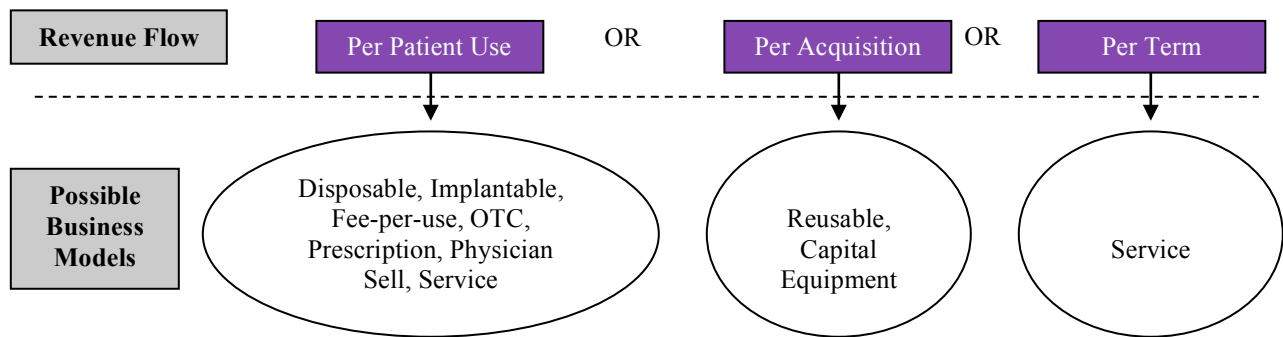


Appendix 4.4.1 Decision Tree and Rules-of-Thumb for Choosing a Business Model

Step 1 – Scale down the possible universe of business models

Determine the **unit** (or units, if taking a blended approach) which defines the revenue flow to the company.

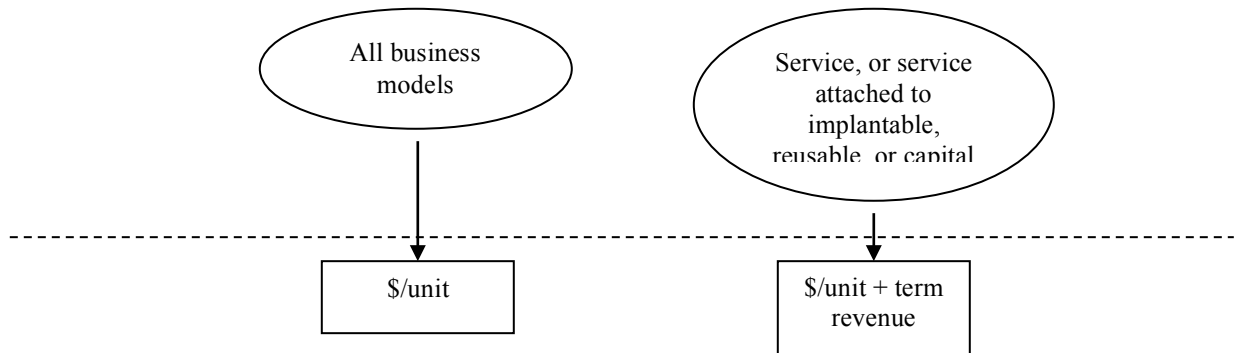
Figure 4.4.1-1 – The first step in choosing a business model is to eliminate those that are clearly not a good fit.



Step 2 – Estimate unit pricing

All models typically have an associated price/unit. Some models may also include after-sale revenue for each term in use.

Figure 4.4.1-2 – An estimate of unit pricing is sufficient at this point.



Step 3 – Calculate the potential market size (revenue/time)

Multiply expected units per time by the pricing/unit. For example, there may be 500,000 patient candidates for a particular implant per year (**units/time**) x the implant **pricing** (set in Step 2). Another example is 2,000 hospitals need this equipment installed over the first 10 years it is available (**units/time**) x the **pricing** (set in Step 2). See 2.4 Market Analysis for a more detailed discussion of how to calculate market size.

Step 4 – Determine the cost per unit

Step 5 – Calculate the gross margin = (price/unit – cost/unit) divided by price/unit

The following rule-of-thumb can be used for validation.

Financing types available:

- If revenue/time is greater than \$500 million per year, it is typically backable by a venture capital firm and may lead to an IPO.
- If revenue/time is greater than \$100 million but less than \$500 million, it may be backable by a venture capital firm and may not have IPO as an option.
- If revenue/time is less than \$100 million, it is probably not likely to be backed by a venture capital firm, but may be interesting to individuals, angels, or other types of investors.

Operating expense coverage (the ability of the business to support high sales costs like a direct sales organization, big advertising budgets, or to repay the cost of extensive clinical trials):

- If gross margin is greater than 70 percent, the business can support higher operating expense costs.
- If gross margin is less than 50 percent, the business most likely will not be able to support higher operating expense costs and may need a partner to support key activities such as clinical trials or marketing.

When additional brainstorming might be needed:

If the business requires an extensive clinical trial to reach the market, and therefore a significant amount of capital, but the revenue/time is less than \$100 million per year, then there is a problem. If it is greater than >\$500 million, then it is probably acceptable.

If a product requires a direct sales force to sell it, and it is a low-margin product, then there is a problem. If the product cannot be reimbursed at a higher level or the cost cannot be reduced, it may not have a future.

If a product requires high margins (e.g., due to a direct sales force, customer training, or large research and development or clinical investments) and has little IP and low barriers to entry, then there is a problem.

If one wants to sell a product OTC, or if insurance providers try to push a product OTC, and the product requires technical training, then there may be a problem. If simplifying the current product is not a possibility, then the product may not be feasible.