Biopure case study

Biopure Case Study Executive Summary * Biopure Corporation developed two new products to enter into the field of blood substitutes: Hemopure, directed to the human market and Oxyglobin, for the veterinary market. Through the end of 1997 no blood substitute had received approval for use anywhere in the world. * What distinguishes both products from other “ hemoglobin-based" blood substitutes is the fact that they are “ bovine-sourced" as opposed to “ human-sourced", i. e. they are derived from the blood of cattle. * Biopure has spent $200 million in the development of Oxyglobin and Hemopure, and the construction of a manufacturing facility. * Oxyglobin is ready for launch while Hemopure is still two years away from final government approval. This situation is a source of concern within the corporation. Ted Jacobs, vice president for Human Clinical Trials at Biopure, argues that the release of Oxyglobin should be done after Hemopure is approved to establish this product in the marketplace. Jacobs’ argument is based on the fact that both products have almost identical and physical properties and appearance that could create an unrealistic price expectation for Hemopure if Oxyglobin is released first. * Andy Wright, vice president for veterinary products argues that the benefits of launching Oxyglobin outweigh the benefits, since the veterinary product could generate useful revenues to launch Hemopure and learning how to market the product before taking any risks with Hemopure. Case Overview Biopure, a biopharmaceutical firm founded in1984 specializes in the ultra-purification of proteins for human and veterinary use, had two major “ blood substitute" products - Oxyglobin for the veterinary market and Hemopure for the human market. These products were almost identical in physical properties and appearance. While Oxyglobin achieved final government approval in

February 1998, Hemopure was still two years away from it. In the human blood market, the dominant practice was transfusion of donated RBCs that had common limitations and risks. Meanwhile, the use of autologous RBC transfusion had become increasingly common. In general, the human blood supply struggled to meet the demand because of low donation rate and relatively short shelf-life of RBCs. Moreover, the demand for RBCs was expected to rise with the aging US population. In contrast from the human market, blood transfusions were infrequent in the veterinary blood market, mainly because of the lack of an adequate blood supply — the sole source of blood for most veterinary practices was donor animals. Eighty four percent of veterinarians reported overall dissatisfaction with blood transfusion alternatives currently available in the market. In terms of a competitive environment, Oxyglobin was by then the only blood substitute product in the veterinary market; additionally, it would take 2-5 years to release a product if other companies attempted to enter the market because of the FDA approval process. However, Hemopure was facing two major competitors in the human market: Baxter International and its HemAssist; Northfield Laboratories and its PolyHeme. Primary Concerns Carl Rausch, president and CEO of Biopure Corporation, was facing a difficult decision regarding whether and when to launch Oxyglobin. Ted Jacob, vice president for Human Clinical Trials, argued that the release of Oxyglobin should be delayed until after Hemopure was approved and well established in the market, because: * Oxyglobin would create unrealistic price expectations for Hemopure if released first * The human market is many times larger than animal market. * It is more likely to achieve high price in the human market, which, thus, is more profitable than the animal market. Meanwhile, Andy Wright, vice

president for Veterinary Products, was eager to begin selling Oxyglobin. He argued that the benefits of immediately releasing Oxyblobin outweighed the risks, because: * Biopure is the only company that had developed a blood substitute for the small-animal veterinary market * The production process for both products is almost identical meaning that launching Hemopure would not involve more investment in the long term * Revenues from selling Oxyglobin could be used to fund releasing Hemopure * Oxyglobin could create a brand image that could help with the release of Hemopure in the future Another concern is that many stockholders were eager to take Biopure public. Which would have greater impact on a possible initial public offering of Biopure stock, a proven success with Oxyglobin or a promise of success with Hemopure? Carl Rausch had to carefully consider how to best leverage the opportunity offered by Oxyglobin without jeopardizing the potential of Hemopure. For Andy Wright, the big question was how to best market Oxyglobin, including pricing, distribution, etc. Opportunities Oxyglobin offers several advantages to the development and expansion of Biopure to the veterinary market as a first step to create a brand that could potentially help promoting Hemopure in the long term. First of all, since the FDA has approved Oxyglobin, the veterinarian market will welcome this product with no hesitation or concerns about safety, especially because of the lack of an adequate blood supply for veterinarian transfusions. Also, the innovative character of Oxyglobin could position Biopure as a pioneer in the blood substitute market within the veterinary market. Even though blood transfusions in the veterinary market are infrequent, it is necessary to keep in mind that this could be explained by the fact that when a dog or cat was in need of a transfusion, it was another dog or cat that transfused blood into

the animal in need. According to the numbers provided by the case study 93% of the transfused blood in primary care practices was provided by donor animals while blood banks provided the rest 7%. Keeping this in mind, the opportunities in the veterinary market could be defined by the fact that pet owners are usually willing to pay enough money to save the life of their loved ones or ensure that they are well for a long term and having a trustable source of blood for their pets could become a good asset to offer. Since 15% of veterinarian practices consider that finding a “ donor animal" is administratively difficult and financially prohibitive, a blood substitute like Oxyglobin would ease this situation for both veterinarians and pet owners. Based on the profile of 15, 000 veterinary practices in the United States made in 1995 (Exhibit 7), if Oxyglobin is introduced to this market at a price of $200, Oxyglobin would generate annual revenues of approximately $1, 080, 000 from an average of primary care. If Oxyglobin is introduced to the veterinary market with a strong campaign that targets vets (as main gatekeepers within this market) and pet owners it will definitely success. Over time, if the product performs well, Oxyglobin will create a demand to treat some animal diseases with a high technology product that is also affordable by pet owners. This development will ensure a market for Oxyglobin which will pave the way for Hemopure when the FDA approves this last product. Recommendations It would be recommended to launch Oxyglobin without waiting for Hemopure to be approved. While Carl Rausch’s concerns are understandable, they can be countered on a few points. Thus, Hemopure will have a very good chance to establish itself on the human blood market. The market is strong and set to expand in the future, so demand will not be a problem. At the same time, competitors will need to

pass the extensive and time-consuming FDA approval procedures and will thus be delayed in their entry. With demand assured and little precedent, Hemopure will be able to have quite a bit of leeway in setting its price. While Oxyglobin will certainly be compared to Hemopure, having the same function and properties, the two products are fundamentally different in the same way that humans and animals are different. So the price of Oxyglobin should not have too great an influence on the price of Hemopure, and the two products are unlikely to interfere with each other. Instead, Oxyglobin can be seen as a good test run for Hemopure and even a kind of “ animal trial" phase that proves that artificial blood substitutes have no negative effects--given how new this entire field is, concerns are certain to arise. While the veterinary market is much smaller than the human market, it is still a viable source of profit. In addition, Oxyglobin will be relatively simple to target, since only a fraction of veterinary practices (5% of 15, 000; about 750 clinics) handle the majority of animal transfusions. It would be possible to conduct a mail or telephone campaign to let clinics know about this new product, or even arrange for in person visits from sales representatives. Though animal transfusions are infrequent, the biggest constraint has historically been the lack of blood supply. There are very few animal blood banks, so most animal blood comes from donor animals housed at the practice for that specific purpose. Needless to say, this creates extra expenses for maintaining them and time consumption for extracting the blood. Also, some practices do not keep donor animals and thus find it difficult to keep enough blood on hand. There is a definite opening for Oxyglobin, as long as this situation is clearly presented to potential customers. Practices should be open to accepting Oxyglobin, if they are

targeted by a strong marketing campaign. It would be important to emphasize the benefits of no longer needing to house donor animals and always having animal blood available, as well as the benefits of having that blood already properly types, as to avoid complications due to incompatible blood types. This would allow Oxyglobin to be marketed at a higher cost than animal blood from blood banks (at $200 dollars, compared to $50-$100). One possibility is to provide Oxyglobin to veterinarians at a reduced rate for a short trial period, to allow them to verify that it is safe and effective. Information should also be included, emphasizing the safety of Oxyglobin, to allow veterinary practices to better assure customers. One possible point of opportunity is the growing number of owners who view pets as members of the family and are willing to pay extra for special care. Emphasis can be placed on the FDA approval earned by Oxyglobin. It would also be possible to increase the number of animal transfusions by presenting blood transfusion with Oxyglobin as something safe and routine, rather than an option of last resort. Conclusion: Oxyglobin and Hemopure appeared to be promising products created, developed, and promoted by Biopure Corporation, a biopharmaceutical company in Cambridge Massachusetts who wanted to revolutionize the supply of blood with oxygen-therapeutic products. Oxyglobin received FDA approval initially and was ready for production and product launch. Furthermore, Oxyglobin was found in over 200 preclinical lab studies to be effective in treating animals. Oxyglobin provided additional benefits of blood compatibility and quality, long shelf life, and no refrigeration as compared to the many problems of using animal blood banks. During the testing phases, it was observed that many dogs suffering from responded well to Oxyglobin after receiving pints intravenously. It

would be useful to start generating revenues to recoup the $200 million dollars spent in development and research. Hemopure was developed to produce a similar product to be used by humans to fulfill the demand for blood supply. In contrast to Oxyglobin, Hemopure required extensive research, resource and experimentation with greater risks and liability as it dealt with human life. The market size included all patients who suffered from blood loss, chronic anemia and 25% of the adult population over age 65 by the year 2030. The FDA approval process for Hemopure would require a lengthy amount of time than for trial and approval for Oxyglobin. Biopure knew that it must be cautious with the research and potential pitfalls for releasing Hemopure. The direction to take the least amount of risk would happen if Biopure chose to release Oxyglobin and generate revenues immediately. The timing to launch the products was slightly off as Oxyglobin was ready to be released and sold while Hemopure was at a different stage and not FDA-approved for manufacturing. To the management team, there were many advantages to launching Oxyglobin initially. The market potential and size was enticing to reach as many veterinary practices and hospitals in the U. S. in order to treat pets with by administering oxygen therapies like Oxyglobin to reduce oxygen deficiency by providing efficient delivery than using pre-donated blood. Special cases of anemia, trauma, and surgery of pets required the product, and the demand was relatively low. The benefits of Oxyglobin provided an alternative to animal blood donations, but the challenges were still apparent to determine an appropriate price and to manufacture the product to ensure recoup of research and development expenses already realized. It was not anticipated that there would be a delay caused by an initial stage following the launch for product acceptance

and trust that would require careful marketing strategies to convince masses of consumers of the reliability of the new biotechnology being introduced. It is recommended to proceed with the production of Oxyglobin and to prepare a carefully planned strategy including specific recommendations to introduce this new technology as consumers would need to be aware of the potential side effects and risks which was one of their main challenges. The objective of the company to produce a high-quality product that lived up to its claims of longer storage periods, no refrigeration requirements, and other benefits including quality and compatibility with all blood types. The reputation of the company and the initial resources spent for research was all at stake based on the performance of the initial product whatever the company decided to choose to launch first. Oxyglobin's success is key to generating revenues to continue gaining FDA approval for further development of Hemopure in hopes of gaining a broader market while minimizing risks for safety and side effects caused by use of the Oxyglobin and Hemopure. In conclusion, when trying to reach a mass market, it's important to look at the production, promotion, price and place. Production: * Production for Oxyglobin was $1. 50 per unit for raw material * Annual capacity for Oxyglobin was 300, 000 units Pro: There was sufficient cattle to provide collection and transportation of bovine blood. which made production feasible. Con: Would consumers be willing to accept the product especially if it was derived from cattle? Promotion: * In 1997, $1. 2 billion of product was sold to veterinary practices with 200 independent distributors (p. 11) * There are 15, 000 small animal veterinary practices in the U. S. that can be reached through trade publications, direct sales, and trade shows to demonstrate the scientific explanation behind Oxyglobin Pro: The sales team

were ready to sell Oxyglobin and start a marketing campaign because the product had FDA approval. Con: Animal blood banks were reliable and also provided blood donations at a lower cost. Price: * It was fairly inexpensive to manufacture 1 pint of Oxyglobin once the FDA and research costs were deducted. * The demand could increase as technologies for pet medicines and treatments are introduced to this market segment. Pro: It is ideal to price one pint at $100 for vets and charge $200-$260 for the end-users. The cost of animal blood donations was typically $130-$170 charged to the pet owners. Con: Animal donations were lower in cost and available in many regions of the U. S. Place: * Launching Oxyglobin first would allow for an experimental phase and possibly make any adjustments to build quality and consistency especially for consumer acceptance. * It would be simple to visit vet clinics for 15 minutes to educate vets on the benefits as opposed to the standard use of animal blood donations. Pro: Selling to vets would increase volume of sales and repeat purchases in this specialized market. It would have to be administered in a clinic with a trained professional. Con: Both small and large vets might not want to jeopardize relationships and service to clients and would have to be reassured that this new product was consistently safe and effective on all pets large or small.