Chapter 9

India: The Case for Longevity

In his office in Madras, in southern India, Vijay Ramachandas picked up the letter from the National Institute of Health Research in Bombay and read it one more time. The news was almost too good to believe. The NIHR was awarding his biotechnology company Ramachandas Inc., a three-year grant of $250,000 to continue its research into extending life expectancy using the company's new drug Imortale. Vijay couldn't stop smiling. This grant was a lifesaver, in more ways than one. Although it seemed that his company was always just one step away from bankruptcy, Vijay had never given up on achieving his goal. He had no doubt that he could find the key to lengthening human life, and with this grant, he felt even more assured. It had been a hard struggle, but recognition was beginning to arrive for Vijay and Ramachandas Inc.

Vijay had received his Ph.D. in biochemistry from Harvard University fifteen years ago and had worked as a genetic researcher at the National Institute on Aging at the National Institutes of Health in Bethesda, Maryland, for nine years. Then, because of his entrepreneurial nature, he returned to his native country to open his own biotechnology company and focus on developing anti-aging drugs. Vijay's first project, the development and production of a drug for Parkinson's disease, won FDA (Food and Drug Administration) approval after a lengthy period of laboratory testing, animal studies, and human clinical trials. It sold moderately well right from the start.

However, R and D for the biotechnology industry was a risky endeavor, with the constant need to drum up funding, whether from grants or wealthy individuals. Still, in the past six years, Vijay had seen his small company grow from employing four scientists to having a staff of thirty-two researchers. The revenues were modest, about $1 million per year, and profit margins were slim. Vijay knew that to solidify his business, he would have to strike it big with a breakthrough biotech drug. And that was exactly what most of his researchers had been devoting their time to: a drug that would safely extend the life expectancy rate for the average healthy person living in a developed country.

The new drug that Vijay and his staff have developed and produced is named Imortale. It is a protein-based substance, an enzyme that prevents the aging of genes. Vijay's firm had conducted laboratory tests and animal studies that yielded positive results, so five years ago it began human clinical trials. So far, the initial results of their study conducted on men and women in the United States have been astonishing. The study involves 2,000 healthy participants, 1,800 of whom began taking Imortale five years ago when they were 75. The control group of 200 does not receive Imortale but takes vitamins. Over 80 percent of the participants taking Imortale are still alive today and in excellent health, compared to 65 percent of the control group. The question is whether the drug has any negative effects, but side effects have been limited to mild headaches, occasional nose bleeds, and skin rashes in only about 10 percent of the participants. Because of the encouraging results, Vijay and his staff have been cautiously optimistic about eventually

getting approval from the FDA to market the drug. Of course, the study must continue for another five years, which is the basis for the grant awarded by the NIHR.

Vijay had just opened his e-mail to send a message to the staff about the NIHR grant when he saw that he had a message from the coordinator of the Imortale study in the States. The message had a red flag on it, meaning urgent. He read the message quickly.

"Vijay: We have some major changes in study results. In the past month, 38 participants taking Imortale have been diagnosed with cancer, including leukemia and lymphoma, compared to 5 in the control group. I just returned from vacation and was given this information. Elliot"

Vijay was stunned. He immediately dialed Elliot's number in Boston. "Elliot, what does this mean?" he asked his coordinator.

"It's too soon to say," answered Elliot tersely.

"Thirty-eight out of 1,800 is only slightly more than 2 percent, but it's not a good sign. "I'll call a staff meeting and get back to you. What are the options?" Vijay wanted to know.

Elliot fired back with his answer. "Ignore the results and keep the study going, or temporarily halt the study and reduce the dosage. Or start all over again--change the protein--find a different way to re-engineer the old genes and make them new."

"OK. Let me think about it and get some feedback from the staff. Send me an e-mail with all the data immediately," Vijay said and hung up the phone.

The meeting with the staff was a chaotic mixture of doubt, denial, and acceptance of the inevitable. Everyone in the room knew that biotech research is a high-stakes gamble, with no guarantees that the goals will be achieved, and that failures are more common than successes. Even though Imortale still had its supporters, many of the researchers were inclined to move in a new direction. Vijay took a low-key, analytical approach.

"We shouldn't jump to conclusions," he told the staff. Wait until we see all the data."

Later that afternoon, Vijay got the e-mail from Elliot with the data indicating the relatively high incidence of cancer in the study participants taking Imortale. Although he had six months before he had to make a progress report to the NIHR, Vijay wondered whether it would be wise to inform the program officer in charge of his grant at the NIHR of the recent developments and request a meeting. Then he opened the file containing the annual budget for the company. He might have to reallocate some funds if the clinical trial was going to be redesigned. It was ironic that two hours ago Vijay had been confident about achieving a scientific and commercial breakthrough with Imortale, but now he had a crisis on his hands. While Vijay was the first to admit that determination

was a major factor in biotech research, he couldn't help feeling less than determined to start from scratch on finding an effective anti-aging drug.

Discussion

1. What areas of research are biotechnology companies focusing on today?

2. What challenges do owners of biotechnology companies face?

3. Should Ramachandas Inc. continue the clinical study of Imortale by reducing the dosage given to participants?

4. How can Ramachandas Inc. determine the safety and effectiveness of Imortale?

5. Would you take part in a study using Imortale if you were asked to participate?

6. What alternatives does Vijay have to improve his company's financial situation?

7. Should Vijay change the focus of research at Ramachandas Inc.?

Case Study Report

I. Statement of the problem

A. Definition

B. Analysis

II. Suggestions of possible solutions

A.
B.
C.
D.

III. Evaluation of possible solutions

A. Advantages

B. Disadvantages

IV. Selection of a solution

A. Choice

B. Justification