products is not approved, the profitability of the Group may be adversely affected.

### **4. Successful launch of substitutes to the Group's products may adversely affect the Group's profitability**

Proprietary pharmaceutical products are usually protected by patents for a long period of time during which no manufacturers other than the patent holders or their licensees may produce products using the patented pharmaceutical formulae. At present, one of the Group's products, Opin, uses two technologies of the Group. However, it is possible that products having medicinal applications or therapeutic effects comparable to the Group's products may be invented and posed as direct substitutes. If such substitutes are successfully launched in the market, the Group's profitability may be adversely affected.

### **5. Change in advertisements control policy may adversely affect the profits and operation of the Group**

Under the Law on the Administration of Drugs (藥品管理法) promulgated on 28th February, 2001 and the Regulations on Packaging, Labelling and Instruction Manuals of Drugs (藥品包裝、標籤及說明書管理規定), the advertisements, packaging and the content of the label and instructions booklet of drugs are subject to the control by the SDA. In practice, the advertisements, packaging and the contents of the label and instructions booklet of drugs are subject to the prior approval of the SDA. Any subsequent amendments on the advertisements, packaging and the contents of the label and instructions booklet of the drugs are also subject to approval. The SDA may require the manufacturers to take remedial measures, including to order the manufacturers to take back all the drugs and to re-package them and/or to punish the manufacturers according to relevant regulations should the manufacturers breach such Law and Regulations.

Currently, the Law and Regulations cited above are applicable to all the products of the Group. the SDA may promulgate new laws and regulations which may require the Group to amend the advertisements, packaging or content of the label and instructions booklet of the Group's products which may impose additional costs on the Group and may adversely affect the Group's profitability. In addition, should the advertisements, packaging and contents of label and instructions booklet of the Group's products fail to meet the applicable requirements from time to time, the Group may be required to take remedial measures which may, in turn, have an adverse effect on the operations of the Group.

---

## RISK FACTORS

---

### RISKS RELATING TO THE PRC

#### 1. Currency conversion and exchange control

With effect from 1st January, 1994, the PRC government adopted an unified floating exchange rate system under which the exchange rate is determined basically by market demand and supply. The Group relied on RMB denominated revenue during the Track Record Period. Upon the listing of the Shares on the Stock Exchange, however, the Company's accounts will be denominated in Hong Kong dollars. Accordingly, if there are substantial fluctuations in the exchange rate of RMB against the Hong Kong dollars, the profitability of the Group, the value of its assets and its ability to pay dividends in Hong Kong dollars may be adversely affected.

Moreover, the conversion of RMB into foreign currencies, including Hong Kong dollars, continues to be subject to exchange control. Under the PRC's Foreign Exchange Control Regulations and the Administration of Settlement, Sale and Payment of Foreign Exchange Regulations, foreign investment enterprises are permitted to repatriate or distribute its profits or dividends in foreign currencies out of its foreign exchange accounts or exchange RMB for foreign currencies through banks authorized to conduct foreign exchange business. Conversion of RMB into foreign exchange by foreign investment enterprises for the use of recurring items, including the distribution of dividends to foreign investors, is permissible. Conversion of RMB into foreign currencies for capital items, including items such as direct investment, loans and security investment, is subject to more stringent control. The Group is subject to the above regulations. There can be no assurance that any change in the new law or regulation prohibits or further restricts the convertibility of RMB into foreign currency or any shortages in the availability of foreign currency in the PRC will not restrict the Company's ability to obtain sufficient foreign currency to pay dividends on the Shares since the Group will receive most of its revenue in RMB.

#### 2. Political, economic and social considerations

One of the basic assumptions for the Group's future plans and business objectives is that there will be no material adverse changes in the existing political, economic or social conditions in the PRC. In the event that general economic, political, legal and social conditions in the PRC substantially change, the operations and prospects of the Group may be adversely affected.

The PRC economy is essentially a planned economy operated under annual, five and ten years' plans. The PRC government has introduced substantial economic reforms in recent years. However, many laws and regulations on economic reforms are at an early stage of development and their interpretation and enforcement involve uncertainties. As the PRC is the major market of the Group, there is no assurance that changes in the PRC laws and regulations or their interpretation will not have any adverse effect upon the business and the prospects of the Group. In addition, any changes in the economic, political or social conditions prevailing in the PRC may lead to changes in the PRC government policies which may adversely affect the business and prospects of the Group.

#### 3. Legal consideration

Since 1979, many laws and regulations dealing with economic matters with respect to general and foreign investment have been promulgated in the PRC. In 1982, the PRC National People's Congress amended the constitution to govern foreign investments and to guarantee the "lawful rights and interests" of foreign investors in the PRC. Since then, it has been the trend of legislation to provide more protection to foreign

---

## **RISK FACTORS**

---

investors and to allow more active management and control by foreign investors in foreign investment enterprises in the PRC. Despite these developments, the Directors believe that the PRC does not have a comprehensive system of laws. The implementation of existing laws may also be uncertain and sporadic and their interpretation may be inconsistent. As the PRC legal system matures, there may be changes in its legislation or the related interpretation that may, in turn, adversely affect the business and prospects of the Group.

#### **4. Risk relating to war**

The recent attacks in Afghanistan by the U. S. has brought about economic uncertainty and this may have significant economical effects all around the world including the PRC. There is no assurance that these will not be any significantly direct or indirect effects on the Group. If the political and economical conditions of the PRC are adversely affected by international instability, the operating results of the Group may be negatively affected.