Medical Devise Case Study Report

1. Problem Statement

This project lies at the intersection of innovation and data-based decision-making since improving productivity through innovation is the key to staying ahead of the competition.

However, we are constantly challenged to choose from multiple innovation opportunities with limited resources. Finding the next “blockbuster” product is like an impossible mission. So, for this project, I devised a framework to strategically compare investing in two potential biomaterial technologies, considering market demand, development cost, and project risks.

I made many assumptions based on extensive but not exhaustive online research, which needed validation from subject matter experts from marketing, R&D, Finance, and Operations teams with industry expertise in medical devices, as well as healthcare providers (like surgeons). I believe the framework and insights from this case study provide a solid foundation for a data-based R&D project selection process with clear guidelines for cross-functional collaboration.

2. Case Discussion

2.1 Background for two potential surgical products to develop

Biomaterials have long been a hot topic in medical technology because of their nontoxicity, biocompatibility, biodegradability, and bioactivity. Recent cutting-edge research has evolved from using biomaterials as inert supports to leveraging their bioactivity to promote tissue regeneration. After initial screening of biomaterials, including metals, ceramics, hydrogels, polymers, and bio-derived materials with applications in bone regeneration, cardiovascular repair, 3D bioprinting, and wound healing, two technologies stand out from the rest.

The first biomaterial is a Pectin Patch developed by a group of researchers at Harvard Medical School. The study found that the slippery serosal surface layer is the major challenge for biomaterial-assisted anastomotic healing. Their study showed that the pectin patch has greater adhesion to serosa than traditional nanocellulose fiber adhesives and pressure-sensitive adhesives. It also showed a better sealing effect on a small bowel segment than commercially available surgical sealants in ex vivo studies. However, due to the challenges in simulating the complex physiological forces in bowel anastomosis, this biomaterial still needs clinical validation for its effectiveness in facilitating anastomotic healing after intestinal surgery (Zheng, et al., 2021).

The second biomaterial is a Gelatin-based Granular Hydrogel Scaffold developed by researchers at Penn State University. I’ll call this technology GHS for short. In their study, the researchers found injecting GHS through surgical micropuncture accelerates cell growth and vascularization in well-organized patterns in live rat tissues. The study showed GHS can guide precise vascularization and has the potential to provide a platform for reconstructive surgery and regenerative engineering. According to the researchers, this technique could be applied to various blood vessel conditions found in cardiovascular diseases. Despite promising, this intricate and novel technology still presents unforeseeable risks in clinical translation (Z. Ataie, 2024).

In summary, the key takeaways are that the pectin patch has the potential to heal after intestinal surgery, and GHS can be applied to cardiovascular surgeries.

2.2 Market Potential Analysis

Now that we have concluded that the pectin patch has the potential to accelerate healing after intestinal surgeries, and GHS can be applied to cardiovascular surgeries, in this section, we'll examine the market potential and financial rewards of commercializing these technologies.

Data from the US nationwide inpatient sample public database (HCUPnet US Nationwide Inpatient Sample (NIS) , n.d.) is queried to understand the potential markets for these two technologies. In HCUPnet, I queried US inpatient data from 2016 to 2021 with gastrointestinal system operating procedures and cardiovascular procedures. The attributes used in this analysis in are 1. Number of operation procedures performed 2. Average Length of hospital stay after the operating procedure and 3. Hospital cost for the entire stay. I'll use these numbers to estimate the market size and pricing points.

The aggregated operating procedures performed for the gastrointestinal system and cardiovascular conditions were calculated and plotted using Power BI. From 2016-2021, there is no obvious trend. So, the median was used to estimate the annual procedure count. The US has nearly 2 M gastrointestinal system procedures and a little over 2M cardiovascular procedures every year.

In addition, the average hospital stay for both types of procedures has remained steady over the past six years, with an average LOS of 7.5 days for Gastrointestinal system procedures and an average LOS of 9.7 days for Cardiovascular procedures. Interestingly, there is a clear upward trend for hospital cost per stay after I adjusted for the length of stay.

Based on the previous analysis, I did the market sizing. The median for annual procedures and average hospital stay is used to forecast future demand, assuming they don't have a clear trend to change. Meanwhile, hospital costs are projected to increase at the same speed in the future as in the past. Thus, the estimated daily hospital cost for gastrointestinal system procedures is around 4900 dollars, and the average daily hospital cost for cardiovascular procedures is around 8000 dollars when the products are ready to hit the market in 3-5 years. Assuming the new technologies can accelerate the healing processes and shorten hospital stays by a conservative estimate of 5%, the hospital will be incentivized to pay for the new products to improve patient outcomes and hospital operation efficiency. This assumption leads to the recommended price of the pectin patch being 1800 per kit and the GHS being 3900 per kit (Corral M, 2016).

2.3 Net Present Value Analysis

In the financial modeling step, some assumptions are made based on the market research.

- The revenue of the two technologies is summed over 10 years after launch. Since not all patients will use those products, assumed a 10% of the patient adoption.

- I assume the medical device company will take about 10% market share and will harvest 32% of the profit from selling the products based on general profit margins on surgical products[(JNJ Financials, n.d.)].
- From the technical side, I assumed the pectin patch would take 3 years to develop, and it would need an investment of 1M per year in the first two years and 2 M in the last year. For GHS, I assumed it would take 4 years to develop, and it would need investment of 2M per year in the first two years and 3 M per year in the last two years.
- I also assumed a go/no-go decision gate at the end of each year, and both projects have a 50/50 chance to pass each year's decision gate.
- Lastly, I used a medical device market leader's IPR&D cost of capital (Johnson & Johnson 2023 Annual Report, n.d.) as the discount rate and applied risk-adjusted NPV methodology to find the value of both projects.
- The risk-adjusted NPV method is chosen in this case because R&D projects' risky nature (Stewart, 2001).

From the sensitivity analysis, I identified 3 major drivers consuming the cash inflow in the risk-adjusted NPV analysis. They are development cost, project risk, and time value of money. And the results undoubtedly proved that the project value shrank from hundreds to tens of millions after adjusting for risk. A mere 10% increase in success probability can easily double the risk-adjusted NPV. These astonishing insights show that having a group of competent experts to solve complex problems creatively in the new product development process and correctly determine the success probability of highly uncertain projects is crucial.

3. Conclusion and recommendation

As for the two technologies examined in this case study, the Pectin Patch presents a slightly more favorable investment choice due to its shorter development time and lower associated risk despite the smaller market size. Moreover, the pectin patch can leverage the company's existing sealant market access, leading to significant market penetration and revenue generation. Nevertheless, GHS is also a promising area for development, given its substantial market size and its complementary nature to the company's revascularization products.

Lastly, this case study also provides a clear framework for effective collaboration between R&D, Marketing, Operations, and Finance teams as they provide their expertise in estimating various components that go into investment decisions and shape the future.

References

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